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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MEETING

OPEN SESSION

+ + + + +

Monday, October 27, 2008

The meeting came to order at 9:00 a.m. in T2B3 of White Flint 2, Leon Malmud, MD, Chairman, presiding.

PRESENT:

LEON S. MALMUD, MD, CHAIRMAN

RICHARD J. VETTER, PHD, VICE CHAIRMAN

DOUGLAS F. EGGLI, MD, MEMBER

DARRELL R. FISHER, PHD, MEMBER

DEBBIE GILLEY, MEMBER

RALPH P. LIETO, MEMBER

STEVEN MATTMULLER, MEMBER

SUBIR NAG, MD, MEMBER

ORHAN H. SULELMAN, PHD, MEMBER

BRUCE R. THOMADSEN, PHD, MEMBER

WILLIAM A. VAN DECKER, MD, MEMBER

JAMES S. WELSH, MD, MEMBER

PRESENT: (cont.)

MICKEY GUIBERTEAU, MD, DIAGNOSTIC RADIOLOGIST

CHRIS EINBERG, DESIGNATED FEDERAL OFFICER

CINDY FLANNERY, ALTERNATE DESIGNATED FEDERAL OFFICIAL

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P R O C E E D I N G S

9:02 a.m.

CHAIRMAN MALMUD: It's now 9:02 and if we may we will resume the session, opening the public session. I would invite -- Chris, are you going to -- just give us a minute to sit down.

In addition, I would again remind us that for the court stenographer, it is useful to introduce your statement by giving your name and therefore it will make this daunting task a little easier. Thank you.

We are also welcoming today as a guest, Mickey Guiberteau, welcome. Good to see you again. It's been a number of years.

DR. GUIBERTEAU: Thank you, yes.

CHAIRMAN MALMUD: And with that, I will ask Chris to begin the session.

MR. EINBERG: Thank you. As the Designated Federal Officer for this meeting, I am pleased to welcome you to Rockville for the public meeting of the ACMUI.

My name is Chris Einberg. I am the Chief of the Medical Safety and Events Assessment Branch. And I have been designated as the Federal Officer for this Advisory Committee in accordance with 10 CFR part

7.11.

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

This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the September 22nd, 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 byproduct material. The Committee products 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 various issues that we will discuss today, but I also recognize that there may be minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

Part of the preparation for this meeting, I have reviewed the agenda for members and employment interests and based upon the very general nature of the discussion that we are going to have today. I have not identified any items that would pose a conflict.

Therefore, I see no need for an individual member of the Committee to recuse themselves from the Committee's decisionmaking activities. However, if during the course of our business, you determine that you have a conflict, please state it for the record, and recuse yourself from the particular aspect of that discussion.

At this point, I would like to introduce the individuals seated at the table today. Dr. Leon Malmud is the Chairman. He's a healthcare administrator. Dr. Richard Vetter, Vice Chairman of this Committee, Radiation Safety Officer. Dr. Subir Nag, Radiation Oncologist. Mr. Ralph Lieto, Nuclear Medicine Physicist. Dr. Douglas Eggli, Nuclear Medicine Physician. Dr. Orhan Sulelman, FDA representative. Dr. William Van Decker, Nuclear Cardiologist. Dr. Jim Welsh, Radiation Oncologist. Dr. Darrell Fisher, Patient Advocate. Dr. Bruce Thomadsen, Medical Physicist Therapy. Dr. Steve

Mattmuller, Nuclear Pharmacist. Ms. Debbie Gilley, State Government Representative.

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

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

That concludes my opening statement.

CHAIRMAN MALMUD: Thank you, Chris. Rob?

MR. LEWIS: Well, good morning, everyone. I think Chris covered it very well. I'm Robert Lewis. I'm NRC's Director of the Division of Material Safety and State Agreements. Let me extend NRC's welcome as well to the Members of the Committee and also to Dr. Guiberteau. Thank you for coming and providing your expertise.

The work of the Committee is absolutely essential towards our mission regarding safety and security and effectiveness and efficiency of our

regulatory process. And your advice is invaluable in that regard. And I do want to note that since our last meeting we've had several significant accomplishments that are on the agenda for the next two days. Looking forward to on-going discussions on those issues. For example, we had recently a workshop on potential phaseout of cesium chloride as a radioactive material used in a lot of relationship applications as well as a lot of radiation. The Committee supported that workshop in a very superb way. And we thank the Committee for that and we look forward for the Committee's report on their view of the efficacy of cesium chloride versus alternative technologies.

We also had made several -- we made a lot of progress on permanent implant brachytherapy rulemaking. The rule is currently out for public comment. Public comments are due on that rulemaking, I think next week and we look forward to continuing to engage the Committee and the members of the public on that rulemaking. We will, as I understand, the Committee intends to comment on the rule. For the public comment process, we will take those comments and respond to them, share the responses with the Committee as we move forward.

Also, fingerprinting. We have issued, as of June of last year, of this year, fingerprinting requirements for all of our increased controls, licensees, and we have thanked the Committee for their input at the Commission meeting on that issue and we have made substantial progress. If there are ongoing issues with fingerprinting that you're experiencing, please let us know. We still have time to work through those before the effective date of December.

So thank you very much. We have -- as I said, on the agenda, we have all of those topics, as well as many more and the Committee is certainly very busy and I think I should be quiet and let's get to the agenda.

CHAIRMAN MALMUD: Thank you, Rob. We'll move on to the next item on the agenda which is item four, old business, and Ashley Tull will make the presentation.

Ashley?

MS. TULL: Good morning. If you'll turn to, I believe it's Tab 4, there should be a big list. I have all of the 2007 and 2008 recommendations. I'm going to start with the 2007 ones. I tried to highlight several of them for anything that's changed or has been updated or we've made progress or it's

been closed, things like that. So I'm not going to go through everything, but you have them all. If you have a question on one of them, you can ask me. But I'm going to go through the bolded ones which starts with number two. It should say 2007 at the top.

NRC staff should remove the attestation requirement. We found the right page yet?

CHAIRMAN MALMUD: It's the second page of Tab 4.

MS. TULL: It's the second page behind the tab. Sorry. Okay, NRC staff should remove the attestation requirement for Board-certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word "competency" but should instead read, "has met the training and experience requirements."

Ron Zelac is currently working on a SECY paper for this, and it's agenda item 14, so we will be discussing this later. But this is still an open item.

Number three, NRC staff should revise the regulations so that Board-certified individuals who are certified prior to the effective date of

recognition or were certified by previously recognized Board listed in subpart J of the previous editions of part 35 are grandfathered. And again, this is something Ron Zelac is working on and we are currently drafting a letter to the Boards and Ron will talk more about that. It's agenda item 10 today.

We're going to jump down item 10. NRC staff should allow more than one RSO on a license with a designation of one RSO as the individual in charge. NRC should create a regulatory issue summary to inform the regulated community of NRC's interpretation and the RIS should be sent to ACMUI and the agreement states for review and comment. The draft RIS was sent to you. Ralph has provided comments and on behalf of the Committee, so we will discuss that. It's agenda item nine.

As I'm kind of going through each one of these, these are just to let you know they're still open items. There was an overall recommendation to keep following up on these things, so this is just to let you know that these are still on the front page and still issues that we are dealing with.

The next one is item 30, the Electa Perfexion should be regulated under 10 CFR 35.1000 until 10 CFR 35.600 is modified to performance based

which would allow the Perfexion to be regulated under 10 CFR 35.600. This will be added to the user need memo and will be considered for rulemaking. So we all know rulemaking is a process and takes time, so we'll keep this one open and I'll keep letting you know where it is in the process.

If you could turn over to the back, items 38, 39, 40, 42, and 43 all have to do with the yytrium-90 microspheres guidance and I'll read through each one of them quickly. NRC staff should revise the microspheres guidance to allow the written directive to include either dose to target tissue in gray or rad or activity administered in millicuries or gigabecquerels.

39. NRC staff should revise the microsphere guidance to include a paragraph referencing medical event reporting for microsphere use.

40. NRC staff should revise the microsphere guidance to reinsert their proposed paragraph with modification. The paragraph should state procedures for administrations requiring a written directive should for yytrium-90 microsphere administration be performed in accordance with the written directive.

42. NRC should revise the microsphere guidance to add a paragraph which states training in the manufacturer's procedures, commensurate with the individual's duties to be performed must be provided to individuals preparing, measuring, performing dosimetry calculations or implanting microspheres.

43. NRC staff should revise the microsphere guidance to read the written directive should include after implantation, but before release of the patient from licensee control. The radionuclide, including the chemical in physical form of yytrium-90 microspheres, the manufacturer, the treatment site, and the total dose or administered activity, all of these changes were approved by the Committee and have been incorporated into the guidance as it is on the web right now. So that was a big task for all of us.

45. ACMUI should form a subcommittee to address issues with 35.600 as they relate to the Electa Perfexion. This subcommittee actually already gave us the reports and that is the recommendations from item 30 where we said Electa Perfexion should be regulated under 1000. So those two are tied together. And the subcommittee has done their work on that.

Dr. Welsh?

DR. WELSH: Ashley, number 43, it says partially accepted, whereas the other is relevant to the yytrium-90 microspheres say accepted. Is there a difference there?

MS. TULL: I believe -- I don't have a copy of the guidance in front of me. The intent is the same. It just doesn't read exactly like the Committee had recommended. I don't have a copy of the guidance right in front of me, but what does it actually say? Release of the patient -- I believe it's from the post-operative recovery room. We had that discussion before they are released. I believe that's the wording, from the post-recovery, post-operative --

DR. NAG: The license control, I think most post-operative recovery area rather than the licensee control.

MS. TULL: I'm trying to find the exact wording. It has to do with post-procedural.

