PRM-35-22
85FR 57148

341

# PUBLIC SUBMISSION

**As of:** 11/20/20 1:59 PM
**Received:** November 14, 2020
**Status:** Pending_Post
**Tracking No.** 1k4-9k33-cqw5
**Comments Due:** November 30, 2020
**Submission Type:** API

**Docket:** NRC-2020-0141
Reporting Nuclear Medicine Injection Extravasations as Medical Events

**Comment On:** NRC-2020-0141-0004
Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

**Document:** NRC-2020-0141-DRAFT-0350
Comment on FR Doc # 2020-19903

## Submitter Information

**Name:** David Williams
**Address:**
200 Arthur Drive
Thomasville, NC, 27360
**Email:** drwpeddoc@aol.com

## General Comment

See attached file(s)

For ACMUI transcript of 2008 meeting see pages 17 - 42 for extravasation discussion.

For ACMUI transcript of 2009 meeting see pages 159 - 175 for extravasation discussion.

## Attachments

NRC Petition Letter

ACMUI 2008-12-18 Transcript

ACMUI 2009-05-08 Transcript

Re: Reporting Nuclear Medicine Injection Extravasations as Medical Events

Petition Docket ID NRC-2020-0141

I am not a nuclear medicine physician and not a technologist. I am a pediatrician in private practice, but I am familiar with nuclear medicine. Some of my patients have been nuclear medicine patients and so have members of my family. My mother was a breast and pancreatic cancer patient who experienced diagnostic nuclear medicine imaging. My father is a cardiology patient and has experienced a nuclear medicine stress test. As a result, I am familiar with radiopharmaceuticals and understand the difference between diagnostic and therapeutic radiopharmaceutical applications. And while I am not an expert, I am aware that depending on the radionuclide, local energy deposition can result from positive or negative charged beta particles, conversion electrons, Auger electrons, and low-energy x-rays.

I am writing in support of the petition to require the reporting of significant extravasations of radiopharmaceuticals as medical events to the NRC. I feel the reporting of significant extravasations is vital to protect patients and will have long term benefits in the practice of medicine.

I have reached my conclusion after careful study of the evidence. Some of the most important evidence comes from the nuclear medicine community itself. I have reviewed the transcripts (which I have attached) of the comments that the ACMUI provided to the NRC in 2008 and 2009 that allowed the exemption that was made in 1980 to stay in force. These comments are embarrassing and do a disservice to the medical community who has an obligation to “first, do no harm.” The ACMUI comments also ignore the ethical obligation physicians have to provide the best care possible, not the care that is most convenient.

A fair reading of the ACMUI's discourse shows a body that came in with a foregone conclusion to the NRC question of whether the 1980 reporting exemption should be revoked. The ACMUI comments then tried to justify this foregone conclusion. Because of this, inconsistencies are revealed in reviewing the transcripts. The ACMUI members were presented a case of an extravasation of a diagnostic radiopharmaceutical that was delivered by an IV infusion. The members acknowledged that the level of exposure exceeded the level the NRC has determined is reportable in all other instances other than in an extravasation. In fact, the patient may have received an exposure of twice the 50 rem that the NRC has determined to be of concern. The members then ignored what was before them and responded on the basis of personal belief and ease of practice rather than on the facts they were presented.

The ACMUI members reaffirmed to the NRC that extravasations are nearly impossible to avoid, but then avowed that therapeutic radiopharmaceutical extravasations are rare, because the nuclear medicine community is much more careful with those administrations compared to diagnostic administrations. Those statements are mutually exclusive and in no way represent responsible patient care, regardless the application being used. Either extravasations are avoidable and thus should be a goal of best practice by all nuclear medicine facilities, or current methods do not prevent them from occurring, and the need for change is even more apparent. Quality control initiatives have shown that the rate of

extravasations can be lessened dramatically if centers strive to do so. The NRC should require nuclear medicine centers employ best practices to administer all radiopharmaceuticals as safely as possible.

The ACMUI also told the NRC that determining whether an extravasation meets a level of 50 rem is very difficult. However, there was no disagreement that at least that level had occurred in the case before them. What is true today, but was not true in 2008-2009, is dose determination is easier now than when the ACMUI made their recommendation. The petition cites an easier way of determining the dosimetry of an extravasation – a way that considers an appropriate volume of tissue and patient-specific biological clearance to ensure that dose to tissue is not overstated. Thus, the NRC has new information to take into account in making policy decisions.

In addition, the ACMUI also told the NRC that while diagnostic administration extravasations are common, there were ways to reduce the incidence of extravasations, mainly by hanging an IV infusion and visually inspecting the site, which is commonly done with therapeutic injections. The transcripts show the NRC staff explicitly reminded ACMUI members that an IV infusion was used in the extravasation case in question; revealing that even more careful administration approaches can still result in an extravasation. The ACMUI members just move on and never address the issue further. From the millions of nuclear medicine cases done today, most of which are not infusions, it logically follows that what happened to this patient has happened to many others.

The ACMUI members told the NRC that even if these extravasations are occurring, they are not clinically significant. The only evidence given is from members pointing out that they have not been made aware of problems by patients, or the doctors treating them. However, neither the patients nor the treating physicians would even know these extravasations have occurred. Indeed, in most cases, under typical practice standards employed today, the nuclear medicine physician would not be aware of the extravasation and the potential harm to the patient. The members discussed how difficult it is to evaluate the effects of these extravasations, but the time frame posited for following them was ludicrously short. Checking someone who has had a significant tissue irradiation to see if their skin shows visible effects days, or weeks later is not an effective method of monitoring these patients. Looking for skin reddening or ulceration as the only sign of a dangerous radiation exposure, is not reasonable. Based on the types of energy being deposited by radiopharmaceuticals and the nature of the infiltrate in the tissue, it is possible that while the underlying tissue may receive a high absorbed dose, the skin may not. And while I am not a radiation biologist, it is well-known that radiation injuries to tissue can take months or years to develop.

Perhaps most alarming, is not one member of the ACMUI in 2008 and 2009 expressed any concern for the patient who experienced the reported radiation exposure. Not one member of the ACMUI inquired as to how the patient would be informed and monitored of the event. Not one member of the ACMUI discussed improving practices at their own facilities to prevent events like this from occurring. The most recent comments from all but one member of the 2019 version of the ACMUI indicate not much has changed with this “advisory” committee in the past decade. Only the ACMUI patient advocate recognized that it made no sense for the NRC to handle a significant extravasation that irradiated tissue

with a dose higher than the reporting limit any differently from other medical events. She wrote the following dissenting opinion:

> *"One member of the Subcommittee expressed concern with the existing 1980 exclusion of extravasation events from ME status. This member acknowledges the Subcommittee consensus that there would be only rare incidence of extravasation triggering ME criteria of >50 rem tissue dose or <80% of prescribed dose delivered to the patient, and believes the extravasation exemption in the 1980 language is unnecessary. Only rare gross discrepancies in delivered dose or tissue exposure would be reportable, and this member believes that those rare instances should be reported just as any other misadministration of such magnitude would be reported as MEs. The fact that they may result in no patient harm should have no bearing on the requirement to report. This would be consistent with the fact that all other ME's that cause no patient harm are currently required to be reported. When/if NRC decides to redefine ME criteria to exclude events that do not cause patient harm, then extravasation incidents would be included in such exclusion. But this member believes that the current specific exclusion of extravasation is inconsistent with other regulation and unwarranted.*
>
> *--Respectfully submitted, Laura Weil."*

I applaud her for it. As a physician, son, friend and relative to many patients who have received radiopharmaceuticals, I need to know that regulations are in place and followed so patients know when extravasations have occurred so that the efficacy of the diagnostics or treatment can be determined and the potential consequences can be monitored.

It is clear from the ACMUI recommendations and attitudes that they would like this "head in the sand" policy to continue and that if the NRC does not require policies to improve radiopharmaceutical safety during administration, the current state of affairs will continue. Why should physicians be allowed to ignore radiation exposures that would be reportable by other industries? This is not reasonable, or safe, and the NRC should not allow it to continue.

A review of the several hundred public comments on the petition at the time I draft my comments reveals the attitudes of the ACMUI are present in the current community. In regards to the petition suggesting that a significant extravasation should be reportable, one physician writes that informing patients of a "trivial" exposure could be upsetting to the patient. It would seem to me that NRC reporting limit is not trivial. The petition cites a document that shows the community believes a dose to the tissue of 100 rem or more will lead to adverse tissue reactions. The petition also cites cases where patients are receiving doses to tissue beyond 50 rem, beyond 100 rem, and the ACMUI has even admitted that doses higher than the reported case of a possible 96 rem dose from 2008 happen frequently. This physician's attitude is unacceptable and directly against the rights of patients to be informed of what has happened to them and makes decisions about their health based on that knowledge. Trust is only built through transparency. The fact that informing patients of an unintended, but significant radiation exposure might be uncomfortable is no rational for hiding the information. The

patriarchal approach of doctors making decisions about what is best for patients without the participation of the patient, has no place in the modern practice of medicine.

The communities' stance evident in the public comments toward therapeutic extravasations versus diagnostic extravasations is especially confounding to me. A review of the actual reporting requirements uses sieverts (Sv) as the unit of measure. That is a unit that considers the type of radiation. It is different from the absorbed dose. A therapeutic extravasation that results in an exposure of 0.5 Sv is directly equivalent to a diagnostic extravasation causing a 0.5 Sv exposure. But they are presented as of different levels of concern in many of the comments to the NRC. The community argument about therapeutic vs. diagnostic extravasations leads to several conclusions; either the community does not understand that diagnostic extravasations can result in doses that exceed reporting limits, or they don't understand the reporting unit of measure, or they are trying to avoid having to report the more numerous diagnostic extravasations, or all of the above.

The use of radiation in medicine for diagnosis and treatment is certainly a huge net benefit for everyone. But requiring the materials to be administered as safely as possible is an obvious and reasonable goal. Unfortunately, this approach is not current practice in some centers and is not likely to be so, unless it mandated. I have read the comments from one center that has aggressively improved their extravasation rate. I also read the supporting references in the petition that described the quality improvement process. These practices are not nearly as onerous as the nuclear medicine community seems to believe. Even if it is inconvenient to report, we must ask why nuclear medicine facilities are allowed to ignore radiation exposures that would be reportable by other industries? To facilitate compliance, the petition incorporates a reporting "grace-period" that will give centers that routinely experience extravasations plenty of time to make changes before reporting is mandated. Facilities that can prove they are administering the radioactive pharmaceuticals safely will have a minimal reporting burden. In fact, if they are doing as good a job as some members of the community believe they are doing, they will have no reporting responsibilities at all.

The reason we have regulatory bodies is because experience has shown that letting industries monitor themselves leads to problems. The NRC has been given the mission of requiring that radioactive materials be handled safely. It is not surprising that those being regulated try to prevent the NRC from shining a light on unsafe practices. However, allowing the nuclear medicine community to exempt themselves from being required to minimize, report, and track exposure to unsafe levels of radiation is an abnegation of the NRC's mission. It is my sincere desire that the NRC will reevaluate these reporting guidelines and improve patient care, safety and the performance of radiopharmaceuticals by supporting the petition.

Sincerely,

David Williams, MD

# Official Transcript of Proceedings

# NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes

Docket Number: (n/a)

Location: (telephone conference)

Date: Thursday, December 18, 2008

Work Order No.: NRC-2577 Pages 1-101

**NEAL R. GROSS AND CO., INC.**
**Court Reporters and Transcribers**
**1323 Rhode Island Avenue, N.W.**
**Washington, D.C. 20005**
**(202) 234-4433**

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

TELECONFERENCE

+ + + + +

THURSDAY,

DECEMBER 18, 2008

+ + + + +

The meeting was convened telephonically at 1:00 p.m., Leon Malmud, ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON MALMUD, Chairman

RICHARD VETTER, Vice Chairman

DOUGLAS EGGLI, Member

DARRELL FISHER, Member

DEBBIE GILLEY, Member

RALPH LIETO, Member

STEVE MATTMULLER, Member

SUBIR NAG, Member

ORHAN SULEIMAN, Member

BRUCE THOMADSEN, Member

WILLIAM VANDECKER, Member

PRESENT (cont.)

MICKEY GUIBERTEAU, Diagnostic Radiologist

NRC HQ STAFF PRESENT:

CHRIS EINBERG, DFO

JAMES FIRTH

CYNTHIA M. FLANNERY, ALT DFO

DONNA-BETH HOWE

SOPHIE LE

ROB LEWIS

GRETCHEN RIVERA-CAPELLA

ASHLEY TULL

GLENDA VILLAMAR

DUANE WHITE

RONALD ZELAC

NRC REGIONAL STAFF PRESENT:

COLLEEN CASEY

JACKIE COOK

SANDY GABRIEL

PATTY PELKE

TOM THOMPSON

OTHERS PRESENT:

CHERYL BEEGLE, NIH

LUCA BRIGATTI

CLARA C. CHEN, NIH

WILLIAM DAVIDSON, University of Pennsylvania

JEFF HEIER, NeoVista

JOHN HENDRICK, NeoVista

PETER HERSCOVITCH, NIH

KAREN LANGLEY, University of Utah

MIKE PETERS, American College of Radiology

BARRY SIEGEL

MIKE STABIN, Vanderbilt University

CINDY TOMLINSON, Society of Nuclear Medicine

BILL VERMEERE, NeoVista

TABLE OF CONTENTS

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

(1:02 p.m.)

MR. EINBERG: I'm going to open up the meeting. As the Designated Federal Officer for this meeting, I would like to welcome you to this teleconference public meeting of the Advisory Committee on the Medical Uses of Isotopes.

I am the Chief of the Medical Safety and Events Assessment Branch. I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the alternate designated federal officer is Cindy Flannery, team leader for the Medical Radiation Safety Team.

This is an announced meeting of the Committee being held in accordance with the rules and regulations of the Advisory Committee Act and the Nuclear Regulatory Commission. This meeting was announced in the September 22, 2008, edition of the Federal Register, Volume 73, page 54635.

The function of the committee is to advise the staff on issues and questions that arise on the medical use of isotope 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 consensus on the procedural issues that we will discuss today. We also recognize there may be a minority or a dissenting opinion. If you have such opinions, please allow them to be read into the record. At this point, I would like to perform a roll call of the ACMUI members that may be participating today.

Dr. Leon Malmud, Chairman, Health --

CHAIRMAN MALMUD: Here.

MR. EINBERG: -- Care Administrator?

CHAIRMAN MALMUD: Here.

MR. EINBERG: Dr. Richard Vetter, Vice Chairman, Radiation Safety Officer?

VICE CHAIRMAN VETTER: Here.

MR. EINBERG: Dr. Douglas Eggli, Nuclear Medicine Physician?

MEMBER EGGLI: Here.

MR. EINBERG: Dr. Darrell Fisher, Patient Advocate?

MEMBER FISHER: Present.

MR. EINBERG: Ms. Debbie Gilley, State Government Representative?

(No response.)

I just understand Debbie will be joining us late.

Mr. Ralph Lieto, Nuclear Medicine Physicist?

MEMBER LIETO: Present.

MR. EINBERG: Mr. Steve Mattmuller, Nuclear Pharmacist? Is Mr. Mattmuller there?

MEMBER MATTMULLER: Yes, I'm here. Sorry.

MR. EINBERG: Okay. Thank you. And Dr. Subir Nag, Radiation Oncologist? Dr. Nag?

(No response.)

Dr. Orhan Suleiman, FDA Representative?

MEMBER SULEIMAN: Yes, here.

MR. EINBERG: Dr. Bruce Thomadsen, Medical Physicist Therapy?

(No response.)

Dr. William VanDecker, Nuclear Cardiologist?

MEMBER VANDECKER: Here.

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

(No response.)

Okay. I believe we have a quorum. Dr. Mickey Guiberteau is representing the Diagnostic

Radiologists. Dr. Guiberteau does not --

THE COURT REPORTER: This is the Court Reporter. I'm having a difficult time hearing you due to the static.

(Whereupon, at 1:06 p.m., the proceedings in the foregoing matter went off the record briefly, during which time the static problem was corrected.)

MR. EINBERG: Okay. Let me just -- the Court Reporter indicated that he was having some trouble hearing me. I'll repeat some of it.

Dr. Mickey Guiberteau is representing the Diagnostic Radiologists. Dr. Guiberteau does not have voting privileges, but he will speak on behalf of the Diagnostic Radiologists. I would like to thank Dr. Guiberteau for acting in this capacity.

I now ask NRC staff members who are present to identify themselves. I'll start with the individuals in the room here, and then we'll turn it over to the other NRC staff members on the phone.

MR. LEWIS: This is Robert Lewis from FSME.

MS. FLANNERY: Cindy Flannery, FSME.

MR. FIRTH: James Firth, FSME.

DR. ZELAC: Ron Zelac, FSME.

MR. WHITE: Duane White, FSME.

MS. RIVERA: Gretchen Rivera, FSME.

MS. VILLAMAR: Glenda Villamar, FSME.

MS. LE: Sophie Le, FSME.

MS. TULL: Ashley Tull, FSME.

MR. EINBERG: Okay. Now, for regions, anyone from Region I?

MR. THOMPSON: Tom Thompson in the Commercial Branch.

MS. GABRIEL: And Sandy Gabriel.

MR. EINBERG: Okay. Thank you. Region III?

MS. PELKE: Patty Pelke from the Materials Licensing Branch.

MR. EINBERG: Thank you. Region IV? Okay.

DR. HOWE: And Donna-Beth Howe from Headquarters.

MR. EINBERG: Okay. Thank you, Donna-Beth. Is that it for the NRC staff?

MS. COOK: Jackie Cook, Region IV.

MR. EINBERG: Okay. Thank you.

Next, I would ask members of the public who are participating on the phone if they would identify themselves, please. For the Court Reporter,

if you could please spell out your name.

PARTICIPANT: My name is -- oh, you're going to spell the name for the public?

MR. EINBERG: Okay. Yes. Ashley Tull here is saying that you don't need to spell out your name.

MS. TULL: If you have notified me via e-mail previously, I have your name on the list already spelled for the Court Reporter.

MR. SIEGEL: Okay. This is Dr. Barry Siegel. I'm here.

MR. VERMEERE: Bill Vermeere from NeoVista.

DR. BRIGATTI: This is Dr. Luca Brigatti. I'm an ophthalmologist.

MR. HENDRICK: John Hendrick from NeoVista.

MS. TOMLINSON: This is Cindy Tomlinson from the Society of Nuclear Medicine.

DR. HERSCOVITCH: This is Dr. Peter Herscovitch from the NIH, Bethesda, Maryland. And in the room we also have Dr. Clara Chen from Nuclear Medicine at the NIH, and Cheryl Beegle from the NIH.

MR. DAVIDSON: This is Will Davidson from the University of Pennsylvania.

MS. LANGLEY: Karen Langley, University of Utah, Salt Lake City.

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

MR. STABIN: Mike Stabin, Vanderbilt University.

MR. EINBERG: Okay. Is there anybody else on the line who has not announced their participation?

MS. CASEY: This is Colleen Casey, NRC, Region III.

MR. EINBERG: Okay. Very good. We'll move on.

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

At this point, I would like to turn the meeting over to Rob Lewis, who would like to make a few opening comments. And then, we will turn the meeting over to Dr. Malmud.

And just one last reminder, for those people who joined us late, please press star 6 to mute your phone if you are not speaking.

Thank you.

Rob?

MR. LEWIS: Thank you. Good afternoon, everyone. I would like to just bring the committee up to speed on a couple of activities occurring within NRC that are getting a lot of attention, the first of which is the national source tracking system. We do have a regulation which requires all licensees to enter the sources and the transactions of sources for IAEA Category 1 and 2 sources -- so, basically, the increased controls licensees -- into the national source tracking system by January 31st of 2009.

The system has received its authority to operate, which is a step under federal information security requirements, and is available at this point. In order to use the system, you have to go through an extensive credentialing program and receive tokens that you plug into your computer to make sure that the users have proper credentials and are actually the users. There is a very high level of security for a federal information system.

And, in all honesty, the credentialing process is not going very smoothly at this point. So for those of you that are in the meeting that are licensees, I would encourage you to get involved with that early. There is currently NSTS training going on

around the country, and the credentialing process itself is rather onerous. But it is nothing that we can control from the program office perspective. So it is difficult, and we are working through issues.

We underestimated the precision with which applicants need to enter information. For example, if you enter your licensee name and it doesn't match a database of companies that the credentialing contractor uses, then you will get rejected from the system. If you enter "corporation" instead of "inc," if your official company name is Something Something, Inc., you would be rejected.

So things like that that we need to work through, and we are working through, but the regulation is set. And the compliance with the rule is mandated as January 31st people -- licensees need to be entering their source information.

Now, using the NSTS website is only one option for compliance with that rule. There are other options of providing the information by fax or e-mail to NRC or an agreement state. So those options exist, but we want to create a situation where people want to use the NSTS because it is efficient once you get into it. Getting into it is the trick.

The second topic area is safety culture.

The NRC has several activities underway regarding safety culture, both internal safety culture for the agency and external safety culture for licensees. I would like to touch a little bit on the second piece of that, the external safety culture.

Our safety culture is basically a corporate attitude from the worker all the way through senior management that is a personal dedication and accountability towards safety issues. And it is often synonymous, for example, with Safety First attitude, willing to stop work if they think something is unsafe and the management would support them, willingness to stop it.

It is a concept that has been around for reactors for maybe 10 years now, but it really caught a lot of focus after the Davis-Besse vessel head erosion that occurred about five years ago. And the Commission has directed the NRC staff to look at extending safety culture into the materials area and extending safety culture concepts into the source material security issue, or just security area in general, or a security culture if you will.

The staff are working on those assignments from the Commission, and in the near future we will be engaging the committee more on our efforts to get user

feedback on how safety culture could be applied to materials, including medical applications.

There is a public workshop currently planned for January 28th at NRC Headquarters on this area. The main focus is soliciting input from the stakeholders and the public. The workshop will just be one opportunity for NRC to obtain the views of the stakeholders.

We will be engaging the committee in the next several months, next few months I should say. We owe something to the Commission in about four months, not the final answer but our initial proposals to the Commission. So more to come on that topic, but it is an emergent issue that will need some attention in the near future.

And, finally, I want to thank the committee members for completing the information security training. We do have several periodic trainings throughout the year, various -- invariably, they have bad timing of when they are announced, and this one happens to be due over Christmas and New Year break. But I appreciate what you did to get -- make sure that you did your part as committee members.

That is a requirement placed upon NRC, as is many of the other periodic training requirements.

I realize that you have to take time out of your busy schedules to do those. But the management of NRC is held very accountable to making sure everyone has jumped through all the hoops on all of those periodic training requirements.

At this point, if Dr. Malmud will indulge me, I would be willing to take any questions from the committee members before we get started on general topics.

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

(No response.)

MR. LEWIS: Thank you, Dr. Malmud. I will turn the meeting over to you.

CHAIRMAN MALMUD: Thank you. We have the next item on the agenda, which will be Cindy Flannery. Am I correct, Cindy?

MS. FLANNERY: Yes. Cindy Flannery. The topic of this first discussion is NRC's position on the applicability of the medical event reporting criteria for an event that was reported to the NRC involving an infiltration of F-18 of FDG.

NRC staff's objective here today is to get ACMUI's input on whether NRC staff should pursue a change to our current position on the lack of

reportability of infiltrations of dosages that may result in doses that exceed the dose threshold in the medical event reporting criteria -- that is, 50 rem to an organ or tissue.

An event was reported earlier this year as possible medical event. 3.6 millicuries of F-18 FDG was infiltrated into the anacubital dermis adjacent to the left elbow. The dose of the tissue was estimated to range somewhere between 200 millirem and 96 rem, and it was based on assumptions such as the entire dose was infiltrated into a tissue of 60 cubic centimeter volume sphere using a soft tissue density of 1.06 gram per cubic centimeter with a range of mean resonance time of .006 to 2.6 hours.

So just a little bit more background on this, the needle was carefully checked for infiltration using a 10 milliliter flush and a 100 milliliter infusion prior to injection of the F-18 FDG. The infiltration was discovered upon image acquisition one hour after the administration, and, unfortunately, the biological parameters were not measured, so it lead to a very large and varied absorbed dose estimates, as listed in slide 3.

But there were no identified adverse effects. There was nothing to suggest any kind of a

radiation injury.

The licensee did file a report 30 days after the event, and they stated that, "Because the technologist noted the diffuse localization of the F-18 FDG, it seems likely that much of the administered dose did not -- or, I'm sorry -- did get into the vein, leaving less than 3.6 millicuries to irradiate the local area."

NRC's internal dose assessor did review the licensee's dose estimates, as provided on slide 3, and found this to be reasonable. Using a different method, NRC's calculations were slightly lower, but, as I said, they were certainly reasonable.

Now, as far as the outcome, the event was later retracted because NRC staff determined that an infiltration does not require reporting as a medical event. Based on some supplementary information that supported the previous equivalent regulation -- 35.33 -- which states -- and it's in 45 Federal Register 31703, May 14, 1980, "Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or an artery. Extravasation frequently occurs in otherwise normal IV or intra-arterial injections. It is virtually impossible to avoid. Therefore, the Commission does not consider

extravasation to be a misadministration."

So based on these excepts from the statement of consideration that I just quoted, it was staff's determination at that time that this case did not qualify as a medical event. It has always been NRC's position that infiltrations do not constitute a medical event.

But that position has been based on the fact that diagnostic dosages, like technetium-99m, that were typically used in nuclear medicine at the time are gamma emitters of relatively low energy and low risk and wouldn't exceed the dose thresholds that are in the medical event criteria.

The language in the FRN is not really based on a distinction between diagnostic and therapeutic administrations, but, rather, on the fact that some of that, such as infiltrations, are an integral part of the procedure, and so their occurrence must be viewed as expected.

At the time that this FRN was published, higher energy radiopharmaceuticals, like PET radiopharmaceuticals, were just not being used. This is from 1980, as I mentioned before.

F-18 is a diagnostic administration, but because of the higher energies that can now result in

a dose to the surrounding tissue exceeding 50 rem, when doses are infiltrated, NRC is trying to determine whether there is any justification based on safety significance to change NRC's policy for these new NARM materials, which are now under our regulatory authority, and also the applicability of the medical event criteria for infiltrated dosages.

And just to take it one step further, should there be a requirement for reporting an infiltration of a therapeutic administration, that is something that also has not been considered before.

So that concludes my opening of the discussion.

CHAIRMAN MALMUD: Thank you, Cindy.

Any comments or discussion regarding the issue of infiltration of F-18 FDG? I heard someone click on or click off.

MEMBER THOMADSEN: That is Bruce joining you. Sorry I am late. I had a patient who was considerably late today.

CHAIRMAN MALMUD: Thank you for joining us. Cindy just presented the material regarding the infiltration of F-18 FDG and therapeutic radiopharmaceuticals. I was asking the group if there are any comments regarding her presentation.

VICE CHAIRMAN VETTER: Dr. Malmud, this is Dick Vetter.

CHAIRMAN MALMUD: Dr. Vetter?

VICE CHAIRMAN VETTER: I just wanted to point out that there is -- it's a bit old, but there is a publication that looked at infiltrations of radiopharmaceuticals back in 1994, Castronovo, et al., and the -- they looked at infiltration of various volumes, various volumes of tissue, etcetera.

And just as an example, maximum specific activity for a thallium -- let's see, infiltrations of thallium at the maximum specific activity available in two gram volume of tissue, worst case possible, would produce skin radiation burden of 417 to 463 rads. If you look at the table in that particular publication, which I can share with the staff if they don't have it, the doses range from about 40 rads to over 500, almost 600.

So the doses from infiltration are potentially significant. In fact, they are quite a bit higher than that particular PET issue that she outlined.

CHAIRMAN MALMUD: Thank you.

MEMBER NAG: Hello. Sorry to be late on the phone. This is Dr. Nag calling in.

CHAIRMAN MALMUD: Thank you, Dr. Nag. We just discussed the infiltration of F-18 FDG therapeutic radiopharmaceuticals. And Dr. Vetter responded that this already had been discussed about 10 years ago or so in a publication by Dr. Castronovo, where the infiltrations resulted in, if I am quoting correctly, an even greater radiation burden than these mentioned. Am I correct, Dr. Vetter?

VICE CHAIRMAN VETTER: Yes, that is correct. Yes, that's correct.

CHAIRMAN MALMUD: And, therefore -- this is Malmud again. And, therefore, the issue really was presented, dealt with, and probably need not be dealt with again. Is that your feeling, Dr. Vetter?

VICE CHAIRMAN VETTER: Well, I wouldn't necessarily say it doesn't need to be dealt with, but it has been dealt with in the literature in the past. I don't know if the NRC has ever looked at that literature, but it has been dealt with in the past in the literature, and the doses reported are considerably higher than that particular case that was outlined.

So I wouldn't view that particular case as being particularly egregious when compared to what apparently happens routinely in the injection of

radiopharmaceuticals.

CHAIRMAN MALMUD: This is Malmud again. Therefore, Dr. Vetter, what would your response be to the question raised by Cindy Flannery? And the question in the last slide is: considering the higher doses from the use of NARM, should NRC change its position to now regard infiltrations as MEs if the resulting dose exceeds the dose limits of 10 CFR 35.3045.

VICE CHAIRMAN VETTER: My opinion is that the -- that the practice should not be changed at this point in time. However, with the increased use of therapeutic radiopharmaceuticals, I think it is a subject that should be investigated, but nothing changed at this point in time.

MEMBER NAG: This is Dr. Nag. My viewpoint would be that this is somewhat akin to the seed migration issue for permanent implant. And that if in the -- if the injection of radioactive material, whether it's 125 ccs or, you know, NARM, if it is routine that some of it infiltrates out, and that this is something that happens in the normal course of a medical event, it should not -- I mean, the normal course of a medical administration, this should not be viewed as a medical event.

CHAIRMAN MALMUD: Thank you, Dr. Nag.

Dr. Vetter, do you wish to make your recommendation into a motion?

VICE CHAIRMAN VETTER: I would be happy to do that. I move that the ACMUI recommend that the NRC not change its practice regarding the definition of infiltrations as medical events at this time.

CHAIRMAN MALMUD: Thank you.

Dr. Nag, are you seconding that motion?

MEMBER NAG: I will be seconding that motion, but I want to make sure that the following definition says that infiltrations are not medical events. I want to confirm that, please. Can someone confirm that?

CHAIRMAN MALMUD: I'll ask -- this is Malmud. I'll ask Dr. Vetter to confirm that in his motion.

VICE CHAIRMAN VETTER: Yes, I would accept that as a friendly amendment to the motion. But I think Cindy Flannery can confirm that that is the practice now.

CHAIRMAN MALMUD: And I'll ask Cindy, is that the practice now from your view?

MS. FLANNERY: Yes. This is Cindy Flannery. Yes, that is NRC's position based on that

supplementary information.

CHAIRMAN MALMUD: Thank you, Cindy. Therefore, Dr. Vetter's motion stands, with Dr. Nag's seconding. Is there any discussion of the motion?

MEMBER EGGLI: This is Doug Eggli. I'd like to speak to the motion.

CHAIRMAN MALMUD: Thank you. Dr. Eggli?

MEMBER EGGLI: There are -- infiltrations just always occur. If they were to become medical events, the NRC would be flooded with more medical events than it could manage. But, in addition, the radiation is a function of the volume of distribution. Obviously, the smaller the volume of the infiltration the higher the local radiation dose. In 30 years of clinical practice, I have seen lots and lots and lots of infiltrations. I have never seen an adverse clinical outcome.

Unlike non-radioactive iodinated radiographic contrast, which often has significant local complications when infiltrated, I have never seen an adverse outcome from a radiopharmaceutical infiltration in my clinical practice. And I strongly support the motion that they should be left in their current status as not medical events.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. I

would second your observation, in that 37 years of nuclear medicine practice I have not seen a negative outcome as a result of an accidental infiltration of a diagnostic radiopharmaceutical.

Are there other comments or discussions regarding the motion?

MEMBER LIETO: This is Ralph Lieto.

CHAIRMAN MALMUD: Yes, Mr. Lieto.

MEMBER LIETO: I would also support that the current policy statement of the NRC be maintained. And maybe what we ought to do is just say that we reaffirm it with the, you know, current terminology of replacing misadministration with medical event.

The only thing I would maybe suggest in terms of change is that I don't think extravasation is a frequent occurrence in nuclear medicine. Otherwise, you'd have patients being repeated beaucoup times, and it is a very uncommon occurrence. So I would say that we just reaffirm the current statement as it -- that was postulated back in 1980.

CHAIRMAN MALMUD: This is Malmud. Mr. Lieto, are you willing to accept and support Dr. Vetter's motion?

MEMBER LIETO: Yes, because it basically reaffirms that.

CHAIRMAN MALMUD: Thank you.

MEMBER EGGLI: This is Doug Eggli. I'd like to comment again in response to Ralph's last statement.

CHAIRMAN MALMUD: Please do.

MEMBER EGGLI: I think that complete infiltrations are not as common, although I see them with some regularity, particularly if you have a very young technologist staff. However, partial infiltrations, as a needle flips in and out of a vein, are really quite common and have neither impact on the diagnostic quality of the study, nor long-term adverse impact on the patient.

MEMBER LIETO: I accept that clarification.

CHAIRMAN MALMUD: Thank you, Mr. Lieto.

Any other discussion of the motion on the floor?

MR. STABIN: Yes, this is Mike Stabin. I would note that even though this has been treated once or twice in the literature, it is very difficult in these situations to establish what you mean by "the dose." When you're talking about dose to a standard organ, it is pretty easy to define it.

But in these cases, as was mentioned by

someone else, it depends on the volume that you assume, the distance from that volume where you assign dose, and so there is not really a good standardized model for people to assign a dose to report.

CHAIRMAN MALMUD: Thank you. Are you also supportive of the motion?

MR. STABIN: I don't have a position on the motion. I just wanted to contribute that comment, that this would be difficult at the moment I think for people.

CHAIRMAN MALMUD: Thank you. I think we all agree with your observation. Are there any other comments?

MEMBER FISHER: Dr. Malmud?

CHAIRMAN MALMUD: Yes. Who is speaking, please?

MEMBER FISHER: This is Darrell Fisher. I would like to follow up on a question raised by Cindy Flannery and ask for your experience and the experience of others, Dr. Eggli in particular. She asked about the case in which a therapeutic administration goes awry in the same way with a high-dose radionuclide such as Yttrium-90, Iodine-131, or even an alpha emitter, when those infusions become more common.

And should the dose be very much greater as a result of an injection of this type? What would be your opinion?

CHAIRMAN MALMUD: Are you asking me specifically?

MEMBER FISHER: Yes. And Dr. Eggli.

CHAIRMAN MALMUD: Thank you. I have not had experience with an infiltration of a therapeutic dose. I have been fortunate in my practice in that the therapeutic doses that we have used have been carefully administered by experienced personnel, and, therefore, the therapeutic doses have not infiltrated.

Having said that, I would also comment that Dr. Eggli's observation is a valid one with regard to diagnostic doses, and they not infrequently partially infiltrate.

Now, getting back to the question of the therapeutic, the therapeutic may in fact result in a radiation burden which will manifest itself with some visible abnormality. But I have not, fortunately, seen that in my years of practice. The doses we used to use were of pharmaceuticals such as P-32-containing pharmaceuticals.

More recently, of course, we are now into other forms of therapeutics, and there is a

theoretical possibility that we will see some untoward effect from an infiltration of a therapeutic dose. However, I cannot personally speak to that experience. Perhaps Dr. Eggli may.

MEMBER EGGLI: This is Doug Eggli. I share Leon's good fortune of never having had an intravenous therapy dose infiltrate. Just as a practice, I think our concern here is beta emitters being extravasated in the soft tissue as opposed to -- or alpha emitters as opposed to gamma emitters. But we really take a whole different level of care in establishing our IV lines on therapeutic data emitters than you do typically on routine diagnostic studies.

And I would think that you will find that the incidence of infiltration of therapeutic beta emitters or other -- or alpha emitters, when they become used, is going to be -- that I think is going to be fairly uncommon because of the quality of the IV that we establish to do that.

When you inject a diagnostic radiopharmaceutical, they are often simply done with a straight stick of a needle. And you can perforate the far side of a vein or partially perforate the far side of the vein. If you get a good IV running and you run in 4- or 500 ccs of fluid prior to the administration

of your therapeutic dose, I think the chances that you have a malfunctioning IV are likely to be detected before you administer a therapy dose.

And we typically put in a fairly large volume of non-radioactive fluid through an IV where we plan to give a therapy, just to make sure that it really is where we -- a good IV, and that we are not putting anything into the tissues.

You can put 10 or 20 ccs of fluid into the tissue and not notice it. It is much harder to put 4- or 500 ccs into the tissue and not notice it.

MEMBER NAG: This is Dr. Nag. I agree with you, Dr. Eggli. However, the question would be: if someone is not very conversant with the technique, and is going to be doing an infusion and puts in only 20 or 30 ccs, and it is running well, and then start infusing a therapeutic dose, it is possible that it will not extravasate.

In that situation, what would the NRC do? I think that's the question that was being asked, or possibly that's a question that would be asked.

MEMBER EGGLI: This is Doug Eggli again. Again, I think the incidence of that would be uncommon. And, again, with the therapeutic data emitter, I think it might rise to the level of a

medical event.

VICE CHAIRMAN VETTER: This is Dick Vetter. I just wanted to point out a subtle difference in the way diagnostic radiopharmaceuticals are administered versus therapeutic. In diagnostic, they are injected. In therapy, they are infused. And that's a huge difference.

As Dr. Eggli mentioned, during infusion it is very carefully -- the IVs are very carefully administered, and then a considerable amount of saline is used to make sure you have a patent IV. And some medical centers, even during the administration of the therapeutic radiopharmaceutical, will periodically interrupt the administration and administer some saline to make sure that the line continues to remain free.

So it is really two different -- totally different types of injection or administration.

MEMBER SULEIMAN: Yes. This is Orhan. Are we in fact discussing the therapeutic? I thought the question was really limited to the diagnostic. I have no trouble discussing the therapeutic, but does the NRC want it answered? And have we digressed?

CHAIRMAN MALMUD: Orhan, this is Malmud again. You are correct. The motion referred to the

diagnostic. And if you wish to -- if there is an interest in discussing the therapeutic, I think that we can, but it might be best to first achieve closure on the diagnostic.

Are there any other comments regarding the diagnostic?

(No response.)

If not, may we move the motion forward? All in favor of the motion?

(Chorus of ayes.)

Are there any opposed to the motion?

(No response.)

Are there any abstentions?

(No response.)

Thank you. Therefore, the motion is approved unanimously regarding the infiltration of diagnostic radiopharmaceuticals.

We are getting static again. Could some -- those who are not talking -- thank you. Thank you.

The discussion regarding therapeutic radiopharmaceuticals I think was well summarized in the comments made by several of you. It is the practice in administering therapeutic radiopharmaceuticals to first establish an intravenous line, and to make certain of its patency.

And that differs from the injection of a diagnostic radiopharmaceutical, which is, as correctly described, an intravenous injection without the prior establishment -- most often without the prior establishment of an intravenous line.

Now, therefore, a question arises, and that is this is a -- first, a statement. It is a common practice for us medically to establish an intravenous line or therapeutic doses that are given IV. Should this be a matter of written requirement that -- and, quite frankly, I am not certain if it already is or is not. Is anyone familiar with the regulations regarding the administration of therapeutic radiopharmaceuticals? Do we require an intravenous line?

MEMBER LIETO: The regulations do not.

CHAIRMAN MALMUD: Should they?

MEMBER LIETO: This is Ralph Lieto. I don't think we should enter into the practice, since things might change regarding that. I think the less we have in the regulations the better.

CHAIRMAN MALMUD: Thank you.

MEMBER SULEIMAN: This is Orhan. I would agree with Ralph. I mean, the route of administration may vary depending on the pathology, and so limiting

it to one way of administering is going to cause problems.

CHAIRMAN MALMUD: Thank you. Are there any other opinions regarding that issue?

VICE CHAIRMAN VETTER: This is Dick Vetter. I agree with that as well. And, in fact, I am sure that the method of administration was worked out during development of the protocol. So it is probably already in the FDA literature on how the material should be administered.

CHAIRMAN MALMUD: Thank you. So with those opinions, we will lay the issue of the therapeutic radiopharmaceuticals to rest at the moment, and move on with the rest of our agenda, if that is agreeable with the participants in today's discussion.

MEMBER NAG: Yes, that is agreeable.

CHAIRMAN MALMUD: Thank you.

MS. FLANNERY: Dr. Malmud, this is Cindy Flannery.

CHAIRMAN MALMUD: Yes, Cindy.

MS. FLANNERY: I think we are also trying to get some input or feedback on how this applies to therapeutics. And I do want to just add one thing, a comment that Dr. Vetter made, that, you know, your

therapeutic administrations are infused. And in this particular case, this F-18 was handled the same way. It was described at a 10 mL flush, and a 100 mL infusion was done prior to the injection.

So I understand that even when you have a line set up like that, to prevent it from happening, realize that it is incredibly rare, but as in this case there is that potential. So we would like to get some input on how this would apply to therapeutic administrations.

CHAIRMAN MALMUD: Thank you. May we have some opinions regarding how this should be ideally worded?

MEMBER EGGLI: This is Doug Eggli. Even though it was given through an IV line, and we give all of our PET doses through an IV line, there are IV lines and there are IV lines, and there are levels of care taken in establishment of the IV line that I, again, think are really quite different in therapeutic and diagnostic.

The quality of the needle catheter used, a butterfly versus an angiocath or some other form of internal catheter makes a great deal of difference in the quality of the line and the likelihood of an infiltration. So, again, I think that the likelihood

in a therapeutic infusion is really very small.

However, we are infusing currently often beta emitters, and I am less concerned with gamma emitters than I am with the local radiation with beta emitters. And if we infuse and infiltrate a beta emitter in large quantities, it is conceivable we could see tissue damage.

I am not as -- I am not opposed to making a therapeutic infiltration of medical event, but I think it probably requires some more discussion about things I am probably not thinking about. But, again, I think it will be uncommon. And, again, let me say that not all IV lines are the same.

MEMBER NAG: This is Dr. Nag. The problem is that, how will you define -- for example, in other areas we say if it is more than 20 percent, you know, we have a number like 20 percent dose, how can you say that -- you know, how much infiltration? Like if one is infiltrated, obviously, that is not going to be a medical event. If the whole dose is infiltrated, I mean, that obviously would be a medical event. So how would you say how much of it infiltrated in terms of quantity? And that may be a difficult thing. It may need a separate discussion.

MEMBER EGGLI: This is Doug Eggli. I

agree with you on that, Subir. But I think, again, the flag would probably be a function of local tissue exposure, and is there enough local radiation deposited that acute tissue injury is likely to occur.

MEMBER NAG: Again, that would be very hard to quantitate.

CHAIRMAN MALMUD: Gentlemen, may I ask if it would be an issue which we should bring to the ACMUI and discuss with regard to which type of material should be used for infusions of beta-emitting therapeutic pharmaceuticals, radiopharmaceuticals, so that we can discuss it at length.

I think the point that was made about a butterfly versus an intravascular catheter is relevant, because butterflies can infiltrate easily, particularly when there is arm movement by the patient. And whereas intra-caths, once established, of one type or another, generally are less likely to perforate the vessel.

So that this is an issue which may be worth discussing at the -- as an agenda item at the next ACMUI. Therefore, I am making a recommendation that it be discussed at the next ACMUI rather than attempting to resolve it on a conference call without having a chance to have thought it through with all of

its ramifications. Is that acceptable to the committee?

MEMBER NAG: I would agree -- I would support that wholeheartedly.

MEMBER EGGLI: This is Doug Eggli. I agree.

CHAIRMAN MALMUD: Is there anyone that doesn't agree?

MEMBER SULEIMAN: This is Orhan. I would agree, but I think it's a much more complicated issue, and I am even hesitant to bring it up without more preparation, because somebody mentioned beta emitters versus gamma. I think you have to look and see that at some point you may see alpha emitters being approved in the U.S. And we are not talking about diagnostic here, we are talking about therapeutic and the optimum administration.

So it is very, very fuzzy to me, you know, where the -- where the practice of medicine and specific protocols come into play, and where the radiation dose excesses or events would come into play. So I think we should discuss it, but I am nervous about bringing it up without adequate preparation. Otherwise, the discussions could be in a very circuitous, neverending kind of mode.

CHAIRMAN MALMUD: Orhan, I think you are right, but it points out once again the complexity of the issue, and, therefore, the fact that this important subject brought up by Cindy is better dealt with in a meeting of the ACMUI than on a conference call such as this.

MEMBER SULEIMAN: I agree.

CHAIRMAN MALMUD: Is there anyone who was opposed to delaying this to the next meeting of the ACMUI?

MEMBER GILLEY: This is Debbie. I am not opposed. I just wanted you to know I am on the call.

CHAIRMAN MALMUD: Thank you, Debbie. We are glad that you are on the call.

Therefore, recognizing that it is a potentially important issue, we will ask that it be included on the agenda for the next ACMUI. The result of the next ACMUI meeting may be that we will establish a subcommittee to look at it, because of its complexity. On the other hand, given the fact that it is brought to our attention today, it seems to me that we should bring it to the next ACMUI, so that we keep it on the agenda and deal with it as promptly as possible.

If that is acceptable with the committee,

we will do that. If not, we will do whatever the committee recommends instead. Is it acceptable to the committee members?

(Several members respond in the affirmative.)

Thank you. Then, Debbie and Cindy, do we have any other items to discuss on today's agenda?

MS. FLANNERY: Yes, we have one more agenda item.

CHAIRMAN MALMUD: And Dr. Vetter? Dr. Vetter? Dick? Dr. Vetter? Is Dr. Vetter with us?

VICE CHAIRMAN VETTER: Am I with you now? I guess my mute was on.

CHAIRMAN MALMUD: Dick, I have to give a therapeutic dose right now. I am going to run out for five minutes and come back, so --

VICE CHAIRMAN VETTER: Okay.

CHAIRMAN MALMUD: -- could you take over for me?

VICE CHAIRMAN VETTER: As long as you make sure that that line is well administered, yes.

CHAIRMAN MALMUD: It's an oral dose, and --

VICE CHAIRMAN VETTER: Oh, it's an oral. Okay.

CHAIRMAN MALMUD: -- the practice of my

department is that I do it personally. So just give me five minutes and I will be back.

VICE CHAIRMAN VETTER: Okay. I will be happy to chair the meeting while you are gone.

CHAIRMAN MALMUD: Thank you.

VICE CHAIRMAN VETTER: So did he try to give the floor back to Cindy for the next item on the agenda?

MS. FLANNERY: Yes. I can open up that one as well. Okay. The next topic is on the NeoVista's device. We discussed it at the October meeting. And just to kind of give a little bit of background information, the current licensing guidance for the use of NeoVista's EpiRad ophthalmic device requires an authorized user to meet the T&E requirements in either 35.490 or 10 CFR 35.690, which essentially means that an AU must be a radiation oncologist.

Now, at the October ACMUI meeting, a recommendation was made to revise the licensing guidance to allow for the training and experience requirement in 10 CFR 35.491, accompanied by appropriate device-specific training to be adequate for an AU for the EpiRad device.

Now, 10 CFR 35.491 allows physicians to be

an AU with only 24 hours of classroom and laboratory training applicable to the medical use of Strontium-90 for ophthalmic radiotherapy, along with supervised case experience of five clinical treatments.

While this may be adequate for the standard treatments of 24 Gray of a single lesion for the treatment of age-related macular degeneration, as used in the clinical trials, NRC staff's concern is whether this would be adequate for off-label use. Now, once the device is FDA approved, it is perfectly legal to use the device using protocols different than the protocol followed under the clinical trials.

And it is also worth noting that just last week FDA granted a waiver to treat a patient who did not meet the criteria for inclusion in the current investigational treatment protocol. So what we would like today is just to get some input from ACMUI on whether their previous recommendation from October's meeting should apply to both the use in the clinical studies as well as to the off-label use once this device gets FDA approved. If not, NRC staff hopes to receive ACMUI's recommendation on what would be adequate training and experience for off-label use.

And I guess another consideration is whether we should have two different categories of

qualifications for authorized use in the licensing guidance. For example, having one for the standard use of 24 Gray for the treatment of AMD, as used in the clinical trials, and maybe another set of qualifications for off-label use.

So that is all I really had for opening up this discussion.

Thank you.

MEMBER NAG: Hi. This is --

VICE CHAIRMAN VETTER: Thank you, Cindy. the floor is open.

DR. HEIER: I would like to acknowledge that -- my name is Jeff Heier, and I spoke at the previous meeting. And I am on as a clinical investigator with the EpiRad 90 device.

MEMBER EGGLI: Okay. Dick, this is Doug Eggli.

VICE CHAIRMAN VETTER: Go ahead, Doug.

MEMBER EGGLI: I think I made the motion, so let me speak to my intent for that motion, which was to specify the training and experience only for the standard therapy as described in the protocol, not for any more extended therapy where dosimetric considerations may become very important.

So I think the motion, as we passed it,

was intended only for the standard treatment and not for anything beyond that.

VICE CHAIRMAN VETTER: Thank you. Dr Nag?

MEMBER NAG: Yes, this is Dr. Nag. I have quite strong feelings on this. Firstly, I think at the last meeting one of the other radiation oncologists, Jim Welsh, was not there. I mean, he had to leave. He had very strong feelings, and I believe he has sent an e-mail to all of the ACMUI and NRC, you know, on this yesterday. So I think those views have to be taken into account.

The fact that neither Jim Welsh was there, nor the Chairman of the ACMUI was there at the meeting at the time of the voting, would have to be taken into account, and I think we should revisit this.

The major concerns that we have are: a) although this is right now being used as a learning tool, once it is FDA approved it can be used for off-label and any other uses. For those things, you do need a radiation oncologist to be on the Planning Committee. The major objection that was made was that, you know, it makes it difficult to have a radiation oncologist onsite.

However, we are not saying that there is the physical presence of the radiation oncologist

needed. We are saying that the radiation oncology and the radiation physicist has to be part of the team, not necessarily to be onsite. So, therefore, to get the program going, this can be gotten going as a team, and it will not delay any treatment, because the radiation oncologist is not onsite.

Secondly, when NeoVista presented this to the CMS for approval, they said that the procedure will be done with the ophthalmologist in conjunction with the radiation oncologist and radiation physicist. And, therefore, the code for the procedure was made with this complex situation in mind, and, therefore, it reimbursed at the higher rate.

If you now bypass this, then basically you are doing a Medicare fraud, because you are now going to charge the higher level for doing something at the much lower level. So these are all considerations that need to be discussed very carefully before we have a vote.

And I would very much like the people who have the most knowledge about this, which is the two radiation oncologists on the panel, plus the radiation medical physicist, the medical -- the radiation oncology medical physicist to be on when any vote is taken, because they have the most expertise on what

are the negative and what are the problems associated with radiation at the high dose in a localized area.

VICE CHAIRMAN VETTER: Dr. Thomadsen, did you want to make any comments on this issue?

MEMBER THOMADSEN: I would second everything that Subir just said. I am very concerned that this type of therapy would be going on without the input of somebody who has grown up in radiation oncology and understands the radiation. And while the results of the trial may be positive, may show very good results at the dose level selected, once people start looking at that they very likely are going to try to find other dose levels.

Once authorization has been given to the retinal surgeons to be authorized users, they will be in charge of that. They won't be using the radiation oncologists as resources during that procedure of dose investigation. And that is probably not good for patients.

VICE CHAIRMAN VETTER: Dr. Heier, did I hear you request to --

DR. HEIER: Yes, I did, if I could make a comment. I certainly understand those concerns. They are -- I think it's very important to understand that, at least as a retina specialist, and a busy retina

specialist who treats this disease, probably to the tune of 20 to 30 patients a day, the intention of the way this study was designed, and absolutely the intention of how we intend to use this, is if this -- if the Phase 3 study or the pivotal studies replicate the results we have seen in the Phase 2 studies, this will be administered as a single dose in a dose that was determined in collaboration with radiation oncology and with the radiation physicist.

If it turns out that this treatment, as described this way, cannot be delivered in that manner, I completely agree that this is a whole different process and should be looked at completely differently, and, quite frankly, probably is not going to be applicable to the treatment for most people with this disease, because the numbers we see with this, our approach to it, and the frequency we have to treat it, it is not going to make that type of approach practical.

And so as it has been explained here, and as I use it in the clinical trials, and as everybody else does, we are looking at it in a very planned, finite approach. And if the studies don't demonstrate that that approach is practical, then it needs to be completely reevaluated.

And whether or not, in collaboration with radiation oncology, that can be determined in a way that is appropriate is a whole other saying. And I know personally that is not an approach that I would be -- I would be applying to my patients, just on the sheer numbers and the complexity of what we have to do already.

As it is right now, all of the determinants in the process are determinations that are made, the type of neovascularization, the size of it, and the surgical approach how the probe is laid, and these are similar approaches that we do in determining our laser therapies, in determining our surgical approaches to patients.

The input is entirely done from a retina specialist standard. If all of that has to be modified, I completely agree this has to be reevaluated. But it is going to completely change how this therapy may or can be delivered.

MEMBER NAG: Hi. This is Dr. Nag. We have inquired within the radiation oncology community. There are not that many places that are doing NeoVista, but the places that are doing NeoVista do have the collaboration of the radiation oncologists. That does not mean that the patients held up until the

radiation oncologist can get to the OR.

No. That -- the whole planning team is part of the planning team. So this -- having a radiation oncologist be part of the team does not hold up any patient. You could be doing 20 patients per day; that doesn't mean that the radiation oncologist is going to be there during -- for all the 20 patients. It means that the program, the radiation safety program, is under the supervision umbrella of a radiation oncologist.

So this -- I would like to emphasize having a radiation oncologist on the team only helps in the safety. It does not hamper the access to any patient, because you don't have to wait for a radiation oncologist to say yes before you go ahead with one single procedure.

DR. HEIER: So, Doctor, I guess I'm a little confused then, because this is -- I have done other radiation trials as well for AMD, and, in fact, they were impractical. The way this study works, there is -- the input from the radiation oncologist has already been determined. So the input from the radiation oncologist has already been determined, and the approach doesn't change from the radiation standpoint for any of the patients.

So right now I guess I am not sure we have a radiation safety officer involved for the handling of the radiation and the storage of the radiation. So I see there are two arguments. One, the argument at the committee meeting was we are probably not treating patients in the best available manner if some of them would not benefit from alterations of either the amount or the approach of the radiation delivered. And that may or may not be the case, but, if that is the case, that is the type of scenario that becomes very impractical.

If the way it is right now, where at the other sites if there is no delay, then I think that is because right now there is no input. All of the approach has already been determined, so any of the different factors per patient are solely determined by the retina specialist.

VICE CHAIRMAN VETTER: Do any other members of the committee with to speak to this issue?

MEMBER FISHER: Dr. Vetter, this is Darrell Fisher. A question for Dr. Nag. In an active clinical setting, where the ophthalmologist is treating 20 to 30 patients a day, what is the contribution of the radiation oncologist?

MEMBER NAG: The contribution of the

radiation oncologist would be --

MEMBER FISHER: But to the individual patient --

MEMBER NAG: Not to the individual patient, to the overall program. It is to make sure that the program is set properly, that the dose levels, and so forth, are set properly. And if individual patients do come in that require modification as the program goes on, there will be someone to monitor, so that the modification, if needed, will be required.

So you don't need to call in that radiation oncologist for every patient, but to set up the program itself.

MEMBER FISHER: What is the modification that would require intervention by a radiation oncologist in a procedure for wet AMD?

MEMBER NAG: Okay. The problem is unless you go into the -- you know, in almost any treatment you always have to modify things as they go on, depending on the response you are seeing. Do we need to change the dose? Do we need to change, instead of a single-point application, maybe a two-point application? Do we need to change the direction?

So those kinds of modifications are

possible. And if you set this that it can only be done one way, you are not going to be addressing it and possibly making things better if need be. You are now -- your hands are tied, because you can only do it one way.

MEMBER FISHER: But doesn't the retinal ophthalmologist performing this procedure have more knowledge and experience than your radiation oncologist?

MEMBER NAG: The retinal specialist has more knowledge and experience on eye. They do not have knowledge and experience on radiation dosimetry and radiation microdosimetry. How do radiation may -- millimeters, how do radiation doses change depending on the angulation? Those minute things are what sometimes makes a huge difference.

I can give you an analogy on cardiac brachytherapy, which is in the domain of the cardiac surgeon or the cardiologist, because they know most about the heart, they know most about the cardiac vessels. When they did their experiment initially without much input from radiation oncologists, they were seeing a large number of failures at the end.

And when the radiation oncologist went into detail, they found this is due to the impact,

and, you know, you have to prolong the length and you have to modify the dose distribution. So unless you have those inputs, you are not going to advance this.

And, basically, you are sort of -- you are preventing this from going further, and, you know, you are now at the standpoint that you can only do 24 Gray. At that point, you cannot do any improvements to that. And, you know, are you getting the -- let's say you get a 70 percent success rate. Would you get 80 or 90 percent success rate if you changed some of the parameters, some of the angles?

Those are questions that will be unanswered if you tie yourself with only one dose, one parameter. You know, I would have liked my colleague, Jim Welsh, to have given his input, but I have talked with him and basically he has very similar concerns. I don't know if Dr. Thomadsen has, you know, any concerns along these lines.

MEMBER SULEIMAN: Well, I have already expressed that I do, indeed. I think it is a very bad idea to try to take the radiation oncologist out of the loop. We have already said that the radiation oncologist does not have to be there when the procedure is being done, so coordination becomes simpler from the retinal surgeon's point of view.

Certainly, in the procedure room, the medical physicist or radiation safety officer should be there to handle any radiation emergency that could happen. And that coordination still would have to be done, no matter what was going on here.

But I think the -- having the radiation oncologist involved is essential, whether or not you need to have each patient seen by the radiation oncologist. If the patient is just on a clinical trial, I think that is questionable. Any patients off the clinical trial start presenting big problems.

VICE CHAIRMAN VETTER: This is Dick Vetter. If I could just ask Cindy Flannery to get us back to square one here and clarify what the committee approved in October. I believe it was to apply the training specified in 35.491 to the 24 Gray standard procedure, standard treatment. And that was the only thing it applied to.

From the discussion here, it sounds like the committee would have a problem expanding the procedure to off-label use or which I guess it was a two-point treatment. But just to be clear, the only -- I think -- if Ms. Flannery could confirm for us -- the only thing we approved was the application of 35.491 to the standard procedure.

MS. FLANNERY: I don't think that's correct. I think the recommendation that was made is that the training and experience requirements in 491 would be adequate to be an authorized user for this new device. It didn't limit it to just the use in the clinical trial, so that --

VICE CHAIRMAN VETTER: Okay. That --

MS. FLANNERY: -- is a question to you is, you know, this recommendation that ACMUI made, is that applicable to off-label use as well? Because that -- you know, it wasn't specified in the recommendations.

MEMBER NAG: This is Dr. Nag.

MEMBER EGGLI: This is Doug Eggli again. I made that motion. And I know what the intent of the motion was, and the intent was to the simple 24 Gray procedure, on-label use only.

MEMBER NAG: This is Dr. Nag. I do remember that day, it was getting towards the end of the day, and end of the meeting. I felt that there was inadequate time for discussion, but the motion was called, and, therefore, voted upon. And I believe it was somewhat premature to have taken the vote, but, anyway, that was done. I believe we really need to think this a little more thoroughly.

Some of the people who are directly

involved, which would have included Dr. Welsh as one of the radiation oncologists, was not present. The Chairman of the ACMUI was not present. And I think this does require more thinking before we, you know, give a blank check.

MEMBER LIETO: Dr. Vetter?

VICE CHAIRMAN VETTER: Yes.

MEMBER LIETO: This is Ralph Lieto. First of all, a point of clarification. Dr. Welsh was there. If you look at the minutes on October 28th, he did make a number of comments, and Dr. Nag has echoed I think nearly all of those concerns that Dr. Welsh expressed at the meeting.

MEMBER NAG: Actually, Dr. Welsh was not present during the voting.

MEMBER LIETO: Excuse me. Point of order. Excuse me. The one thing that I would also like to -- I would agree with Dr. Eggli in that the presentation, and I think that the manner in which the vote was taken, was that the training and experience requirements were based on the fact of the presentation that this was a fixed dosimetry -- in other words, 24 Gray at the center, and I think it was 6 Gray, or something like that, out to a perimeter of five and a half millimeters.

The second point was that this was a fixed -- a visually identified location by the retinal specialist, so there was visual confirmation of the treatment site by the retinal specialist. And that there was -- this was a single site treatment per application.

And so I think all of those things were I think the predicate for the vote that was taken and the motion made by Dr. Eggli. At least that was my interpretation at the time.

I think, based on some of the concerns raised here, that since this is not -- this is a 1,000 -- or, actually, not a 1,000, but in terms of regulatory guidance for this, we might want to think about adding as a part of the regulatory guidance for this application that the authorized user training and experience requirements are the same regardless of off-label versus labeled use; two, that an AU with 35.400 approval is on the license.

So that you would have to have the -- that type of training and experience available, and that a person that needs to be present in addition to the -- say, the retinal specialist is the RSO or his designee.

CHAIRMAN MALMUD: This is Malmud. I've

been listening back on the committee with you again.

Mr. Lieto, is that a motion?

MEMBER LIETO: Before I make it a motion, I just would like to have it discussed as possible. Or does it have to be a motion to be discussed?

MEMBER NAG: I think we can have a discussion -- I think this does require more discussion before we can crystallize it into a motion.

DR. HEIER: I'm sorry. This is Dr. Heier again. I would also just like to point out that all of the potential changes are by no means changes that have been put forward by the users of the NeoVista device. From a retina specialist standpoint, the intention is exactly as it was proposed before. This is a single dose, single site treatment, and, in fact, if the pivotal study does not demonstrate the efficacy of this, that is an issue for the treatment overall. There are no intentions on the clinical investigator's part to modify this in any way.

MEMBER LIETO: Thank you for clarifying that, Malmud.

MEMBER NAG: This is Dr. Nag.

MEMBER THOMADSEN: This is Thomadsen.

CHAIRMAN MALMUD: Yes.

MEMBER THOMADSEN: And I think that is one

of the problems, that if there were a successful trial here, assuming that you don't cure 100 percent of the patients in that trial, the next step of course would be to investigate what you could do to improve that. That is sort of the nature of most radiotherapy regimes.

The fact that the -- that it is being said now that that would not be part of the thought, I think is either disingenuous or narrow-sighted.

DR. HEIER: That would be the focus of another study. That would then have to go through the same types of parameters and criteria that this one has. I mean, it has been my experience that if we look to modify a procedure, we then need to go through all of the steps to do that. And especially with devices such as this, there are very appropriate critical steps you have to do in order to have that go through a study.

MEMBER SULEIMAN: This is Orhan. This is Orhan Suleiman. First off, I want to clarify that once a protocol or a medical product has been cleared or approved by FDA, how it is used by the medical physician is really up to them. So you're getting under this practice of medicine issue.

They can -- if they think it is in their

professional judgment that if they change the dose they change a dose, they modify the protocol in any way that they think is medically necessary, they can't do that. The issue that I see -- and I'll ask the NRC staff to step in -- is when does the radiation safety aspect that is the responsibility of the NRC come into play in terms of they may be deviating the medical process, but, in fact, are we now introducing a very, very different radiation safety issue that needs to be addressed?

So I don't want anybody to assume that just because it has been approved in a very specific way, with a specific protocol, that that is necessarily how it is going to be practiced out there. And if it is changed, it may be because of other trials, it may be very well because of the individual's position or practice. They want to -- it is their prerogative to make some minor -- what they would perceive as minor but maybe better adjustments in the protocol.

MEMBER NAG: This is Dr. Nag. You know, the issue was raised that if this does not work, there would be a new policy made. Where would you get the input if the radiation oncologist has not made the input now? They need to get -- they need to know what

are the problems that are occurring. Maybe the wrong angle, maybe it is the positioning. So all of these little things are known only when you are in the OR.

I used to do a lot of eye plaque. We modified a lot of eye plaque based on what I saw in the OR. I am not an ophthalmologist. But when I go to the OR, I see what the ophthalmologist is doing. I learn from them, and I give feedback to them. So the feedback cycle is very, very important.

DR. HEIER: Doctor, this is a totally different procedure. You won't have a view of this. This is done through the operating microscope, and the only other person who will be there is an ophthalmology surgical trained assistant. So you won't have a view of this. If you have a view through the monitor, it doesn't give you 3-D. It won't give you any of the type of input you are talking about that would enable you to make modifications.

If this -- there is -- at least in my circles, there is no intent of redesigning the protocol if this does not work. I understand that this may not be the ideal approach from a radiation oncology standpoint, but this is a very practical approach to 200,000 new cases of wet AMD we see every year, and two million patients with this.

There is a practical component here that we have to deal with. And if that changes, there is no intent of this going further.

MEMBER NAG: This is Dr. Nag. If, for example, you get a 70 percent response, and if there was a way to get a 90 percent response, would you want to deprive your patients from going from that 70 percent to 90 percent, because you said there is only one way of doing it? This is the dose I chose at random, and this is the dose I am going to go forever. If you can improve it, why not?

DR. HEIER: I understand. But I fail to see how radiation oncology will modify that from the basis of this procedure. We've got fluorescein angiograms that take us two years of fellowship to truly appreciate and read. We have the surgery which is being done, which goes through a two-year fellowship, which you are not going to be able to look at directly.

So it is -- I am not questioning the skill of the radiation oncologist in modifying that. Some of the intricacies and difficulty of the whole process is how this is applied and the manner in which it is applied and how to interpret that. And right now the only means we have of interpreting that are with the

retinal techniques and diagnostics that we have.

And that requires -- does that mean the radiation oncologist is going to go through a two-year fellowship to enable him to interpret the angiograms and be involved in the surgical assist, so that we can eliminate the surgical assist, so he can have the view?

MEMBER NAG: We can ask the same question. Do you want to go through a four- or five-year radiation oncology training to know all of the nitty-gritty details of radiation oncology and how the microdosimetry is presented? So this is a collaborative effort, and you need the skills of both, and you are depriving your patients right now of the skills of one.

The second point is that when this was presented to the CMS, the CMS approved this and gave us codes, the complexity of which was due to the coordination that NeoVista said this would be done under collaboration with the ophthalmologists and the radiation oncologists and radiation physicists. And now, you know, they are going back on their word to the CMS.

DR. HEIER: So I would defer. I am not privy to those discussions. I wasn't involved with

them. I would defer those discussion to NeoVista.

MEMBER NAG: Okay.

CHAIRMAN MALMUD: Gentlemen, have you all had an opportunity also to read Jim Welsh's e-mail regarding this issue?

(Several members respond in the affirmative.)

Thank you. So it doesn't need to be read into the minutes?

MEMBER NAG: It could be an attachment to the minutes.

CHAIRMAN MALMUD: I will put it as an attachment, if you have all had the opportunity to read it. Yes, it will be an attachment to the minutes.

Okay. Thank you.

Now, let me get back on track. And the question on the table is training and experience requirements for the medical use of the material. And do we have any kind of a motion from a member of the committee regarding such?

MEMBER NAG: This is Dr. Nag. I would like to formulate the motion.

CHAIRMAN MALMUD: I think I heard Cindy's voice?

DR. HOWE: No, this is Dr. Howe. Just

before you make a motion, I wanted to clarify that during the last ACMUI meeting I asked for a clarification as to whether the AU had to be a retinal surgeon, and the ACMUI voted no, it is just a physician. So I want the ACMUI to remember that we have not designated the AU as someone with retinal specialty.

CHAIRMAN MALMUD: Thank you for reminding us of that.

DR. HEIER: I'm sorry, this is -- the reason that wasn't designated, it was felt that nobody would be going in to do a peritectomy who wasn't a retinal specialist.

CHAIRMAN MALMUD: Thank you.

DR. ZELAC: Dr. Malmud?

CHAIRMAN MALMUD: Yes. Who is speaking?

DR. ZELAC: This is Ron Zelac.

CHAIRMAN MALMUD: Thank you, Dr. Zelac.

DR. ZELAC: If you can indulge me, I would like to just make a brief statement.

CHAIRMAN MALMUD: Please do.

DR. ZELAC: Clearly, I think everyone understands that patient safety is an NRC concern. That is the first point. Secondly, the principal approach that is used by NRC is through assuring that

the patient gets what the physician wanted. That is as far into medical practice as we go.

But the decision on what is needed is in fact the physician's. Therefore, NRC relies on having qualified physicians, qualified on the basis of their training and experience requirements being met. Approvals are not protocol-specific, but they are use-specific. An AU is an AU, and can do what he or she wants. So modifications of the protocol are within the scope of the authorization.