DR. NAG: Right. When we are talking about permanent implant, we had decided when were making a permanent impact rules that the timing would be from the post-operative -- that the post-operative recovery area and -- but they're still under licensing control. Here, in licensing control, it would before

the needs of the patient from the post-recovery area.

CHAIRMAN MALMUD: Perhaps you could get us the wording a little bit later in the meeting?

MS. TULL: It is. Is there a microphone over here?

MR. BROWN: Do you want a wireless?

MS. TULL: How about this. I will print off a copy of the guidance and give it to you. It was something that was discussed and it's not a major change. It goes back to the 2008 recommendations that we're going to cover. And it's the wording from the 2008 recommendations that basically replace this.

I'll print off copies and give it to you.

CHAIRMAN MALMUD: Thank you.

MS. TULL: Okay, so jumping to the 2008 recommendations --

DR. EGGLI: Actually, it's in 11.

MS. TULL: Yes, it's the post-operative versus post-procedural. We revised that. Yes.

CHAIRMAN MALMUD: Back on the -- this is Malmud. We're now back on the other page of 2008 recommendations?

MS. TULL: Yes.

CHAIRMAN MALMUD: Which item are we looking at now, number 11?

MS. TULL: Number 11, NRC staff should make all changes as proposed except on page 2, the word post-operative should be replaced with post-procedural. That's the wording that replaces the 2007 wording. Does that answer your question?

CHAIRMAN MALMUD: Thank you.

MS. TULL: It was an ACMUI approved thing that made this partially accepted. You modified one of your previous recommendations. But I will print copies and give everyone that.

CHAIRMAN MALMUD: Thank you.

MS. TULL: Okay, so number for the 2008 recommendation. NRC staff should provide the basis for the decision to only allow one RSO per license. This was a closed item. We provided emails from the OGC during the last meeting.

We will be discussing it though as agenda item nine. So this is an on-going issue.

NRC staff should pursue rulemaking to allow more than one RSO on a medical use license with the indication of one RSO as the individual in charge. Again, this is going to be agenda item 9. It's an open item.

3. NRC staff should promptly notify ACMUI members in a separate memo when an ACMUI

recommendation is not accepted. I think that this is a practice that we've picked up and we'll continue to do.

4. ACMUI should form a subcommittee which includes Dr. Darrell Fisher, Mr. Ralph Lieto, Dr. Bruce Thomadsen, as the chair; and Dr. Richard Vetter. The subcommittee's charge is to evaluate the efficacy and cost of cesium chloride versus current and proposed x-ray technologies and cobalt. And this is a subcommittee report that was actually submitted on October 13th. So if you want to mark this as closed, it is actually a closed item now.

5. NRC staff should incorporate the subcommittee's recommendations for the Gamma Knife Electa Perfexion in future rulemaking. Again, we will add this to the user need memo. It is in the process.

6. Dr. Subir Nag suggested ACMUI form a subcommittee to discuss the permanent implant brachytherapy rulemaking. The subcommittee would include Dr. Nag, Dr. Bruce Thomadsen, and Dr. James Welsh. The subcommittee would consult with other knowledgeable individuals as necessary. This motion did not pass, but was later, if you look at item 14, there was a subcommittee formed that actually did this. So we'll get to that.

7. Dr. Leon Malmud requested the NRC staff email Dr. Nag separately once the permanent implant brachytherapy proposed rule is published. That was done and the email was sent on August 7th.

8. NRC staff should arrange a public full Committee teleconference meeting in July to discuss the permanent implant brachytherapy rulemaking. That did happen. The item is closed as of July 21st.

9. NRC staff should revise the abnormal occurrence criteria to read: a medical event that results in (1) death, or (2) a significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the treatment regimen as determined by an NRC or agreement states designated consultant physician.

This is in progress and actually we talked to the Office of Research. They are the ones who are responsible for revising this abnormal occurrence criteria and they have indicated that in 2009 they will be open to revisions. So our group, our medical group will send our proposed revisions to Research in 2009. Until then, we'll keep this item open.

10. NRC staff should incorporate the three hands-on, in vitro, simulated cases approach as

proposed during the meeting. Additionally, NRC staff should indicate when it is appropriate for a licensee to submit a license amendment to add the authorized user or yytrium-90 microspheres to the license.

Lastly, NRC staff should add a statement to the guidance to require the manufacture to proctor the first three cases performed by an authorized user. This was accepted and it is included in the current guidance.

11. NRC staff should make all of the changes as proposed, except on page two, the word post-operative should be replaced with post-procedural. This goes back to the issue that we were just discussing.

This has been incorporated and is in the current guidance.

12. NRC staff should send an EDO daily note indicating the ACMUI discussed the part 35 permanent implant brachytherapy rulemaking at the July 21st ACMUI teleconference. We did send that out on July 24th.

DR. THOMADSEN: Question?

MS. TULL: Yes.

DR. THOMADSEN: What's EDO?

MS. TULL: Executive Director of

Operations.

DR. THOMADSEN: Thank you.

MS. TULL: It's us notifying upper management of something that went on at the staff level. So they're aware that you discussed that.

13. NRC staff should proceed with -- this is SECY 08-0080. It's just a formal document that staff members sent to the Commission. It was suggested that NRC staff should proceed with this document and publish the proposed rule in the Federal Register as directed by the Commission. That is closed. The SECY paper did go up. The Commission approved it. The proposed rule is published and we have draft comments from the Committee and we will be discussing those comments further later during this meeting.

14. ACMUI should form a subcommittee for the permanent implant brachytherapy rulemaking. The subcommittee's charge is to meet within the next two weeks to prepare ACMUI's comments on the proposed rulemaking. The subcommittee includes Dr. Nag as the chair; Mr. Ralph Lieto; Dr. Bruce Thomadsen; Dr. Richard Vetter; and Dr. James Welsh. And this is still on-going and in progress since we will wait for a final report from the subcommittee, once we have a

discussion later today.

The proposed comment period is expected to end on November 7th. Now that was extended officially.

15. NRC staff should provide a status update on the technical basis for the Rittenour or the AAPM petition at the October 2008 meeting. That is on the agenda, item 10. So we will be discussing that.

16. NRC staff should distribute request letters for information on the individuals impacted by the Rittenour or the AAPM petition to the certifying boards as well as the professional societies.

I believe there's a draft letter in your binders behind Tab 10 and Dr. John Zelac will be covering this in more detail during his presentation.

17. NRC staff shall allow the manufacturers to continue to use their current standards for proctoring the first three patient cases for new authorized users for Sirtex. At least the first two cases will be proctored by a physician and from the MDS Nordion, all three cases will be proctored by an MDS Nordion employee.

This has required no change to the guidance, so the guidance stood as it was written.

Any questions on any of those

recommendations or any others?

CHAIRMAN MALMUD: Are there any questions for Ashley Tull?

Are none.

MS. TULL: Okay, we will keep sending you updated charts.

CHAIRMAN MALMUD: Thank you.

(Pause.)

CHAIRMAN MALMUD: Once again, we are ahead of the agenda. May we move on to the next item which is the Cesium Chloride Subcommittee report. Will that be acceptable?

Dr. Thomadsen?

DR. THOMADSEN: This is great. This as you've heard was the subcommittee that we were directed to form and look at issues regarding replacement of cesium chloride irradiators. And the Committee was set up because of the Report of the National Research Council which suggested that the cesium chloride irradiators be phased out and eliminated.

And we were directed by the Commission to address those issues. And the three issues --

MS. TULL: Really quickly -- the handout that's in your binder is actually a draft subcommittee

report. It's dated July 22nd, I believe. And I'm passing around the -- it's dated in September. This is the October 13th report, which is the final subcommittee that was approved by the full Committee via email.

So please pull out what's in your binder and replace it with the handouts that are coming out.

(Pause.)

DR. THOMADSEN: The three issues that we addressed was the need for cesium-37 chloride irradiators viable alternatives and the current security.

Addressing the need for irradiators, there are several uses that they perform. One is the radiation of blood products. The original report that came out assumed that approximately 10 percent of the blood in the U.S. was irradiated and that is the blood used in blood transfusions.

Discussions that a subgroup of the subcommittee had with hematologists and oncologists indicated that for these practices the value was somewhere between 15 and 40 percent depending on the particular practice. In patients involved with hematology and oncology with particularly depressed immune systems and that's why the irradiated -- that's

why the blood needs to be irradiated.

The lower number in the report probably comes from a higher fraction of trauma cases and that may be a factor of where the survey was done that was included in the original report.

So the -- for the trauma cases irradiation of the blood is irrelevant since it's not a matter of immune system response, but just getting blood back into people who are often in accidents.

The other uses that these irradiators have is for animal irradiation where a lot of the research is done, particularly for stem cell research and other systemic therapies where you need whole body radiation of the animal, often mice, before infusion, so that you can eliminate the animal's blood marrow before you would be infusing other bone marrow into the patient into the animals rather.

The use for animal irradiation is growing as the research on stem cell is growing. And of course, it may soon lead to other treatments for currently untreatable conditions, so the use of the irradiation in animals is very definitely a great benefit to the society.

If we just summarize the need for irradiators without the irradiators available,

hematology and oncology patients would suffer potential death from the lack of irradiated blood. Without the irradiators available, much of the stem cell and systemic drug research could not be able to proceed.

The Committee then looked at alternatives at cesium 137 chloride irradiators. And the alternatives are conventional x-ray units or linear accelerators. Both have been and are used for blood, animal, and material irradiation. The conventional irradiators, in the report, we go through a number of the models that are available.

For blood irradiation, only one of those units is FDA approved. Another one is up before the FDA at the moment, from my understanding. The National Research Council listed the price for these units as $180,000, with $10,000 a year for service contracts. We looked at the prices. The current prices seemed to be closer to $250,000 with around $33,000 per year for the service contract.

Replacement tubes are not counted under that service contract, and would be extra. As is calibration and quality management, which would be required to a much greater extent than with the cesium chloride units. So the expenses are considerable for

replacing a cesium chloride unit with a conventional x-ray unit.

Throughput is lower for the x-ray machines, with 48,000 blood product units that have to be irradiated. And x-ray tubes would last about, at the rate of about 50 units per day, would last about 3.7 years. So the replacement tubes would have to be replaced about every four years on an average. As we mentioned in the last slide, this adds to the cost of running the machine.

For animal irradiation, there are about 10 x-ray units available. Most of them are lower energy, around 160 kVp. Very few are above the 200 kVp, and that limits the use to, use in animal irradiation because of the lack of penetration. Most of the prices range between $146,000 and $250,000, again, plus the service contracts, all of which run around $10,000 per year.

They do have cheaper units, but they are of the low energy type with short distances, which means that penetration is very small and have small field sizes, again, limiting their use for the animal irradiation.

There is also the question of whether the x-ray units can actually replace the cesium chloride

as standards for animal irradiation. The relative biological effectiveness of the irradiation is different, possibly by a factor of two with the lower energy units. That's not a good, hard fixed number. The relative biological effectiveness is not well known, and in addition to that it depends on the species, it depends on the biological endpoint in addition to the energy of the radiation.

The dose rates can have an effect on the biological effectiveness as well, which can change how the animal would respond to a given dose, and also if the dose rates are lower, which they usually are in these x-ray machines compared to the cesium, it makes giving anesthesia for the animals more difficult, and you end up having to use drug anesthesia as opposed to gas.

The penetration, or the lack thereof, requires irradiating animals from several directions as opposed to the cesium irradiators, where you can just put the animals in and shoot them in one procedure.

Use of medical linear accelerators has been used for blood and for animals. We used to use that, must be 25 years ago, for the blood irradiation in the hospital. It was very inconvenient both for us

and for the blood bank before they got their cesium irradiator. It can be done. It presents a challenge, particularly in a busy facility as far as timing and who is going to be doing the irradiation. But it's also a problem when people need the blood after hours, and you have to train the blood bank people in either running the accelerator or you have to have a call schedule for the technicians running the accelerator to come in.

If you are not using the radiotherapy department's linear accelerator, but trying to get an accelerator for the blood bank proper, the price becomes quite an impediment at around $1.5 million as a start.

Turning our attention to the security of these devices, because it was the security that was raising the issue for the National Research Council. Since the time that the Council looked at these units, several things have changed.

The security of the users has been enhanced through the required background checks and fingerprinting. The security of the facility has been enhanced following the directives of the NRC, and I'll point out such as in our place sometimes at great expenses to the facility.

And finally, there is the security of the units themselves which there is a program with the DOE and DHS to harden the machines themselves, to make it much less likely that somebody who does get passed the facility's security could get into the source proper.

So following these three security enhancements, the units present little hazard for unauthorized source removal or disruption. The lack of such security was a major factor in the original report so the current situation doesn't really -- doesn't compare with what the original report was looking at.

Summarizing all of our results, the irradiation facilities are essential for the irradiation of blood and research. It's -- their loss would be a great detriment to our society, the health and well-being of the people of this country.

Forced replacement of 137 cesium chloride based units would force many facilities to stop irradiating because of the great expense to replace the units. Also, to keep them going once you replaced it.

A few of the facilities, as most of the facilities are nonprofit and few have resources for funding and new x-ray unit or maintaining the unit and

since the time that we wrote this report and the economy has tanked, there was just an article in today's USA Today about the money that goes into nonprofits which has essentially stopped going into nonprofits. So the likelihood that all of these places could replace their units is dwindling.

If not leading to the termination of irradiation, the replacements would place an incredible financial burden on these facilities which have little funding.

While the x-ray units have been used for blood, animal, and material irradiation, the difference in the RBE complicates just simple replacement and at the moment just the exchange wouldn't provide the same quality radiation that we are used to.

And finally, the enhanced security programs for the 13 cesium chloride units make replacement unnecessary.

Thank you.

Questions?

CHAIRMAN MALMUD: Thank you, Dr. Thomadsen. Are there questions for Dr. Thomadsen?

CHAIRMAN MALMUD: Dr. Eggli?

DR. EGGLI: Not too much as a question,

but a comment on using linear accelerators for radiating research animals. In the Commonwealth of Pennsylvania that violates Department of Health regulation. It requires a special exemption so that would be another additionally limiting factor using linear accelerators for animal research.

If a human is used on the machine by DOH regulation you can't do an animal without a special exemption from the state.

DR. THOMADSEN: Thank you.

CHAIRMAN MALMUD: Other comments.

DR. NAG: I would like to make a comment here that the radiation oncology immunity uses ceramic form of cesium chloride, not cesium chloride, cesium in ceramic for a low dose rate therapy and that should not be confused -- this is going to a public place and the public just sees cesium and cesium and they just confuse one with the other.

DR. THOMADSEN: I'm sorry?

DR. NAG: Would you like to amplify on that?

DR. THOMADSEN: No, you're absolutely correct.

DR. NAG: The other one is cesium 131 which is another new radioactive material that is

being used for therapy again the layperson may confuse that with the cesium 137 chloride.

CHAIRMAN MALMUD: Thank you, Dr. Nag, your point being that both the ceramic enclosed cesium and the cesium 131 are not issues of concern in this discussion?

DR. NAG: right.

CHAIRMAN MALMUD: Thank you. Other comments?

Rob.

MR. LEWIS: Thank you to the subcommittee for this work. I would echo what Dr. Nag said that currently the nonchloride forms of cesium are limited to a matter of tens of curies just from a material science property of production.

So the smaller sources of industrial uses and in medical uses tend to be ceramic or glass whereas the chloride form is only used in large sources such as blood irradiation or research irradiation or calibrators.

But I would ask the Committee to pull on that issue a little bit. Given the cost you described, if there was a ceramic form at a large curie quantity available, if some fundamental research was done and production was available, that's a big

if, whether that's possible, would replacement of the chloride form be attractive to hospitals?

You can speculate a little bit.

CHAIRMAN MALMUD: Dr. Vetter?

DR. VETTER: I'd like the chair to go first.

CHAIRMAN MALMUD: I'm sorry, I didn't see your hand. Dr. Thomadsen.

DR. THOMADSEN: I didn't put it up. I was --

CHAIRMAN MALMUD: Region One is on the line. Region One? I beg your pardon? We'll move on if we may with Dr. Thomadsen.

DR. THOMADSEN: The Committee, in the actual report, it's mentioned that we considered that issue and originally in one of the graphs we had a recommendation that manufacturers --

CHAIRMAN MALMUD: Could I ask the people on the telephone to mute your phones please?

MS. TULL: It is.

CHAIRMAN MALMUD: On VTC as well. Thank you. I see you just did.

DR. THOMADSEN: But as we discussed this issue, two items came up. One was that the manufacturer, which is not in this country, has

indicated that at the moment, at least, changing the form to something solid would present a hazard to those involved in the manufacturer, and they were not interested in trying to work on that.

More importantly, however, the Committee was not convinced that the solid form would actually provide a safer source, and that may not be a justifiable recommendation. The Committee is not convinced that it would make a less safe source. It just didn't feel that there was the research there to make such a recommendation.

CHAIRMAN MALMUD: Thank you, Dr. Thomadsen.

Dr. Vetter?

DR. VETTER: Just one further comment, which is more of a question. We did not have the information to tell us whether the activity concentration would be equivalent, and if the ceramic source, it actually occupies larger volume, it is possible that it simply could not be done in our current irradiators. You couldn't simply switch out the sources.

MR. LEWIS: It would be a lower specific activity.

DR. VETTER: Consequently, we may not, it

may not be practical to switch the sources out, which means you would have to trade units in again. We'd be back to the same question of trying, of affordability.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Yes, I'm not sure, but I do know there has been advances in the ceramic industry, so that if this were a high enough priority, the ceramic industry would be able to find some ways of getting enough of the cesium into its ceramic form. So the first thing then becomes, is it more important to release it on an electronic or electrical version that will make the cesium all together, or is it more important for us to find research or to do research to find ways of getting higher quantity of cesium in some safer form. I think that has to be explored.

CHAIRMAN MALMUD: Thank you, Dr. Nag. Dr. Sulelman?

DR. SULELMAN: I attended the cesium workshop along with Debbie Gilley, and let me share some of my observations.

Bottom line, cesium 137 seems to be more reliable, a little bit less expensive, than alternative technologies. The technical differences, notwithstanding, I think the transition to a non-cesium source would be feasible, but wouldn't be

necessarily cheap. It would cause a lot more problems. I think the report also emphasizes the fact that we think with the enhanced security and other aspects, why do you want to eliminate it? There's a comic that somebody made, and I repeat it myself, we did not ban airplanes after 9/11.

So I think this is, you know, maybe terminating a technology that is really the best technology out there. I was also surprised at how widespread it was in terms of calibration standards internationally, just not in the country. I knew it was used for calibration purposes, but I didn't realize that it was almost like the de facto standard for radiation metrology.

The other thing I think I would like to clarify, which I learned going through this whole process, that the big issue here is really the powder form, and the thing that's been obvious to me is that with all the technology and metallurgy, you know, why isn't there a solid form of it?

And what distressed me personally was because we don't manufacture this in this country, we get it from the Russians from their Maya facility and it is part of reprocessing. It's not their reactor operation, it is their reprocessing of spent fuel.

And so, talking with people at the meeting, I'm convinced, I said you ought to make them have a million dollar award, but I'm convinced that a solid form of the cesium source is feasible, notwithstanding some attenuation characteristics or whatever. I think it was a drastic difference, but we get back to the, the Russians seemed to be preoccupied with other, they're the only site in the world that's doing this, and so to start manufacturing from a technical, from a solid form on a large scale would be creating some occupational issues that they were concerned with.