Therefore, it behooves us, as regulators, to be sure that the qualifications of those who are approved as authorized for a particular purpose indeed are appropriately qualified to do the variety of things which are available once that authorization is granted.

MEMBER NAG: Could you repeat that last portion, Dr. Zelac?

DR. ZELAC: I'll try.

MEMBER NAG: Or clarify, basically.

DR. ZELAC: What I was trying to put across is the point that once an individual has met the training and experience requirements, and is designated as an authorized individual for the particular purpose, meaning this class of therapy, he

or she then has full authority under that responsibility to make whatever modifications he or she feels are appropriate to those techniques.

So if you give authorization to an individual, you are essentially saying this person is qualified to use this device in any manner in which he or she feels is appropriate. Therefore, it behooves us, as regulators or as advisors to regulators, to be sure that those persons who are authorized in fact are qualified to make those kinds of adjustments.

CHAIRMAN MALMUD: Thank you for that clarification, Dr. Zelac.

I believe Dr. Nag wanted to say something.

MEMBER NAG: Well, I wanted -- if the discussion is finished, I would like to make a motion once the discussion is finished. But I would like everyone to have the opportunity to have their discussion heard.

CHAIRMAN MALMUD: Well, the discussion can follow the motion.

MEMBER NAG: Okay. I would like to make the motion that the -- for the NeoVista device, which is under 35.1000, the training and experience requirement would be under 35.400, to be someone in the 35.400 or the user to be involved in the

treatment. However, that person does not necessarily have to be onsite or does not have to be physically present during the treatment.

CHAIRMAN MALMUD: Is there a second to the motion of Dr. Nag?

MEMBER THOMADSEN: Could you repeat the motion?

CHAIRMAN MALMUD: Dr. Nag said that --

MEMBER THOMADSEN: I got lost somewhere.

CHAIRMAN MALMUD: -- a person should be an authorized 35.400 user, to be involved in the therapy, but that that individual need not be physically present at the time of the therapy.

MEMBER NAG: And this can be modified to make the language, you know, more appropriate. But the idea is that the 35.400 -- I mean, the 35.400 person should be involved in the planning, and so forth, in the protocol but does not necessarily have to be present during the procedure. You know, we can tighten up the language.

CHAIRMAN MALMUD: That is the motion on the floor. Is there a second?

MEMBER THOMADSEN: I will second that. This is Thomadsen.

CHAIRMAN MALMUD: Yes, Dr. Thomadsen.

MEMBER THOMADSEN: I will second that.

CHAIRMAN MALMUD: The motion has been made by Dr. Nag and seconded by Dr. Thomadsen. Now it is open for discussion.

MEMBER EGGLI: This is Doug Eggli.

CHAIRMAN MALMUD: Yes, Dr. Eggli.

MEMBER EGGLI: I think sometimes perfect is the enemy of good. If, as the retinal surgeons tell us, if we make this too difficult, the procedure will be abandoned and patients will not be offered this procedure, I think we are doing a disservice to a large, large number of patients with a disease leading to blindness, which is a severe impairment in lifestyle.

I think that I can support any modification from the standard protocol requiring a full court radiation oncology involvement. But in the limited procedure, as described, which we hear from the retinal surgeons is their intent, in spite of the fact that the regulation allows you to do other than that, I think that we really limit the availability of a potentially useful therapy by making it too difficult. Again, perfect can be the enemy of good.

MEMBER NAG: This is Dr. Nag. I would like to ask Dr. Eggli, how will it limit, if the

individual patient does not need to be seen by the radiation oncologist, the radiation oncologist doesn't have to be onsite, how would that limit? You can have 100 patients per month. The radiation oncologist, they don't have wait for the radiation oncologist to be -- to see them before they can be treated.

So I do not understand how it will limit the access. Would you explain that to me, please?

MEMBER EGGLI: I will give you a roundabout explanation. Again, we are talking about a standard protocol, which has already been reviewed and has had the input of the radiation oncology community in its original design. And I see no added value to adding a radiation oncologist on top of something that is now a standard procedure, and dosimetry isn't going to change it any. And even the process of having to form a committee for this may cause some ophthalmologists in practice to be dissuaded from even pursuing it.

I think that if they follow the simple standard practice, which has been evaluated by radiation oncology and been deemed to be an appropriate treatment algorithm, that the radiation -- if they follow the standard practice, the radiation oncologist adds no additional value reviewing this

once again.

MEMBER NAG: This is Dr. Nag again.

CHAIRMAN MALMUD: This is Dr. Malmud. Dr. Eggli, are you suggesting that if the standard protocol is followed, and not varied in any fashion, that it would not require the continuing intervention -- participation of a radiation oncologist?

MEMBER EGGLI: Yes. But that any deviation from the protocol would.

MEMBER NAG: This is Dr. Nag. As Dr. Zelac reminded us a few minutes ago, when this is opened as a regulation, it is not protocol-dependent. It is dependent on the class of applicators or the class of radioactive material. And that point will apply to the NeoVista device, irrespective of how it is being used. That is point number one.

And that being the case, once this is put in the regulation, if someone wants to change it, they can. And that is a major problem.

Secondly, when you send that this protocol has already had the input from the radiation oncologist, why was that there? Because initially when this was started, it required the input of the radiation oncologist. If that requirement was not there before, it would have started without any

involvement, because obviously it takes a little effort to try to get help from anyone else.

And unless you have that help from the beginning, you are not going to --

MEMBER EGGLI: Well, the --

MEMBER NAG: So, again, having a radiation oncologist will not delay anything.

MEMBER EGGLI: This is Eggli again. I have to respectfully disagree with that. The protocol was designed with the assistance of the radiation oncology community, because that was an appropriate input. And you're right, in the practice of medicine, I can do almost anything I want. But I'm probably not going to. I'm going to follow good practice.

And in the places where people are going to vary from that, odds are they are going to do it on protocol, and those protocols are involved -- will involve a radiation oncologist to design those clinical protocols. You know, you can't regulate against the rare occurrence of something untoward, and then deprive everybody of an opportunity for a very beneficial treatment.

Essentially, I think that you are worried about edge cases. And you can't -- you can never regulate edge cases out of existence. I don't think

that if the standard protocol is followed that the continued involvement of the radiation oncologist adds any value, and all of your arguments deal with the retinal surgeon doing something different than the standard protocol, which may or may not occur.

And my inclination is to listen to what the retinal surgeon says, which is that they don't anticipate that this deviation will occur. And if it were, it would go back to the protocol stage. Do we have any reason not to believe the input we are getting from our professional colleagues in retinal surgery?

CHAIRMAN MALMUD: Thank you both for your comments. I would ask: are there any other members of the committee who wish to make comments? I think that the positions of Dr. Nag and Dr. Eggli are clear.

MEMBER GILLEY: Yes, this is Debbie.

CHAIRMAN MALMUD: I'm sorry. Who is this?

MEMBER GILLEY: Debbie Gilley.

CHAIRMAN MALMUD: Thank you, Debbie Gilley.

MEMBER GILLEY: I have two, one to NRC staff. I want to make sure that these guidelines do not require adoption by the agreement states. Can I get a confirmation on that, that they are just

guidelines?

CHAIRMAN MALMUD: You are asking the question of NRC staff.

MEMBER GILLEY: Yes, I am.

CHAIRMAN MALMUD: Anyone on the NRC staff want to answer Debbie Gilley's question?

MS. FLANNERY: Yes, this is Cindy Flannery. Debbie, the answer to your question is, no, the agreement states are not required to adopt the guidance. It is under 35.1000.

MEMBER GILLEY: Thank you. And the second question I have, if you are going to have this team approach, and we have a medical event, is the radiation oncologist who now wants to be listed as part of this team going to step up and be accountable for activities that he had general overview for?

MEMBER NAG: Well, that would be part of the requirement if you have an oversight. That person would be playing an oversight role in the design and overall responsibility. I mean, we have many other instances where we have an overall responsibility of radioactive material where they are, although we don't necessarily see it every day. But we do oversight of that, you know, in --

MEMBER GILLEY: You have missed my point.

You have made it very difficult on the regulatory community in implementing this to identify who should be accountable in the event of a medical event. If you remember when we did the cardiology that I -- the intravascular brachytherapy, we didn't list the cardiologist. We list the authorized user.

They were the ones that were responsible as the medical person in the event of a medical event. Now you were looking at putting two people as being part of the team, and it concerns me in trying to write regulations and implementation to have clear guidance given to everyone as to what the responsibilities are of both of these professions.

CHAIRMAN MALMUD: Debbie, I ask you a question. Are you in support of the motion of Dr. Nag, or opposing it?

MEMBER GILLEY: I am opposed to the motion.

CHAIRMAN MALMUD: You are opposed to Dr. Nag's motion.

MEMBER GILLEY: That is correct. I voted when we met in October, and I stand by that vote.

CHAIRMAN MALMUD: Thank you for that clarification.

DR. HEIER: I apologize. This is Jeff

Heier. And I don't want to speak out of turn, but I wonder if I could just make one point and ask one question.

CHAIRMAN MALMUD: Please do.

DR. HEIER: The first point is, in any clinical trial that we design, there is input of a whole vast number of medical specialists. Every clinical trial we looked at for AMD, we speak to a cardiologist, we may speak to a pulmonologist, we may speak to a neurologist, because treatments we are going to do may have an impact in their area, and we want their expertise in the design of the study.

Once we have had their expertise, they are almost never further involved in the study. And that is very common.

The question I have is, it is not clear to me, if the proposal is to now have a radiation oncologist as part of the team on every patient, meaning they are going to have input into every patient, because that, once again, will eliminate this as a practical application for these patients. We see them too often.

It is too hard to just coordinate with their primary care physician or their families on the extent of treatment. And if we are having to

coordinate with another medical specialist, and it is a fairly -- what you are proposing in terms of the coordination is not simple now.

Now you are talking about changing dosimetry and maximizing outcomes based on lesion characteristics and lesion size. If these are things that we agonize over and speak among our colleagues, I can only imagine the type of intervention that is going to occur if we have to do it with another medical specialty. I think you eliminate it as a practical approach.

CHAIRMAN MALMUD: Thank you. Thank you for that information.

VICE CHAIRMAN VETTER: Dr. Malmud, this is Dick Vetter. I just have a question for NRC. If we approve this motion, how would they implement it?

CHAIRMAN MALMUD: Excuse me. Dr. Vetter? Dr. Vetter?

VICE CHAIRMAN VETTER: Yes.

CHAIRMAN MALMUD: I am also going to ask you to take it for another five minutes. I have another patient to treat, and ask NRC to answer your question.

VICE CHAIRMAN VETTER: Okay.

CHAIRMAN MALMUD: Thank you.

DR. ZELAC: Dr. Malmud, this is Ron Zelac. I think that the motion that Dr. Nag has put forth is in fact consistent with respect to the requirements for the authorized user for this device with our current guidance. So, in effect, it would be an endorsement of the current guidance and puts to the side the motion that was made at the October meeting concerning modified, substantially reduced training and experience requirements for the authorized user for this purpose.

So that is the answer to the question. If you will indulge, I have something else I can add I think.

VICE CHAIRMAN VETTER: Please do.

DR. ZELAC: It appears that there are really two things going on here. One is concern to be sure that patients who could benefit from this treatment have an opportunity to receive it, meaning specifically the protocol that is in place right now. And the second is concern about the possibility that authorized individuals could go on, using medical judgment, and make modifications to the usage of this device for select patients.

The suggestion I would have and throw out for consideration is whether the Advisory Committee

would be supportive of essentially letting your previous recommendation stand with respect to the training requirements, but limit those who are authorized under those limited training requirements to only be authorized to use this under the existing protocol. That could be accomplished through a license condition for anyone who was authorized for 491 use for this particular purpose.

In that way, you know, the persons who are interested and wish to be participants in this protocol could have access to the device for that specific purpose, but yet not have the full range of authority that would be associated with an open, untethered authorization.

MEMBER NAG: This is Dr. Nag. Dr. Zelac, I really liked your suggestion. And what I can do is to reword my motion to basically say that for patients being treated under the existing protocol, the 491 user would be sufficient. However, for the overall use of the device under any other -- under any other condition, it will require a 35.400 level user.

DR. HOWE: Dr. Nag, this is Dr. Howe. I guess I have an underlying question. That is that we know that there was a recent humanitarian compassionate --

MEMBER NAG: Exemption.

DR. HOWE: -- exemption, and we don't know how that patient differed. Maybe the patient wasn't qualified to be in the test. Maybe there was something else. Now, you don't necessarily want to be in a position where for the compassionate choices you now have to go to a higher level. I mean, we are already seeing some variation, and I don't know how to address that. But I just want to bring it back to the discussion.

MEMBER NAG: But, basically, I think what we are trying to do is to make a fast track for the large number of patients who will be treated by one single means and have back on the fast track, so that they could be seen by the ophthalmologist as an authorized user. And any modification, therefore, thereof, whether it is a humanitarian exemption, whether it is someone trying a different dose, etcetera, would have to be done under the supervision of a 35.400.

I think this -- there would be only a limited number of them, and I think it will provide a good balance between excess and the overall safety. And I think that is why I kind of support Dr. Zelac's recommendation.

MEMBER EGGLI: This is Eggli. I can support this as well. And in response to Dr. Howe's statement, even though it is compassionate use, it is a different use that would benefit from the input of a radiation oncologist, and probably should have it. And, you know, compassionate use doesn't necessarily always mean emergency use.

But I think that a formal dosimetry planning would be very appropriate where you vary from the protocol. So that -- I think that is perfectly compatible with what we agreed to before. As long as the practitioner agrees to practice the limited protocol, then we can give a limited authorization. If it is anything different, it requires a Part 400 authorization.

So that is perfectly compatible with what I believe we agreed to in the last meeting.

MEMBER THOMADSEN: Dr. Vetter? This is --

VICE CHAIRMAN VETTER: There is -- I'm sorry. If everyone could quiet down for a moment, there is someone in the background trying to get our attention, and the volume is very low. Go ahead, please.

MEMBER THOMADSEN: Dr. Vetter?

VICE CHAIRMAN VETTER: Yes.

MEMBER THOMADSEN: This is Bruce Thomadsen.

VICE CHAIRMAN VETTER: Bruce.

MEMBER THOMADSEN: And the question for the proposal is -- assume that the current trial will close relatively soon, and a new trial will probably open. Are we stating that we would be limiting people to the -- limiting the retinal surgeons to what is in the current trial, without regard to the next trial? And if it turns out the next trial is doing better, do we come back and revisit this each time there is a trial and a change?

DR. HEIER: If I could -- I don't -- this is Dr. Heier again. I don't know for certain that the -- what the compassionate use was. But I know I almost had a compassionate use, and the disease was exactly the same. It was choroidal neovascularization. But the patient didn't meet the exact criteria of the study guidelines, which was a visual acuity change.

And yet the disease -- the underlying disease was exactly the same. And what I have seen in compassionate use for diseases like this is the compassionate use is usually for the same process -- choroidal neovascularization -- which by far the large

majority are age-related macular degeneration. But there are some other causes, like hymyopia and histoplasmosis.

And those occasionally are what get the compassionate use and not -- so it is the same underlying problem, a growth of new blood vessels from -- growing in a similar manner, but it is usually patients who don't fit the exact criteria from the study. It is not a change in the study application at all. It is not a change in how it is delivered. It is simply they didn't meet one of the criteria.

CHAIRMAN MALMUD: This is Malmud again. Was that the question that you were asking, Dr. Thomadsen?

MEMBER THOMADSEN: No, not at all. It was -- I was not discussing the compassionate use, but with the changes in a protocol, that a new protocol would probably open once the old protocol changes.

CHAIRMAN MALMUD: Thank you. That's what I thought you meant, Dr. Thomadsen. I think your question might be best addressed to a member of the NRC staff who was with us on this conversation. Would a -- is this applicable only to the existing protocol?

DR. ZELAC: My thought personally, and this is strictly only personally, would be that the

license condition would limit the authorization of the individual named to follow -- to be -- to use the device in approved protocols, you know, FDA-approved protocols for example.

CHAIRMAN MALMUD: Thank you, Dr. Zelac, but --

DR. ZELAC: So if you went off of that, then you'd be in another sphere entirely.

CHAIRMAN MALMUD: But you used the -- this is Malmud again. Dr. Zelac, could you clarify this for us? You used the plural "protocols." Does that mean that it is beyond this single protocol?

DR. ZELAC: To me it does, because Dr. Heier was speaking of this going from Phase 2 to Phase 3, which I presume would be a different protocol.

DR. HEIER: No.

DR. ZELAC: No? Same protocol?

DR. HEIER: It is in the pivotal phase already.

CHAIRMAN MALMUD: Thank you, Dr. Zelac.

Dr. Thomadsen, Dr. Zelac says this is applicable to protocols, with a plural.

MEMBER THOMADSEN: My question to Mr. Zelac, then, is: when the protocol closes, does that

mean that the practitioners would have no recourse to treat their patients?

DR. ZELAC: My answer is yes, it would have to come back to have the license condition removed.

MEMBER THOMADSEN: So if I may clarify, what we are saying is we are giving approval to retinal surgeons to treat patients according to the protocol on the protocol only. Is that their authorization that we are approving?

CHAIRMAN MALMUD: This is Malmud. That is my understanding of it. Dr. Zelac, is that your understanding of it?

DR. ZELAC: Yes, it is.

CHAIRMAN MALMUD: Thank you. Now, with that understanding, is there any change in concerns regarding the approval?

MEMBER SULEIMAN: This is Orhan Suleiman.

CHAIRMAN MALMUD: Yes, Dr. Suleiman.

MEMBER SULEIMAN: Yes. Let me explain something in terms of if the manufacturer decides that they want to expand their indication or their -- or if a user is trying to do experimentation of a significant deviation, at some point it is not -- there is a questionable area, just like everything

else, of when it is the practice of medicine and when it is human research.

And so if it is practice of medicine to treat a patient, and the changes that they are advocating are within the overall scope of practice of medicine, it is okay. But if they are really doing experimentation and trying to test new protocols and whatever, that is human research. It has got to come under, you know, FDA umbrella, and the whole nine yards again.

So I think the -- it is never an easy answer. But I want to make clear that you've got these different little areas that are actually distinct, but they are not -- the borders are not very, very sharp and clearly defined.

But there is following the protocol that has already been approved in a very specific manner, there is deviating from that under the practice of medicine, which could be minor differences, you know, which will have a significant, you know, change in the patient safety and whatever, but how much you start to deviate is a different issue.

If the physician is deviating in a very terrible way, you know, then you get into litigation and liability issues. If you are doing

experimentation to come up with something very different, very dramatic, and you are doing it in a much more formal manner, then you are back into a clinical trial environment. Those are very, very different areas, and one size doesn't fit all, so I think we -- I am just trying to remind the committee members that we do have those differences.

So I think what Dr. Zelac is proposing sounds like it has enough flexibility, but at the same time assures enough safety -- radiation safety in terms of patient protection.

CHAIRMAN MALMUD: This is Malmud again. I'm going to -- as chair, I am just going to ask you to clarify something, Orhan. Are you suggesting that you are in favor of approval of this if it adheres to the current protocol, and that it is limited to the current protocol?

MEMBER SULEIMAN: Again, I am a little confused in terms of how -- what are the radiation safety or radiation dosimetry assurances. Does the protocol in fact address that? Or what I'm hearing also is that, if it is under practice of medicine, is it possible you may deviate enough that you may change the dosimetry characteristics, that you may cause a safety issue?

CHAIRMAN MALMUD: For the dosimetry issue, may we refer either to a radiation oncologist or to a radiation physicist?

MEMBER SULEIMAN: Well, somebody who knows what they are doing.

CHAIRMAN MALMUD: That is why I chose those.

MEMBER SULEIMAN: Yes.

MEMBER THOMADSEN: Well, certainly, depending what the changes you want to make are, if it is the criteria for accepting a patient, no. If it is going to be sizes of lesions, yes. So, I mean, that depends.

MEMBER NAG: Again, I think that is where -- the way I had framed my motion was that, if it is exactly opposing the current protocol, then that is fine. But anything that is already in the dose, whether it be notifying the patient, and so forth, or number of areas that are irradiated, then it does require a 400 user to be involved.

MEMBER THOMADSEN: And the patient has --

CHAIRMAN MALMUD: I'm sorry. Who is speaking now?

MEMBER THOMADSEN: I'm sorry. This is Thomadsen again.

CHAIRMAN MALMUD: Thank you.

MEMBER THOMADSEN: And in some of the patient selection criteria, such as diabetes, for example, it would definitely affect how the patient responds to radiation. So there are -- while some things would change the dosimetry, some things would change the effects of the dosimetry.

DR. HEIER: This is Jeff Heier again. I certainly agree with that, and those are there for a reason. But there are certain things that are there just because it is a study. And, for instance, any AMD study that treats wet macular degeneration has visual acuity guidelines. And usually it is vision of 20/40 or worse.

Yet when the treatment is approved, those are automatically wiped out. Every single AMD study that has had approval in the last 10 years has had those same criteria. And once the drug is approved, then the visual acuity criteria is wiped out. And those are usually there solely so you can demonstrate certain degrees of improvement.

If a patient starts with 20/20 vision, they are not going to be able to gain three lines of vision. So they keep those patients out of the study intentionally.

MEMBER THOMADSEN: And is the proposal that if once -- let's say this meets approval, the study is successful, and there are those guidelines. Is the proposal that when patients meet those guidelines, that disease with that criteria, you can treat them in a medical setting? It is not that the patient has to be in a study protocol to be treated.

VICE CHAIRMAN VETTER: Yes. This is Dick Vetter. My understanding of this is that what we are approving are the training and experience requirements for medical use, for routine clinical use once this protocol is completed. Is that correct? Maybe Cindy Flannery can clarify that.

MEMBER THOMADSEN: Can Dr. Zelac address that? Because that was my question before, and the answer was it was just for this protocol.

DR. HEIER: Right. Which makes no sense to train people, have them do it all, and then say, "Okay. You've done it, you've been successful, now we have to retrain you differently."

DR. ZELAC: This is Zelac. I understood from Dr. Heier and the discussion at the last meeting that we are talking about a specific -- in terms of inclusion for the patient, a specific limited size lesion, one treatment with a particular given

angulation of the device, and that's it. Correct?

DR. HEIER: Correct. That is correct.

DR. ZELAC: Now, my intent was essentially to, in appropriate fashion with wording, limit the authorizations of individuals as authorized users to that, to that particular use, and not to offer -- open it up to variations in any one of those characteristics, be it, for example, dose painting as being within the realm of the authorization.

MEMBER NAG: This is Dr. Nag. This is what I was afraid of, that we will be going to a slippery slope. Once we allow a limited application, then the next thing will be, well, we have this limited application. This is somewhat similar, so that point will extend to that. And, you know, you change a few other things, very much similar, so, therefore, it doesn't require any further approval, and so on.

So, you know, that leads to a slippery slope. And, therefore, I had only -- in my motion I had only said in this particular protocol, and then, if there is some other new protocol coming in, we can reexamine that, see whether that makes sense, before we give approval for that protocol.

CHAIRMAN MALMUD: So the -- my

understanding -- this is Malmud. My understanding is that we are approving a use-specific approval. Is that correct, Dr. Zelac and Dr. Nag?

MEMBER NAG: Well, that was my intention, that this -- that the 491 user, authorized user, would be for this particular protocol. And if anything else changes, it goes under the 400 user until, you know, they bring back anything else on the table and we examine it and see whether that would be something that can go back to a 491 user.

CHAIRMAN MALMUD: Thank you. Dr. Zelac, was that your understanding also?

MS. FLANNERY: He just stepped out. This is Cindy Flannery.

CHAIRMAN MALMUD: Cindy, is that your understanding?

MS. FLANNERY: Well, I just want to clarify that when the recommendation was made at the October meeting, it was not clear or specific to -- you know, when the recommendation was made for 491 to be adequate for the T&E, it didn't really specify whether it would be just for the clinical trial protocol or for any use.

MEMBER EGGLI: This is Eggli. If you look at statements of consideration, I think in the

discussion, again, the intent of the motion was that it was for this protocol as applied to clinical patients, once the FDA approves this protocol. So what we are talking about is not per se a research protocol, but a clinical treatment protocol. It was the intent of my motion to limit the authorization to that treatment protocol.

MS. FLANNERY: And I not sure that everybody understood it that way. And the reason why I say that is because one person on ACMUI, you know, abstained, and with the reason being that when this device gets approved it could be used off label. And, you know, the T&E that was being suggested in the motion might not be adequate, and it was too early to tell. So I -- I'm not certain that everybody in the ACMUI understood it that way.

CHAIRMAN MALMUD: Thank you. Dr. Vetter, you chaired that session of ACMUI. Do you recall what the feeling was? I know what the minutes said, but do you recall what the spirit of the committee was?

VICE CHAIRMAN VETTER: This is Dick Vetter. I can only say what my understanding was, and it was exactly as Dr. Eggli outlined. It was limited to once the clinical trial was complete, and the procedure is approved by FDA, that it would be limited

to this 24 Gray standard procedure.

CHAIRMAN MALMUD: Thank you. Thank you for clarifying that again.

So that was the spirit and the decision of the committee in the October meeting on day 2. And now, the motion on the floor -- before us today, Dr. Nag's motion, reaffirms that. Is that correct, Dr. Nag?

MEMBER NAG: Yes. Except that I added that for any other uses it has to be under 35.400. So I basically clarified the previous one, because the previous was slightly ambiguous because it didn't state, you know, what happens if it is not on that particular protocol.

CHAIRMAN MALMUD: But in a brief statement, your motion simply says that if there are any changes it has got to go under 35.400. Is that it?

MEMBER NAG: Yes. That if it is done under the current protocol, 35.491 authorized user is sufficient. However, if there are any deviations or alterations, it has -- there has to be a 35.400 authorized user involved.

CHAIRMAN MALMUD: And that is your motion with us today.

MEMBER NAG: Yes.

CHAIRMAN MALMUD: May we move the motion, it being five after three? Or does anyone else have something they wish to say?

MEMBER LIETO: This is Ralph Lieto. I -- just for clarification, to be sure I understand, when you say "involved," you mean that he would be -- that they would have to have an AU on the license --

MEMBER NAG: Yes.

MEMBER LIETO: -- for this use. That's what you mean by "involved," correct?

MEMBER NAG: So what I had said in my previous one was that a 35.400 authorized user would have to be involved, but does not have to be physically present during the procedure.

CHAIRMAN MALMUD: So by "involved," do you mean it has to have an authorized user who does not need to be physically present?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Thank you. May we move the motion?

MEMBER MATTMULLER: This is Mattmuller, Dr. Malmud.

CHAIRMAN MALMUD: Yes.

MEMBER MATTMULLER: First of all, I want

to come out and say that I am in full support of Dr. Eggli's position on a number of the points he made. My concern with Dr. Nag's amendment is that, does this -- with the way it is worded, would this preclude, if yet another protocol was verified through a clinical trial, that the individual couldn't use this device under 491, it would have to then go to 490?

MEMBER NAG: Well, basically, my intention is that this protocol has been approved. We have noted that, and, therefore, it is approved for this protocol. If there is a new protocol that is made, it is very easy to bring it back and say, "This is a new protocol. Is this acceptable?" And if we find it equally acceptable, we'll say yes. If we find that, you know, that new protocol is for some reason not acceptable or not safe, we do have the right to say that.

CHAIRMAN MALMUD: Does that answer your question, Dr. Mattmuller?

MEMBER MATTMULLER: Yes, it does. Thank you.

CHAIRMAN MALMUD: Thank you. Call the motion? All in favor, aye?

MEMBER THOMADSEN: Excuse me. Can you please read the motion back, so we are quite clear on

exactly what we are voting on?

CHAIRMAN MALMUD: Thank you. Who was speaking?

MEMBER THOMADSEN: That is Thomadsen again. Sorry.

CHAIRMAN MALMUD: Thank you, Dr. Thomadsen. Dr. --

MEMBER NAG: Nag?

CHAIRMAN MALMUD: -- Nag?

MEMBER NAG: Okay. I make the motion that for this NeoVista device, under the present protocol, a 35.491 use -- authorized user will be acceptable. If there are any deviations or changes from the protocol, it will require the involvement of a 35.400 authorized user who does not necessarily have to be present during the procedure.

CHAIRMAN MALMUD: Thank you. Does that clarify your question, Dr. Thomadsen?

MEMBER THOMADSEN: Yes. Thank you.

CHAIRMAN MALMUD: Thank you. If we may, we will call the question. All in favor of Dr. Nag's notion?

(Chorus of ayes.)

All opposed to Dr. Nag's motion?

(No response.)

All --

MEMBER GILLEY: Aye.

CHAIRMAN MALMUD: So there is one opposition.

MEMBER GILLEY: Yes.

CHAIRMAN MALMUD: Is that you, Debbie?

MEMBER GILLEY: Yes, that's me.

CHAIRMAN MALMUD: Thank you.

MEMBER GILLEY: Thank you.

CHAIRMAN MALMUD: Any abstentions?

(No response.)

So the motion moves forward with all in favor except for one.

MEMBER NAG: How many ayes were there?

CHAIRMAN MALMUD: How many ayes were there? Shall we -- let's count the ayes. Please identify yourselves by your vote.

MEMBER NAG: Dr. Nag, yes.

CHAIRMAN MALMUD: Nag, yes.

VICE CHAIRMAN VETTER: Vetter, yes.

CHAIRMAN MALMUD: Vetter, yes. Lieto?

MEMBER LIETO: Yes.

CHAIRMAN MALMUD: Yes.

MEMBER SULEIMAN: Suleiman, yes.

CHAIRMAN MALMUD: Mattmuller?

MEMBER MATTMULLER: Yes.

MEMBER EGGLI: Eggli, yes.

CHAIRMAN MALMUD: Thank you.

MEMBER THOMADSEN: Thomadsen, yes.

MEMBER FISHER: Fisher, yes.

CHAIRMAN MALMUD: Thank you. Other members of the committee? Malmud is a yes, if you want my vote.

MEMBER NAG: Thank you.

CHAIRMAN MALMUD: Thank you. Does that answer your question, Dr. Nag?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: And does that meet the requirements of an approval?

MS. FLANNERY: Yes, it does. This is Cindy Flannery.

CHAIRMAN MALMUD: Thank you, Cindy.

That I believe covers the items on the agenda for today. Are there any other informational items or comments from the public that we would entertain?

(No response.)

If not, I want to thank all of the participants, both the members of the committee, the NRC staff, and the public, for their participation,

and wish you all a very happy holiday season and a healthy new year. And we look forward to our next committee meeting.

Thank you.

(Whereupon, at 3:10 p.m., the proceedings in the foregoing matter were adjourned.)

# Official Transcript of Proceedings

# NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes: OPEN SESSION

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Friday, May 8, 2009

Work Order No.: NRC-2797 Pages 1-206

**NEAL R. GROSS AND CO., INC.**
**Court Reporters and Transcribers**
**1323 Rhode Island Avenue, N.W.**
**Washington, D.C. 20005**
**(202) 234-4433**

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

FRIDAY, MAY 8, 2009

+ + + + +

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, Ph.D., Member

DEBBIE GILLEY, Member

MILTON GUIBERTEAU, M.D., Representative

RALPH P. LIETO, Member

STEVEN MATTMULLER, Member

SUBIR NAG, M.D., Member

ORHAN SULEIMAN, Ph.D., Member

BRUCE THOMADSEN, Ph.D., Member

WILLIAM VAN DECKER, M.D., Member

RICHARD J. VETTER, Ph.D., Vice Chairman

JAMES S. WELSH, M.D., Member

NRC STAFF PRESENT:

ROB LEWIS, Director, MSSA

CHRIS EINBERG, Branch Chief, RMSB

CINDY FLANNERY

STEVEN BAGGET

NEELAM BHALLA

ASHLEY COCKERHAM

DONALD COOL, Ph.D.

RON ZELAC, Ph.D.

DONNA-BETH HOWE, Ph.D.

DUANE WHITE

GRETCHEN RIVERA-CAPELLA

GLENDA VILLAMAR

LEIRA CUADRADO

CASSANDRA FRAZIER

SANDY GABRIEL

DORIS LEWIS

ED LOHR

PATRICIA PELKE

MARK SCHAFFER

MARK THAGGARD

DARREL WIEDEMAN

MEMBERS OF THE PUBLIC PRESENT:

GARY BECKER, ABR (PHONE)

MEMBERS OF THE PUBLIC PRESENT CONT.

MELISSA CACIA, AACE (PHONE)

ROBERT DANSEREAU, NY (PHONE)

WILLIAM DAVIDSON, U OF PENN (PHONE)

RICHARD EATON, MITA

EMILY GARDNER, ASNC

LYNNE FAIROBENT, AAPM

BONNIE HAMILTON, MDS NORDION

KAREN LANGLEY, UT (PHONE)

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)

A-G-E-N-D-A

P R O C E E D I N G S

(8:12 a.m.)

CHAIRMAN MALMUD: Because of yesterday's extensive discussions, today's program will be altered slightly. However, we are beginning with Dr. Cool, who is scheduled at 8 a.m., and the topic of discussion is "Options to Revise Radiation Protection Regulations."

Dr. Cool.

DR. COOL: Good morning, ladies and gentlemen. Thank you for inviting me down to speak to you again. You will recall that I think the last time we met, last fall; I came down and talked to you about what the staff was, at that time, thinking about suggesting to the Commission in terms of next step for radiation protection regulations and requirements following on the publication of the International Commission on Radiological Protection's recommendations.

Well, I'm back to talk with you today to refresh that, and to move forward. So, I'm going to very quickly go through the first few of these, because we had a chance to talk to them before. As you know, of course, 10 CFR Part 20 was last revised in 1991. It's based on recommendations that went back

all the way to 1977. And some regulations and NRC requirements were not updated at that time, if they had their own separate explicit dosimetric criteria. The one that was catching everybody's attention was not the one you would be so much interested in, but was very important to our friends that run the reactors, because that was the requirement dealing with effluent controls, 10 CFR Part 50, Appendix I. Those go all the way back to the recommendations from 1959. So, there was, obviously, a bit of a question about trying to update the requirements.

In 2001, we had asked the Commission on the next steps, and everyone had agreed that we would wait for ICRP to be done. We didn't quite figure it would take ICRP seven years, but nothing moves quickly, and greatly benefits from the multiple rounds of public comment that transpired during the course of the development of those recommendations. So, those came out in December of 2007.

So, now to catch up to where we were last time, the staff did go to the Commission in December of last year, SECY Paper 080197 is publicly available, as a notational paper. We asked the Commission to provide us with directions on a set of options for moving forward. We provided them some background on

the information, and some of the technical issues, and we -

(Off the record comments.)

DR. COOL: Okay. And, as I said, we recommended to the Commission that the next step be to engage in further discussions with the stakeholders, various groups of licensees, and work on developing the technical basis, because there was much that was necessary before we could actually begin rulemaking.

The Commission gave us direction in an SRM just a month ago. The SRM approved the staff going forward to develop a technical basis and to start interacting with the stakeholders. That's part of the reason that we're here with you today, is to start making that move forward. Our objective, then, is to explore the implications, looking for what's appropriate, what's scientifically justified to move towards a greater alignment with ICRP Publication 103 and the recommendations for radiation protection.

We must keep in mind that the baseline from all this is that the standards do provide adequate protection, so questions become what the benefits and impacts, the pros and cons, different possibilities for modifying the framework to get more consistency with the requirements that might be

associated with that.

You saw this slide last time, I believe. To quickly overview some of the key questions that we are going to be looking for interactions on, this group last time had quite a bit of discussion on the very first item, the use or not use yet of effective dose. Other major issues being the dose limits, the application of constraints, and, of course, some of the numeric values, and otherwise. And I'm going to go into those in greater detail now just to go through those briefly.

On the occupational dose limits, the one that everyone seems to focus on, ICRP both in the current set of recommendations and the previous set of recommendations from 1990 recommended an occupational limit at 10 rem over any five-year period, with a maximum of 5 rem in any one year. That has been translated internationally, in some cases, as a simple 2 rem per year limit, period. Nice and simple, straightforward. Many countries, in fact, have the 10 rem over five-years, sometimes the five years is a rolling average. Sometimes it's a fixed five-year period and you get to restart the clock again every five years, so there are some variations on the theme.

The United States is about the only place

left in the world that still has a limit which is only 5 rem. So that, obviously, poses a question as to whether or not some adjustment needs to be made. As I noted to you last time, of course, since the ICRP recommendations were a maximum of five in any one year, you could argue that we are still consistent with the international recommendations, particularly since most all occupational exposure after you've applied ALARA is very much below that. And, in almost all cases, even below the 2 rem per year average.

So, the key options that we, at least, laid out to the Commission, you could not change, you could move to the ICRP recommendation, you could go to a simple 2 rem per year value. And there are pros and cons associated with that. There are a number of impacts, a little bit of which we talked about last time. That includes record keeping and reporting. Some of us are old enough to remember the days of 5N minus 13, 18, I'm trying to get myself younger, and all of the ongoing record keeping and figuring out where you were, and looking back at dose histories and otherwise, which you no longer needed when you had a simple yearly value. Those would have to come back if you went to a five-year average of some type.

There are also, as we know, some issues

around certain types of uses, industrial radiography being one, nuclear pharmacy being one that was identified here last time. So, we're going to be looking specifically for the views of this Commission, and your various constituent's organizations in terms of the pros/cons, implications, and impacts on that.

Moving on to the next one, which we also had some discussion on last time, dose limit for protection of the embryo fetus for a declared pregnant female. The ICRP recommendation now is a fairly straightforward 100 millirem after the notification of pregnancy, consistent with a generalized statement of protection consistent with that provided for a member of the public. Currently, Part 20 is at 500 millirem for the entire gestation period, which means that under our requirements, you have to go back and assess the exposure that's already taken place before the individual declared her pregnancy to determine what's left, and what you can apply.

So, again, as you can see, there are possible implications of moving to the new system, or retaining the old system. Obviously, again, options would include not changing anything, going to the ICRP recommendation, going to some other single value after declaration, or otherwise, that have been suggested.

Since you know the individual is not going to declare on the day of conception, and it will be somewhere between there and the day of birth. And depending on what the individual wants to do, and it is her choice, it is not a requirement that there be a declaration, the degree of protection then varies. If the declaration is very early, then an ICRP recommendation of 100 millirem after declaration would be more protective than 500 millirem over the duration. But if you get the individual who waits until four, five, six, seven months in before declaring her pregnancy, then, in fact, you could argue that the ICRP recommendation might be less protective. So, there are various pros and cons, and again, there are implications associated with the record keeping and update, and the analysis that would have to be done.

Moving on to what may be one of the biggest points of discussion, that is the concept of constraints. ICRP has in its current set of recommendations emphasized the use of constraints in planning values in the process of optimization of ALARA. This is probably the single greatest feature of the revised recommendations, is the emphasis upon this as a planning tool in optimization. It's not a limit. ICRP doesn't intend it to be a dose limit. It

intends it as a planning value, prospectively used to figure out where you want to be, and where you don't want to be in the process of figuring out what options, and what activities you'll conduct as part of your ALARA program.

Now, the NRC already has constraint defined in the regulations. In fact, there is already a constraint value for airborne effluents from material facilities of 10 millirem per year. That went in as a result of our interactions with EPA under the Clean Air Act. This would go, potentially, substantially beyond that current position.

We know, for example, that many licenses, certainly all of the big licensees, all the reactors, many broad scopes, and otherwise typically and normally use planning values in deciding what their ALARA program is going to be, what their ALARA objectives are going to be for the year, and otherwise. That's a constraint.

The question really becomes, do we see a value in requiring licensees to do that, because some do, and some don't. And antidotal at this point, the evidence would seem to indicate, perhaps, that in those areas where that is not a standard practice, or is not consistently used, those are areas where you

tend to see higher exposure, and potentially have more issues, so there is the possibility that you could be improving protection by having people do a better job of planning. Actually makes a fair bit of sense.

So, the questions really become do we want to put such a requirement in, or is it an overreach of a regulatory burden and a requirement to require them to do such a thing? Do we want to have them make it part of it? And, then, do we want to go so far, if you were to put it in, to suggest to them a numeric value, or, perhaps, a maximum value that they could use as part of the process?

There are, obviously, a number of implications that we want to look at and explore with various groups. Do you or do you not already do this? If you already do this, it's just a matter of okay, now there's a requirement for it. Are the benefits to protection to be seen? As I indicated, many times there is a benefit to making sure your planning is done well, and going back and checking that. But is there a benefit sufficient that you might want to make that part of the requirements? What might be the relationship to the dose limit?

As I briefly outlined to this group last time, one of the things that the staff has explored

internally is the question of whether instead of modifying the dose limit, we could achieve the same degree of protection out there in the field in practice by using constraints, and having people do a better job of planning, rather than by ratcheting down the limit, itself. So, there is some interplay that we would like to explore with groups. And, as I said, is this appropriate or perhaps not appropriate insertion of a regulatory requirement in an area where many people are already doing something?

So, to interact with you, and to move forward, what we're looking for are your thoughts, both the Committee, you folks as individuals, and each of the various types of medical uses that are represented around this table. What are the impacts of the options? What other options may be out there? I, by no means, suggest to you that we've thought of all of the possibilities, nor am I suggesting to you this very quick list today is by any means the entire list of issues that needs to be addressed. This is just the very first wave. There are many, many others. What happens with extremity doses? What happens with the public dose limit? What happens with the numeric values? Do you want to continue to have those available? What are the underlying calculations

and criteria that are used? ICRP raises questions because when you start to underlie this, we know that there are some differences between the risks in males and females. This has a balance. Is that the appropriate balance? Do we continue to move forward? Are there legal implications associated with some of these other decisions? All of that needs to be built into the information that we need to gather in order to be able to make a recommendation for rulemaking in a couple of years. Now, we do, in fact, have a couple of years.

So, the schedule, at this point, now through this summer, at least, maybe on into the fall some, some initial discussion, presentations much like I'm doing for you today to raise awareness and to get people thinking, and starting the discussion process. Starting in the fall through the winter, and into next year, to get into more detailed discussions, to really start digging into the details, getting the pros and cons, debating it back and forth, looking for the issues and impacts. We will, at some point, be looking to try and hold specific interactions with groups of licensees, some workshops, and otherwise. We do not have those scheduled yet. We're looking for your thoughts and inputs on what are the good places,

and times, and groups to be doing that with. Continue that through 2010.

Part of the schedule on this is driven by the fact that the ICRP is still working on revising the dose conversion coefficients that are used to translate a unit intake of radioactive material into an effective dose. That underlies the annual limits of intake concentrations that are in Part 20, Appendix B, and otherwise. The first of those, the first of those will not be available until 2011. The complete set may not all be there in place until more like 2014, so we're going to face a question of when do we have enough to get started, when will we have enough to be finished? How can we work through this process in an orderly manner, meet all of our requirements under the Administrative Procedure Act, and otherwise?

We, of course, all through this process will be continuing our analysis, working on technical basis, interacting with our federal partners, EPA, DOE, OSHA, and others to try and - I was going to say gently move, I'm not sure that's quite the proper word - the whole federal family in the same direction to try and achieve a little better alignment than what's currently present today. Of course, you all know that all of the federal regulations exactly match each

other, not exactly.

We are developing a whole series of things to try and facilitate the discussions. There will be a set of web pages on our public website. They're not quite up yet. You know there are many, many steps in the process of making sure you've got it right, and getting the infrastructure people to agree that you have it sufficiently right that they'll let you post it out there, so that will be a little while. But, in the meantime, we do already have a dedicated email address for people to use, so you don't actually have to send it to me personally. Regs4rp. It does work, we've already tested it. The State of Iowa has already sent us in some stuff, so we know it's working. There was a press release on the 27th that has stimulated a bit of interest. We have a whole series of these initial presentations scheduled. We'll be at CRCPD in just a couple of weeks, the Society of Nuclear Medicine in June, the Health Physics Society in July, the State Liaison Officers, the Fuel Cycle Information Exchange, the list is growing. These slides get out of date almost as quickly as I hit the save button on the PowerPoint presentation.

So, for our purposes today, because I know

that you do not have the time that you might wish to really start talking about the pros and cons, and issues, but what I'm particularly interested in is to get the Commission starting to think about how we can work together over the next couple of years to work through some of these issues, to explore your views on the pros and cons, and options, and how we can engage with your various communities that you represent to get the information from them.

I'm looking for suggestions of particular meetings of societies and other groups of licensees that we might be able to talk to, and explore these issues with. And I would like your thoughts and views on the right mechanism of interaction with this group. I know that with the ACRS we now have a dedicated subcommittee that Dr. Mike Ryan actually chairs, to work with us some of the HP issues. Whether or not you would wish to do a similar sort of thing, or continue interactions with the Committee, we hope to get your views and find the right ways that we can be exploring that with you.

And, with that, I complete this little run-through presentation, and open up for questions and discussions. Thank you very much, Dr. Malmud.

CHAIRMAN MALMUD: Thank you, Dr. Cool.

Are there any questions for Dr. Cool, who has invited questions? Dr. Vetter.

MEMBER VETTER: Not a question, a comment. I really do like the idea of a subcommittee from the standpoint that it takes too long to interact with the Committee, as a whole. As you know, Bruce had trouble with trying to get his Subcommittee to come to consensus, and it had to come here to finally get settled. That's a long time. And if a subcommittee can more actively interact with Dr. Cool and his colleagues on various questions that come up, even if it's not coming to decisions, if it's simply getting information and feeding it back, it can be done much more quickly, than interacting with the entire Committee.

CHAIRMAN MALMUD: Thank you. I, personally agree with you. It's a much more efficient approach to it. Other comments, other than how we might interact with respect to a subcommittee, rather than the Full Committee? Dr. Vetter?

MEMBER VETTER: Yes. I'm speaking a little out of ignorance here, but as I recall in the -- -somewhere in the early `80s time frame, the NRC sent out a questionnaire to materials licensees to voluntarily report their exposures. And it wasn't in

any kind of a regulatory sense. NRC was trying to learn something, and I even forgot why they were doing it.

The reactors send their occupational exposures into a database of some sort, but you don't know what the materials licensees' exposures are, I don't think. I don't think you have a database. And, so, if you were to sample all of us, that's a very, very, very small sampling of what the occupational exposures are. So, maybe it's possible to explore how can you get some real occupational data from materials licensees? That might be useful.

DR. COOL: If I could respond to that? Certain classes of licensees are required to report their information, and that does pick up one or two materials uses, particularly industrial, and radiography has to report. So, we get the information for those that remain as NRC licensees.

We face two things here. First is that we need to explore how to do this, particularly given that three-quarter plus of the licensees now are Agreement State licensees. And, so, the Agreement States may well have some of the information. In some cases, they have even more information than we do, and try to share that and gather. The second is that at

least for NRC, and in most of the states, there are a couple of places where this is not true, the medical licensees do not have to provide their occupational exposure. That is maybe one of the biggest holes in the data set. The third component, of course, related to the interest of this Committee, is that our regulatory jurisdiction goes to the materials. The bigger piece of the pie is the machine-produced radiation, and only some of that would be an interaction as a result of multi-modality, and otherwise. But we need to explore the implications not just for the materials, but for the entirety of the program, if there's going to be anything like consistent national system. So, I would welcome any and all of your suggestions. I know that we've been doing some interactions, but we don't have a lot of data, at this point, and information.

CHAIRMAN MALMUD: Dr. Fisher.

MEMBER FISHER: Don, you take a very complex subject and make it easy for us to understand. And I think you have a nice way of presenting the ICRP concepts, and the challenges that NRC faces. And I concur with your initial recommendations, and request for information.

One question, these changes will impact in

the practice of medicine some elements more than others, cardiology, in particular, and radiopharmacy. Could you state that -- could you give us any information about what the implications of the new ICRP recommendations are on workplace monitoring, assessment of exposure, or even assessment of internal dose from materials? Are there any implications for workplace monitoring that you'd like us to consider?

DR. COOL: I think there are certainly some things that ought to be considered; per se, the recommendations don't go to the level of detail of specific suggestions related to workplace monitoring, or otherwise. But that has to be looked at in the context of what the requirements are. Currently, the requirements are for there to be monitoring sufficient to demonstrate compliance. If you are to change the limits, or otherwise, then almost automatically the threshold levels, which are usually percentages of the limit would change and come down. That could certainly have some implications.

There are changes, we know, in the annual limits of intake, derived air concentrations for at least some radioactive materials. They are not going to be huge, earth-shattering moves one way or another. They will be small adjustments, for the most part, as

we understand them. So, those do not, necessarily, have significant impacts on workplace monitoring, other than the connection back to limits or otherwise.

The other component, which I really don't know how to predict, but I would invite you to think about is, to what extent there's an interface between the issues of establishing constraints, and otherwise, and the values that you would establish associated with monitoring. I would hope that there would be connections between what you use when you plan your program, and where you want to be in terms of your ALARA effort, and the criteria that you would use to monitor, because it wouldn't seem to be of very much use if you set up a lovely program and planning, and then your monitoring systems didn't allow you to detect whether you'd actually achieved it. And that may end up, in fact, being very facility-specific.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I have a few comments. One, I think sometimes when you wait long enough, it gets easier. I think the world has standardized in terms of the effective dose, and the scientific community has accepted that. So, in some ways, your transition actually will be easier in terms of people understanding the difference between effective dose,

and effective dose equivalent. I think the first transition to effective dose equivalent was clearly more difficult, and challenging. That doesn't minimize the effort that's going to have to go on.

My focus the last several years has been more on research, which is really a much minor set of issues. FDA, you guys aren't as outdated as we are. We have some dose limits for some research applications that date back to `75. We intend on changing those at some point. But you don't say anything; you basically do not address human research. You defer to the IRBs, and to FDA, and so on. Would you be willing to readdress, or do you think you'd maintain that same stance?

DR. COOL: I would expect that the Agency would maintain its stance in not getting into the middle of the question of the doses to the individual research subjects as part of the protocol, just as we don't go to the question of what's the appropriate exposure for a patient. Obviously, we would be looking at the question of protection, occupational, public, and all the things that go along with it, but I would not expect us to be trying to open up a new piece of discussion.

On the other hand, we would welcome

continuing to interact with you as you look at those subjects, so that we can be putting all of these consistently together into a federal framework.

MEMBER SULEIMAN: Right. And I really empathize with your statutory constraints, as well as -- because we deal with them all the time, as well. But the body doesn't differentiate how -- where they get the radiation, so I think -- I do think you're going to have to -- you should get -- I suspect you don't collect medical exposures, because some of the doses are from x-ray, and, so, that doesn't cover -- you're not responsible for that, and you can't differentiate between that. But I think from a public health point of view, it would be collect that information and have a little asterisk, and say that some of this radiation doesn't come under our direct jurisdiction, if that's the reason why you didn't collect it in the first place. But, I think, sort of like the states when they -- you don't differentiate.

MEMBER GILLEY: Radiation is radiation.

MEMBER SULEIMAN: That's right.

CHAIRMAN MALMUD: I think first was Ralph Lieto.

MEMBER LIETO: Me? Dr. Cool, sort of a follow-up question, or not question, but comment, to

what Dr. Suleiman just mentioned. There are other federal agencies that have dose limits that are extremely archaic. And I would -- I know that, again, that there are some constraints that the NRC has, but I believe that there is the Memoranda of Understanding. Is this an avenue by which you can sort of encourage these other agencies to sort of come up into the -- out of the darkness and into the light on this subject? I don't know if that's something that you've been looking at, or have been considering. But I think it's important that all federal agencies sort of come up to speed on these dose limits, since many of them are still back in the `70s.

Another question I did have related to the term, to the constraints. And as you go forward, I think this being an entirely new concept, I think a lot of people are going to try to look at this in the context of, is this analogous to the ALARA levels that are set in terms of action levels of dose, responding to dose limits in their various licenses, or is this an investigational level, which is a concept that's quite commonly used in radiology.

I think the biggest problem in going forward with this concept is, if I wrote this down correctly, was that the constraint is considered a

numerical value licensees cannot exceed. I mean, that's a limit. If they can't exceed it, it's a limit, and that's how it's going to be viewed. So, I think as you go forward in conveying this to other societies and agencies, and groups, that if you can kind of put this in a context that they're familiar with, that this might have to be replacing, I think that would be helpful.

DR. COOL: Thank you. The two pieces of the puzzle. First, the other federal agencies. Yes, we are working with them. We've had a number of discussions with them, in fact, through the Inter-Agency Steering Committee on Radiation Standards. We are looking at exactly what each of the agencies has, what each of the agencies is thinking about doing, and looking to try and have a consistency as we move forward. Obviously, we cannot do more than influence, cajole, push, pull, and otherwise, but that is exactly what we intend to do.

On the concept of constraints, yes, you're very right. This is an area where a lot of careful discussion and then very careful wording is going to be necessary if the concept were to be considered to be in the regulations. Because, there is a very fine line between words which become a limit, and words

which are where the licensee would not plan to exceed in their ALARA program, which is not a limit, but which has similar connections to investigation levels, and otherwise. So, there's a whole set of concepts where you might initially plan to be, the boundary of your ALARA process, what your ALARA process might suggest to you is the best place to be, the establishment of the targets or the goals, which might be the result of the optimization, so it might actually be less than their initial plan, and at what point you would go back in and investigate whether or not it was working, or not working. And there's a whole set of things, which does need a very careful understanding and alignment in order to decide exactly what the right relationship is. And it takes a lot of time.

CHAIRMAN MALMUD: Before Dr. Vetter asks his question, I wanted to follow-up something that you said, Ralph. When you said some of the regulations are archaic, in what ways?

MEMBER LIETO: OSHA limits are basically the limits that were set before the NRC modified theirs in the early 1990s. They're basically the limits that were in place in the early `70s, 5N minus 18, 3 rem per quarter, these types of limits that are

still in place.

CHAIRMAN MALMUD: And these limits are excessive compared to current standards? When you say they're archaic, do you mean that they are -

MEMBER LIETO: In some instances -

CHAIRMAN MALMUD: In their definition?

MEMBER LIETO: Yes. In some instances, the numbers are higher, higher dose limits that are permissible. But they're in areas that usually the NRC does not have regulatory authority over.

CHAIRMAN MALMUD: Yes. Thank you. Dr. Vetter.

MEMBER VETTER: In response to Dr. Suleiman's comments, I don't know if he was going there relative to establishing limits for patients, for human subjects. But the ICRP recommendations are justification and optimization for patients and human research subjects, and I really don't, at this point, see anything that would suggest that the regulatory structure go beyond that.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman, did you wish to comment?

MEMBER SULEIMAN: I just want to clarify, most of our research, there are no limits. I think the Radioactive Drug Research Committee is a very

special set of circumstances, where we allow researchers to not actually have to get filed in the investigation of new drug application, and, so, to release them from that additional burden, they have to comply with certain limits. But if they -- they have the option. They can do it under an IND, and then there are no limits. It's up to the expert on the committees.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: I can appreciate that this is a very sensitive and important subject. It's sensitive because we're talking about regulation. And I can appreciate all the thought and effort that ICRP has put into ICRP 103. I know it came out at a very controversial time, 2007, when doses from medical procedures, such as CT, were in the news on a regular basis. And if we are going to be discussing adoption of some of the recommendations herein, the ICRP report, therefore, would have to be very, very carefully analyzed and evaluated.

Questions that come to mind surround the controversy about LNT. I know we don't have time, and this is not the venue or forum for a discussion about that, but can you tell us if the LNT model was used in ICRP 103, as a starting point?

DR. COOL: Yes, I can tell you, and yes, it was. The underlying model of Linear Response continues to be the basic model used for the establishment of an appropriate regulatory regime. ICRP was actually rather careful in their language about appropriate for a regulatory regime, versus an absolute we believe that this is the way the body actually behaves, because there is a lot of things going on, and there are a lot of unknowns associated with that, as you know.

Furthermore, ICRP has backed away from that, or can be viewed as backing away from that, because they have been very careful to say that a collective dose calculation, as in integrating number of people and their exposures for some period of time, is not an appropriate measure for assessing the risk of that radiation exposure in that population, because of the wide uncertainties at the low doses, the uncertainties associated with the exposure. So, ICRP has, in fact, suggested that it not be used in risk assessment, which is one of the places that the Linear No Threshold hypothesis would drive you to, and from a purely mathematical construct.

CHAIRMAN MALMUD: Dr. Van Decker.

MEMBER VAN DECKER: Thank you. I've

served on chaired enough Radiation Safety Committees in 20 years to know that from an occupational worker perspective, the people that are going to be the most affected, obviously, by dose reductions would be people in constant fluoro environments, and interventional radiology in the cardiac cath lab by far and away. To the degree that this discussion will interact on those people who are being exposed by machine-produced radiation, and clearly take them into the realm where a large percentage of those providers will be affected, and the amount of activities they perform in a year, clearly say that you need to be involved with those societies which are not represented at this table right now, Society of Interventional Radiology, which was here yesterday, and the matching one on the other side would be known as the Society of Cardiac Angiography and Intervention, CA&I, known as SCAI in the vernacular. But I think that they would have strong interests in some of this discussion, and understanding the technical and scientific basis for why we would be making this move, when most of those members, obviously, have battled through the badging, and monitoring, and trickiness of those requirements in that environment, and these types of dose levels that

are easily within this realm for -- well, let's see, my partner has been doing it for 40 years, 40 years. So, I think they'd be interested in being part of the discussion, and I could facilitate half of that for you.

DR. COOL: Thank you.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: So, if I could ask Dr. Van Decker to expand a little bit, if we were to change our recommendations from 5 rem per year, to 2 rem per year, do you think that would have a significant impact on some of the workers in those fields you mentioned?

DR. COOL: Oh, in the large centers, this would affect more than 50 percent of the practitioners.

CHAIRMAN MALMUD: Debbie Gilley.

MEMBER GILLEY: Dr. Van Decker, does your facility allow the weighting of badges, or are you using simply a personal dosimeter on the outside collar?

MEMBER VAN DECKER: I leave those types of technical considerations up to Radiation Safety Officers that have battled with this. I've seen it done both ways. A lot of times it's been done by

mathematical calculations for the obvious reasons.

MEMBER GILLEY: And you would still exceed the 2 rem a year, even with an alternate reporting requirement technique?

MEMBER VAN DECKER: I would see it close enough in the realm of consideration.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: Just to sort of follow-up on Debbie's question. On the Radiation Safety Committee, I review these sorts of doses quarterly. If you take the external badge, and then you do the calculations for deep dose, most of our interventional radiologists would be pushing that 2 rem limit, pushing or exceeding that 2 rem limit. It is not uncommon in a quarter to have 2,000 or 2,500 millirem on an external collar badge.

CHAIRMAN MALMUD: Debbie Gilley.

MEMBER GILLEY: My next question is for Dr. Cool. How are the Europeans meeting the 2 rem requirement? Are they simply not doing the number of procedures we have, or is there a better method that they are using?

DR. COOL: That's one of the things that we want to explore more with them. The first blush we get back is, there aren't any difficulties, they've

been complying with it for years. What we do not know at this point is, when we dig under the surface, do we find that they're doing an effective dose calculation from external sources? Are they not wearing badges, or some other combination of possibilities? That is a question that we do intend to pursue, and for which, at the moment, we do not have a real good answer on.

MEMBER GILLEY: Thank you.

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: One of the problems that we have in this country at this point in time relative to badges worn by interventionalists, and cardiologists, and so forth, is that we are regulated by 50 different regulators relative to those badges. And, in some states, they're more progressive than others, and they will allow you to correct those mathematically based on more recent computations. Some states say well, we want to take the most conservative point of view, and we will allow you to divide that external badge reading by three. And that's the rule, and you must follow it. It doesn't matter what ICRP has said. So, if we could all get on board with the latest estimates of risk and computations, I don't think we would have a problem with a 2, although there still are some

interventionalists that will become close to that. But we certainly today have a huge problem with meeting that limit if we have to divide the external badge -- the badge worn on the outside of the apron by three.

CHAIRMAN MALMUD: Thank you, Dr. Vetter.

MEMBER VETTER: That's to estimate effective dose equivalent.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman.

MEMBER SULEIMAN: I think the need to standardize, actually using effective dose, or effective dose equivalent, it's conceivable some people could actually get more dose, because you may find out that some of the extremities may be weighted much, much less, and so you could actually -- it would be conceivable to have a high -- to fall below the effective dose limit, and still get some pretty high doses to some other tissue. But the need for standardization, and not to dumb down, sometimes we do to keep it simple, but we pay the price, because then you have people say I'll just use the badge, which is a good health physics principle. It gives you the upper limit, but it's not going to give you an accurate estimate as to the total risk that the individual was subjected to.

In terms of the practice, I think the whole purpose of radiation safety is to constrain, because, in my professional opinion, my doctoral thesis was in fluoroscopy, but I think technology, and how I think modern day medicine can be conducted to meet a lot of these constraints. I think in some cases, technology can help reduce the doses significantly. I don't want to go into a large-scale discussion on that, but I think the potential is really there, and you see variations of that across the country. So, the constraints do what they're supposed to. The limits do what they're supposed to, and, so I think you're on the right approach. But I think the need to standardize would help solve some of those problems.

CHAIRMAN MALMUD: Dr. Cool.

DR. COOL: Thank you. A couple of quick notes. Effective dose is what's now in the NRC regulations, and we do allow the use of the different formulas for calculation. So, that's where the NRC is. Yes, there is the continuing discussion of how that gets implemented in various states and otherwise, the degree of conservatism and things. And noting, of course, that with the new tissue weighting factors, the algorithms that people use are another one of the

things that are being updated. There's already been an article in the Health Physics Society that goes through and updates the algorithms for the new tissue weighting factors.

Secondly, to note that there are also requirements in the regulations now for extremity doses. And while there can certainly be some discussion around whether or not there should be changes in those, the ICRP recommendations don't suggest any changes in those areas, so you have that.

The third piece, which I'd just like to pick up on, is again the issue of constraints, and the interactions of constraints in the optimization process with the limits. The limits as a legal boundary, someplace that we would hope we don't ever actually get people over, because then there are all sorts of ramifications. Part of the reasons I offer the suggestion to you for discussion is, I can conceive of regulatory requirements utilizing the idea of constraints carefully constructed that might allow increasing the protection, accomplishing things for some of these interventional radiologists and cardiologists, and otherwise, and getting them in the place where we might wish them to be from a protection standpoint, but not, necessarily, do that by means of

just taking down the limit, which would put them in a legal quagmire, where it was do I become illegal, or do I take care of this person before they die?

CHAIRMAN MALMUD: Dr. Cool, not being a fluoroscopist, but having observed fluoroscopy in a number of institutions, and having observed human behavior, I would fully agree with your last comment, that lowering the limits will not achieve the goal. The first thing that should be done is, perhaps, to collect a sound database, which we do not have currently. It might be required that before the exposure to a machine, or to a radiopharmaceutical, that there be a timeout, just as there is in surgery, in which there is assurance that the badges are being worn by the individuals who are supposed to be wearing their radiation exposure badges, so that a sound database can be obtained. Right now, it's not at all uncommon for someone to forget his or her badge, or to forget a portion of the badging, the finger badge, the badge on the collar, what have you, and that to tighten the rules in the face of the absence of a sound database, would create problems, which you've alluded to for the population as a whole, particularly those who provide radiologic services. So, my own inclination would be, though I am a firm believer in

ALARA, that a database is the first thing that we need, and we don't have one. And I doubt that the Europeans have one either. I have a number of European colleagues and they have the same beliefs and practices as my American colleagues. And I see it, and this is among very educated people, who just forget the badge on the day that they're going to -- at a moment when they're going to get some exposure. So, I would first argue for a sounder database before the rules are tightened, but that's a personal opinion, and I'm certain that my colleagues in diagnostic and oncologic radiology would have their own opinions with regard to professional behavior in these environments. And, also, this applies to technologists. I don't think we have a database. We'd be measuring the unknown with the unknown under current circumstances.

Having observed the tightening of the rules in the operating room, which have been very effective in reducing a number of untoward incidents in operating theaters, it may be that we need the same kind of practice in the world of radiology, not regulated by the NRC, but within each institution so that we could achieve a database in which we might make some observations. Otherwise, some people will

feel that their livelihood is being interfered with, and there's a natural tendency not to want that to occur, even when it puts the individual at risk, or when the individual feels that he or she can't provide essential patient care on behalf of the lives or the well-being of a patient because of an abstract concept. Mr. Lieto.

MEMBER LIETO: Just to follow-up on your statement there, Mr. Chairman. As you go -- if you do go forward with getting a database of information in medical users, I would encourage you to try to separate, where possible, machine users from radioactive material users, because I think you might find that although there are very high-end machine users in interventional radiology, there is a tremendous amount of what I call psychological monitoring that's done in medical institutions for nursing staff, OR staff, so forth, because they think they might get exposed. So, when you look at the averages of x-ray users, it's going to be maybe low, and when you look at radioactive material users, where you're monitoring the people that are actually handling it, and there's very little of what I call psychological monitoring that goes on, you may find that the numbers are a little bit higher, I'll say

above maybe the ALARA levels. So, if you can, as you go forward, if you can separate out this database by those users, it might provide some differing information on what the exposure levels are in the different groups.

DR. COOL: I think we would very much agree. Yes, we need a database. We need information with which to have a basis to propose or not propose anything. And the better the fine structure that we can get on that database, the better the information and the decisions will be. I think we're much in agreement with that.

CHAIRMAN MALMUD: I think we agree. And my observation would be that we'll never be able to achieve a sound database if the penalties are too great to the individual in the collection of that database. Was there someone else? Yes, Dr. Suleiman.

MEMBER SULEIMAN: I hate to throw in an idea, but why not? Have you ever thought about, if the medical community feels so strongly, would they allow a higher occupational limit for some life-threatening, or for some high-risk procedures?

DR. COOL: I'm going to say first, thank you. Nothing is outside the realm of possible consideration. And, thirdly, today in the

requirements there is, in fact, a special case provision called, "Plant Special Exposure", which would allow, upon a careful set of considerations, to exceed the dose limits, very highly restricted. I know of only one case where someone has ever actually gone through the process, and applied to be able to have permission to use that, and their controls were such that they didn't ever actually do that.

MEMBER SULEIMAN: I think the kind of person that would go for that would probably have good enough procedures; they wouldn't exceed it, yes.

DR. COOL: But we can engage in all sorts of discussions on the possibilities, and back and forth. That's the whole purpose of starting the dialogue now, while there isn't a proposal on the table, so that people don't feel like they have to defend their particular turf, and can rather help us understand what the entire landscape looks like.

CHAIRMAN MALMUD: Thank you, Dr. Cool. Dr. Eggli.

MEMBER EGGLI: I don't think in the materials arena at my institution we're going to have any trouble meeting these limits. But in the machine-generated, we are. And I am absolutely certain that there isn't a single interventional radiologist in our

institution, or interventional cardiologist in our institution that's the least bit worried about their cumulative exposure. And they have the education to understand what those risks are.

The other problem is if this is a patient care issue, not all interventionalists are created equal. Some are more talented than others, and they tend to take care of the most critically ill patients, and they tend to be the more complex procedures, and they tend to get over-exposed in those procedures. And I could name to you the people I consider are most talented interventionalists, both in cardiology and radiology, and I can tell you that when I look at their quarterly exposure reports, they're going to top the charts.

CHAIRMAN MALMUD: Dr. Eggli's observations, my observations from different perspectives are the same. I mean, among radiologists and cardiologists, the interventionalists are really the heroes of the profession. They're the ones who are called on true emergencies. When I provide I-131 therapy, I'm getting some beta radiation, it's scheduled, and all the safety regulations could be employed in a careful, timely fashion. When an interventional radiologist has to do a procedure on a

patient whose life is really at risk for that moment, or the interventional cardiologist, same situation, their natural tendency is to put the patient first and not themselves first. And anything that we would do that would interfere with that would be counterproductive in terms of the welfare of the public. But, we still should have database, so that we understand where we are, and I think we're all pretty much saying the same thing. And all of us, from different perspectives, have made the same observations. We're dealing with an issue that profoundly affects emergency patient care, or could affect emergency patient care. It's very different in my situation.

In my situation, when I'm giving a patient an oral dose of I-131, and the resident shows up with the white coat, but without the badge, I say, "Out. You may not participate in this therapy without your badge." If the excuse is they lost or misplaced the badge, that's fine. They don't participate in that therapy that day. But that's very measured, as opposed to the patient who's brought into the emergency department with acute myocardial infarction who's rushed to the interventional lab, and then a lifesaving procedure is performed, very different set

of circumstances, and a very committed physician, who's performing this procedure without concern for his own well-being, or her own well-being. Dr. Welsh?