Again, I don't think those are insolvable. I think those are all addressable, but you're dealing with one source and so I think the technical problems are resolvable. I think the economic issues are feasible, and I also second, because I raised it also. I question whether the solid form would be any less secure or more secure. You can't predict what a terrorist, I don't have a terrorist manual that tells me how terrorists behave.

Even though the powder form is more dispersable, there are hazards associated with the solid bolus of material as well. But I think everybody is sort of, the consensus I felt was that,

don't panic, you know. Come up with some technological solutions to maintain that source.

CHAIRMAN MALMUD: Thank you, Dr. Sulelman. Other comments?

Dr. Nag?

DR. NAG: When we had reviewed this last year what I remember the powder form easily put it into a dispersing material and it flows up into the air so although the radiation level is not high it is easily dispersed and is something you cannot clean up. The solid form, even if you do explode it, you can shut down, or gather it up, clean it up a lot faster and therefore that represents less of a problem.

MR. LEWIS: We are dancing on some nonpublic information. What you said is okay, but we wouldn't want to go any further about dispersing.

DR. NAG: That was a public -- it is a public comment.

MR. LEWIS: What you said was fine.

CHAIRMAN MALMUD: Dr. Fisher?

DR. FISHER: Darrell Fisher. Having the assignment of reviewing the impact of NRC guidance to licensees on source security especially with respect to blood irradiators, I was impressed with the degree to which licensees have gone to providing safe and

secure facilities.

For example, one institution with 4 cesium 137 blood irradiators that are used primarily in research had located these irradiators in places in facilities that were highly secure, only accessible through multiple locked entries with coded entry pads with several layers of video monitoring, with limited access to a select group of highly-trained users, with high level of coordination with local law enforcement on both protection of these facilities and local response to a breach of security.

It almost seemed as though these facilities were protecting these sources to a degree of overkill. Nonetheless, I found them to be highly safe and secure. In addition, the units themselves had been secured with additional steel locks. It seemed almost incomprehensible that even a knowledgeable person could gain entry to and access and remove a cesium-137 source from these irradiators. And that the impact of improved security as Dr. Thomadsen has mentioned has to a large degree eliminated the need for source replacement to find alternative sources.

The other interesting aspect of this review was the importance of cesium chloride in a

research setting, that merely substitution for an x-ray source would provide enormous scientific hardship on institutions that were using cesium chloride in stem cell research to develop new treatments for cancer.

From a patient rights perspective, it did not seem that the change out of sources would be beneficial to research and that the forced change in irradiator types would actually be detrimental to on-going research and could cause not only excessive cost to federally-funded medical research, but also significant delays in on-going research without a perceived benefit of any kind.

CHAIRMAN MALMUD: Thank you, Dr. Fisher.

Do you wish to respond, Rob?

MR. LEWIS: Sure. Again, we thank the Committee and the subcommittee for their efforts on cesium chloride.

The next step -- I do want to address one point that was made. The National Academies Panel was aware of the enhanced security of facilities of NRC and agreement state licensees. It did occur after they started their report, but they were in place by the time they had finished their report and they were aware of those -- I don't want to put words in their

mouths, certainly, but they made the recommendations in full awareness of those and they thought cesium chloride merited additional security beyond that of all of the nuclides because of its dispersibility and potential attractiveness or criminal acts.

The next step will be for the NRC staff to develop a Commission paper which will include an attached ACMUI report and it will also consider the results of the workshop, the National Academies Report, our own visits to each of the vendors for cesium chloride, and additional work we've done with Department of Homeland Security and the Department of Energy on this topic. That Commission paper is due in about a month. And some portion or version of it will be public so that we can provide the Commission all the options they need to make a policy decision on this matter and I think we also are going to be looking at the existing facilities, existing irradiators that have been in place and have paid for themselves at this point long ago, as well as any new licensees that are looking to be an irradiator and whether down the road in the long term we can do some kind of fundamental research that will make an attractive replacement for those new licensees at the very least, but may be for all licensees.

And although the paper will be forthcoming, we need to realize that despite the economic and the scientific arguments, and practice of medicine arguments that are being brought to bear on cesium chloride issue, there is an increasing expectation by Congress and by members of the public that something needs to be done. In fact, legislation was drafted and introduced into both the House and the Senate that would essentially phase out this material.

And what you have provided in this report and through your support at the workshop will be our best defense, if you will, against those types of political arguments and provide the Commission the ammunition they need to make a sound policy, public policy. So thank you very much.

CHAIRMAN MALMUD: Thank you. Any other comments? I want to thank you all --

DR. NAG: Not me.

MS. GILLEY: I just have a procedural question. Now that the ACMUI has given the report to NRC and it will be part of the recommendations that go to the Commission, will this ever be a public document or able to share?

MS. TULL: Yes.

MS. GILLEY: After the final report is

done --

MS. TULL: I just distributed it within NRC and kept it there for now. Your report is final, as ACMUI, but I really wanted to kind of hold the report back until the full report went to the Commission with all cesium chloride recommendations. At that point, I'll actually put it as a subcommittee report on the ACMUI website.

MS. GILLEY: Thank you.

MR. LEWIS: And if we are on procedural issues, another one might be did the full Committee want to consider the subcommittees, or do we need to --

MS. TULL: It was voted on email. So it is final.

DR. NAG: Could I have a question? I understand that another cesium chloride, round table meeting or something, that you all went to. What is the relation between the two? Is the ACMUI committee report and round table do they have any relation to each other, they are totally separate or what? Were you referring to some other --

CHAIRMAN MALMUD: Are you talking about the workshop?

DR. NAG: Workshop. What are the two --

could someone give me a differentiation between the two and --

MR. LEWIS: They are unrelated. They are independent data points that will go into the Commission paper.

DR. NAG: And what was the workshop? What was that?

MR. LEWIS: The workshop was a public workshop and it had several roundtable sessions on various topics. We brought in industry, other government agencies, other foreign agencies, to talk about many of the things that are talked about in this paper, but to just give us a separate industry and government and member of the public point of view on moving forward.

DR. NAG: This one is only a medical use.

MS. TULL: Dr. Malmud, this is Ashley, and to answer Dr. Nag's question, ACMUI was formally invited. We asked Dr. Thomadsen as the subcommittee chair to attend. He was unable to attend, but Debbie Gilley and Dr. Sulelman came on behalf on ACMUI and basically just translated what was in the report that was approved by the full Committee.

MR. LEWIS: Your report was not provided at the workshop.

MS. TULL: No, but the viewpoints.

CHAIRMAN MALMUD: Thank you, Ashley.

Does that address your concern, Dr. Nag? Thank you.

That ends this discussion. We will now take a break at 10 o'clock to resume at 10:15 with the next item on the agenda, which will be the Fingerprinting Subcommittee report by Dr. Vetter. So thank you. A 15 minute break.

(Off the record.)

CHAIRMAN MALMUD: As we get together, Ashley Tull has some handouts for us, and we'll -- those will be passed out as soon as you all have a chance to get to your seats.

MS. TULL: This is Ashley. The first handout is the microspheres guidance that I promised a few minutes ago. And if you look on the second page, there is a number 2 that's kind of highlighted. That's the actual sentence that we were discussing for the recommendations, so if you want to focus on that, that's the final outcome. And the second handout is the fingerprinting report that's in your binder. It's dated July 22nd. This is an August, so this is the final Subcommittee report that was approved by the Full Committee via email. So if you'll pull out

what's in your binder for Tab -

CHAIRMAN MALMUD: Six.

MS. TULL: Six. This replaces that. And the microspheres guidance that's coming around, if you want to stick it in your binders behind Tab 8, we're going to have a microspheres discussion later today.

CHAIRMAN MALMUD: Thank you. If you will turn to Tab 6. Dr. Vetter will introduce the subject. Dr. Vetter.

DR. VETTER: Thank you, Dr. Malmud.

At the last opportunity that we had to address the Commission, we brought up the issue of fingerprints, and that many licensees were having difficulty with the fingerprinting requirements. As a result of that, a Subcommittee was appointed to examine fingerprint options to improve efficiency, and reduce costs for licensees. The team members were Ralph Lieto, Dr. Bruce Thomadsen, and myself.

Rather than go through -- I don't have a set of slides, and rather than go through the report line-by-line, I'd just like to focus on the last section of the report, which is basically conclusions, "How to Decrease Costs and Increase Efficiency". You'll find that on the last page of the report. I'll wait for a moment here as we flip things around. And

I apologize, my remarks are based on the report that was provided to us. Let me just quickly review and see if there's -- okay.

So how to decrease costs and increase efficiency. First of all, under Item 1, actions that licensees could consider, use fingerprints submitted under other state and federal requirements. For example, if for purposes of using biological materials, if your institution was registered with CDC, and individuals had to have fingerprints, and these individuals also needed to be fingerprinted for purposes of the T&R requirements, you could actually request the NRC to allow you to use those.

That requires some -- if you go to Paragraph 3 of the order, which we don't have in front of us, but if you go to those procedures, that requires quite a bit of paperwork, and it's probably easier simply to re-fingerprint. And, to the best of my knowledge, that's what licensees were, in fact, doing.

Number 2, reduce the number of people approved for unescorted access. For instance, by pairing up, or designating one person in a laboratory to do the irradiations, or two or three people, rather than everyone. And, in fact, some licensees, I think,

we doing that to a fairly limited extent, however, because schedules and cost schedules depend on who's available, and in order to assure that someone is available to do the irradiation all the time, it gets to be a little bit complicated. And so I think in most cases, the laboratories, blood banks, in particular, simply felt it would be impractical to do that, so they designated a rather large fraction of their people to actually go through the T&R, including the fingerprinting. But that's something in the future that labs, as they get more comfortable with this requirement, could continue to explore.