MEMBER WELSH: I think most of the points that I was about to make have been eloquently stated. I concur with the idea of having a database. I suspect if we have an accurate database, Dr. Van Decker's prediction might come true, and that we will see individuals who are critically important in medical care approaching the proposed 2 rem per year limit. And if that happens, I would say that from a patient perspective, we have to be cognizant of the potential consequences.

I have the good fortune of practicing at a major academic facility in Wisconsin, but, also, at a much smaller facility, where it's approximately 70 miles between any given radiation oncologist, and maybe 120 miles between interventional radiologists. And we've heard that not all interventional radiologists are created equal, so, therefore, the one that's 120 miles away is the one that's of choice. If that individual exceeds the limit, you might have to drive 500 miles, 300 miles to get to a competent interventional radiologist. And I think that that has to be factored into some of these regulation

decisions, as well.

CHAIRMAN MALMUD: If I may, part of what I'm trying to drive at is, is all these statements are valid. If the database exists, there may evolve from the database a better way of reducing the radiation burden to the provider. But in the absence of a database, there's no urgent need to change the methodology, currently. But the interventional radiology field is filled with brilliant individuals who will respond, if necessary, to changes that are necessary. That's my general observation of these highly trained individuals, so I'm optimistic that a database will generate a better standard of practice, if it's needed. But constraining the current limits will have the opposite effect. Everyone will forget to wear his badge. We have Dr. Guiberteau.

MEMBER GUIBERTEAU: Well, I've been listening to this with a lot of interest. This topic is one that is of major concern to the diagnostic radiology community, primarily from the point of view of the interventional radiologists. I think in our discussions in various organizations, there is, as has been mentioned by various commenter's, the need for an understanding of what interventional radiology consists of.

I do think the average procedure, it's well understood that you can stay within the limits of exposure. But there are studies, outliers, both with respect to the individuals performing them, and to the difficulty of the case, that place them at higher dose levels.

There is also an exceeding interest in if the physician badged is exceeding his limits, then the dose of the patient is exceeding the values that would not be tolerated in most circumstances, and those need to be justified.

There have been numerous articles in the last several years in the literature imploring further investigation of these incidents with patients, and with physicians, and I think we would all agree in the radiology community that a valid database would be the place to start. And I guess my question is, to you, is that where in terms of being a regulatory agency could this information be achieved?

DR. COOL: I think the answer is yes, we are trying to think about the right ways to try and gather the data. There are, of course, two opportunities. One is to try and go back and capture by some voluntary means data that has been collected over the last couple of years, recognizing that it has

the potential for I forgot my badge, and other things, which make the uncertainties greater. There is, of course, always the possibility, I suppose, for trying to do some special effort prospectively for some period of time to try and improve on the quality of that data as we go through the process, as well.

Step one, I think, for us is recognizing that there is a lot of data that is out there, which we do not have access to, is to try and find the right ways to get access to that data. And sadly, that means that we have to go through a series of commotions and steps, including our friends in the Office of Management and Budget in terms of how many people we can ask questions of, and what kind of data we can ask for, and otherwise. But we are exploring, trying to get what's out there, in order to try to start building upon that. My colleague, Vince Holahan, may have something to add to that, as well.

MR. HOLAHAN: Good morning. I'm Vince Holahan. I'm Senior Advisor for Health Effects in the Office of Research. One of the things that our group does is, we set up the REIRS database, that's the Radiation Exposure Information Reporting System. We use that for all of our power plant workers, and a number of material users. With that, we can look at

trends, annual trends, three-year rolling trends, and so forth. Unfortunately, we don't -- at this time; we don't have the authority to collect the medical data from the states, and particularly, the Agreement States.

Fortunately, you'll hear about this in the next hour, the NCRP issued Report 160. And in Chapter 7 of that report, it addresses occupational exposure to include medical. They went to the dosimetry vendors and used the dosimetry vendors to provide information to look at years 2003-2006. And what you find among the 600,000 badged medical workers, there are about 600 that are exceeding the occupational dose limit of 5 rem a year in each of those years. The good news is most of the workers are receiving very little or no exposure.

What we can possibly do is go to those vendors and see if we can get additional information from them, and that will provide us information sooner, rather than later, to address some of the questions you're talking about. If we have to set up an individual database, that's going to probably take a change in statute to give us the regulatory ability to do that, because right now, as was indicated earlier, I think it was by Dr. Vetter, some

institutions report to the state on an annual basis what the exposures are, some do not. They're just inspectible type of reports, so there is no mechanism to obtain that information now. And what we're finding is, in particular with the industrial radiographers, our database is actually getting smaller, because as soon as a state decides to become an Agreement State, they no longer send that information to us, and we put it into our database.

CHAIRMAN MALMUD: Thank you. Dr. Vetter.

MEMBER VETTER: I wanted to point out just one caution relative to interpreting data from the vendors, and that is that all they have is a badge reading. And that will not take into account whether the individual is wearing an apron, so the badge reading, itself, does not, necessarily reflect the effective dose, or effective dose equivalent.

CHAIRMAN MALMUD: It also depends whether the individual is wearing the badge outside of the apron, or inside the apron. Mr. Lieto.

MEMBER LIETO: It's also the aggregate of radioactive material users and machine users lumped together, so you're looking at that cross-aggregate, if you will, of wearers. It's not separating out the radioactive material wearers versus the machine

wearers. And that's something only really I think the licensee or registrant can do.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I think it's a probably soluble problem. The data is out there, and rather than argue the argument like these arguments always are argued in terms of anecdotal stories about individuals, let the data speak for itself. I think most hospital RSOs, I would assume, are looking over their data. It wouldn't take much effort to parse by department and get an idea. If everybody in the group is giving high doses, or whether you've got low doses, collect the data, maybe work through the vendors, maybe work through some of the hospitals or some of the societies. There ought to be a way to get some preliminary information.

There was a global effort to put the NCRP report together. It's just a case of going one level further and trying to parse by the different specialties. And the data will just leap out at you. You'll either get a very broad distribution, or you'll get some clustering. And then you'll have some numbers to make some valid discussions with.

CHAIRMAN MALMUD: Thank you, Dr. Suleiman. I think Dr. Howe was next.

DR. HOWE: This is just kind of a generic comment. As I'm listening to the discussion, I'm hearing that we need to make a clear distinction between machine dose and materials dose. As we move into more emerging technologies, such as intervascular brachytherapy, such as microspheres, we're starting to pick up more of the interventional radiologists. Now, we're clearly not picking them all up, but we are starting to pick up a group that wasn't in our regulatory sphere in earlier days, so I think that's something that the Committee and the NRC needs to keep in mind, as we move forward.

CHAIRMAN MALMUD: Thank you for bringing that to our attention. If I may address Dr. Suleiman's comment, I'm still concerned, Dr. Suleiman, that we don't have an adequate database, and that further constraints on the limits in the face of an inadequate existing database would be counterproductive. The goal is -- we agree on our goal, which is to reduce the radiation burdens, the unnecessary radiation burdens to providers. My concern is that if the limits are reduced, as might an outcome of agreement internationally, that the database will never be achieved. Dr. Lewis.

MR. LEWIS: Thank you for the promotion.

I'm not a doctor.

(Laughter.)

CHAIRMAN MALMUD: Honorary Dr. Lewis.

MR. LEWIS: I would like to make a suggestion to the Committee, and Vince Holahan has already kind of invoked this, that much of this discussion, I think, will be very relevant to the next topic on the agenda, which is what to do about NRCP 160. And just a suggestion, if we want to revisit that, or kick that off now, that's -- I'll leave it for the Chair's discretion.

CHAIRMAN MALMUD: Thank you. Dr. Guiberteau.

MEMBER GUIBERTEAU: Just two comments. One, to comment on Dr. Howe's observation. As we move into hybrid technologies in both nuclear medicine, and diagnostic radiology, where we're performing both CT and materials imaging, there have been a number of reports of occupational exposures, depending on the state, where some states have very strict rules about who can operate these -- perform these procedures, and others do not. We have found that there are large lapses in those who are trained in materials use, technologists, who are now trained to operate a CT unit, but not, necessarily, the radiation safety

aspects of it. And usually vice versa, particularly when you're using high-energy radiopharmaceuticals in addition to this. And that is something that I think this Committee should be very interested in.

Secondly, just a matter of expression of the difficulty in collecting valid data, that I'm certain that the radiology community understands how difficult this methodology is due to compliance issues with those who are performing the procedures, with the methodology of calculating doses, and what is being reported. And, finally, just with deformation of the data due to observational scientific collection of the data, as per the Hawthorne Westinghouse experiments many years ago. So, it isn't very easy, and I think the only way to start is to try to get to the information as broad as possible, and as granular as possible, so that you can separate out what we're collecting.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau. Dr. Thomadsen.

MEMBER THOMADSEN: Just a potential suggestion. Since you're talking this June to the Health Physics Society, maybe they could bypass the problems that were discussed with having the NRC establish a database, and they might be able to

facilitate a database for you.

DR. COOL: Thank you. That's certainly another possibility. We've also been in discussions with Lynne Fairobent and others in AAPM to try and find some mechanisms that would get us a view of some of this data without it having to appear that the regulatory agency was going to come after you.

CHAIRMAN MALMUD: Thank you. Now, if I may, we'll get back to a suggestion that Dr. Vetter made earlier, and that is that we establish a subcommittee within the ACMUI in order to work with you. Are you receptive to that idea?

DR. COOL: Yes, sir.

CHAIRMAN MALMUD: Then we will come up with a subcommittee for you. Did I interfere with someone asking a question? And we will find a subcommittee of three that can work with you. We're currently in a state of transition here. We have three very experienced members of the Committee who are leaving, and we're recognizing their service and the loss to the Committee of their services today. And I will get back to you with a recommendation.

DR. COOL: Thank you very much. We appreciate that, and we very much look forward to interacting with that subcommittee, and with all of

you. And I would, again, ask - I know that following the last meeting, I had conversations with a couple of you about groups and otherwise. We were not able to follow those up because of the time frame of the Commission decision, and otherwise, but I am very interested to find connections to some of your organizations, and to your respective groups of licensees, because these are the discussions that are needed now, and we look forward to it. Thank you very much.

CHAIRMAN MALMUD: Thank you. We will move on to the next item on the agenda. Ashley, are we sticking to the agenda thus far?

MS. COCKERHAM: Yes, until we get to this afternoon.

CHAIRMAN MALMUD: Who will be the next presenter?

MR. LEWIS: I'd be happy to tee up the topic, if you'd like. But we were really looking for just a brainstorming open session from the Committee about the report, the NCRP report. So, with that, before I start, as Chris mentioned in his opening remarks, the NRC staff is aware of at least three Committee members who were involved substantially in the NCRP 160 report preparation and publication. And

we just need to remind you of the conflict of interest provisions that are in the ACMUI bylaws. And any member who was involved in this report would need to recuse themselves of the discussion. I believe you can just answer factual questions, but any kind of substantive discussion you should recuse yourselves from the areas where you have a conflict of interest in preparing for the report. And if there are any other Committee members who are involved that the staff isn't aware of, they should identify themselves, as they should with any topic.

MEMBER NAG: Excuse me. Could I have -- I know they prepared the report. Wouldn't that be helpful in the discussion? I mean, why would they have to recuse themselves?

MR. LEWIS: Because, legally you're required as a Committee member to recuse yourselves of any discussion if you're trying to influence the Committee on a report you prepared outside of your ACMUI duties.

MEMBER NAG: Oh, outside. I see.

MEMBER SULEIMAN: I want to clarify this. If you look at the preamble of the report, it's just a scientific collection of data. It doesn't make any recommendation. It's just a census, so it's not

advocating any specific position.

MR. LEWIS: Well, let me finish my tee off, and you'll see kind of -- because we are -- the NRC staff is asking the Committee to give us policy advice about what to do about the report. So, from that perspective, it would be a conflict according to our attorneys.

Okay. On March 3rd of this year, the National Council on Radiation Protection Measurements, which we've already referred to as NRCP, held its annual meeting in Bethesda, and they issued a report called NCRP 160, titled, "Ionizing Radiation Exposure of the Population of the United States", which I believe you all have a copy of at this point, at least the pre-publication copy. And we had heard just last week that it went to final publication, so the ring binder that you have.

The report has a punch line finding that essentially says that the increase -- Americans were exposed in 2006 to more than seven times as much ionizing radiation as they were in the early `80s. So, the average dose to the population has increased by a factor of seven over the recent times. They attribute this increase, primarily, to the use -- machine-produced radiation, such as increased use of

computed tomography, and also to diagnostic nuclear medicine procedures.

These two modalities were responsible for the majority of all the increases, so in addition to more minor contributors, such as increased background radiation. I believe the occupational exposure where they had data actually went down over that time. So, the NRC is asking for the Committee to give us policy advice, as is your primary mission, about this report. And we're asking, in particular, does this report contain any information that suggests that there are gaps in NRC's policies and requirements that need to be addressed. And where there are already NRC policies, such as our medical use policy, are those policies serving the public well. For example, should NRC revisit its decision to not intrude in the practice of medicine, as regards to diagnostic nuclear medicine, and protection of patients, given that the increases in diagnostic nuclear medicine are primarily responsible for these dose increases? And any additional issues that the Committee may wish to bring to the NRC's attention, such as the lack of a database for material licensees that we were just discussing.

You have pretty much -- that's kind of the extent of the task we're asking for you. You have

kind of an open book to tailor that task. We have, of course, limited NRC authority over machine-produced radiation, but we do have policies that are related to non-machine-produced radiation, some of which is mentioned extensively in the NCRP report.

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

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: As a nuclear medicine practitioner, I could talk about some of the increased patient exposure that has arisen in diagnostic nuclear medicine. I think it probably comes in predominantly two areas where we have seen significant growth in the use of diagnostic nuclear medicine over the last several years. One of them would be nuclear cardiology, and then secondly, PET imaging. And let me start with PET imaging first in my comments.

PET is a high-energy photon. There are patient exposures that result from this. However, you have to look at the benefit that that's creating. If you look at all cancers, and the "conventional" imaging modalities, what a conventional modality is, are what other people, other than you are performing. You're the forefront, and they're the conventional. So, if you want to look at CT, it has been the gold

standard for diagnosis and monitoring of tumors for years. And the CT has an accuracy, and a sensitivity and specificity that's always down in the low 60s percent or worse. Now you add PET to the mix.

The diagnostic accuracy, the sensitivity, and specificities rise into the high 80s and low 90s, when you combine with PET CT. It has made a huge difference in the quality of care provided to patients. And then if you look at the cost across the board of diagnosing and managing diseases, the adding of PET CT into the diagnostic algorithm has reduced the cost of diagnosing and following diseases between $500 and $2,500 per patient. So, economically it makes sense, and from a patient care point of view, it makes sense. And anything that is done that reduces the diagnostic efficacy for a cancer patient is morally unacceptable.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. You said that there were two. The first one you mentioned was PET, and the second one was nuclear cardiology, or cardiovascular nuclear medicine. I think that the figures for cardiovascular disease, and we have a provider here, Dr. Van Decker, they speak for themselves, and that is the death rate from coronary artery disease in the United States has seen

a profound change. There are many elements to it; perhaps one would credit the statins more than the interventional radiologists, but both contribute to the change in the mortality and morbidity associated with cardiovascular disease.

MEMBER EGGLI: I thought it would be better for Bill to speak to that, than me.

CHAIRMAN MALMUD: All right. I'm going to introduce Bill. So I'm going to ask Dr. Van Decker, whose life is committed to nuclear cardiology to speak on behalf of that technique. Clearly -

MEMBER VAN DECKER: I like the way I could save my voice here.

(Laughter.)

CHAIRMAN MALMUD: But, clearly, the techniques that you employ have reduced the death rate from cardiovascular disease in the United States. Dr. Van Decker, with that introduction.

MEMBER VAN DECKER: I'll make a couple of comments, also. Obviously, I think that -- first of all, I'd like to say I think that the report is a scientific report. Staying away from anything that this may mean as a useful thing for everyone involved in ionizing radiation. I mean, I think that it's actually somewhat helpful, if it hadn't been such a

long period of time between the look-see, because two points in a line to see where you are, when you look at large decades of time when technology is growing, it gives you a skewed idea, sometimes, of what's gone on. But I think that a lot of people put a lot of work into this, and I think the information is useful for all providers to kind of look at, and try to make some thoughts about.

Now, as far as the cardiovascular disease and nuclear medicine portion of this goes, I guess I would make the following comments. You know, if you look at CDC data from 1980 to 2006, the life expectancy of females has gone from 77.7 years to 80.7 years. The life expectancy of males has gone from 70.0 years to 75.4 years, which means that men have made proportionally a larger increase in the life expectancy over the last 40 years than females. If you want to look at statistics and what they really tell us, that's probably because, unfortunately, men have more coronary disease than women, and men die of coronary disease. And we do a much better job with that situation than a lot of other things we need to focus on.

The second thing -- and, so, the use of diagnostic techniques has not decreased life

expectancy over the last 30 years, that's for sure, or our therapeutics, obviously. The other thing I would point out looking at CDC data is that the death rate from ischemic heart disease from 1980 to 2006 has taken a dramatic decrease. It's gone from about 492 per 100,000 to about 211 per 100,000, which is a reduction of way over 50 percent. And I would agree with Dr. Malmud that obviously there are a lot of things that go into that in the cardiovascular provider community. My cousin is an interventional, the medical work with statins, some lifestyle issues that we've tried to push with the public, but when we recognize the fact that the incidents of diabetes and the incidents of obesity is going up, and up, and up, and that we're dealing with an older and older population with a much, much more higher incidence of the disease process, I think that speaks very, very well for what some of the diagnostic techniques have been able to identify and allow us to do.

I would also point out from the CDC data that if you looked at death from malignant neoplasm from 1980 to 2006, that that number has also gone down, not to the same percentage, from about 198 per 100,000, to about 183 per 100,000. So, I guess we need to be finding it sooner, and doing better things

with it from other ends, but it certainly has not gone up.

MEMBER EGGLI: And if I could add to that just slightly, Bill, the incidents of cancer continues to rise, while the death rates are decreasing.

MEMBER VAN DECKER: Which is probably more a reflection of more people living to elderly ages, and from the cardiovascular provider community, we look it as, if we keep hearts alive longer that somebody is going to have to treat the cancer that will eventually declare itself from bad DNA repair mechanisms, so our goal for the oncology community is, we'd like to try a few peaks going along longer to see where we get. But I think that's all an important piece of the discussion.

I mean, what really has happened here on a treatment paradigm is that the cardiovascular nuclear medicine piece of this has become the seamless major screener in cardiac disease for significance of chest pain symptoms, and significance of who goes on to mechanical intervention in the Cath Lab, or by coronary artery bypass grafting.

I think whatever modality or whatever technology fills the role of what is our screener to our high-risk interventions, what is our screener to

more patient reassurance, and medical management is going to have a very high number in this nation, because that's what we need, and that's what we do, and that functional piece is incredibly important. And I think that you will see multiple competing modalities, and multiple competing thought processes for trying to fill that hole, because that hole -- or trying to compete in that hole, because that is where the rubber hits the road of how we take care of patients. As we've taken care of more and more patients that are going to clearly be where we are.

I would just make a couple of more comments. I don't think that the community is blind to the fact that this is an ionizing radiation technique, just as CT scanning is. And, therefore, on a performance improvement basis, which I always credit Dr. Suleiman for bringing out so well in all our discussions, we need to see if we can do better and better in that regard. I think if you looked at the professional component of this, we see strong evidence that we have been reacting to this over the years.

I think that the protocols of acquisition have been maneuvered around to try to give the least amount of dosing possible to the patient, much more emphasis on maybe doing stress only imaging. There

are clinical appropriateness criteria out there, so that we're only trying to use this in our highest risk chest pain patients, and our highest risk coronary artery disease patients, and maybe use other modalities for the less at-risk patients. And appropriate use criteria have been popularized throughout this nation, both in the provider section, and in the reimbursement section.

I think that the interest of the community in trying to -- and in all of nuclear medicine, not just nuclear cardiology, to reduce dosing has actually pushed for some great science in the realm of camera development. I think for the first time in the next three years we're going to see detector acquisitions that are more solid-state, more efficient. And rather than decreasing the amount of time the patient is under the camera, a lot of that efficiency will probably be utilized to decrease the amount of dose given to acquire in the same period of time. So, I think that there's a variety of things in place to try to improve these dynamics.

And I think that the community has, obviously, worked very, very hard to make sure that the quality of studies is at the highest level, so that the benefit of the patient undergoing the study

really has a quality outcome, and it really makes a decision in the patient decision tree for where they're going in their care.

Obviously, people are living longer, and so sometimes several years later, especially if they've had interventions, they need to get screened again, so the more we carry people along and make this a chronic disease process, rather than dead in Cath Lab with their MI coming in, because the first presentation frequently can be death, the more of some type of study doing this functional assessment we're going to see. This certainly has been our most reliable to-date.

I would also point out a couple of last points that the population that we're studying is mostly in the 50s, 60s, 70s, and 80s, so it is an older population. Other than anomalous coronaries, when people have really been screened for all kinds of things, it sometimes happens in the younger age groups. We're really dealing with people who are more along in their life expectancy, and, therefore, obviously, on a 10-year mark from the exposure, even an LT model becomes less of an impact, hopefully.

And the last part of this I would point out is something that the report kind of alluded to,

which was predicting the growth of studies down the line, which is why I think when you look back, and you're looking over 20 years, and medical technology is rapidly advancing, it becomes very hard. I think that at some point in time you kind of define your population of where your technology has saturated into what you need to do, and then your growth rate slows. I think that if you looked at the growth of nuclear cardiology studies over the past three years, they've actually been flat, if anything, slightly down. And I think that, obviously, they will probably truck along at about that rate, or maybe grow a few percentage points as the population ages. Some here, depending on what other -- depending on how much better the oncology community gets at treating oncology, so that people can develop their cardiac disease, so that we can treat it some down the line. And we would be happy to be able to do that.

And, in that regard, probably on a clinical basis, I'm seeing a lot of care go on around me, probably a growth of CT, which has become such an incredible tool from a large variety of disease processes, probably we'll end up seeing much more growth in that realm than anything in this realm. So, I've probably gone on too long in all this regard, but

it is my passion, and part of what I do. I just wanted to make sure we put this in some perspective. I do think the information is useful. I think that it is understandable, given the prevalence of cardiac disease. It's understandable, given then niche this has filled for us in patient management. I think that the life expectancies and death statistics prove out that this has been a very positive effect. And I'm sure other people will say that diagnostic testing is important in providing good patient care.

My recommendation, if there was going to be a recommendation is, I think that something like this should be updated every once in a while. We should see how things go on a line, and how the medical community reacts to the facts before we decide if there's a regulatory piece to this that's important for interfering with how medicine gets practiced more than other things going on right now, but that's one person's thoughts.

CHAIRMAN MALMUD: Thank you, Dr. Van Decker. Dr. Eggli, and then Dr. Nag.

MEMBER EGGLI: I would like to follow a little further on the PET CT. Unfortunately, cancer is less discriminating than heart disease. The youngest PET CT I've done is a six-month old. But I

think you've actually already seen the high water mark on this exposure. And I think that by the time a report is created, the data is already old.

Machines are better now than they were two years ago. They're capable of dose modulation. In the PET CT arena, some of the radiation exposure in nuclear medicine is from the CT portion of a PET CT. The vendors have figured out how to use modulated doses in the attenuation correction algorithms. Plus, what you begin to look at is a decrease in overall CT use.

Initially, in the era of PET CT, patients would get a PET CT. There would be an exposure for the CT portion of the PET CT, and then the patient would go across the hall and get a diagnostic quality CT, the same day, or within a week in follow-up. We're beginning to no longer do that, as both physicians and payers recognize that there's excess radiation exposure, and excess cost. So now, interestingly, instead of cranking down our techniques on the PET CT, we're cranking them up, giving IV contrast, and we're doing diagnostic quality CT scans with the PET CT, saving the patient an additional CT scan. And, effectively, the exposure savings would have been the equivalent radiation of what we would

have done on a PET CT previously, that wasn't diagnostic. So, I actually think we're passed the high water mark on these radiation exposures on a per individual patient basis, and that we are doing many things to reduce the exposures to those patients.

What Bill was speaking of the better detectors, will allow us to dramatically reduce the cardiac doses. There are newer detector materials out there in PET scanners now. If you look at the difference of what you have to give to get a good scan on a BGO crystal versus an LYSO crystal on a PET CT scanner, we can have some dose reduction of the PET dose on those more efficient scanners. The fact that the algorithms for reconstruction have become more sophisticated, and we're doing 3D PETs rather than 2D PETs, has allowed us to decrease the dose to the patient, while improving the quality of the overall imaging. So, again, I think you've seen the high water mark. And I think you'll see it dropping from this point forward.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. Dr. Nag.

MEMBER NAG: Yes. I'm going to talk from a radiation oncologist point of view, who has treated cancer patients for about more than 30 years now.

There are several risk-benefit determinations for analysis that needs to be made. On one hand, you have patient and the general public who are scared to have a CT done, when that patient is going to get thousands of rem from the radiation from the therapy, and you're going to get an additional million in the order of millirem, they are scared of that. And that fear, we have to educate them about that fear.

On the other hand, you have to promote the ALARA principle that not to have indiscriminate screening CT where the CT may have been done somewhere else, or similar information may already be there, but it may be that for the non-availability of the previously done CT, or the physician did not properly analyze and order the CT for every patient no matter what. It's like a screening CT. So I think that critical cost-benefit analysis has to be done. So, you do have major benefits, as we have heard, from both CT, PET scan, and other studies. But, at the same time, you have to lose so-called unnecessary CTs, and other imaging.

CHAIRMAN MALMUD: Thank you. Are there other comments? Dr. Guiberteau.

MEMBER GUIBERTEAU: Just a couple of comments from the diagnostic radiology community,

which also performs nuclear medicine, and cardiovascular nuclear medicine. And I think in terms of the overall spectrum of ionizing radiation procedures that are performed, nuclear medicine has done an outstanding job in doing what we can to decrease the doses to patients, both with better management of the doses, and better technology.

I do think that the two areas involved are, as we've discussed, primarily the increasing use of cardiovascular nuclear medicine as a screener of high-risk patients, has only increased, and generally to the benefit of our population. And I have to also say, we're doing a better job in PET CT, primarily, better regulation of our doses. You have a high-energy radiopharmaceutical, but it's very short-lived. And, in many cases, there are difficulties in determining what dose a patient will get when that patient shows up. But we're doing a better job with that.

I also think that the protocols that are coming out for the procedure, even though we're doing what we can to manage, the treatment protocols -- as you know, most of these studies are ordered by non-radiologists, or non-nuclear medicine physicians based on the protocols that they use in other disciplines.

And many of the protocols coming out of the oncology community, medical oncology, and the oncologic major hospitals in the United States are using more frequently this in terms in individual patients to determine the success of a treatment regimen they're giving. And, so, if you perform a PET scan and find out that the patient is not responding, you can change the dose to -- you can change the regimen to something that works. So, I think the monitoring of patients has increased somewhat in most of the current protocols, and that, again, contributes to this.

Finally, I also believe that the American College of Cardiology, the Society of Nuclear Medicine, and the American College of Radiology have all cooperated in terms of what we consider the appropriateness of these examinations. And this is a medical practice issue.

The inappropriate utilization of these procedures, and there are various numbers, depending on how you look at it, is something that we are trying to decrease, so that we don't get shotgun medicine being performed, and procedures being done that basically are not indicated. The American College of Radiology has 160 appropriateness criteria, with 700 iterations under that, which we distribute on a

regular basis to payers, and to medical practitioners outside of our discipline, so that they will know what the guidelines are before we will perform these procedures. And I think with, again, the new payment protocols that are coming in from CMS, that these will only increase. So, we're trying our best, and I have to say in terms of both nuclear cardiology, nuclear medicine, and radiology, we're all trying our best to keep these doses down. And I think in nuclear medicine, we're doing really a pretty outstanding job.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau. Dr. Fisher.

MEMBER FISHER: Thank you. I'd like to address this from a patient perspective, if I might. The NCRP report is really well done. I've read it. I spent a lot of time going through it. It's a fabulous piece of science. A lot of data have been collected. The issues are, at least as you've explained them, one of collective dose versus individual dose, collective risk versus individual risk, and collective benefit versus individual benefit. The increases in medical exams, including pediatric exams, pediatric CT have increased the collective doses to the population of the United States. And the effect on the individual, however, is one case at a time. And some

people who have received these exams, their individual dose has gone up quite a bit. Many others have had no exams.

The collective risk from these doses, there is going to be a calculation of some increment of collective risk. The individual risk, however, as Dr. Nag pointed out, is close to negligible. The collective benefit is difficult to measure. The individual benefit is either going to be zero, or very great.

I have a neighbor, close friend who went in for one of these storefront CT exams, was diagnosed with a very small tumor, had that cancer removed, and is very fortunate today. And I was really quite surprised to hear that anecdotal story, because that's usually not the case. Usually, patients go in for a CT exam on a well-patient history, and nothing is found, and so there's a little bit of dose, and no real benefit. But in that one individual patient where the radiographic, radiologic exam finds something, or helps to find an illness, or helps explain damage to a childhood brain from a sports injury, helps in the diagnosis of that patient, leading to better treatment. I think what needs to be pointed out is that the individual benefit of those

exams is very high. And the individual risk is very small, in those cases.

CHAIRMAN MALMUD: Thank you, Dr. Fisher.

MR. LEWIS: If I could just -

CHAIRMAN MALMUD: Oh, please. Mr. Lewis.

MR. LEWIS: -- respond slightly, because I agree with 99 percent of everything you said. But I would not go so far as to say the individual risk is zero of a several rem exposure. That does introduce, at the minimum, an increased chance of a latent cancer appearing. And that's the basis of our entire regulatory structure, but in cases where the individual benefit is great, that's an acceptable risk. In cases where the individual benefit is zero, as you said, then that's the question at hand.

MEMBER FISHER: Yes. I didn't mean to imply that the risk was zero. Certainly, that would be a foolish thing to state, but the enormous benefit in those cases really has to be taken into account.

CHAIRMAN MALMUD: Thank you. I think, Dr. Suleiman, you -

MEMBER SULEIMAN: Yes. I mean, my takeaway from the report is that first, when you look at the medical doses, you've got to realize those doses are associated with a benefit. So, I look at it

from a point of view that this is just one risk of many that patients undergo, radiation being just one of them, and all the benefits that you get with this.

What I take away from this is, look at all the other components that the public gets radiation from, and they're so much lower. And I think, as a society, the biggest problem is, we just don't understand risk very well. We were talking the other day, the risk of getting killed in an automobile accident is very high. And if you translate the risk, it's very negligible. It's never zero, but it's close to zero, so I think the take away message here is, if you were to exclude the risk where there's a medical benefit from it, how much radiation are people getting, trying to sort of put a better perspective on it. That's what I think the snapshot is intended to do, and not be a debate about what are the values of all these.

I mean, there are societal values from nuclear power, from all these other technologies, and there are benefits, both individual, and societally. But I think this is just one element of that, because we get risk from many, many other things. We probably do a better job in radiation of quantifying than any of the other risks we deal with.

CHAIRMAN MALMUD: Thank you. Dr. Eggli, then Dr. Vetter.

MEMBER EGGLI: I would like to make an additional comment of things that we in the profession are doing to mitigate radiation exposure risk. In many situations in an emergency department, a CT scanner has come close to replacing a stethoscope and a physical exam. A patient comes in with abdominal pain, the likelihood is the ER doctor is going to order an abdomen and pelvis CT. We now run our department with extremely sophisticated information systems, and we've set flags in those systems to trigger an alert when a patient has frequent radiologic exams. That allows us then to go back to the practitioner and say, you know, this patient was in here 17 days ago with the same abdominal pain, and we did a CT at the time, and it was negative. So, the profession is doing what it can, again, to help mitigate. And one of the additional things is the use of these information systems that we can use to track histories.

CHAIRMAN MALMUD: Thank you. I think Dr. Vetter was next.

MEMBER VETTER: Thank you. I agree with what's been said around the table about the scientific

rigor of this report. I think it's an outstanding report, but bottom line is, it's simply a scorecard, and it's a scorecard that was last published in the `80s, and now it's updated. And like Dr. Van Decker said, it's appropriate to update it periodically, but it's simply a scorecard. And it tells -- what does the scorecard tell us? It tells us that the largest increase in exposures, almost all the increase in exposures, due to the application of radiation in medicine, which the NRC does not, in terms of patient doses, does not regulate. And medicine -- why has that gone up, is because of increased availability of technology, and new technology, and increased availability of the technology to a wider variety of patients. More patients have opportunity to be exposed.

Medicine, if you read the medical literature, medicine is very concerned about that, and they are looking at utilization, they're looking at doses, try to reduce doses. They're looking at all of that, so I don't think any of this has been done irresponsibly. So, what the report tells me, and if you look at the other areas of the report, I don't think we have a problem. Where would you go to try to reduce exposures? In the consumer products area,

you'd try to get people to stop smoking. In the background area, you'd try to get people to do something about radon on their homes, but in the occupational area, as you mentioned, Mr. Lewis, actually, the occupational exposure has gone down a little bit. So, if you look at all of the other areas of the report, what the report says to me is that the NRC, relative to these exposures, the NRC and regulators have been doing their job. And I don't see any -- I don't think the report makes any suggestion that regulators need to take any action to reduce exposures.

CHAIRMAN MALMUD: Thank you, Dr. Vetter. Was there another comment? Dr. Welsh.

MEMBER WELSH: I agree with Dr. Fisher's points about the benefits of medical imaging. And I can appreciate the anecdote. I think that any clinician can come up with dozens of anecdotes that they've seen with their patients, and the medical literature is replete with documentation of the numerous benefits.

I don't disagree with Dr. Lewis' comment, that the risk may be non-zero. But I think that we have to acknowledge that the data in this very low dose realm is a bit sketchy, and it's difficult to

fully interpret. While I agree with the ALARA principle, I think that it has to be acknowledged that the scientific data is not complete. And we're all familiar with Kerala, India, Ramsar, Iran where doses from background radiation can be the equivalent of dozens, if not a hundred CT scans annually, so if you look at the epidemiology and life expectancy in Kerala, it's higher than most of India. It's sometimes difficult to put all of this together, and then integrate that with our instinct to say that we should reduce the number of medical imaging studies because of the increase in dose to the public. I think it does have to be tempered with a little bit of common sense.