Three, isolate irradiator in a small room to reduce the number of people who need access. Large blood banks actually had the irradiator in a rather central location in the lab, and there were many, many people who could walk by that. They didn't all use it, but they were all in this very large lab where the irradiator was located. And by moving the irradiator to a smaller room and locking that room, as Dr. Fisher mentioned earlier, he observed that some licensees had done that. In fact, that has become a rather common practice.

It's expensive to do that. If you build another room, you build some walls and a door, and you

put a security lock of some sort on it, that can be several thousand dollars, so it's expensive for labs to do that. But, in fact, in the long run, it does turn out to be justifiable, even though it is a bit costly, because it does reduce the number of -- it does, number one, increase security. And, number two, it decreases the number of people who have to go through the T&R process.

Point Four or D in our report, research facilities could establish a core facility. A core facility is a small laboratory that's been set up to do a very specialized procedure. So, for instance, they might have a core procedure for mass spectroscopy, and if any -- or core procedure for doing PCA analysis. And so, if a laboratory didn't want to set up that particular procedure, but had some research where they needed to utilize that, they could simply pay the core facility do it for them.

For irradiator, I talked to several different researchers, the Committee talked to several researchers who didn't think a core facility for irradiation was a good idea. It's setting up a specialized laboratory where you have to hire -- you probably have to hire someone to be there and operate it. And it gets to be a problem with scheduling, as

well. And researchers don't like other people controlling their schedules.

In fact, those of you who are familiar with research facilities know that they work 24/7, so the core facility I think is probably not practical for most facilities, but it is an option that larger research facilities could consider.

Point F, if employees have to travel some distance -- did I skip one? Yes, okay. E, sorry, I skipped Point E. The order allows relaxing certain requirements for specific individuals, so an example is someone with an active federal security clearance would not have to go through the fingerprinting. So, for instance, in my own case, I could have requested the documentation from the NRC confirming that I have a security clearance. And I could have sent that documentation in for a -- to request a special exemption from the fingerprinting requirements. And we could probably guess how long all of that would take, or when our security unit was in our area doing all of the fingerprinting for all of those individuals in our building, I could have taken the 10 minutes it took me to walk across the hall and get my fingerprints done. So, obviously, that's what I chose.

So even though the order does allow relaxing certain requirements for specific individuals, it does require a fair amount of paperwork, and the paperwork may, in fact, be onerous. It is an option people can consider, and perhaps in some small number of cases it is justifiable to do that. But I think most licensees would find that to be onerous.

F, if the employees must travel some distance, like 20 miles for fingerprinting, perhaps they could arrange for their own licensee security, or local law enforcement to do the fingerprinting on site. That is something that I think should be considered. That's not always workable either, though. In fact, a couple of licensees told me that local law enforcement would not do the fingerprinting for them. They simply didn't want to get involved in this NRC business, and so they ended up traveling to another jurisdiction 20 miles away.

Well, if you have a large number of people who have to do that, that's considerable amount of time, considerable impact on the time that those people have at work, so what they should explore, if they haven't already, is setting up a time when that jurisdiction would actually come to their own facility

and fingerprint a large number of people at one time.

Then under actions that the NRC or others should consider to remove obstacles for licensee, we considered two things. One is that licensees have, and, frankly, they continue to experience unclassifiable fingerprint cards. Some tell me as high as 25 percent. I think a more realistic number, a more typical number is 10 percent or less. Nevertheless, there are some individuals whose fingerprints simply come back unclassifiable. And in my own case, we had 10 individuals that we've gone in six times, and we have now asked -- Minnesota is now an agreement state, so we have asked for an extension of the deadline for those 10 individuals. And, frankly, we're trying to explore options now. We don't know what we're going to do at this point, but the state did give us an extension on the fingerprint deadline for those 10 individuals.

What's puzzling about this is I have not, and my experience is very limited, but I or other members of the Committee have not heard about any problems when fingerprinting physicians for licensing purposes. But in those cases, the fingerprints are done through local law enforcement to the FBI. In the case we're discussing here with T&R, they're first

going to the NRC, and then they go to FBI. And we don't understand what all happens in that process, but, apparently, we're just more or less guessing here, the fingerprints -- we think the fingerprints, the images are being degraded somewhere along the way. And so, for a very small number of people, especially those who have skin conditions, the fingerprints simply are coming back unclassifiable.

We don't know what the solution to that is. We propose, perhaps, there is a way to look at this in a jurisdictional manner that would allow the licensee to have local law enforcement take the fingerprint and send it directly to FBI, rather than through the NRC. We don't know if that would help or not, but it, perhaps, is an option. But there is a small number of people, real people, real workers for whom we are unable to get classifiable fingerprints. And that issue simply must be addressed, and we don't know -- the licensees are simply sort of stuck. So the NRC, we're asking that the NRC take a look at that, and remove those obstacles.

And finally, the Committee recommends that the NRC should address portability of results; that is, transfer of T&R determinations from one licensee to another so that when an individual who's granted

unescorted access at one institution moves to another institution, they could transfer that T&R, or at least the fingerprinting portion of that. Perhaps, in a manner analogous to exposure history requests, where we can simply write to another licensee and get the exposure history of that individual when they come to work for us, or perhaps there's a national registry of some sort that could be set up, or there may be some other process to accomplish portability of results. But we would like to see something done, so that when an individual who's been granted unescorted access at one institution doesn't have to go through the entire process when they transfer employers.

And that is our report. Would Mr. Lieto or Dr. Thomadsen like to add anything?

CHAIRMAN MALMUD: Additional comments? I want to thank you all for the effort on behalf of this item. As you will recall, we are responding to a request from an authority higher than our own with respect to the need to do the fingerprinting. And, therefore, our response was not an argument for or against the fingerprinting. We understand that it will be done. The question is, how can it be done most efficiently? And this is the Subcommittee's report with regard to those issues.

Did I understand that what you said could be interpreted as when the fingerprints go directly to the FBI, they have a very high rate of acceptability, but when they go through another agency first, that the number of rejects is up to 25 percent?

DR. VETTER: That's stating it a little bit more confidently than the Subcommittee is. We simply have not heard of any problems associated with physician fingerprints that are sent directly from local law enforcement to the FBI. We've not heard of any problems. We don't know if any exist, but in my own case when I asked about that, physicians said no, we've never heard of any problems in that regard. That doesn't mean some didn't exist. But in this particular case, we are hearing of problems when we talk to RSOs at other institutions, that unclassifiable fingerprints are fairly common. A small number, but -

CHAIRMAN MALMUD: Thank you.

DR. VETTER: We're simply guessing that there is something different about the process that results in degrading the fingerprints when they are going through the NRC first, rather than directly to the FBI.

CHAIRMAN MALMUD: One other item that you

mentioned was questioning the need to re-fingerprint when relocating to another institution.

DR. VETTER: Right.

CHAIRMAN MALMUD: But let's say that there is another educated, distinguished, good-looking gentleman, such as yourself, who purports to be yourself as he transfers from the Mayo Clinic to another institution, but is not you, and yet has an I.D. that says he is you. How would that person be confirmed as being you without fingerprints?

DR. VETTER: I suppose in any other way that an institution who would hire me confirms that it's really me, regardless of the fingerprinting issue. I don't have a good answer for that.

CHAIRMAN MALMUD: Is there any other -- because it may be that we're raising a question for which there already is an answer, and that is that they either have another way, or there is no other certain way. I don't know the answer. Rob?

MR. LEWIS: Well, on that particular point, and there is a question, I believe, in our fingerprinting questions and answers, so it was raised before of, can a doctor who works at many different hospitals use the first hospital's result at the subsequent hospitals? And the answer is yes and no.

I mean, you can use the first fingerprinting result, but each hospital has to have its own T&R determination, because each hospital -- one hospital might say I don't want anybody with unescorted access that has any criminal record. The second hospital might say I don't want anybody with unescorted access without a felony. Since the individual licensees can define their T&R, then you can use the original fingerprinting result, but you put them through your own process at a subsequent facility. And that's the way it's set up. Whether that's the most efficient is something we're interested in feedback in, but that's just the way we've asked people to do it.

DR. VETTER: If I could just react, just very briefly. The intention of the Subcommittee was to recommend some sort of a process whereby the individual wouldn't have to be re-fingerprinted. We certainly do understand, as Mr. Lewis explained, that each facility has to do its own T&R.

CHAIRMAN MALMUD: I wanted to thank you again for a very thorough -- you and the Subcommittee for a very thorough job.

I think that Chris wanted to say something.

MR. EINBERG: Yes. Thank you, Dr. Malmud.

Thank you, Dr. Vetter, and the Subcommittee for this report. I'll respond to a couple of the points you made, but I just want to let you know what has happened to your Subcommittee report. We've transmitted this to the Commission through a Commission Assistance Note so the Commission has a copy of your Subcommittee report.

Additionally, this Subcommittee report has been provided to the Rulemaking Working Group that's dealing with fingerprinting, so they'll be using it for this in their consideration as they move forward in codifying the fingerprinting.

To now address some of your points that you raised. You raised some good points, and I want to take time to clarify some of the issues that you did raise. Regarding the rejection rate, you indicated that some licensees, may be as high as 25 percent.

I did speak to our Office of Administration, who processes the fingerprints for NRC, and handles the submissions of fingerprints, and they confirmed that there are some very high rejection rates with certain licensees. Overall, the rejection rate is approximately 7 percent, and they attribute the high rejection rate for certain licensees to

perhaps the lack of experience in taking fingerprints. And so, licensees that tend to use local law enforcement who are trained to do fingerprints have a lower rejection rate.

For those licensees that are experiencing difficulties, they do refer the licensees to the FBI's website, and does give some guidance on taking fingerprints. The FBI and other local law enforcement and professional organizations do offer training in regards to taking fingerprints, so that's available to licensees to decrease the rejection rate, as well.

Regarding submittal of fingerprints directly to the FBI by either local law enforcement or by licensees, that's not permitted under the Energy Policy Act. The Energy Policy Act basically states that the fingerprints must be submitted by the NRC to the Department of Justice, which is, in essence, the FBI. And so, under the current law, there is no mechanism for submitting fingerprints directly to the FBI. It has to go through the NRC, and so that's why there's that second step. And that pertains for agreement states, also, so agreement state licensees have to submit their fingerprints to the NRC, and NRC forwards those fingerprints to the FBI.

MR. LUEHMAN: Can I interject there,

Chris, for just a second?

MR. EINBERG: Sure.

MR. LUEHMAN: And one of the reasons for that is that -- well, there's two reasons. One is, that the NRC does -- our Office of Administration does do a quality check, not necessarily just of the fingerprints, but of the cards themselves before they go to the FBI. That's Point A, but then Point B is that if you -- when you go to the FBI directly, if you went to the FBI directly, they have to have, and we have to have verification that your requesting the right kind of check. I mean, the FBI can run checks in all sorts of databases. They can run them on individual databases, they have a number of different databases, and one of the things that sending them -- the reason the Policy Act was written the way it was was, the NRC will insure that the right check is being requested. Because, again, the FBI can run through a number of databases, or they can run specifically through one database, depending upon what the check is being done for. So that's an administrative burden that the FBI doesn't want to do. They want to get the Agency to make sure that the checks are classified for the proper series of checks, or a single check that has to be done. So those are some of the reasons

behind, I think, why the Energy Policy Act says what it does.

MR. EINBERG: Thank you, Jim.

To kind of clarify some of the other points, also, address some of the other recommendations that you made, Dr. Vetter. You had recommended that perhaps there is a master list, or a list of entities that are authorized to approve fingerprints. And the NRC cannot endorse a list of entities who are authorized to perform fingerprinting.

We do have a question and answer that's developed, Supplemental Q&A, Number 3. And, basically, that says you can have your local law enforcement agency, or other authorized individuals take fingerprints, but we cannot get into the business of endorsing a list of entities, because, inevitably, there's going to be somebody who's left off that list, and has reason to be dissuaded about that, to put it lightly.

And then just to also echo a point that Ron made about the portability of the fingerprint results, or the T&R determinations. Basically, Ron did correctly indicate that each individual licensee is responsible for making their own trustworthiness, reliability determinations based on their own

criteria. Each licensee will have their own criteria for determining who's trustworthy and reliable.

For the fingerprinting results to be transferred from one licensee to another, written permission has to be given by the individual requesting that the first agency who requested the original fingerprints release those fingerprints. Now, anecdotally, when we were giving the workshops around the country on this, a lot of licensees said that they would probably be reluctant to provide or release those types of records, because of liability concerns. And so, most likely, the second licensee, or the new licensee would need to request the fingerprints once again.

Those are the only points that I wanted to address.

CHAIRMAN MALMUD: Thank you. Mr. Lieto.

MR. LIETO: Well, two points. One, I think I really would challenge your statement that licensees would be reluctant to transfer that information at the request of the individual. You do it all the time for film radiation badge records, and I think the inconvenience of repeat fingerprinting, I think that you would find that the individual would be more than willing to have that information transferred. So there

may be some licensees that are -- may have expressed some reluctance, but there may be questions more to the fact of if the information would violate some confidentiality issues. And I think, again, the NRC could go a long ways to answering those questions by emphasizing the fact that that can be done.

The other point that I wanted to make about the unclassifiables is that it's my understanding that the ink card method of fingerprinting is not the standard practice with most law enforcement, or with law enforcement agencies period. So the high rejection rates -- we're experiencing high rejection rates, and we're using one of the same agencies that's endorsed by our state police. So it may be that what you say is true, that there may be a problem with people's experience in doing this, but it also relates to the fact that the ink card method is a very time consuming, because they have to send it in, it has to be looked at, and then you get the rejection notice. It comes back. We still aren't in compliance with the order, because we're still going through this unclassifiable re-fingerprinting methodology. And I think the intent was to have everybody done by I think what, June? And so, I think if there would have been some acceptance

early on that you could go ink card or electronic, I think there would have been a lot more of the individuals not being rejected than there are. And I think we're still going to have the problems with the ink card methodology.

CHAIRMAN MALMUD: Mr. Luehman.

MR. LUEHMAN: To respond to that, I agree. I mean, I think that the standard is rapidly becoming the electronic, because, in fact, the electronic -- the system can tell you whether you've got -- right away whether you've got an acceptable set of prints. Unfortunately, I don't think -- the availability of that is not uniform across the large numbers and types of licensees that are involved in this. But to the extent that that's accessible to them, I think you're correct, that the electronic is the way to go.

That having been said, the FBI does, in fact, our working group that considers this, which is the IICWG, which is the Increased Controls Working Group, has just - we've just approved a supplement to a question and answer on this, because even despite electronic and/or correct ink fingerprinting, the FBI does experience a certain amount of unclassifiable fingerprints, even with what we consider a valid fingerprint card. And we have recently added to, or

we are about to add to our list of questions and answers the procedure that will be followed that after a certain number of attempts to get a set of fingerprints classified, that there are special circumstances where there's a special process that could be followed with the FBI that does not involve fingerprints, does not involve the submission of fingerprints.

Again, the criteria under which those can be used, that method can be used is limited. And an inadequate set of fingerprints on the card is not a good reason. But there are -- we have supplemented our questions and answers, or we will shortly be supplementing our questions and answers to address what the FBI says is a valid issue, which is a certain number of people do have unclassifiable fingerprints, regardless of quality of the fingerprints taken.

CHAIRMAN MALMUD: Thank you. Chris. I'm sorry, Bill.

DR. VAN DECKER: As someone who didn't serve on the Subcommittee, I heard more about fingerprinting than I probably want to know right now. And second, I wanted to thank Chris' little interaction here, because it answered a big part of my question I was going to start with, is where we go

with this Subcommittee report, and where things are going.

I think there's two pieces to this, as I see. Number one is an informational piece to what all the licensees know, at a time where there's some give and take on codification of what's going on. And I would just say knowing how many small hospitals there are out there, and lots of other stuff, that some way of at least not creating more confusion in all of this will help things down the line, including some of this information that was given as background in the report, which you can't say do this one way, or do this the other way. Some of that information may be helpful to arrive you at places and choosing how they're going to go about doing something like this. So I think that the informational piece of this is important.

And I guess the second piece of this is, I'd be interested in what you see as the time line until you have something "codified" in place, that this becomes a more rote issue, and utilizing some of this information. I guess the last piece of that to Dr. Vetter would then be, looking at your report, are there certain key pieces of it that you would like to see as motions from Full ACMUI to at least give some

direct consideration in this process, rather than continuing ongoing discussion. It sounds like it's going to take a while.

CHAIRMAN MALMUD: Was that a question to Dr. Vetter?

MR. LUEHMAN: The second piece was a -- I guess the first piece was just a reaffirmation from NRC that some type of informational piece is going to be put into place, either through NRC, or through what other groups of interest. And the second piece of the question, NRC's time line to codification. And then the third piece to Dr. Vetter was, what were the key pieces of this report that you see we should have like one or two sentences about that we think are key? That was reasonable.

MR. LEWIS: For the first part, could I ask -- could I answer your question with a question? And I had the same thought as you did as we were walking through the presentation. Many of these are things that the Committee or the Subcommittee is advocating that licensees should do. So process-wise, does the Committee have a view on how those things should be communicated to licensees? And I can offer up some ideas. We could put it on our own fingerprinting toolbox website, or we can do some more

formal communications, or we could put it on the Committee's website. There are many options, but I was wondering if the Committee had a particular view, aside from the internal communication, which Chris mentioned, that has been provided to the Commission, and is being considered by the implementation of Increased Control Working Group, and the Rulemaking, which is many -- a couple of years down the road, frankly.

The recommendations you have for licensees seem to be more near term recommendations about given the current situation, here's some things you can do.

CHAIRMAN MALMUD: Dr. Vetter.

DR. VETTER: My response to your question would be, what would the Committee -- how would they like to see the information conveyed to licensees? I guess this, just off the top of my head, I wouldn't push, necessarily, that the report itself, as it exists, be put anywhere for licensees. But I think we would appreciate if the information in the report is incorporated into Q&As, or these other websites, web pages you were talking about.

It's the content that might be useful to licensees in one form or another, not necessarily as this particular report. Though I wouldn't object to

that if that -- so I think whatever the NRC felt was the most expeditious way to communicate the information to licensees, Q&A or some other way, would be fine.

And in response to Dr. Van Decker's question about whether or not the Subcommittee thinks -- requests that any of these points be put in the form of a motion for further support or whatever, the Committee -- the report, itself, was, if I understand correctly, was sent to all of you, and you all approved it. So the report has been approved, so, thus, in terms of being integral part of the report, each of these recommendations has been put forth to the Commission to consider. Notice we use should, we don't have the authority to use shall, anyway. But these are recommendations for them to consider.

We would hope that they would have a little more precise view of some of these things, a deeper understanding of some of the issues, such as the unclassifiables, and they would know what's workable, and what isn't. But that they would take the intent of the report, which is supported by the Committee to heart and do what they can to implement those two particular recommendations.

CHAIRMAN MALMUD: Thank you, Dr. Vetter.

Is there another comment?

MS. GILLEY: I have one.

CHAIRMAN MALMUD: Please, Debbie.

MS. GILLEY: Debbie Gilley. In the unclassifiable fingerprints, are you seeing an increase of number of unclassifiables in the medical community versus the industrial community, or is the 7 percent across the board?