CHAIRMAN MALMUD: Thank you. If I may, I'll try and summarize what the Committee appears -- what I've heard the Committee say. Number one, there's a consensus that the report is an excellent document, and we're grateful to those who prepared it. Number two, we believe that the NRC should continue to maintain records, keep us aware of radiation exposure so that we can bring that into the thought processes with regard to caring for patients. Number three, it's a medical principle first, do no harm. And the medical community is eager to adhere to that

principle. But the current belief is that given the data with regard to the morbidity and mortality of cardiovascular disease, and the incremental progress being made in cancer, that the benefits currently appear to outweigh the risks. And, lastly, you heard several members of the Committee comment on our continued concern with regard to radiation exposure to children, who appear to be more radio sensitive, and whose life expectancy is such that we need to be continuously aware of the risk to them of unnecessary radiation. Does that summarize what the Committee has concluded? That's our response. Mr. Lewis?

MR. LEWIS: Would the Committee like to comment at all on the -- on whether or not NRC should revisit any of its policies in this area, as a matter of going forward?

CHAIRMAN MALMUD: Well, I believe that one -- my second point was that the -- we would encourage the NRC to continue to keep records of, and keep us aware of radiation exposure, so that that data may be brought into the diagnostic armamentarium and assist physicians in decision making with regard to the advantage, or disadvantage of employing a radiologic technique in the care of patients. But the actual decision should be within the realm of medical

practice, and not NRC. But we're appreciative of the data. In fact, we need the data.

Dr. Eggli, were you going to make a comment?

MEMBER EGGLI: Your question is, did you want that in the form of an official statement from the Committee, in the form of a motion, or is Dr. Malmud's summary adequate for your purpose?

MR. LEWIS: Well, that's a good question. I will defer to the Committee to decide if they want to have a motion, but it will be on the record what he just read.

MEMBER EGGLI: I would propose a motion that because the increase in exposure related to materials was for medical indication, and not occupational, in keeping with the NRC's policy of not dabbling in the practice of medicine, that no new action is required on the part of NRC.

MEMBER VETTER: Second.

CHAIRMAN MALMUD: There's a motion which has been seconded. Discussion of the motion? Mr. Lieto.

MEMBER LIETO: I have a question regarding the policy. Does it state in the policy something to the effect that will not interfere with the practice

of medicine because studies are medically justified, some type of medical justification terminology?

MR. LEWIS: Donna-Beth and Ron have that committed to memory, so I will defer to their expertise.

DR. HOWE: I think the medical policy says that we will regulate the radiation safety of patients when necessary, and the NRC has traditionally taken a position that when you're into procedures that require written directives, that's your threshold, and we do require written directives to make sure the administrations are in accordance with the physician's wishes, and that they're in writing to make sure there are no errors in there. So, we don't get involved in the actual dose to the patient, we use the physician as the gold standard. And that's the point at which we jump into protection of the patient.

MR. LEWIS: And just to be fully clear, being an NRC policy, we do have the legal authority to do it, and we've taken a policy decision to not get into the practice of medicine, so there is an issue of should we revisit that policy, as the Committee has weighed in.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman.

MEMBER SULEIMAN: This is a snapshot of some scientific information. Why do we need to make any kind of motion just for the sake of making a motion? I tell you what I think would be of value in terms of -- if the information is collected both by the NRC and the Agreement States in terms of the occupational doses, that this is the discussion prior to this one, where if that information could be collected somehow, or looked at as an early warning, you may have some new technology creeping in, and get an early warning. Let's say PET with the high gamma is exposing those workers at a higher rate than previously, that would sort of fall in the realm. I think it's more -- that could be useful. I don't know whether they can collect that information or not, but I think we need to use scientific objective data. And if it's being collected, let's use it beneficially. But I don't see the value of having some sort of motion, unless there's a real specific objective to it.

CHAIRMAN MALMUD: Thank you. Mr. Lieto.

MEMBER LIETO: Just a follow-up to my question before. It was pointed out to me that in a policy that states that the NRC will not interfere with medical judgments of authorized users in the

course of their practice. And I think, to me, the current policy is adequate. I don't think there's anything, in light of what's been discussed already, that indicated that either there is a deficiency in the current regulations, or the current medical policy that the NRC has. I think it is of the appropriate scope that this document does not reflect any further action that's needed by the NRC in the area of medical use of radioactive materials.

CHAIRMAN MALMUD: Thank you. Dr. Nag?

MEMBER NAG: Yes. I feel that saying that the NRC does not intrude into the practice of medicine applies here, because we are not trying to intrude into medical practice. We are trying to say to use the best judgment, and to weigh cost-benefit ratios. That's not interfering with medical judgment, so I would not go along with this motion. I think a better response to this would be to say that the ACMUI agrees with -- and the summary you made was an excellent summary, and say this was the response of the ACMUI.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: To respond to that, my understanding is that Mr. Lewis' question was, should NRC reconsider that policy, and consider engaging in some degree of control. Am I correct, sir?

MR. LEWIS: And are there any gaps in any other policies.

MEMBER EGGLI: Yes. So that's why I think the motion is appropriate to make the opinion of the Committee clear, is that the current processes are adequate, and there is no need to go further into this. That's the intent of this motion, and that's why I think since the question was asked, why it's appropriate to respond specifically to that question.

CHAIRMAN MALMUD: Thank you. Any further discussion of this? Dr. Welsh.

MEMBER WELSH: I'm fully in support of the motion. If I understand the concepts and questions on the table, is NRC -- should NRC take any change in its practice based on information gathered about increasing dose to the public from medical diagnostic procedures involving isotopes. I think to do so would be encroaching upon medical judgment, and that's, perhaps, not within the purview of NRC.

More importantly, or also importantly, yesterday, when we were discussing INES, International Nuclear Event Scale, it really is International Nuclear and Radiological Event Scale. Similarly, today, NRC will be talking about possibly regulating diagnostic studies, therapeutic interventions using

isotopes, and then 50 percent of the medical radiological procedures would, or more than 50 percent would not be under such regulation. And if we were to endorse regulation, we might come to a point where a person can't get a bone scan, but they can get a bone survey, and that just doesn't make any sense to me. So, I think that unless there was an agency that were going to take over all aspects of radiation exposure to the public, and to patients, that NRC probably should not make any changes based on this information.

CHAIRMAN MALMUD: Thank you, Dr. Welsh. Any other comments with regard to the motion that Dr. Eggli has made? Dr. Eggli, may I request that we find a synonym for dabbling?

(Laughter.)

MEMBER EGGLI: I will accept any appropriate synonym.

CHAIRMAN MALMUD: All right. That the NRC and agreement -- by the way, this should also -- we're also looking for the Agreement States to give us a database. Is that possible, Debbie?

MEMBER GILLEY: You can surely make a recommendation, but there is no authority for ACMUI.

CHAIRMAN MALMUD: Regardless of authority, it's just with encouragement. Alright. So that the

second part, number one, I think there were four parts to the issue. The first one was that we commented on the excellence and thoroughness of the report, and are appreciative of it. Number two, that we would hope that the NRC and the Agreement States should be encouraged to keep us aware of the radiation exposure to patients, that we encourage them not to -- to continue not to intervene in the practice of medicine. Is that, intervene?

MEMBER EGGLI: Perfectly good word.

CHAIRMAN MALMUD: Thank you. The third point is that Committee members recognize that as a basic premise in tentative medicine to first do no harm. And the profession is aware of that, and is concerned about radiation exposure. And the fourth one is that we always are reminded of the need for the benefit to the patient to outweigh the risks, regardless of the procedure being performed. And that was the motion. Does that sum up what you said?

MEMBER EGGLI: I'll accept that as the motion. Thank you.

CHAIRMAN MALMUD: Who seconded the motion?

MEMBER VETTER: I did.

CHAIRMAN MALMUD: Is that acceptable?

MEMBER VETTER: Yes.

CHAIRMAN MALMUD: Any further discussion? All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions? Two abstentions. Oh, three abstentions. Thank you. Mr. Lewis?

MR. LEWIS: Yes, if I could make a final comment. I would request that the Committee make its views known to the Commission at the upcoming ACMUI meeting with the Commission.

CHAIRMAN MALMUD: Thank you. We will. We move on to the next item, which I believe is a brief break.

(Whereupon, the proceedings went off the record at 10:23 a.m., and resumed at 10:38 a.m.)

DR. EGGLI: Okay, start again. This is the report of the subcommittee on the board certification pathway for authorized individual status. This report has partially been presented before, where a framework for a recommendation was presented at the last meeting, but I will briefly review the problem.

Basically if there is a significant time delay between the completion of training and final board certification for trainees who intend to become

authorized individuals by the board certification pathway, they may be unemployable for a period of time.

As a result the only way for those individuals to become immediately authorized for materials is to utilize the alternate pathway which effectively invalidates the board certification pathway for those certification boards.

The problem was recognized, and I need to mention and applaud both the American Board of Radiology and the NRC staff, because the problem is not imminent yet, and the time frame for solving the problem is probably quite adequate.

So the subcommittee was charged to recommend a potential solution that would allow an authorized individual - allow a trainee to become an authorized individual prior to that board certification. The subcommittee was specifically charged with developing a recommendation that could apply to diagnostic radiology and the American Board of Radiology.

However, the subcommittee thought it would be important to make a recommendation that could be generalized, and could be utilized by any certification board that perceived a problem with

their trainees becoming authorized individuals between the completion of their training and the final board certification.

It is important to state that this is a framework design and that no board would be required to utilize this framework if they didn't perceive a problem. It's simply a framework available to be used when there is a problem to be solved, and that problem being the time delay between completion of training and final board certification.

The initial proposal to - was that NRC recognize certifying boards could issue a separate certificate at the end of training to attest to the trainee's completion of all the TV requirements and necessary examinations to achieve authorized individual status. So the first recommendation is that the boards separate the training - the certification of training for authorized user status from the rest of the board certification.

The second proposal was that the NRC accept this certification for the board certification pathway to achieve authorized individual status.

This effectively preserves the integrity and utility and intent of the board's certification pathway, while at the same time provides a level of

assurance of the quality and completeness of the individual's training.

The NRC staff asked a series of clarifying questions about the proposal. There were actually four numbered questions, but we divided question three into two parts, so there are five questions we will be answering.

The first was to provide clarification that separate AU certificate issued at the end of training is indeed recognized by the board or in effect stands alone, and is not just a piece of paper. And the subcommittee in this case recommends that the certification of completion of T&E is considered by the board a stand alone recognition; which is to say it is not then dependent on the board's subsequent determination at the end, but that it stands alone and remains in force effectively forever once it's issued.

The second question was that - provide clarification that the proposed certification is indeed separate, which is sort of a further refinement of the first question. And again the subcommittee recommends that the certifying boards clarify that the AU training and experience is not an interim but a stand alone certification, and the subcommittee in response to, again, staff questions, recommends that

the certifying boards specifically state what training this is certifying, whether it be training under Part 200 - training under 290; Part 300 training under 390, 392, 394; or for any other board part, 400 training under 490 or Part 600 training under 690, in a broadly applicable training algorithm.

The next question is to clarify whether or not successful completion of the NRC tailored examination will be required for trainees who do not pursue or do not achieve the proposed authorized individual training. The - in this case the subcommittee understands that different certifying boards may take a different approach to satisfying this concern. There are two possible approaches that I saw in a general basis, and the first path would say all trainees would be required to acquire the necessary training and experience and to pass the required examinations to become an authorized user as part of their board certification requirement; that if they do not complete this first phase then they are not eligible ultimately for board certification.

Alternatively a certifying board could offer two pathways, one that leads to board certification effectively as ABR does now; one that leads to board certification with authorized user

eligibility; and one that leads to board certification without authorized user eligibility.

And the question is, what is the impact of that? And I think that is what the next question effectively answers, which is to say that if trainees do not achieve the authorized user status as part of their board certification program and they subsequently determine that they want to become authorized users then their option becomes the alternate pathway and it is no longer an obligation of the board to go retrospectively and provide them with something so they can get authorized user status.

So that if the board were to offer a dual pathway and the individual did not choose to participate in the training and examinations necessary to become an authorized user, and sometime later determined that they wanted to become an authorized user or authorized individual more broadly, then their option becomes the alternate pathway, and they are no longer eligible for authorized individual status via the board certification pathway.

The final comment from staff, which I'm not sure was a question but more of a comment, is that this represents a change in the approval that - or recognition that NRC has already provided to the

individual boards, and that the boards would have to amend their proposal to the NRC and have that amended proposal recognized.

And again the subcommittee's recommendation would be that the board would do exactly that, which they would submit their modified proposal to NRC for review, for the board certification, and to make it clear to NRC as to whether this proposal represents a replacement of their existing recognition or whether this represented an addition to their existing recognition.

And that is pretty much as far as we could go in making a recommendation. I don't think that we could make a recommendation that is more specific and yet broadly applicable. Again the goal is to provide a framework whereby the boards can provide the opportunity for trainees to become authorized individuals prior to the completion of the final board exam, and when there is a large gap between completion of training and final board certification, a program that is not required to be used by any board, but is a framework available to be used if the board chooses to do that.

If a board does not perceive that they have a problem, then they have no need to utilize this

pathway.

So that I think concludes the subcommittee's report.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

Questions or comments for Dr. Eggli?

DR. NAG: I have been asked by many of my colleagues in radiation oncology that if this were to come into effect, what would happen to those individuals who got the NRC annual status; they did not appear before the board, or they appeared before the board and they failed; and all they decided that they do not need the board and they would not appear for the board. So would you clarify that?

DR. EGGLI: Yes, again, for the subcommittee's point of view, and I guess this is as much a question for NRC staff, is that if they achieved this authorized user status technically they could apply for authorized status, but the reality is they are unemployable, that if their limited employment opportunities for individuals who do not achieve board certification these days. And that is not an NRC regulation; that is coming more and more from third party payers who are beginning to impose credentialing requirements for payment.

But I think that the way this proposal

stands is that they could conceivably apply.

Now the other thing is if though the American Board of Radiologies, radiation oncology section, did not modify their request to NRC to include this pathway, then it doesn't exist. So it is up to the individual boards to determine whether or not this sort of solution is either viable or useful for them as a board.

So one solution might be that radiation oncology says, we are not going to use this framework; that we are happy with what we have now, and that's it.

So again this is not imposed on any board. The solution is not imposed. It's a framework, and it's not the individual candidate who decides whether or not to use the framework; it is actually the board that determines whether or not they want to implement a program within the framework.

CHAIRMAN MALMUD: Dr. Nag, did Dr. Eggli answer your question?

DR. NAG: Partly, but I still think that it will use the authority of the board if they were to apply -- if they were to rank two separate -- because many people would say I am going to apply for the NRC AU status, but I don't want to take the trouble to

take the exam and get the board certification. On the other hand, I don't really see the importance why would a candidate go through the entire residency clinical plan, go to the board, go through everything else, and not apply for the AU status at the same time. So I'm a little -

DR. EGGLI: The solution is intended is intended for the boards that have a significant time gap between completion of training and final board certification. No board is required to utilize it. This may not be the appropriate framework for radiation oncology at all. They are not required to implement that pathway if it doesn't apply to their diplomates.

DR. NAG: No, it does apply to our diplomate, I thought the solution was that people who are going through the board certification, they finish their residency, and at the end of that residency they are given an AU - NRC AU certificate, that means basically available to them so they don't have to go through the alternate pathway. And then they appeal to the board, and when they appeal to the board then this becomes a permanent situation. That is my understanding.

DR. EGGLI: Okay. What I took away from

NRC's questions, and maybe I read too much into staff's questions. But my - the feeling that I got out of this, and please, the staff should respond to this, was that I saw this as the staff wasn't interested in having to police an interim certification that might have to be taken away. And therefore the solution needed to be such that it was not an interim certification.

CHAIRMAN MALMUD: I believe that Dr. Zelac is able to comment on the subject.

MR. ZELAC: The NRC regulations list specifically particular requirements that an individual board has to satisfy in order for candidates, its candidates, that the board has to require of its candidates in order to have this certification process recognized. In other words the regulations say, if you want a recognized certification process so that your diplomates can follow the certification pathway to authorized status, here are the things that have to be met.

Those are in the regulations now. What they are basically saying is that through this suggestion from the subcommittee is that, as I understand it, that if a board chooses to, at the end of the residency program, provide an examination which

will fulfill that portion of the NRC's requirements and subsequently if the candidate passes that examination the board issues a certificate to that person so stating, and then that individual can follow the certification pathway in seeking authorized status.

DR. EGGLI: That's the impact. Debbie Gilley has been trying to get in here.

MS. GILLEY: I'm a little confused. Don't we already have an alternate pathway for these individuals? And what are the advantages of setting up a third pathway versus trying to make sure the alternative pathway meets the needs of the board eligible authorized users?

DR. EGGLI: I think that the alternative pathway, and I covered it in the four-page single spaced document which would put you to sleep if you tried to read it, but the recordkeeping requirement is significantly different for alternate pathway than the board certification pathway.

The - and many preceptors these days are not willing to write alternate pathway preceptor statements.

The other thing is that the boards have some leeway in how they compose the training to meet

the regulations, where the alternate pathway is significantly more rigid.

So it imposes on the board certification pathway a recordkeeping burden which is very different than if they have to train rigidly to the alternate pathway and keeping all the records that document the alternate pathway than the board certification pathway does.

CHAIRMAN MALMUD: Dr. Guiberteau.

DR. GUIBERTEAU: Just to reply to Debbie, I don't believe this was intended to be a third pathway.

DR. EGGLI: No, it's not. It's still the board certification pathway. It is the proposal of what will NRC accept as evidence of completion of the board certification pathway.

MS. GILLEY: But my concern as a regulatory is that alternative pathway, we put somebody on a license, an authorized user, and they do not pass the board or choose not to sit for the board, I have no regulatory authority necessarily to remove them because of that, because they have already demonstrated that they are capable of doing these procedures without any supervision.

So there is some legalities, regulatory

coordination activities that are very very concerning to those folks who must implement this particular regulation.

CHAIRMAN MALMUD: Dr. Guiberteau?

DR. GUIBERTEAU: May I respond? I realize this, and wisely so, and I thank our chairman, Doug Eggli, for doing a superb job on this, and Cindy Flannery for advising us. But if I might give you what the ABR is willing to propose or would like to propose, to give you an example, not to be put into writing at this point, because there is no reason we would do that quite yet. But what has happened is, the American Board of Medical Specialties, which is a combination of 24 boards of which the ABR is one, we have not been in line with the other boards in that we do not require a clinical year after training before they take their final exam.

So in the past completion of all the training, completion of all the certification including the AU eligible status portion of our certificate, was given at a time when they could apply and use it in that year of practice.

At the moment our final certification is given 15 months after they go into the practice or further training. So if we did not - were not allowed

to give the AU, that is, take the AU portion of our certificate and put that off and give it to them earlier if they complete all of it, they would have a 15-month gap in which they would not be able to function as an AU, even though they were qualified.

Our current process for this that we are proposing is, in the four years of residency, at three years they take a comprehensive examination. This comprehensive examination covers 17 topics, okay. And including in these are the examination on radiation biology, radio-pharmacy, radiation safety, radiation physics, nuclear medicine, et cetera, et cetera.

They must pass this examination at the end of the year - or they must pass this examination before they can then take a dedicated AU examination which is a separate - we propose to be a separate examination.

So together those two examinations by the end of their fourth year when they leave us will qualify them we believe - because it is the same process we are basically using now - so that we might give them documentation that they should be AU eligible under this board certification pathway.

This includes the board collecting documentation in terms of they must have attestation

from their program that they have completed the - to us that they completed the necessary training. They must give us their case logs that were preceptored of their 300 cases. They must pass this extensive core examination, and they must pass the AU examination.

So what we are proposing is, rather than waiting for 15 months to give them one certificate saying that they are ABR certified and AU eligible, we would like to take that off and give it to them earlier.

The examination that they take at 15 months is based on the practice that they are in. They get to choose three of the topics that they are examined on, and the board gives them two standard topics, both of which are clinically oriented, but for noncognitive - many with non-cognitive skills, professionalism, ethics and those sorts of things.

So in effect they have completed all of the necessary training. Everything has been documented, at the time they go into practice, when they leave their programs by the board. And in order not to have a deficit in terms of the number of Aus coming out that are eligible for AU status, we would like to present this as a variation on the certification pathway.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau.

Debbie?

MS. GILLEY: Currently we are doing this through the alternative pathway. There is a gap now I believe between getting board certification and actually completing your educational requirement. So they are sending to us their alternate pathway attestation clinical cases, some of the same things that the American Board of Radiology is looking at doing to provide this document.

I'm still confused as to where the gap is in alternative pathway to get them on a license -

DR. EGGLI: Debbie, let me try to explain that. As a preceptor I will not write an alternative pathway statement for anybody.

MS. GILLEY: But we are looking at changing those regulations?

DR. EGGLI: Not the alternative pathway regulations we are not.

MS. GILLEY: We are looking at taking the competency statement out of that. Are you not willing to write an attestation letter -

DR. EGGLI: No, what I -

MS. GILLEY: Because that is what you are

doing -

DR. EGGLI: No, that is not quite right. It is the recordkeeping requirement for all the individual components in the alternate pathway. I don't have to keep those records now, and I don't. Because essentially the program director is certifying to the American Board of Radiology that that has been completed. The bottom line is, I'm not willing to put my signature on an alternate pathway document that is supposed to have this many hours of this, this many hours of this, this many hours of this. And if you look at NRC's form 313A it asks for the number of hours in each of those areas. I'm not willing to try to document that and put my signature on it.

MS. GILLEY: But you are willing to do that for the American Board of Radiology to get them -

DR. EGGLI: No, the attestation to the American Board of Radiology is that they have completed the training requirements within the description of the program of the American Board of Radiology. The board certification pathway covers the topics that must be covered, but no real distribution other than the 80-hour requirement; no real distribution efforts.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: Dr. Eggli, perhaps you could clarify a misunderstanding I might be having. Since this is for new graduates to accommodate that brief interval between completing residency and board certification, does this new proposal in essence obviate the alternative pathway? Is there not going to be -

DR. EGGLI: No, there will always be people who do not graduate from a recognized training program who are qualified to become authorized users. For instance right now I don't believe there is endocrinology training program that is recognized; and I could be wrong on that. But yet, via the alternate pathway, endocrinologists can become authorized users. So there will always be categories of people who have training and experience appropriate for authorized user status, but do not have a certification from a recognized board, even though they may be board certified.

DR. WELSH: But for endocrinologists they wouldn't have this particular problem that we are talking about with radiation oncology and radiology, so this solution is primarily directed towards radiology and radiation.

DR. EGGLI: This solution is directed

toward diplomates or trainees who train in training programs where their program is recognized by NRC for board certification status, but who have a significant time gap between completion of training and final board certification; and that time gap is perceived as causing a problem with either employment or the ability to deliver care to a patient population.

CHAIRMAN MALMUD: If I may, we are under a time constraint in that we must be at the hotel by 11:15. May we pick up this discussion after lunch? Thank you.

DR. EGGLI: Personally, I'd rather just see a motion made to pass.

CHAIRMAN MALMUD: I don't think we are ready for a motion.

We will reconvene promptly at 1:00 o'clock, which means we should leave the hotel around 12:45 to get back here at 1:00.

(Whereupon, the above-entitled matter went off the record at 11:06 a.m. and resumed at 12:59 p.m.)

DR. EGGLI: While people are coming in let me make if I could, Mr. Chairman, make two clarifying points. One is that this is - Steve, we have your briefcase - one of the clarifying points is

that this is a framework. The proposal was that again that the candidates would complete training experience and any appropriate examinations, and each individual board who chooses to use this framework would submit their proposed program to NRC for evaluation, and NRC would need to concur that that proposal met the requirements of the regulation.

So there is no obligation placed on NRC to accept any one proposal if NRC is not satisfied that the requirements and the regulations are being fulfilled.

I think that is the primary clarifying statement. And the other one is, no board is compelled to implement something along this framework if the board has no need for it. We wanted to make this reusable so that the wheel didn't have to be reinvented every time a certifying board came up against a delay if they changed their training paradigm from how it currently exists.

So again the point is that the proposal does say that all candidates or all trainees meet the training, experience and examination requirements; and it says that the board submits a proposal to NRC that NRC would have to accept as meeting the regulations, and qualify it as meeting the requirements of the

board certification pathway.

And then Mr. Chairman, I will turn it back for what residual discussion is left.

CHAIRMAN MALMUD: Does anyone else wish to comment on the issue? Dr. Nag.

DR. NAG: The solution that was passed at the last meeting was something that was applicable to everyone. We then - NRC official asked for a number of qualifications. What I wish to ensure is that radiation oncology has some of the similar problems in that we have the examination at the end of the third year, and they finish residency at the end of the four years. But they do not appear before the board until a year later. So we do have a gap problem.

However we do not have the problem that we need a separate examination because our regular written board has plenty of questions on NRC rule, regulations and so forth. So I wish to ensure or I wish to clarify that if we pass the new regulation or the new qualification it will not require a radiation oncology candidate to mandate a third examination with the NRC examination.

DR. EGGLI: Mr. Chairman, on this, again the program that is adopted is a negotiation between NRC and the certifying board using the framework.

Again, the thing says, appropriate training experience and examinations. There is nothing in the proposal that says that mandates a separate examination. ABR may go that route, but there is nothing in the proposal that obligates an additional examination. If NRC, I would think - I would staff to comment, please, if NRC is satisfied that the examination given adequately tests and separately scores performance in those portions, NRC may or may not require something separate.

Again a separate exam is not mandated, but what it says is this is a negotiation between NRC and the certifying board.

DR. NAG: The reason I am asking for the clarification is that both the diagnostic and the radiation oncology, both are called radiology. With the name, ABR, it is what you have to do because you are certified by the ABR, someone may mistakenly think that it applies to diagnostic and radiation oncology as well.

I want to prevent such misunderstandings in the future. I am trying to look in the future and people - and it has happened before. Just because we have written ABR, people have misunderstood that it means to both.

DR. EGGLI: Cindy, you are our touch point with NRC on this. Could you please comment?

MS. FLANNERY: Yes, with regard to Dr. Nag's concern, I don't think that will be an issue, because there - on our website we have three different specialties of ABR listed. So I don't think that that should be an issue. So just because you have a certification process for ABR diagnostic radiology, that same process wouldn't apply for ABR radiation oncology. So it does differentiate the three different specialties on our website, as well as listing them under the various sections for 10 CFR 45.

And the third specialty being the medical physics, or radiological physics.

CHAIRMAN MALMUD: Thank you.

MS. GILLEY: Again this is a question from NRC. Would this require rulemaking?

MR. LEWIS: We're not entirely sure at this time. But we would have to talk to our rulemaking people and our OGC to decide that.

MS. GILLEY: Okay. The second comment then is the way that currently the situation is set up NRC could make these changes because their compatibility. They would be forced onto the Agreement States, but without better Agreement State

participation I would be a little hesitant to step forward in any kind of support of this activity since they have not really been informed of that activity.

CHAIRMAN MALMUD: Thank you for bringing that to our attention.

Any other discussion of this item? Dr. Eggli.

DR. EGGLI: Again, certainly a vote by this committee to endorse the subcommittee report doesn't mean this is going to happen. This just says that this is recommended as a potential solution. And I would agree with Debbie that the work is clearly not done, once a recommendation is made.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: Speaking as a radiation oncologist, I acknowledge that there is the very same problem in radiation oncology as there is diagnostic radiology. Therefore a solution has to be sought.

The proposed solution of an AU certificate sounds like a very reasonable solution until those individuals go on a year later or whenever to take their formal board examination. But I would submit that for the radiation oncology residents, that an additional examination might be required.

DR. EGGLI: Yet there is nothing in the

proposal that would require a separate examination. There is nothing in the proposal that would require a separate examination. What it says is that the NRC is satisfied that the training experience and examinations whatever they are that the board submits to NRC for approval meet the requirements.

So I don't think there is anything in this proposal that suggests that necessarily a separate exam would be required, as long as the core examinations met the requirements.

DR. WELSH: And the core examination is the one that would be taken in the future?

DR. EGGLI: The core examination would be whatever the radiation oncology section of the American Board of Radiology defines as its board exam.

DR. WELSH: So maybe there was a misunderstanding. There is no separate examination for the AU certificate?

DR. EGGLI: Right, and there is nothing in this proposal that suggests that there needs to be.

DR. WELSH: In that case, I agree with this.

DR. EGGLI: Offering a second exam would be the American Board of Radiology's diagnostic radiology section proposal for how they would manage

it for diagnostic radiology; that is not imposed on any other portion of any other certifying board.

DR. NAG: When we make the motion, when we are voting on the motion, could that qualification be added into the motion? Because I am always afraid that they will all be lumped into one. So it would help if in that motion you say that a separate examination is not necessarily required.

DR. EGGLI: I guess I think that is overboard, because again NRC has stated that they do not consider these the same board. That statement has just been made, that NRC does not consider the diagnostic radiology board exam of the American Board of Radiology to be the same exam as the radiation oncology exam, and there is nothing in the proposal - there is nothing in the proposal that says a second exam. The second exam just happens to be the way that the American Board of Radiology diagnostic radiology may approach it. But this, all this says is that the patients - that the candidates pass whatever the appropriate examination is. There is no reference to a second examination in the proposal.

DR. NAG: I'm sorry. Let me read it out word by word. Please clarify whether successful completion of the NRC tailored examination will be

required for ABR candidate, not diagnostic candidate, ABR means ABR, for both diagnostic predictions as well as therapy candidate, who do not pursue or do not achieve the proposed certification.

DR. EGGLI: That is the question.

DR. NAG: Yes, I think the qualification that they ask for, and if they do not qualify, which part of it you are recommending that a second exam be required, I am afraid that later on it may be lumped together as ABR.

DR. EGGLI: But the response to that doesn't make reference - and the proposal doesn't make reference to a second exam. The answer to the question does not make reference to a second exam.

CHAIRMAN MALMUD: Dr. Guiberteau.

DR. GUIBERTEAU: The ABR certification process in diagnostic radiology decided on its own to offer a separate examination for several reasons. First of all if the candidates do not - their programs do not submit the proper paperwork, or if they do not pass their core exam the first time, then there is no need for them to take the AU examination because they don't qualify.

If they go forward, or they take the AU examination and do not pass it, or they go out into

practice and decide well, I don't want to be an AU and never apply, but later on do, then we will have the possibility of opening that examination to cure these issues in the eyes of either the Agreement States or the NRC by allowing them to come by and come back to the ABR and to take this examination and pass it.

So it really is mechanistic in our point of view to be able to offer it in that form. It has nothing to do with requiring a second examination because no one ever brought that up to us. It was our idea to do that so that we would have a free standing examination that we could offer to people who needed to cure an issue with their AU status.

DR. NAG: I agree with you completely. You have offered a solution for the diagnostic component of the ABR. But what you are writing here, just ABR and not writing diagnostic ABR, and that may create problems later on. That's all I'm trying to say.

DR. EGGLI: That is not in the proposal; that is in the question. Let me specifically read the proposal that is put forward in response to that question.

The proposal says, all trainees would be required to acquire the necessary training and experience, and to pass the required examinations to

become an authorized user. There is no reference to any specific number of examinations.

So this proposal does not, in response to NRC's question, does not propose necessarily any additional examination. So this subcommittee's proposal is that they - that the candidates get the training, they get the experience, and they pass whatever the required examinations are. The required examinations are - NRC will determine whether or not the proposal the board makes meets the requirements.

If - I would again ask if you could try to address the question - if NRC is satisfied that the examinations as they exist meet the requirements, I can't see that NRC would necessarily require a separate exam.

Could you specifically address that issue, Cindy? If NRC is satisfied that the exam as it currently exists meets all the requirements, would the NRC require a separate or additional exam?

MS. FLANNERY: Okay, I think just to clarify a little bit. I guess a couple of things. One is, NRC does not recognize a board; we recognize a certification process, okay. And if that certification process meets NRC's requirements then it will be recognized.

And just to kind of break it down, there are three sections really. There is a classroom laboratory training section; there is a supervise experience section; and then there is the exams section.

And in each of those sections there are required topics that need to be included.

If a board can demonstrate that all of those requirements are met, NRC will recognize that certification process, okay.

So I think that kind of hopefully addresses Dr. Nag's concern in that we are not recognizing the ABR as a whole; we are recognizing the different certification processes.

As far as the question on the exam itself, NRC does not review or evaluate exams. But the board does need to demonstrate that the exam does improve the listed topic the NRC has in its regulations. And if a board can do that with just one exam, then that is fine. Another exam is not required later if that was your question.

DR. NAG: Thank you.

DR. EGGLI: I think that was - does that satisfy your question, Subir?

CHAIRMAN MALMUD: The other point I would

make is that we have been sitting on this committee for a number of years together. And the only instance in which there was a challenge to someone's status as an AU was supported by the NRC, but voted against by the members of this board - of this committee. So the NRC has been reasonable and has shown flexibility not with regard to its standards but with regard to interpretation of the standards.

Dr. Vetter.

VICE CHAIRMAN VETTER: I move that the advisory committee endorse the subcommittee report of the board certification pathway for AU status.

CHAIRMAN MALMUD: Is there a second?

MR. LIETO: Second.

CHAIRMAN MALMUD: Any further discussion?

All in favor - oh, Dr. Welsh.

DR. WELSH: In relationship to Cindy's comment that NRC recognizes certification or processes but not boards. So the solution proposed is that there would be certificates that say AU eligible. Will that carry any weight given that it is outside the formal board certification pathway that is issued by the American Board of Radiology?

CHAIRMAN MALMUD: that's a question to you, Cindy.

MS. FLANNERY: I'm not certain I understand the question. The way ABR when they submitted the documentation for our review, it was explained that the certificates that have AU eligible on them would be issued to the diplomates who meet NRC's criteria. If it does not have AU eligible on it, those diplomates for some reason did not meet NRC's criteria, and there are various reasons for that.

And that is identified on our website that way. Basically saying that anybody who got certified after the identified year with the words, AU eligible on the certificate, would be able to apply for AU status under the board certification pathway.

I don't know if that clarifies it.

DR. WELSH: The certificate comes 18 months after finishing residency program. So the problem at hand is that there is an interval, 12 to 18 months, in which somebody could complete their residency training and not have that certificate whether it says AU eligible or not. They won't have it for 18 months. There is a proposed solution, but I'm questioning whether or not this proposed solution would have any merit or weight with NRC given what we just said.

DR. EGGLI: One of the direct statements of the proposal is that NRC will accept that verification by the board that the candidate has completed all of these requirements. And what I thought I had previously heard is that NRC is open to considering that as a solution dealing with resolving any residual legal questions.

DR. WELSH: And that is my question, given the wording I just heard about recognizing the board's certification process versus recognizing the American Board of Radiology.

DR. EGGLI: I know, but this would be part of that process now.

MS. FLANNERY: And it was our understanding of the proposal is that this would be a new certification process, different than what is currently recognized.

CHAIRMAN MALMUD: The question has been called.

All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(Show of hands.)

CHAIRMAN MALMUD: One opposed. Any abstentions?

(Show of hands.)

CHAIRMAN MALMUD: One opposition, one abstention.

MS. GILLEY: May I make a comment on my opposition?

CHAIRMAN MALMUD: Please do.

MS. GILLEY: Okay. Without the assurance of rulemaking this would have an impact on the Agreement States because of the opportunity to evaluate this change would not be brought before 36 Agreement States as to the change in the certification process. Thank you.

CHAIRMAN MALMUD: Thank you.

I'm sorry, I heard a comment? Oh, please.

MS. CHIDAKL: My name is Susan Chidakl. I am a senior attorney in the Office of General Counsel that assists and advises the staff with regard to rulemaking. And with regard to whether regulations need to be officially - go through a rulemaking process in order to accomplish what it is that you or the staff is trying to do.

I've been sitting in this meeting, and I apologize, because obviously I was not familiar with this issue before I heard about it being on the agenda today.

I really don't understand what the issue is. So I think that is why the staff is having a hard time answering the question as to whether a rule change is going to be necessary or not. And of course I'm going to have a lot of input as to whether we have to go through a rulemaking or not. Could somebody please explain to me why there is this gap now? Why is there this problem?

In order for me to understand what it is you are proposing to resolve the problem.

CHAIRMAN MALMUD: I think Dr. Eggli can handle that.

DR. EGGLI: The American Board of Radiology was one of the few certifying boards that gave its certification immediately on completion of training. The vast majority of certification boards in the American - that are under the American Board of Medical Specialties have a - either an advanced training or a clinical period of time after the completion of training before they issue a final board certificate.

The people when they complete their training go out and actually work, and this is true of all the specialties, they go out and work as sub-specialists in this area. If the use of materials is

unique in that it requires some form of authorized status to be able to handle those materials.

The diplomates in the time gap between completion of training and all testing have - what?

MS. GILLEY: Completion of testing.

DR. EGGLI: A completion of training and completion of testing relevant to the authorized user status, because they won't be tested on that again as they complete this additional year; will not be able to work as radiation workers in that gap, which will basically create an employment problem and possibly an access problem for patients as they complete that final critical phase of training that gets them their final board certification.

MS. CHIDAKL: May I ask a question? When you are talking about this clinical aspect, is that what is the same thing as in our regulation that says work experience?

DR. EGGLI: No, they will have completed that work experience in the core portion of their training. This is purely clinical experience.

MS. CHIDAKL: It is not required by NRC?

DR. EGGLI: That is not required by NRC. So the American Board of Radiology diagnostic radiology is modifying its program to come in line

with what the rest of the boards do. The only option then for these diplomates in the gap is to be certified by the alternate pathway.

The way I personally see the alternate pathway is, it is for folks who are training and meet all the training and education requirements, but are not training in a program where the training process has been recognized by NRC.

Now what we are doing, if these people would have to go down the alternate pathway, that would completely abrogate board certification as a pathway to user status for the 1,500 annual diplomates of the American Board of Radiology. So part of this is to maintain board certification as a relevant process to achieve user status and to allow these people in the gap between completion of all training relevant to authorized user status to become an authorized user prior to getting that final tag that says board certified.

MS. CHIDAKL: In other words if I understand you correctly the final bit as you - or whatever you want to call it, the final segment, is something above and beyond the NRC's requirements.

DR. EGGLI: Above and beyond.

MS. CHIDAKL: Thank you for that, I

appreciate that.

CHAIRMAN MALMUD: Thank you.

That completes the discussion of that item, and we will move on to the next item on the agenda, which is Mr. Lieto.

MR. LIETO: Thank you, Mr. Chairman.

This is the annual report of the ACMUI subcommittee on medical radioactive material events. This will now be an annual report in the future, not a partial report in the fall.

And the subcommittee membership listed there, everybody had a piece of the pie and contributed, so you are looking at the sum of all those contributions.

The report is based on the NMED database for fiscal year 2008. It is based on the events that had been reported during that time. Again in this report I will talk about that a little further and its importance.

The medical events were reported by category of use in Part 35 as well as a section that includes other reportable material events related to the medical use.

This is the second annual if you will report, so obviously it's still undergoing some

iterations of improvement, and three features in this report that we have attempted to include to better describe the impact of these reports is to indicate the number of patients involved in each event. We are trending over the last couple of reports, the number of patients involved as well as the number of events for each category of use of medical events, as well as the other reportable events, to give us some type of trending information, and have made an attempt to estimate on the frequency of occurrence of these medical events. And I will describe the information that was used for that.

The first category of use, or two categories of use, for Parts 35/200, there were three events involving diagnostic prescriptions of radionuclides in which patients got I-131. There were four events involving therapeutic radiopharmaceuticals requiring a written directive, involving four patients for I-131, and one event involving eight patients with Samarium-153.

The table here indicates three of the events for I-131; each are singular events in terms of patients being affected. The type of error that was described in the NMED report, as well as the actions that affected the - as a result of the event being

discovered. All three types of errors reported here are human errors, and the actions were - ranged from additional training to a policy procedure modification, as both technicians and all those involved with a written directive.

The next table here related to these events, again, all human errors related to following either written directive, the written directive or written instructions - excuse me, policies and procedures. In one case follow up action involved disciplinary action. Modification of procedures and retraining. The one event related to the Samarium was discovered after a patient assay of the therapeutic dose, it was determined that the wrong setting was used for the dose calibrator; it was a syringe setting instead of a vial setting - or excuse me, a vial setting instead of a syringe setting. And then they looked back at previous Samarium administrations there were the same type of error that had been included.

The one event down at the bottom of the table there involved sodium iodide 131, two patients were in the department; both scheduled to receive iodine therapies. And the dosages were switched as to - regarding the therapies that they were supposed to receive.

To compare a number of patients to last year's report and the radionuclide involved, not much of a change in the number of I-131 patients. There were no Y-90 patients involved, but we did see a big jump in Samarium. But I think again this was a singular event that occurred. So you can see that the - comparing the number of patients involved from `07 to `08 it almost doubles due to one singular event.

In providing an estimate of frequency of occurrence of the medical event, the committee used three sources of data in - to use as a denominator for the treatments involved. The principal source was the IMD medical information data. This source of information was the same that was used in NCRP 106 that we talked about earlier. Another source of information was data provided by the American College of Radiology of CMS procedure data for the year 2006.

As probably members of this advisory committee can probably better describe, one of the limitations of CMS data is that the data are Medicare-Medicaid patients, and that it does not include private payers, and those types of sources of information. But it does provide us with a lower bound of number of individuals that received the treatment. So as a result any estimates of frequency

would maybe provide us with an upper bound on the frequency of occurrence.

For the 35-1000 uses, we contacted the vendors themselves, principally Dr. Thomadsen and myself, and got 2008 data in terms of number of treatment dosages that were provided by the vendor. And this reflects the Y-90 microspheres and the I-125 gliasite administrations for 2008.

So if you look at frequency of occurrence, there were 15 patients involved. Our estimated number of treatments were 26,000, dividing a frequency of occurrence of roughly 6 X 10^-4th.

And this compares favorably with the number estimated in last year's report.

For 35-400 manual brachytherapy events, there were nine events, and you need to note in your handout, there is a change in this data regarding 35-400. After the presentation was sent out for inclusion in your packet it was discovered that one of the I-125 seed events was determined on follow up investigation to not be a medical event. And that was an event that involved three VA patients. So this - the slides are intended to reflect that update, and you may want to make changes in your packet accordingly.

There were nine events involving 111 patients. The radionuclide distribution on these events were seven events involving I-125 seeds. The one involving palladium 103 seeds and one involving cesium-137 low dose brachytherapy.

Looking at the distribution events, I want to point out here, this should in this second to last row here, that should say two hospitals in the VA systemic error category.

But as you can see the type of errors that were identified, there are three events involving misidentification of the prostate on trans-rectal ultrasound; faulty weld after implantation resulting in seed leakage; a Mike applicator jam resulting in leaked seed - a leaking seed during implant; a wrong dose being entered into the treatment planning system and resulting calculating error; a wrong magnification entered inn to the treatment planning for - I believe that was a gamma knife - or excuse me, I'm trying to remember which one it was - but any how it was a wrong magnification factor in the treatment planning system which resulted in two patients being referred as a medical event.

And again the two VA situations currently being reported, one involving 92 patients, and the

other involving 10 patients for a total of 102 patients in that VA system events.

So a total of nine events for a total of 111 - involving 111 patients.

A common issue, observations regarding these events, a common error found was with the prostate implants an improper identification of the gland boundaries; Mick applicator errors which were user failure errors, not the device itself. And then the bulk of these involving the VA situation which has been more than adequately described in previous presentations.

In attempting to provide an estimate on the frequency of occurrence, the number of treatments were based on the IMD data for 2006. So 111 patients over 50,000 treatments for the year resulting in an estimate on the frequency of occurrence of about 2 X 10^-3rd.

Recommendations submitted by the subcommittee were, calculations and data entry need to be checked by a second person; that a use of a nomogram as a secondary check for these types of treatments; better user training and practice with Mick applicators are needed. And I believe this is a repeat recommendation from last year was adequate

training on trans-rectal ultrasound and fluoroscopy use for confirmation of the boundaries.

Going to medical events for remote after loaders in teletherapy, devices in comparing 2007 through 2008, the - there were 17 events in 2000, ten in this year. There were 14 events last year in HDR, eight this year, and you see the distribution, based on descriptions in the NMED that did provide descriptions, we did break these out as to how many involved MammoSite versus vaginal cylinder applications for the HDR treatment.

There were no events involving a low dose remote after-loaders. There was one event involving Gamma knife, and one event involving a cobalt-60 teletherapy.

Regarding the HDR there were four events with a nucletron device. Three of these events involved wrong catheter link being entered into the treatment planning, and one event involving wrong step size entered into the treatment planning.

For the variant HDR there was - there were two events, one involving wrong length, and the other in which the MammoSite balloon deflated during treatment and resulted in an event causing wrong - or not wrong, but unintended dose distribution.

There was one event involving a variant HDR gamma med involving MammoSite application - or a therapy, and this was wrong dose entered into the plan.

There was one event involving Gamma knife in which the image descriptions were reversed, so the wrong side of the brain was treated. And in the cobalt-60 teletherapy unit event, the therapist misread the written directive, and a wrong dose was - the patient was treated with the wrong dose.

If we look at the HDR errors, there were two things that stood out: wrong length being entered into the treatment planning system; and wrong dose.

Compared with the number of - comparing the number of procedures by HDR, Gamma med and teletherapy, in terms of number, coming up with frequency of occurrence, for HDR there were eight failures - and again this was based on the IMV as well as the ACR data. HDR, there were eight failures over 62,000 procedures for a 1 X 10^-4 frequency of occurrence. Gamma knife, much less, 8^-5th frequency of occurrence. And for teletherapy which is the least - shall we say the least number of procedures that are performed - was one event over the roughly 2,000 procedures, and a frequency of occurrence of 5 X 10^-

4.

And all these events involving the HDR errors were attributed to human error, as opposed to any type of mechanical.

Regarding radioactive materials - this should actually be broken out with the 35-1000 separated out, but Part 35 events that are not medical - that are other events under 35-1000 there were four events, medical errors. There were two events involving pregnant patients who were administered therapeutic amounts of radioactive materials, actually 131, sodium iodide 131. And then the other reportable errors, the categories were broken into lost sources, leaking sources that were not implanted in patients, contaminated licensing packaging, and basically a catch all group called miscellaneous.

Regarding medical events in 35-1000 uses, these all were Y-90 microspheres. The two involved TheraSpheres. The other two were not described in the NMED documentation as to what form they were.

There was one patient involved with each event. And estimating the frequency of occurrence, there were four patients, and based on the vendor data provided for the number of dosages supplied, which was roughly around 3,500 - 3,600 treatments, resulting in

an error of 1 X 10^-3rd.

There were two pregnant patients. What is notable about this is that both patients had timely serum HCG pregnancy tests prior to administration. Both tests were negative. I don't see any errors here provided - shall we say on the part of the medical licensees. They did everything that I think can be expected; yet two of these events occurred.

And the doses, the embryo doses, were estimated, and these were both in the range of between 30 and 40 rads.

Regarding other reportable medical occurrences, regarding lost sources either sealed or unsealed, there were 13 events. The events are described here, ranging from I-131 capsules, iridium-192 seeds. There were six events involving I-125 seeds being lost, either after implant or during autoclaving process, source being inadvertently disposed into scrap recyclers.

One event involved a shipment of 114 palladium seeds that were in storage prior to implant - I don't know if they were prior to implant or after receipt - it was determined to not do the implant. But these became lost in a storage area undergoing renovation prior to return to the vendor.

There were two events that were reported after our last - I guess our preliminary report in the fall. A patient after implant was with - for I-25C prostate treatment, was cremated; there was quite a lengthy description in the NMED report on follow up and decontamination of the crematorium. But there were no excessive exposures to members of the public that resulted from this event.

One was loss and recovery of a plutonium cardiac pacemaker. I guess there are still some of those out there that have not been returned yet. And obviously that speaks to their reliability, but I don't go there.

But anyhow evidently upon death of a patient the funeral director removed the pacemaker; didn't realize the type of pacemaker he had, and just kind of threw it into the box. The other pacemakers are removed, and then when the licensee found out that the patient had passed away conducted an investigation to try to find the pacemaker. And actually there was sort of a back and forth, no it's not here. Then the funeral director realized that he actually did have it, and it did get recovered and returned to Los Alamos for proper disposal.

Regarding leaking sources there were seven

events; all involved iodine-125. These were reported in the fall. Also three of these events were found from white testing, surveying, visual inspection of storage containers and prepackaged cartridges which were found to be contaminated.

Two events were found on seeds which were unused after implant, and another was done after autoclaving and cartridge loading.

Vendor analysis found that one seed was likely damaged during use in the applicator. One had surface contamination but no defects in terms of the weld or encapsulation. And one event was determined to be excessive force with the seeds being stacked in the shipping container, and the excessive force on the package resulted in the seeds becoming compromised and leakage occurring.

Regarding leaking sources again here are description specifics of events that occurred. One was a jammed applicator, and a technician improperly unloading the seed cartridge with bare hands found both the cartridge and the hands contaminated. There were two events discovered by the vendor during seed assembly. In one case seeds were shipped out before the event was discovered, and then another example was the crimping work tool was found to be contaminated

before any seeds were sent out.

And the last event did involve a patient post-implant for seeds coming back for follow up treatment regarding their condition. The patient was being addressed and treated with a cauterization tool, and the cauterization tool nicked one of the seeds resulting in leakage of the seed and I-125 uptake by both the patient's thyroid and contamination of the equipment.

Regarding packaging this was a little - there were four events. Three events involved technetium contamination exceeding reportable limits. And again emphasizing the importance of doing obviously leak tests - excuse me, wipe surveys on packages that are coming in. I think a lot of nuke techs think this is sort of one of those things that you need to just go through for formality purposes. I think this exemplifies the need for this obviously. Packages involved in the events that resulted in this are described in the slide.

One package involved the I-125 seed shipment for implant. It came open but the package itself was not compromised; so the sources were all contained in the package but they were not in their lead shipping container.

There were four events involving machine malfunctions. One was a Gamma knife. The shielding doors failed to close after treatment resulting in staff having to manually close the door, a negligible dose was reported. I don't know what negligible means, but I'm assuming that we are talking something that is probably less than background levels, or background limits.

There was no deviation from the written directive, so the net result in any increased dosage to the patient from the treatment outside the expected directive.

There were two events involving HDR machines in source failures. The sources failed to retract. Both of these occurred during field engineering servicing events, and in one case the source became disconnected, and the top of the source capsule was clipped off in the vault, and the second event involved the during a source exchange the old source failed to enter the container. The cause of both the dummy and active sources were extended at the same pathway and became stuck. In both cases the vendors sent out teams to recover the sources, and take care of the devices and put them back into service.

Another event again did not result in any exposure to personnel. It was a Gadalinium-153 attenuation sources that are part of a Gamma camera system, do attenuation correction. These were timed to do attenuation corrections when sort of in a pre-program mode when staff was not present. And basically late in the evening - or excuse me, early mornings. And the shielding failed to retract. The cause was that during cleaning the cleaning personnel entangled the cables in such a condition that the - after the shields opened the signal to retract failed to occur.

But the reconstructions determined that no inadvertent exposures occurred because staff was not present.

There were - there was a singular event involving overexposure to the extremities. These are radio-pharmacy techs manufacturing sodium iodine 131 capsules in a radiopharmacy. Extremity doses ranged from 50 to 100 rem for the extremities, and the lack of written procedures and proper handling tools were cited.

So I tried to trend some of these events. If we look at the events over the last three years that have been reported by the subcommittee, for 200

events, 300 events, the number of events has not changed much although you could say that the number of patients involved almost doubled.

For 400 events, again, principally due to the VA event, the number of events has not really changed, but the number of patients affected increased by over a factor of 10.

For over 600 events, again, number of events actually have decreased, and the number of patients involved is almost half.

Regarding 35-1000 uses really can't say there is any trend there at all; goes up in `07 and has dropped down dramatically in `08.

This to compare this report in the - from the subcommittee, when you look at the NMED annual report which was published in March, this looks at the medical events determined by the NMED annual report. Now as you can see here, the medical events are fairly constant, or maybe slightly trending downwards. The abnormal occurrence reports are events which are determined by NRC staff and reported annually to Congress appear to be increasing, but it's a variance that really - we're looking at such a small number of events it's really hard to say whether this is - has any trend associated with it. And not knowing the

denominator we can't really say that there is an increasing trend for this, because most of these tend to be therapeutic events, therapeutic administrations, and there is increasing use over this five-year time period of therapeutic applications.

Now one of the things that I think needs to be noted is that the numbers on the medical advance in this - from the NMED annual report doesn't jibe with what this subcommittee has been reporting. We've been within plus or minus three events overall, and so I was trying to figure out what the discrepancy in this was. And the major factor is that the NMED annual report is based on the date of occurrence. So if an event let's say occurred in fiscal year 2007 but was reported in fiscal year 2008, it would go into our report, but those numbers would go into the previous year's report, and that report would then be adjusted.

The big contributor to this issue appears to be that some Agreement States do not report their events in a timely manner. Because if there was timely reporting the reports from this subcommittee should match the NMED report and that I think is one of the biggest causes for the discrepancy.

The subcommittee's opinion - or I should say the subcommittee chair's opinion is that it's

process is the better of the two, because otherwise you are constantly going back and having to adjust for or provide amendment reports, because of events that were not reported in the year that they occurred have to be adjusted for those events.

And so at this time I want to express my appreciation for Duane Wright who is in the back here, and Tom Smith from Idaho National Lab, who maintained the NMED database for their assistance in answering my many emails and phone calls in this - on this report. And anytime I had an NMED question on an event or a query, results or whatever, they got back to me very very promptly, and were quite patient in some of my questions to them. So I want to express a great deal of appreciation to Duane and Tom.

Regarding trending the other medical events, you see what appears to be an increase in the number of lost sources. The subcommittee consensus at this time is not to make any recommendations regarding this. We felt that we needed to maybe see if this changes over time a little bit, or the trend continues.

Leaking sources were up and down over this three-year period. Fetal embryo dose is the same. Landfill alarms which we reported in the past, I

didn't talk about it previously, but just from the fact that we did report it in past reports, I did include that, and it's fairly low.

And then miscellaneous events. Again, you can't really make assessment or comments about trends. It's been way down, and it goes back up.

Regarding recommendations, there was an event that involved a lot of discussion by the subcommittee involving a 90 eye-applicator event involving three patients which was initially reported as a medical event, and because it was originally reported as having a wrong calibration resulting in a 50 percent overdose. This was later retracted, because it was determined that at the time the prescribed dose was administered, and it wasn't until a recalibration of the eye applicator was done that it was determined that the calibration was off based on the current NIST calibration procedure.

But it did I think bring up a point that the subcommittee wanted to emphasize, which is that strontium eye applicators must have a calibration by the current NIST traceable standard.

So basically it's a reaffirmation of the NRC information notice that went out in May of 2002. I think the reason this came to event is that the

Agreement States had three years to implement that recalibration requirement, and I think that is the reason why this came to light.

But the - and again I want to thank both Duane and Dan and Beth for their assistance on that issue.

Finally our recommendations: events reporting needs to be improved. The subcommittee said very often it's devoid of causes. The remedial action information needed to analyze events for areas of improvement. I think establishing a consistent requirement. And I think also timely reporting is very important.

Recognizing events that were reported - or excuse me, events are underreported, this was in the OIG audit of the NRC Agreement State program, I think emphasize the importance of gaining value from these reported events, both medical events and other material events.

And again, NMED improvements, I think being able to do some queries by more than a single word so that we are not missing these events would be a very beneficial improvement. And also just being able to do queries by license type. This is not something currently available but maybe something that

NMED may look at in improving our queries and reporting and being able to identify events that relate to medical use.

So I think there is a lot of information that are not medical events that are valuable to licensees.

And with that, Mr. Chairman, that concludes the subcommittee's report, and the subcommittee as a whole would be glad to entertain any questions, comments.

CHAIRMAN MALMUD: Thank you, Mr. Lieto, for an extraordinarily thorough job. And we appreciate all the effort.

Are there any questions or comments for Mr. Lieto? Dr. Vetter.

VICE CHAIRMAN VETTER: Was there any attempt, or do you think it's feasible to find - on your third from the last slide you have leaking sources, lost source and so forth. Is it feasible, or do you have denominators, have you tried to find denominators for those?

MR. LIETO: For the other medical events it was really difficult to come up with denominators. For leaking sources, do you look at the number of individual seeds shipped? Or do you look at the

number of treatments for seeds? And for some of these events in - I'm sorry, for leaking seal sources -

VICE CHAIRMAN VETTER: There must be half a million sealed sources out there.

MR. LIETO: I would not be surprised. I mean if we look just at the I-125 I suppose we might be able to go to vendors and determine how many seeds were shipped in the U.S. for treatment use and use that; that might be a possibility. Because all these events - at least in this case I believe all the leaking sources involved I-125 sealed seeds. But if it involved other sources, it might become problematic. But that's something I think maybe the subcommittee might consider for that.

For a lot of the other ones, we really just could not come up with anything that would be logical to use as a denominator, so we just stayed away from that.

CHAIRMAN MALMUD: Thank you. Any other comments?

DR. THOMADSEN: Just as a rough number -

CHAIRMAN MALMUD: Dr. Thomadsen.

DR. THOMADSEN: Just as a rough number, apparently rough, on the slide, a number of manual brachytherapy procedures, there were 50,000. Roughly

you have around 100 seeds per procedure; that would give you about 5 million seeds out there.

CHAIRMAN MALMUD: Thank you.

If there are no other comments, I want to thank you for your report - oh, Mr. Lieto.

MR. LIETO: Just one other thing: it doesn't require any action by the committee at this time. But at the end of the packet in your booklet is a brief set of slides on a topic described as 6-Sigma. This is being presented for the committee's edification. It's not anything we need to address at this time, but it's a concept that might be considered for future reports as a means of describing these events, the medical events especially.

Dr. Thomadsen is probably the subcommittee expert on this, and is probably the most versed. But we would welcome your feedback if this type of analysis would provide added value for these reports in the future, or is just the frequency of occurrence, percentage of occurrence, adequate?

But it was a new shall we say method of analysis that the subcommittee had kicked around, but we thought it might be a little overwhelming to present in this report, and also time considerations.

CHAIRMAN MALMUD: Thank you. Is this the

system that the airline industry uses?

DR. THOMADSEN: Right, developed mostly by Motorola and the automobiles. It is used in the airlines and many other industries at the moment.

CHAIRMAN MALMUD: Thank you. It's a goal. Our problem remains one of knowing what the denominators are, doesn't it?

MR. LIETO: Yes.

CHAIRMAN MALMUD: Doctor?

DR. VAN DECKER: I was wondering if I could ask a question out of curiosity. Going back to yesterday's discussion on the international INES scale, what percentage of these several hundred odd little pieces here and there do you think would have been reported under this, especially under lost sealed sources and a few other things under level one, and whether you think any of this stuff would have reached more than level one in the reporting scheme.

MR. LIETO: The loss sources, no, because I think these are all category four sources. Regarding the medical events, I think the majority of them might - based on the discussions from yesterday, might be rooted in that. I mean like the 600, there was one event with gammonite that we got -

PARTICIPANT: Pull that mike closer.

MR. LIETO: Oh, I'm sorry. Because the one event under 600 for gammonite would probably definitely have been on that scale, and I think the 400s, or the manual brachytherapy. I guess another one, that are not medical events that might be of interest, or a question as to whether they would be reported, would be the fetal dose events to pregnant patients.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: I have a question just out of curiosity regarding the fetal embryo dose cases. Both followed a negative pregnancy test. One of them said that the patient failed to follow directions. Do you know what that meant?

MR. LIETO: Well, the patient had been instructed after administration of the therapy, and I guess threw caution to the wind after the therapy and - well, let your imagination do the rest.

(Laughter.)

CHAIRMAN MALMUD: Dr. Eggli.

DR. EGGLI: On the Part 200 events, on the first one where failure to write an adequate written directive was taken, the action was training for scheduling staff? And how is failure to write a written directive a scheduling problem? Just out of

curiosity. This sounds like a physician error, not a schedule error.

MS. GILLEY: You have as much information as we do, which is one of the - excuse me, Debbie Gilley. You have as much information as we have. As many of these are very cryptic explanations of what happened. So that's - made them out of the NMED report.

DR. EGGLI: It sounds like some poor scheduler is taking the rap for a physician error.

MR. LIETO: I think that was an event where the patient was intended to get an I-123 diagnostic uptake study, and instead got an I-131 dosage.

DR. EGGLI: And he got - the person who writes the written directive doesn't bother to verify that before running the written directive?

MR. LIETO: Well, it wouldn't have required a written directive, because the intent was to give a 123 diagnostic study. So there wouldn't have been a written directive.

DR. EGGLI: Well, if they actually administer a dose greater than what is it 30 microcuries of I-131, to administer that does would have required a written directive, regardless of what

the patient was scheduled for.

CHAIRMAN MALMUD: Thank you. May we move on?

Thank you very much, Mr. Lieto.

We will move on to the next item on the agenda. And Cindy Flannery is on for infiltration, infiltrations of therapeutic radiopharmaceuticals as medical events.

MS. FLANNERY: Well, this presentation is really just a continuation of a discussion we had at the December 18th, 2008 teleconference. And I will just briefly summarize that discussion and where we left off.

I have provided a description of an event involving infiltration of F-18 FDG, and it was reported to the NRC as a possible medical event because the dose to the tissue potentially exceeded the medical event criteria of 50 rem to the surrounding tissue.

I explain how the event was later retracted, because it is and has been NRC's position that infiltrations do not need to be reported to the NRC as medical events. And that is really based on supplementary information to a previous equivalent regulation which is 35.33. And that states, quote:

Extravazation is the infiltration of injected fluid into tissues surrounding a vein or artery. Extravazation frequently occurs in otherwise normal intravenous or intra-arterial injections. It is virtually impossible to avoid. Therefore the commission does not consider extravazation to be a mis-administration, unquote.

So this supplementary information doesn't provide a distinction between diagnostic and therapeutic administrations. This language is also almost 30 years old. I think IV administrations of therapeutic radiopharmaceuticals are more common now than they were back then, and also now NRC has regulatory authority over NARM, which with its higher energies if infiltrated, it will result in a higher dose to the surrounding tissues than, say, something like technetium 99m.

So I think with all these things being taken into consideration, NRC staff felt that it was prudent to seek ACMUI input on whether we should reevaluate our current position on infiltrations.

CHAIRMAN MALMUD: Thank you for bringing that before us. Does anyone have any comments on the issue of therapeutic infiltrations? Dr. Eggli?

DR. EGGLI: As a person that does some of

these things, I have mixed feelings about how it ought to be handled. We certainly - the vascular access we obtain for a therapeutic administration gets a whole different level of scrutiny than the vascular access we obtain for a diagnostic administration.

I will not push a radioactive treatment dose forward if I cannot draw blood back from the line. Now, that doesn't give you 100 percent assurance depending on how you catheterize the vein. A stainless steel needle can give you a blood return, but you have to tip the needle out. But however we almost never used butterflies anymore for treatment, and we use plastic catheters which are far less likely to produce a blood return with a partial extravazation.

So our efforts at making sure we really have a good line before we push a therapeutic agent into a vein is a whole different level of assurance when we administer a diagnostic pharmaceutical for the very reason that you mention here, that the potential tissue consequences are very different.

CHAIRMAN MALMUD: Anyone else wish to comment? Debbie?

MS. GILLEY: Cindy, your example was for fluorine 18. You were able to give tissue dose enough

to meet the requirements of a medical of 50 Rem?

MS. FLANNERY: Yes, there was an evaluation done by a licensee, and we also did the evaluation internally, and that potential was there, that the 50 Rad limit could be exceeded.

MS. GILLEY: However you are really requesting for therapeutic application, because fluorine-18 is a diagnostic -

MS. FLANNERY: Right. And as far as the December 18th, discussion, ACMUI did give a recommendation for NRC to keep its current position and to not require reporting of infiltrations of diagnostic administrations as medical events even if that 50 rad was exceeded.

We think the question that is really on the table right now for ACMUI is applicability to therapeutic administrations. So if ACMUI had a recommendation on whether that should be considered for infiltrations of therapeutics.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: We have had in injection of therapeutic, liquid radioisotope, for many many years, even when I started my residency, even in the `70s we were injecting things. So injection of therapeutic is not new. My feeling is that that we need to restate

our previous position in the December 18th 2008 meeting that accepted that it would not be considered a medical event. We always take the best precaution we can, as Dr. Eggli had stated. But the 50 centigrade really it is very difficult to apply, because it depends on the volume that you are considering. If you take a very small segment of the stint. That portion will get 50 centigrade even if you exhibit a very small amount of radioactivity. The 50 centigrade, in almost every circumstance, it will be exceeded depending on what volume you are considering at 50 centigrade.

CHAIRMAN MALMUD: Dr. Vetter.

VICE CHAIRMAN VETTER: Yes, that gets to something I was thinking too: how would you define infiltration in this sense, and how would a technologist recognize that infiltration had occurred?

CHAIRMAN MALMUD: That's part of the question we are being asked. Dr. Eggli?

DR. EGGLI: I think there is a partial position that might be reasonable, which is, if a therapeutic extravazation results in clinically obvious tissue damage, then maybe it becomes a medical event, that first of all if there was no extravazation there wouldn't have been local tissue damage. And if

there wasn't tissue damage it's probably not of real interest. So whether the possibilities would be to consider the criteria of tissue damage resulting.

This is one of the things that we actually worry about very often in diagnostic radiology but we extravagate nonradioactive iodinated contrast materials there is actually probably a greater risk of tissue damage in that arena than anything we are going to do therapeutically, certainly by volume of cases.

But if you wanted to track something I certainly would track anything that fell short of actually producing tissue injury.

CHAIRMAN MALMUD: I have a question. Has the - has anyone reported to the NRC an incident of tissue damage from a therapeutic injection of a radiopharmaceutical?

MS. FLANNERY: Not that I am aware of. However there was a very recent report that was made of an infiltration of iodine-125 monoclone antibodies. The patient support was not located properly, and so that is an example of I think an infusion that still an infiltration had occurred.

In this case there was an estimated skin dose of 360 to 710 rads, but there were no adverse effects seen at the injection site.

CHAIRMAN MALMUD: No visual evidence of tissue damage was reported. Thank you.

Someone? Steve?

MR. MATTMULLER: I guess I would like to add on to Dr. Eggli's remark. I guess the first question that comes to mind, how would you know? Because after most therapeutic infusions, we don't scan. So unless there is obvious tissue damage afterwards we would never know.

CHAIRMAN MALMUD: It may become an issue in the future. I'm old enough to remember the earliest days of chemotherapy when the infiltration of a chemotherapeutic agent intravenously, nonradioactive, would result in tissue damage. And at that time the hospital that I was training in hired a nurse whose sole responsibility was the injection - preparation and injection of the chemotherapeutic agents so that they wouldn't be in the hands of everyone else who was doing IVs. But I'm not aware of anything that has occurred as yet with a radiopharmaceutical.

Dr. Howe?

DR. HOWE: I don't have an example of that, but just to answer an earlier question, and that would be, if we were to go in this direction, what

kind of criteria would we use? We don't use the word, diagnostic, and therapeutic, very often. And so I would think we would make the distinction between written directive and non-written directive.

That would eliminate the 30 microcuries of I-131, because that is oral. And we are talking about something that is being injected.

So you would be in essentially for all practical purposes your therapeutic administrations. And then if as Dr. Eggli said you wanted to go to obvious tissue damage then that limits the number further to effects. And to answer your question about the future, as we get into more beta pharmaceuticals we have a higher potential.

CHAIRMAN MALMUD: Yes. Dr. Welsh.

DR. WELSH: So I would say I like Dr. Eggli's comment because if we need to do anything at all. Because if we want to say that we are going to go with the dose, more than 50 centigrade and 50 rem, first of all how do you verify the dose? And secondly, as Dr. Nag pointed out, there are area and volume concerns here, so that a small microscopic area might get 50 Rem. Other square centimeters might get less than that.

So it becomes a very tricky analysis.

Therefore if we are going to do anything at all I would favor what Dr. Eggli said, that the important point is if there is any tissue damage, that's the important criteria.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: If you go by tissue damage, the tissue damage can be called both by the extravazation of the radioactive material or by the saline or whatever material that you are giving before or afterwards. And it becomes difficult to say that this was - number one it becomes difficult to say what caused the damage; and number two, the damage sometimes is caused way later, so you have to come back and find it late in the day.

CHAIRMAN MALMUD: Dr. Eggli.

DR. EGGLI: I'm not aware of any case of saline extravazation causing tissue damage. As a matter of fact, when you can't get an IV administration of saline to a vastly dehydrated patient interstitially is an accepted practice. So again I'm not aware of the vehicle for a radioactive treatment having the capability of being responsible for tissue damage.