MR. LUEHMAN: I don't have the details of the breakout. I understand it's 7 percent across the board.

MS. GILLEY: I think it might be the nature of the applicants in the medical community, and some of their hygiene maybe issues that have the sluffing of the skin cells that make it more difficult. I had a lot of trouble getting fingerprints for this particular ACMUI requirement, and that was some of the things that were suggested to me by the fingerprint specialist when I went there.

CHAIRMAN MALMUD: I hope that you're suggesting that the health care providers hands are cleaner than most.

MS. GILLEY: Absolutely.

CHAIRMAN MALMUD: Thank you. I just wanted to clarify that for the record. Any other

comments?

MR. GUIBERTEAU: I guess I just have -- Dr. Malmud, I just have one, clarifying Dr. Lieto's statement about the local law enforcement taking hand-rolled fingerprints. And as you had correctly pointed out, ink is quickly being replaced by electronic fingerprinting.

The local law enforcement can take electronic fingerprints, but they have to be reprinted out on the cards and submitted directly to the NRC, so they don't have to necessarily take ink-rolled fingerprints. They could take electronic fingerprints with the machines that they have, and print them out on the NRC cards. And so that may improve, perhaps, the rejection rate, as well.

DR. VETTER: It was my understanding, though, the order said ink, ink prints on cards. I mean, because we specifically ended up having to go that route when we had the other alternative available to us. So I would -- if that's the case, then there is a huge misconception out there and misinformation. And I think really that needs to be clarified, because, like I said, it's a route that we would not have gone.

MR. EINBERG: I think this is good

information, and it could be fed back through the IICWG, and a Q&A could be developed. As you may or may not be aware, electronic fingerprinting submission is allowable to the NRC by licensees, as long as the licensees establish electronic fingerprinting program with the NRC. And this is afforded to any licensee, but it's more cost-effective to large licensees. And that may also cut down on the rejection rate.

DR. VETTER: Well, I think it goes to the recommendation from the Subcommittee that there is locations where, especially where the electronic is much more available, it facilitates those individuals going to those locations. And, plus, the ready feedback when they do it, that oh, this fingerprint was not acceptable, we need to redo it. And, again, facilitates getting people done, and not having to go through the repetition process.

CHAIRMAN MALMUD: Thank you. I think that completes the discussion regarding this item. If we may, we'll move on to the next item, which is under Tab 7, Permanent Implant Brachytherapy Rulemaking Subcommittee report. Dr. Nag. Dr. Nag has a slide presentation.

DR. NAG: Yes. Thank you very much. This is the work that has been going on for the last three

or four years into forming new rules for permanent brachytherapy because there were some drawbacks to the way the rules were written. They would not apply to permanent brachytherapy, and that was started sometime I believe in 2004. And the report, or the proposed rules were published on August 6th, 2008. And the Subcommittee is making comments on that report. I would like to thank the members of the Subcommittee who are up there, Bruce Thomadsen, James Welsh, and Ralph Lieto. We did have teleconference.

In addition, we sought input from practicing members of the radiation oncology community as to how it would affect their practice. What we felt was that the proposed rules or written directives for permanent implant is source strength based rather than dose-base was really appropriate. And we, therefore, support this rule, because when you place permanent seed, you know what source strength you're placing in, or what source strength you want to place in. You may or may not know the actual dose that comes out afterwards, because the source is removed, and the organ can expand and so forth.

One little comment, that is in the rule the word "activity" and "source strength" both being used. The correct word is "source Strength", and,

therefore, whenever you are having activity in that rule it should be replaced by source strength.

Now, when the rules were made, or were formulated, it was developed with the idea of pre-planned permanent brachytherapy, prostate brachytherapy in mind. Now, the rule, however, is going to apply to every kind of brachytherapy. Therefore, you cannot extrapolate from pre-planned prostate brachytherapy to all forms of brachytherapy. And because it was done with a pre-planned prostate brachytherapy in mind, the proposed rule led to some unintended consequences.

I'm sure no one thought that these would apply, and it would create some unintended consequences. And I'm going to give some examples of what these unintended consequences are, and what the Subcommittee proposes.

One of the unintended consequences would be that very well-performed implant, that's medically acceptable would be classified as medical event, and I'll tell you why. Now, if the source strength administered by more than 20 percent or more from the total source strength documented in the pre-implant written directive, it will be called a medical event. And the NRC has said that the pre-implant written

directive cannot be changed, and the pre-implantation written directive serves as the basis for determining a medical event had occurred.

This seemed quite logical. However, it is logical if you are using a pre-planned method. However, there are more than one way of doing a permanent implant. In fact, many times we do permanent implant based on a real time adaptive interactive technique, meaning that the source strength we are putting in is not based on some pre-planned volume, but on the actual volume that we are seeing as we are doing our implant. I'll show you a diagram of that. This is a more accurate method, and we are constantly updating our plan as we are implanting. If we see that the prostate or the organ is expanding, or is getting bigger, or smaller, is moving, we update that. And this to show you an example.

On the -- we are having an ultrasound where we are seeing the image of the organ. We are feeding it into a computer, into a treatment planning computer. So what's happening is you are seeing, this is -- the little one is the preplanned volume, but as we were implanting, on the ultrasound we are seeing that this now the new volume. So if we were going to

put the seed according to the old volume, we would be under-dosing this new volume. So, therefore, the more accurate way of doing it is seeing where you are actually implanting, and because you have a computer that is linked to your ultrasound, you can update that dose. And, therefore, doing it this way, we are now putting in the source strength that is required for implanting the organ as it is in the OR. So you cannot base that on a pre-implant volume, or pre-implant written directive.

Therefore, the basis for the ME, the recommendation is that the basis for the Medical Event should be the total source strength implanted after administration, but before the patient leaves the post-procedure recovery area. And not to be based on the pre-implantation written directive, and this will allow any intraoperative adaptation, if required, and most of the time it is required. And could then apply to both a pre-planned technique, and a real time adaptive technique. And to add to that, even those who are doing a pre-planned method very often, if they see that the volume is changing on the day of the implantation, they will modify their written directive, anyway. So this will allow both techniques. And if you are doing that, then the pre-

implantation word should, therefore, be deleted from pre-implantation written directive in the other section, as well, to match. So that's our recommendation.

The other concern is that it will be considered a medical event if the total source strength implanted outside the treatment site, and within the three centimeter boundary of the treatment site exceeded 20 percent of the total source strength documented in the pre-implant written directive. Now, what do you mean by the treatment site? It's rather simple. Treatment site is the area you treat, but to a radiation oncologist, there are various definitions, and we're going through those definitions.

The definition in NRC is anatomical description of tissue intended to receive a radiation dose as described in a written directive. And, therefore, that's somewhat ambiguous. Now, let's see how does the radiation oncologist do a plan, and I think this diagram will help us to understand.

The one in the center is the gross tumor volume; that is, if you have a tumor and you can see it, or you can feel it, that area is the Gross tumor volume. However, we do not just implant -- that is not our only target, because tumor can spread

microscopically along that. And, therefore, that microscopic expansion is usually not equal in all directions. Therefore, I have drawn what's called a clinical target volume purposely that it's more in one direction, less in the other direction, because clinically, we see how it the plane spread. If there's a plane where the spread can go more, there will be a bigger margin there; where, for example, if you have a bone or some issue that will prevent the spread, the margin will be less in that direction.

But once you have that area where you have the tumor and the microscopic spread, then you have to add the margin in the planning process, because many other things happen in the planning. When you put source in a certain area, there are dips in the isotopes, and there are uncertainty about where exactly the tumor is, and so forth, so we have like a punch for the planning target volume.

Again, the margin in the planning target volume is not equal on all sides. In the area where you have a critical structure, for example, you have the spinal cord, you have the bowel, you will have a less margin in that area, more margin in a place which is like muscle or something that you cannot damage. So that was the area we are really interested in, is

the planning target volume, and not necessarily the Gross tumor volume. So the previous definition makes it quite ambiguous. Are you referring to this volume? If you are referring to the Gausse target volume, then if you say well, more than 3 cm, you are having a problem, or you are having medical event, then this could be different.

So, therefore, what we want to say is that because there are various volumes we have to be more specific of the volume. And the other thing is that the margin, how much to place in the margin, how much to place inside the tumor which is in the margin is a medical decision. That is a clinical judgment. NRC is not supposed to interfere into the medical judgment. And, technically, when you say tumor site, are you meaning the Gross tumor volume, the margin as in the clinical target volume, or the margin as in the planning target volume? This is quite unclear from the definition we have now.

So what is the recommendation? We want to clarify that to be considered a medical event, the total source strength implanted outside the treatment site, and here we want to clarify that the treatment site will include the Gross tumor, the clinical target volume, plus invariable planning margin as defined by

the authorized user exceeds 20 percent of the total source strength documented in the written directive.

If we are having this definition, then the NRC will not be interfering with the clinical judgment, because you are saying outside the planning target. And the planning target volume is defined by the medical judgment.

The other concern is that it will be a medical event, even if a single brachytherapy source were implanted beyond 3 cm outside the boundary of the treatment site. However, what we have seen is that in the normal course of a properly executed implant, few source strength end up beyond the 3 cm outside the boundary. Why? Because seed can be deposited into the periprostatic-like vessels, and then they can migrate to a distant organ, like the lung, but this is correctly recognized by the NRC not to be a medical event, so that's not a problem. However, a few of the deposited seeds can travel to the adjacent pelvic area, maybe 4 cm away, but still in the pelvis, via the pelvic vessel, and then it will be impossible to judge whether it was something that was deposited and migrated, or whether it was implanted in that area.

A few seeds can be implanted into the urethra which is right in the middle of our volume, or

into the adjacent bladder. And they're normally excreted in the urine, and you don't see them. But sometimes they may not be totally excreted in the urine, but may be traveling downward, and be somewhere halfway, and then it will be considered a medical event.