CHAIRMAN MALMUD: I think you are correct with regard to the saline. You perhaps, Dr. Nag,

meant the pharmaceutical itself rather than the radioactive component of it causing the irritation and the tissue damage.

Dr. Howe pointed out an interesting element, and that is that the way we might describe this is with a written directive rather than therapeutic dose. The question is, should this be just reported as a non-event but at least reported for recordkeeping. Or is this something that really is already handled with regard to the individual institution or lab or office that injected the pharmaceutical, radiopharmaceutical, having to deal with sequellae of a local reaction? Which is what can happen on a regular basis in other situations. These things occur without radioactivity in the hospital, and the patients are certainly quite eloquent in pointing out the pain or the irritation that has occurred, and the hospital does have to deal with these issues directly. I'm not sure I have an answer.

Ralph.

MR. LIETO: If we have then reported, then what are you going to do with the data? I mean are you going to - I mean in terms of like a remedial action or a root cause, I mean I'm really at a loss as to you are reporting this data, but what are you going

to do with it if you have them report this? And I think you are looking at such an extremely unusual occurrence. If this was happening more often, I would have thought we would hear about this as occurring with licensees. Which I have a question, the report that you have with the monoclonal antibodies, was this something that was in the literature? Was this something just reported to a region? Or -

MS. FLANNERY: It happened in an Agreement State, like it was just reported two weeks ago.

MR. LIETO: Okay, so this was like an event report?

CHAIRMAN MALMUD: It may be that we should - oh, go ahead.

MR. LIETO: Because you know a question regarding the dose, which I think either Dr. Vetter or someone talked about, is the methodology that they are using to calculate these doses I think needs to be reviewed, because looking at the - with the fluorine-18 I mean it's kind of like, okay, you pick the size, and then this is the dose that you will get. And then they range from above reporting to below reporting.

So I think if we are going to do some type of dose assessment on this, I think there needs to be

standardization on the dosimetry and how we are going to calculate this.

CHAIRMAN MALMUD: And certainly part of the issue will be separating the reaction to the radioactivity versus the reaction to the pharmaceutical. And we don't have any database or expertise for handling that. Also, the issue hasn't occurred yet, so we are talking about a theoretical issue at the moment.

Dr. Suleiman and then Dr. Nag I think.

DR. SULEIMAN: Something like this should be reported to FDA under their adverse event or severe adverse event reporting system. If it's a pharmaceutical that causes some severe problems, it would get - it should get reported. It could be that there is misinformation on the labeling in terms of how it's used. It could be the medical device through which it is being administered.

So there are also - the nonradioactive risk components of the whole process. So there are mechanisms to get this reported. So if we see a trend with a specific drug, or if we see a trend with a specific medical device we will take action.

CHAIRMAN MALMUD: Then we will hope that Dr. Suleiman's agency will inform us at the

appropriate time if necessary.

Dr. Nag.

DR. NAG: I would highly support Dr. Suleiman's suggestion that this is already being reported as an adverse event. However the first thing before us is, should NRC consider it as a medical event. Now if we consider this as a medical event, if we go through all the procedures and identify whatever-3 or 4 or 5-- the patient will have to be informed; the physician have to be informed, blah blah blah, and the - you have to go into all the reporting mechanisms. And therefore I am thoroughly against this being reported as a medical event.

CHAIRMAN MALMUD: Would you make a motion that this not be reported as a medical event at the current time?

DR. NAG: Yes.

CHAIRMAN MALMUD: Second to your motion? Dr. Welsh seconds the motion.

Is there any further discussion of this motion? Dr. Eggli?

DR. EGGLI: Just one residual comment. If I were to use residual damage, I would put permanent in front of it. And I'll tell you what, the patient already knows. So there are no reporting

issues.

But that doesn't mean I disagree with the motion that Subir is making.

CHAIRMAN MALMUD: You wish to amend the motion to have the word, permanent -

DR. EGGLI: Well, no, right now Subir's motion is that therapeutic infiltrations not be considered medical events. But regardless if there is permanent tissue damage, the patient knows; the referring doctor knows; and everybody knows.

CHAIRMAN MALMUD: And it would go through the FDA probably.

So the motion is not amended. It has been seconded. Any further discussion of the motion? Yes.

DR. FISHER: Just a quick question. It may not be a medical event. Is it still a misadministration in your view?

DR. NAG: The word, medical event, has replaced mis-administration. So mis-administration and medical event are now synonymous. We don't use the word, mis-administration, anymore.

DR. FISHER: That's why I asked the question, because does the intended radiopharmaceutical provide any benefit to the patient? Was there enough material that - I mean

maybe you had skin damage at the point of injection. Did the patient still receive the intended benefit of the infusion? Or was it a mis-administration that resulted in the patient not receiving the desired treatment?

DR. NAG: There is a technical definition of medical event, and it is very specific. For example in a permanent implant you administer the required number of millicuries. It went to the proper place, but then migrated to other areas. That is not called a medical event. It is not what we intended, but that is not a medical event.

I think this is something very similar.

CHAIRMAN MALMUD: Excuse me, Dr. Nag, what Dr. Fisher is saying, if I may interpret it, is that if you intended - if the intention was to administer 10 millicuries, but 8 millicuries infiltrated at the injection site, and the patient only was able to get two millicuries intravenously to the target organ, since he only got 20 percent of the administered dose was that - isn't that a medical event? That's what Dr. Fisher meant by his question if I interpreted his question correctly. Then Dr. Eggli, you had a comment.

DR. EGGLI: I think in response to

Darrell on this, the answer is by the definition of medical event, yes, it's a medical event. However this particular medical event is specifically exempted from being defined as a medical event. If that sounds circular, but this occurrence would meet the medical event criteria, but it is specifically exempted from consideration as a medical event.

CHAIRMAN MALMUD: What exempts if from consideration?

DR. EGGLI: Infiltration. It is specifically exempted from being defined - by definition the medical event, the infiltration is exempted from being classified as a medical event.

MS. FLANNERY: That is correct. Based on the statement and the supplementary information.

CHAIRMAN MALMUD: Thank you.

Mr. Lieto?

MR. LIETO: I'm going to be maybe on thin ice by disagreeing with Dr. Eggli, but I would not consider it a medical event. Because not based on the exemption; it's because the written directive was to administer 10 millicuries. They administered 10 millicuries. The written directive isn't a 10 millicuries - that so many millicuries goes to a certain organ, so forth and so on. So if they

administer 10 millicuries -

DR. EGGLI: I have to disagree -

CHAIRMAN MALMUD: You are both agreeing though that it is not a medical event.

DR. EGGLI: But I have to disagree with Ralph because part of the written directive specifies route of administration.

CHAIRMAN MALMUD: And Flannery has explained the reg, and the reg speaks for itself; so we will live with the reg as it is. And it still is in line with the motion on the floor.

Have we voted on the motion?

DR. NAG: Not yet.

CHAIRMAN MALMUD: No. May we vote on the motion? Want to call the motion?

All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(Show of hands.)

CHAIRMAN MALMUD: Any abstentions?

(Show of hands.)

CHAIRMAN MALMUD: One abstention - oh excuse me, two abstentions. So the motion passes. Thank you.

MS. FLANNERY: All right, thank you very

much.

CHAIRMAN MALMUD: Thank you.

We will now move ahead, and the next item is the summary of the enforcement process and enforcement actions against medical licensees.

MS. COCKERHAM: Dr. Malmud, can I suggest that we take a break, and then we will resume with the outgoing member presentations?

CHAIRMAN MALMUD: Yes, we will. We will follow your suggestion. Thank you.

(Whereupon, the above-entitled matter went off the record at 2:36 p.m. and resumed at 2:49 p.m.)

CHAIRMAN MALMUD: Ashley.

MS. COCKERHAM: We can go straight into outgoing member presentations, if Dr. Nag wants to start, and then Mr. Lieto, followed by Dr. Vetter.

CHAIRMAN MALMUD: All right, thank you. We now invite our outgoing members to give a presentation, if they wish, beginning with Dr. Nag.

DR. NAG: I am not going to make any formal presentations. I know everybody is waiting to -- would like to finish this off very quickly. But I would really like to thank and appreciate all the NRC officials, all the current as well as the past ACMUI

members whom I have had the honor and privilege of working with.

I don't know how much I have contributed to the ACMUI or NRC, but I can tell you that I have learned a lot from my experience in the last nine years. I have learned how the process works, how the government works. I have learned how to say my contribution and also learned when to shut up and not talk.

I have seen over the last nine years that there has been quite a bit of change in the NRC over these years. Specifically, what I have seen is that the NRC has become more willing to listen to the ACMUI, and that that has been increased or heightened by having recommendations that have been made into formal motions and that have been written into formal motions, into action items and not only into action items but there has been a close follow-up in the subsequent meeting to make sure that the action items have been worked upon.

That, I think, has been a major change in the NRC from the time that I first started.

Another point I might want to make comment is that in the Federal Register there was a notification for a radiation oncologist physician to

fill up my position, and specifically it stated that person must have gamma knife experience.

I heartily agree that the person who is going to fill my position should have both gamma knife and brachytherapy experience. It is highly imperative that this new person have brachytherapy experience as well.

So the ideal situation would be someone with both brachytherapy and gamma knife. However, if you do not find someone with both brachytherapy and gamma knife experience, I would highly recommend that the person have at least a broad brachytherapy experience, the reason being as follows.

Brachytherapy is not a narrow subject. It is a very broad subject, including HTR, including low dose removable brachytherapy, low dose rate permanent brachytherapy and many of the new emerging modalities, and this cannot always be fulfilled by one person. So you would need a second person to help along with that.

Secondly, a gamma knife usually -- not always, but usually is done by someone with basically external beam experience and someone who is specialized in brain tumors.

So it is very difficult to find someone

with that kind of specialized experience to have also a brachytherapy -- a broad brachytherapy experience.

Looking at the number of medical events and the number of concerns that have been brought before the ACMUI over the last nine years, a vast majority of that has been problems or incidents with the brachytherapy component, very small number with the gamma knife component and, if it does come up, I submit you can very easily get a consultant to advise you on that specific problem or that specific issue.

So I think this would sum up my observation over the years, and again I wish to conclude by thanking all the members of the ACMUI and the members of NRC, obviously, who are here for the very great learning experience that I have had in my tenure in the ACMUI.

CHAIRMAN MALMUD: Thank you, Dr. Nag. I can assure you, having been a member of the Committee for the last number of years, that you have contributed considerably to the Committee, both in the subcommittee work that you have done and, very importantly as well, in looking over the fine details of some of the motions that have been made and making recommendations for refining them in order to avoid unintended consequences.

So the entire Committee and, certainly, the NRC is equally appreciative of your efforts. You have not been here without contributing. I can assure you of that.

The next individual is Mr. Lieto.

MR. LIETO: I guess it is me. As I thought about attempting to put my experiences on the ACMUI into some thoughtful and unbiased perspective, I figured that such an attempt probably requires a wisdom I don't possess and is better possessed by my learned ACMUI colleagues, both past and present.

As I was preparing this presentation, I was reflecting on my past years in the ACMUI and some of the accomplishments which far exceed any disappointments, as well as some of the compromises that have occurred. But I figured, since Ashley insisted that this be brief, these things probably are better addressed by a reflection of the minutes and summaries that already exist.

Being a fan of old movies, I remember when I first started on the ACMUI the first year at least was somewhat -- I was really, I have to say, naive, and I think a lot of members might have the same impression, and I was totally in a reactive state to what was going on.

There was no advance preparation for coming into this, and I think the current process has been so far improved for incoming members from when I first started that you are kind of almost like a deer in the headlights for your first year or so. But I would not -- I would be remiss in not expressing my appreciation to those that assisted me, both past NRC staff and past colleagues, on the NRC workings at the time.

I would also like to express my appreciation to my outgoing colleagues who also assisted me, but especially Tom Essig from NRC staff, but also past members like Nicky Hobson, especially Sally Schwartz and Jeff Williamson who was a very, very quiet influence on all of us.

I guess I would also be foolish to expect that anyone who comes into this role possesses all the information and expertise to adequately support what they need to do.

I think one of the things that I have learned in representing the nuclear medicine/physics area of expertise in my role is that I have always been a firm believer in the words that Woodrow Wilson quoted -- in this Woodrow Wilson quote, which is "I not only use all the brains I have, but all that I can

borrow."

I think we need to gain that expertise from other parties, but we need to be careful not to develop a partisan perspective in this role, and I think we need to maintain a process that what is in the best interest of the patients and what is also in the best interest of the practice of radiation medicine.

I guess I was asked to provide some words of wisdom. Again, you guys are going to look out, because they really don't exist. But I thought there might be some areas that are opportunities for improvement, which are in areas that, I think -- there is a term that management likes to use, but maybe this might better be expressed as challenges for the present or future.

One of the things, I think, that we all recognize is that medical technology is developing far faster than the regulations can stay abreast. Licensees and, I think, especially the NRC, want to avoid major rulemaking, which takes years to do.

Now whether these opportunities or suggestions that I am going to briefly describe occur in rulemaking or guidance based, I think that will be determined by what are the best by applying sound

scientific principles and performance based approach to problems and using a team approach.

I think the first thing that I wanted to mention was the training and experience or board certification. This Part 35 revision has been in some phase of development or revision for almost 15 years, from what I can tell, and it still has problems.

This has, I think, been maybe a major disappointment during my stay on the ACMUI. I think it went from a straightforward, workable process and has just been an ongoing quagmire that has expended a tremendous amount of not just only NRC staff resources but also the affected parties involved, and we still have the board certification process somewhat marginalized.

So I think it is an area that we still need to address and, hopefully, can resolve and improve. Maybe what we need to do is look at a whole different paradigm as to the training and experience and what that needs to be established in the regulations.

I also wanted to say a comment about NRC support for the ACMUI. The agenda, the ongoing items, the subcommittee activities far exceed anything that existed when I started, and I want to say that I know

that NRC employment, looking at some of your staffs, has increased over about 20 percent in the last three years, but there really has not been anything to address the increased needs for the medical use activities supporting this committee.

I think when I was looking at the NRC website, I think there is about 20-plus FTEs that support the Advisory Committee for the Reactor Waste Group, but there is about .6 assigned to the ACMUI, and I think this inequity needs to be addressed.

I would like to personally recognize those two ladies over there, Ashley and Cindy, for all they have done. There have been some improvements since my arrival here, but what these guys have achieved has been super, and I think that there are some times, especially with all the phone calls I make to Ashley and e-mails and so forth, there's got to be three people there that are answering all that stuff. I think she does a tremendous amount in supporting and what she accomplishes for the ACMUI, and for the assistance I want to say thank you.

The one thing, I think -- Another thing that we need to be aware of in the future is the patient release rule. This is still under attack. The Part 35 patient release -- or excuse me, the

Section 3575 that provides this -- I don't know if many of you know this or realize this, but recently Mr. Peter Crane filed an appeal in Federal Appeals Court, a move to rescind this patient release rule again.

Maybe he thinks what is going on is well intentioned, but I most definitely think it is wrong-headed, and I think that I would like to emphasize that it is critical for the ACMUI to continue its support of NRC staff in the denial of this petition, because I think it is not in the best interest of patients, and I think the ACMUI, if needed, should also encourage the medical community to provide assistance to the NRC, if that is what is needed.

The other area that -- items or, I guess, opportunities or challenges to be, I think, addressed in the future is the National Source Tracking System.

Currently, this only affects Category 3 and Category 4 sources. While I can understand the need for it in that range, I think its implementation to date has been very expensive. It is still fraught with some problems in its implementation, and still, I think, it needs added input from affected licensees. But my concern is mostly of this is extended into the category 3 and 4 sources which will affect a large

number of medical shipments.

I think it has the potential of being extremely burdensome in requiring resources that far exceed any benefits for tracking into that range.

The other item I wanted to bring up was ICRP-2005 recommendations. But I think we have already seen, as discussed earlier in our presentation, and I think we know where those areas of concern may be problematic. I will kind of leave that there.

The last item was something that, I think, is going to be of increasing concern and needs to be brought up before this committee, is that as health care is rapidly moving into an electronic records situation where, in fact, some medical centers already have announced that they are paperless, there is a current need to establish, I think, acceptable guidance for electronic signatures for required NRC documents.

I would suggest that this be done initially in guidance base, because it is going to involve, I think, rapidly evolving technologies, but having an electronic signature standard is going to be critical to NRC inspection and enforcement teams as they go out in doing their activities with licensees,

and I think there needs to be a standard to determine what is acceptable as they perform these licensee inspections.

Leaving the ACMUI is bittersweet. This is a group photo of ACMUI when I started, and I want to say that I have enjoyed participating with every single person on this committee, both past and present.

I think the interactions have been professional and collegial and productive. Even though NRC staff may also find this hard to believe, I have enjoyed working with all of these people, and -- I was trying to say this with a straight face, but I really do. There's been differences and disagreements, but I think it was all done in the best interests of the patients and trying to minimize any burdensome nature of regulations.

I firmly believe in the value and necessity of the Committee, and to both the NRC and licensees, and have the best wishes to all present and future members in achieving success over past disappointments as well as future challenges to be addressed.

So with that, I want to say thank you, and arrivederci.

CHAIRMAN MALMUD: Thank you, Ralph. I will tell you that the feelings are mutual. We have all enjoyed working with you, and your accomplishments are also numerous in terms of the subcommittees that you have served on.

You know, it is easy to be Chairman. It is very difficult to be a chief of a subcommittee, because the subcommittees really do the work. So I am very appreciative of the work that each of you has done in your subcommittee work.

We have enjoyed working with you very much, and you have been a major contributor as well.

Now we will move on to Dick Vetter. Dr. Vetter.

VICE CHAIRMAN VETTER: Thank you very much. I would like to add my thanks to my colleagues' for the opportunity to work with this committee.

One of the things that I have been most impressed with is the intelligence seated around this table, from all walks of medicine and from the leadership at NRC. It has really been a pleasure to work with all of you and, like Ralph said, I think most times it has been collegial, but there have been some challenges for us now and then.

If we can measure success as Booker T.

Washington suggested, it is to be measured not so much by the position that one has reached in life but by the obstacles which he has overcome while trying to succeed, we have been a very successful committee in the past nine years while I have been working on the Committee.

We have faced many, many issues which are obstacles, and we have worked through them. The NRC has had its perspective. We have had ours, but we have, in fact, overcome them.

The obstacles that surprised me the most when I became a member of this Committee were those of personalities and how some people expressed themselves, some behavior and parochialism. In fact, that really surprised me, how some people acted out, and I think really were rather vocal on how they addressed members of the NRC. I was a little bit embarrassed at times by that.

On the other hand, we did work through it. I certainly don't question their motives, their values, etcetera, but there times when I was a little bit surprised how certain members of this Committee conducted themselves when interacting with the NRC staff.

Perhaps some of that is driven by --

conflicting may be too strong a word, but values that aren't exactly always the same or are perhaps directionally a little bit different, and that is the NRC's primary value here is to protect people and the environment. And as we sit around the table listening to all of us present our positions, our value, obviously, is the needs of the patient come first. In fact, if it weren't for patients, we wouldn't even be here.

So the needs of the patient come first. It is a strong value for all of us. And I know -- I don't mean to imply it is not a value for the NRC, but they come from a little bit different perspective. So of course, the challenge then is for us to work together in that regard.

In recent years, it is my experience that this Committee has become extremely collegial. I think we are working very well together. We are working very well with the NRC staff. I think part of that may have something to do with leadership on the part of the NRC and this committee.

Some of it has to do with the make-up of the membership of the Committee, but I personally think that we are now all looking at the same elephant, to where when I first joined the Committee,

I am not sure that was the case, but we certainly are now. So I would credit that to the excellent leadership and to the intelligence and collegiality associated with the membership.

So as we struggled together, as you struggle together going forward with these different values, I would say that the way we work through that is to focus on quality. Here is a quote from John Ruskin who says, "Quality is never an accident; it is always the result of intelligent effort."

So I would appeal to all of you to recognize that, in terms of trying to resolve any conflicts in values, recognize that the needs of the patient come first within a regulatory system that protects people and the environment.

I think we can work together. I don't -- Well, and we have been. I think it is just a matter of recognizing that.

New challenges, just briefly: From the medical side, for most of us sitting around the table, this is obvious. For some members of the public and for some NRC staff, it may not be so obvious.

Medicine is under a great deal of pressure to both increase quality and reduce costs. The cost reduction pressures are tremendous and, in fact, there

has to be a transition in medicine over the next several years as more and more people retire, become qualified for Medicare, and as reimbursements consequently go down for hospitals.

It is going to be a very, very significant issue. So we have to be -- While we want to improve quality, and we want to use our regulations appropriately to help drive quality, we have to be very careful about any unfunded mandates that increase the cost of medicine. It is simply going to be very difficult in this country to accommodate that.

I am not trying to make excuses, not trying to say we shouldn't do what is necessary to increase quality. We need to recognize that the cost is a very significant issue.

Then for all of us, of course, we want to do what we can to improve the health care safety culture, in spite of these cost reductions, the need to reduce costs.

So we are leaving. You will be -- You are left to continue on. We have had a few things to say, and we appreciate the opportunity to contribute; and as T.S. Eliot says, "For last year's words belong to last year's language, next year's words await another voice, and to make an end is to make a beginning."

So we are making an end, but it is also a beginning, as you know. A transition always has two sides to it. There will be some times when I will be your patient, and I hope, when I am your patient, that the needs of the patient come first. But I am also going to step out of this role as time goes on a little bit more, and I hope that the NRC does what it can to protect the environment, because I am going to be out there sampling that environment and spending as much time as I can.

Thank you once again for the tremendous opportunity to work with you.

CHAIRMAN MALMUD: Thank you, Dr. Vetter, and a personal thanks from me as well for being so supportive in serving as the Vice Chairman of this Committee, in addition to all the other roles that you have played.

Your voice has been one that I have always relied upon for your judgment and your knowledge. You also come from an institution which is able to provide health care in a most efficient way in terms of its costs per discharge compared to other hospitals of less fame but greater expense.

So having you with us has been an advantage, even in such issues as the cost of

fingerprinting, which you were able to provide to us in a way that no one else was in terms of the actual expenditure on behalf of an institution to meet a requirement for -- not so much for the NRC, but for the Homeland Security Department.

We will miss all three of you. It has been a wonderful experience for all of us to work with you. I agree -- Oh, there is a photo of you holding a fish. I didn't see that before.

VICE CHAIRMAN VETTER: That is why I want that environment protected.

CHAIRMAN MALMUD: You are going to make some of us jealous.

I think we agree that the number one reason that we are here is on behalf of the patient, and the NRC is driven by rules and regulations which govern it, sometimes without a full awareness of the impact on patient care. That is the reason that this Committee exists.

It is at the request of the NRC so that we may assist the NRC in being responsive to patient care issues as well as its major mission, and I appreciate that role on behalf of all of us to society via the NRC.

My father was an immigrant, and he said to

me that no one born in the United States could understand how wonderful it is here compared to elsewhere. Now he didn't come from Canada or another nation such as our own. He came from an oppressive environment in Europe.

As I have gotten older, I understand fully what he meant. I have served on more than one government committee, and it is astonishing how responsive our government is to the desires of its citizenry.

For that reason, it is a very inefficient government. Democracy is extraordinarily inefficient. It has to represent every opinion. It has to respond to every opinion, and we see that here.

We see all of us, everyone on this Committee, everyone in the NRC, having the same desire, which is to serve the public, and the bottom line for us is the patient, but we come at it with different viewpoints and sometimes different parochial interests, as you point out, and yet the overriding interest is always the welfare of the patient, the welfare of the individual.

We live in an extraordinary society. We are very fortunate to live at this time in this nation, and this is another example of it, and the NRC

is another example of a Federal agency that is reflective of the government that we enjoy.

So on behalf of the members of the Committee, and I know I speak for each one of us, we will miss you. We will miss the input from the three of you, and your legacy will not be buried with your departure. Your legacy goes on in all of the deliberations that have occurred, and will continue to occur as we continue to deal with some of the challenges before us.

So thank you very much.

Did you wish to say something?

MR. LEWIS: If I may.

CHAIRMAN MALMUD: By all means, Rob.

MR. LEWIS: Thank you very much, Mr. Chairman. The meeting started with Charlie Miller thanking you personally and also passing on Chairman Klein's thank you for a job well done and appreciation of your work, Mr. Leito and Dr. Vetter and Dr. Nag.

Anything I can add to that would kind of be silly at this point, but I can only add my personal thank you, and also I would like to associate myself with Dr. Malmud's comments that you show a lot of humility in your contributions, but they really are great through the work of the Committee.

Personally, it is very inspiring to me to work with people that put the welfare of others high on their list of things to do, and the ACMUI participation is just another form of that.

So in that regard, as I said, it is very inspiring to me and also to all my staff, and we have so many new people that it is very important that we have people that provide that inspiration for people on the NRC staff that are just entering their careers in this field. So thank you for that.

Also your contributions are directly relevant to the NRC's mission protecting health and safety. This I can't stress enough, because it is not an exaggeration. We cannot do our job without the advice we get from this Committee and the advice we got from the three of you over the years. So thank you for that.

You won't be replaced. I think it is -- There will be three new people, but I don't think that it is realistic for us to believe that the contributions that the three of you have made will be replaced by the next three. We hope it will, but we have to be realistic.

We ideally would have liked to bring on your replacements to this meeting, but we are a little

bit behind on that front. We are working on that. The one area that we immediately have to replace is the Vice Chair position. So I will say something about that in a moment.

Anyway, on behalf of the NRC staff, thank you very much, and we wish you the best, and congratulations.

(Applause.)

MR. LEWIS: Also, that was the only farewell speech in history that used the word lymphoscintigraphy. So we will remember that.

The Vice Chair position is a very important position, as you all know, and as this meeting closes, I would like to ask, and he has graciously accepted, Dr. Bruce Thomadsen to assume the duties of Vice Chair for the ACMUI. So thank you.

(Applause.)

DR. THOMADSEN: All I can say is I am going to not be able to fill Dr. Vetter's shoes or hip waders, as the case may be.

MR. LEWIS: Thank you very much. I let us continue with the agenda.

CHAIRMAN MALMUD: Ashley?

MS. COCKERHAM: I was just going to go to the next topic, if you are ready.

CHAIRMAN MALMUD: Please do, yes.

MS. COCKERHAM: We are just going to do the administrative closing. For members of the public that are ready to leave, if you will just grab a feedback form, fill it out, on your way out the door, I would appreciate it.

We are going to go over the seven, eight motions that were made during this meeting. Then we will choose the next meeting date.

Alright. We will start with Item Number 1: NRC staff should allow interventional radiologists to become authorized users for yttrium-90 microspheres with (1) 80 hours of training, which was summarized on Slide 4, and then I just read the title for Slide 4. So I will copy/paste that into the actual recommendation.

For number (2), training that includes the eight items on Slide 5. Again, I will copy/paste that into the recommendation -- and the operation of a quality management -- that is probably not worded correctly -- quality management for dose calibrators.

Obviously, we will have to work on the wording here, but I think we have the gist of what we want. Does anyone disagree or have questions about that? I know that one is written poorly right now.

Alright. For the last piece: Have completed three years of supervised clinical experience in diagnostic radiology and one year in interventional radiology.

Alright. We will move on to Item Number 2: NRC staff should revise 35.39-B(1)(ii)(g)(3) to read: "Parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its beta emission or low energy photon emission or AJE electron and/or -- and then I guess the regulation skips to 35390-B(1)(ii)(g)(4). That will be revised to read, "Parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its alpha particle emission."

Go to Item 3: NRC staff should revise 10 CFR 35.490 and .690 as proposed, with one exception. Delete the words "private practice." So the regulation should read: "Five hundred hours of work experience under the supervision of an authorized user who meets the requirements in 35.490 or .690 or equivalent Agreement State requirements at a medical institution or clinic."

VICE CHAIRMAN VETTER: Excuse me. Didn't we -- I thought we had changed "private practice" to

"solo practice" or something of that sort. Did we just eliminate it?

DR. NAG: We just replaced with "clinic."

MS. COCKERHAM: Okay. That was discussed, but I don't think it made it into the formal recommendation. Okay?

Item Number 4: To prevent recurrence of events like those at the V.A., ACMUI recommends: (1) Every brachytherapy quality assurance program should include peer review as published by the American Brachytherapy Society; and (2) authorized users should perform post-implant dosimetry.

That item was tabled. So I am guessing we will get back to that at a teleconference.

Item 5: ACMUI will create a subcommittee that includes three members, and get back to Dr. Don Cool.

This is in response to the ICRP report. So you guys will get a subcommittee together.

CHAIRMAN MALMUD: I recommended a subcommittee.

MS. COCKERHAM: You have?

CHAIRMAN MALMUD: Yes. Dr. Thomadsen has agreed to chair it, and the other two members are Debbie Gilley and Dr. Van Decker.

MS. COCKERHAM: Okay. I will add that to this chart. And is Dr. Cool aware of that?

CHAIRMAN MALMUD: No, because the committee was drawn together after Dr. Cool left.

MS. COCKERHAM: Okay. So make sure he gets the memo.

Item Number 6: This is in regard to NCRP Report 160. For Part A: ACMUI came to a consensus on NCRP Report 160, which is believed to be scientifically sound and well written.

(b) ACMUI believes NRC and Agreement States should co-act and maintain dose records and keep ACMUI aware of the issues, but should continue a policy of not intervening with medical practice.

(c) ACMUI supports the medical principle of, first, do no harm, and expressed continued concern about exposure to children.

(4) or, I guess this should be (d): ACMUI's current believe is that the benefit of medical procedures involving radiation outweighs the risk.

Did we get the idea of what we wanted here? Okay.

Item Number 7: ACMUI endorsed the subcommittee report for candidates who may experience a delay between the completion of their training and

experience and receipt of their board certificate.

For Item 8: NRC staff should not require licensees to report therapeutic infiltrations as medical events.

Any questions? Okay.

The next thing I have are calendars for potential dates for the next meeting. I have gone ahead and crossed out all of the dates that the ACRS room is not available. So we will be back in the other meeting room.

I have also tried to look at society meetings, professional organizations, things like that that would be going on.

So do we want to go back to the Monday-Tuesday meeting schedule? I know those on the west coast prefer to travel on Sundays. Would we want to go with the 26th and 27th of October? Okay? The 19th and 20th?

DR. WELSH: I can't speak for everybody. So I encourage people to voice their opinion, but Thursday-Friday seems to work out far better for me as a practicing clinician.

MS. COCKERHAM: Okay. Is anyone opposed to Thursday-Friday? This is your committee meeting. So everyone please speak up. You are the ones that

have to fly to D.C.

Okay. So it looks like we have two Thursday-Fridays on the schedule. How about October 29th and 30th? Is there any preference to keep it at the end of October or in the middle? The 15th and 16th or the 29th and 30th?

DR. EGGLI: I will be away on the 15th and 16th.

MS. COCKERHAM: Okay. So 29th and 30th, do we have any conflicts? Wide open?

DR. WELSH: Astro might begin on November 1st.

MS. COCKERHAM: November 1st through 5th.

DR. WELSH: But there are committee meetings.

DR. NAG: A committee meeting for Astro starts on 21st of October. So it means that for people who go to Astro, they will have to fly from here straight to Chicago.

MS. COCKERHAM: I guess that affects you, Dr. Welsh. Oh, yes, that does affect travel for NRC. The way it does work, though, is that you purchase your own flight anyway. So you would be fine. Would anyone else be attending the Astro meetings? Dr. Thomadsen?

MS. FLANNERY: Ashley, maybe the new oncologist coming on.

MS. COCKERHAM: So we have two days in November, and they are a Monday-Tuesday preceded by a Federal holiday. I don't know if you can see November from here, but it has X all over it.

Debbie was suggesting November, and I had November originally on here, and by the time I got done with my X's, I had two dates left, and they are Monday and Tuesday, which are the 9th and 10th, which is followed by the 11th, which is Veterans Day.

DR. THOMADSEN: This year?

MS. COCKERHAM: This year.

CHAIRMAN MALMUD: The point was made that this year the 9th and 10th are followed by the 11th.

MS. COCKERHAM: Yes. My point was the 11th is a Federal holiday. I don't know who that impacts, but just so you are aware, and we are going back to Monday-Tuesday, if we do that.

CHAIRMAN MALMUD: Is there any objection to the 29th and 30th?

DR. THOMADSEN: No objection.

DR. FISHER: If that is a problem for anyone, the 26th and 27th are also --

MS. GILLEY: I can't be here.

MR. LEWIS: We can look into if there any options for traveling from here to Chicago. We can't guaranty anything, but we can look at the question.

MS. COCKERHAM: I know in Dr. Welsh's case it is possible, because the airport that he flies out of is very small and is very expensive. So he is able to purchase his own flights, which he already does. So he could easily purchase the flight that goes from home to D.C. to Chicago, back home for well under the government rate. But I don't know for the new radiation oncologist who comes on and for Dr. Thomadsen if that would be the same case.

DR. THOMADSEN: Actually, what I would probably do would be to take the bus to Chicago and then fly Chicago-D.C. back to Chicago and then take the bus home from there.

MS. COCKERHAM: It's going to get complicated.

DR. NAG: It is only one and a half hours. How long does it take, one and a half hours, two hours?

DR. THOMADSEN: About four hours.

MS. COCKERHAM: I don't think we can guaranty anything on travel. I think that may get complicated. The 15th and 16th does not work.

DR. WELSH: What about the 19th and 20th?

MS. COCKERHAM: Those dates are open, and those are fine.

CHAIRMAN MALMUD: Nineteenth and 20th? Anyone have a conflict?

MS. COCKERHAM: It is a Monday-Tuesday.

CHAIRMAN MALMUD: October.

MS. COCKERHAM: No conflicts? Alright. I am going to go with the 19th and 20th as our first dates. If we have to have back-up dates, we always choose those as well. I guess would they be the 29th and 30th? We don't want to get into a Tuesday-Wednesday or a Wednesday-Thursday meeting, do we? I am seeing noes. Okay, and the 15th-16th, which is a Thursday-Friday doesn't work.

CHAIRMAN MALMUD: So first preference is the 19th and 20th. Second preference is the 29th and 30th.

MS. COCKERHAM: Yes. Alright. That's all I have.

Closed session.

CHAIRMAN MALMUD: We will now go into a closed session.

(Whereupon, the foregoing matter continued in Closed Session at 3:37 p.m.)