In the permanent implant of other organs, some seeds can be sucked along the middle plat has been retracted. When you place these seeds, we are placing them one by one. When you're putting them down, if you pull them down, one or two seeds may be pulled down along the middle plat, and may be deposited along the path of the middle plat, but more than 3 cm. And then the patient may accidentally move during the middle of retraction causing some seed to be deposited more than 3 cm.

None of these things would be recognized while the implant is going on unless you are doing a pleural continuously doing the implantation of seed, which is not possible.

So the other thing is that the permanent implant are done in prostate, but the rule would apply to permanent implant everywhere, in the liver, in the brain, in the abdominal cavity, and so forth. And in other organs, you may or may not have a strong capsule

to define the boundary. And in that case, you may not know exactly where the Gross tumor volume is, and, therefore, you might want to make a volume, and you may not have tissue to anchor the seed. For example, if you are trying to do implant against the bone, what we do is we put this -- or against the surface of the peritoneum, what we do is we place the radioactive seed in gelfoam, and then we plaster the whole gelfoam on top of the area of concern. And sometimes, or in the lung we do the same thing. We place it in a gelfoam, and put it on the surface of the organ, and sometimes the gelfoam will be absorbed, and some of those seeds can then float into the open cavity which will be the thoracic cavity, or the abdominal cavity. And if that happens, then a couple of seeds may be then deposited more than 3 cm away.

So all of these would then be considered a medical event, and they are medically not a problem. And we would be spending hours trying to determine whether that was a medical event or not. So our recommendations are medical event would be if the total source strength implanted outside the treatment site, and now we have accepted that the treatment site should include the planning target volume, exceed 20 percent of the total source strength, so this will

take care that if you had a few seeds moving, which can happen, we still have that 20 percent. And it will take care of any source migration, any seed that has dislodged, but will still hold accountable some practitioners who have wrongly identified the organ and placed a lot of seed in a different area. And we are still holding accountable people who are making mistakes, but a few seeds being dislodged, et cetera, would not be called a medical event. If you define it this way, then Section 8-2.3 will become superfluous, and, therefore, can be eliminated.

An area of concern that the section licensee shall report as a medical event any administration requiring a written directive, if a written directive was not prepared. Not having a written directive prior to the administration is already a violation, so creating that into a medical event, that will -- it will serve only to add to the number of medical events without adding to the safety. The proposed rule change will only add medical events that are rule violation only, but they're not harmful. And administration done without written directive would, therefore, be cited as a regulation violation, rather than be called a medical event.

So, basically, I would like to summarize

at this point, that we are concerned that with the proposed rules, the above situations that I have mentioned will inappropriately be deemed to be medical events, when, in reality, they sometimes occur in the course of some normal properly executed brachytherapy implants, and these are beyond the control of the authorized user. We are concerned that this neuro will then simply abandon permanent brachytherapy procedure rather than risking having medical events.

In fact, as we know, many people are shying away from doing brachy because the regulations are already so burdensome. And if you are going to now say even good implants will be called medical events, many people will just say I'm going to stop doing it. And this will be then detrimental to patient care, because technically speaking, brachytherapy is still the most conformal form of therapy. It's the best way to put a maximum dose into the tumor compared to any other form of radiation therapy. We, therefore, recommend that in Section (a)(2)(i), (2), (3), and (4), the word "pre-implantation" will be deleted from pre-implantation written directive. In Section (a)(2)(ii), clarify that the treatment site includes the Gross tumor, clinical target volume, and a variable planning

margin, as defined by the AU. And, therefore, (a)(2)(iii) will become superfluous, and, therefore, be deleted. Activity should be made by source strength wherever it applies to permanent brachytherapy, and that administration without the written directive should be cited as regulation violation, and not medical event, per se.

The other thing is that some of these things could have been avoided if the NRC had sent the rule back to the ACMUI before sending it out for public comment, because as we have mentioned before, these rules were made on basis of recommendation of the ACMUI several years ago, about five or six years ago. But when those rules were formulated, they never came back to the ACMUI to say is that what you meant, or is that -- because sometimes the changing of one or two words may mean a huge difference. And, therefore, our plea is that if the NRC is going to form some rules based on the recommendation of the ACMUI, they should at least come back to us before they are published. And I think we have to thank members of the Subcommittee. I got a lot of input from members of ASTRO, ACRO, which is a colleague of radiation oncology, and the Brachytherapy Society. This is the sum total of the opinion of a large number of

practicing physicians. Thank you.

CHAIRMAN MALMUD: Thank you, Dr. Nag. If I may just ask some brief questions. Was this a consensus report, or was there a minority report, as well?

DR. NAG: This is -- we did not get any -- when we voted in the Subcommittee, there were no abstentions, and there were no nays. They were all yes.

CHAIRMAN MALMUD: Thank you.

DR. NAG: In the meeting in Ashville in the public radiation oncology forum, again, this is the sum total of their own report. And whatever -- there were no minority, they were all addressed.

CHAIRMAN MALMUD: So this has the strength of a consensus report.

DR. NAG: Yes.

CHAIRMAN MALMUD: Thank you very much. Other questions for Dr. Nag? Debbie.

MS. GILLEY: Debbie Gilley. Is there a definition of a gross tumor volume, a clinical target volume, and a planning target volume in the current regulations? And, if so, does the planning target volume include the pelvis and the urethra?

DR. NAG: Okay. First of all, in the --

if you are talking about following regulation in the NRC on the Federal Register, that does not have these three volumes. The only volumes they have is the treatment site. And that is why we are saying it's ambiguous, because the word "treatment site", we don't know whether it refers to which of these volumes. These volumes are taken from the ICRU report, the International Commission on Radiation Units, and these are the volumes, these three volumes are used by radiation oncologists universally. So in the radiation oncologist and ICRU report, none of those three volumes are defined in the NRC.

MS. GILLEY: Currently, we have had medical events that have included implanting seeds in the wrong anatomical position that may have been included in the planning target volume, for instance, for the pelvis, and the rectum. Is this definition going to allow those type of medical events to still be reported, or are we now going to look at the medical community taking the definition of the planning target volume to have it be the practice of medicine?

DR. NAG: Can we go into that slide where I had the volume, because I think that is very important, because that will show you -- the reason we

cannot give a standard 2 cm or something, the margin cannot be a constant margin. For example, if you are taking a prostate, less than 1 cm from the posterior border of the prostate is the rectum. So, therefore, when we make a planning target volume, the planning volume does not expand posteriorly, because you have the rectum there. The planning volume expands laterally, and anteriorly, but it does not expand superiorly because that will go into the bladder. So that's the reason why we want to use the word planning target volume, because the planning target volume is clinically relevant, because -- for example, here is the gross target volume. So if you were implanting the prostate, you would -- this is the prostate, for example. Then critical spot here would be the rectum, so the planning target volume would not go into the rectum, because you are not going to implant the rectum. So the planning target volume would stop here. On the laterally, where this is no tissue, you expand as much as you want. And I think this is the reason why we have been trying to hammer that it means more clinical -- previously, there were all right, how many cms do you need to expand? We cannot say it's 2 cm, because if you put 2 cm posteriorly, you are going to go into the rectum, and that is absolutely not

allowed. But if you go -- and if we take then only half cm, then if you go only half cm laterally, it's not enough. So we have to define the planning target volume for each organ according to the clinical needs, and the clinical should I say risk of harming normal tissue. So the planning target volume includes the risk of spread, and the risk of damaging normal tissue. And it's a balance of normal tissue with the risk of the spread.

CHAIRMAN MALMUD: Dr. Vetter.

DR. VETTER: On one of your slides, Dr. Nag, you were referencing 35.3045 (a), "A licensee shall report as a medical event any administration requiring a written directive if a written directive is not prepared."

DR. NAG: Yes.

DR. VETTER: I'd like to ask a question, perhaps of Dr. Howe. I think that particular paragraph was intended to address Iodine 131 events, where therapeutic levels were administered when diagnostic were intended.

DR. HOWE: This is Dr. Howe. That's not quite true. In Part 35, we have written directives for unsealed material, and when you have a written directive for unsealed material, that is you go back

into the definitions and you have a prescribed dosage. A prescribed dosage includes both diagnostic and therapeutic type of administration, so we have, because we can go back to a procedure for the lower activities of I-131, or maybe I-123, that we have a way of identifying those as medical events.

But for the sealed source therapy, the written directive is -- the prescribed dose is the dose in the written directive. So if there is no written directive, there is no prescribed dose, there is no prescribed dose to be out of compliance with. And we ended up with a situation where you could have -- with the sealed sources, you could have a therapy dose given to an individual that would not be considered a medical event. And, therefore, would not be reported to the NRC.

Yes, it may be a violation, but it wouldn't be reported to the NRC, and so whether we found it or not would be very arbitrary. And so, the purpose for putting 3045(viii) in was to capture those sealed source events in which there was no written event, no written directive. It wasn't that there wasn't a complete written directive, it's just there wasn't any written directive at all, because we had no way of getting out of that circular argument that the

dose for those sealed sources is what's in the written directive. And if there is no written directive, there is no dose, there is no medical event. So that was the hole that we were trying to fill. With that wording, we will not capture any more I-131s, because we're already capturing those as medical events.

DR. NAG: Now, if they are ruled violations, but they are not let's say harmful to the patient, is there any way we can say that we can have then a rule violation, because that itself is already -- doesn't that have to be reported?

DR. HOWE: No. If you have a rule violation, you do not have to report rule violations.

DR. NAG: I think this is something Ralph, you had worked on this portion of it. Can you -- do you have any comments?

MR. LIETO: Well, I think you've summarized it pretty well, Dr. Nag. I see Dr. Vetter's concern that there might be these medical events that are not getting reported. And, to me, again, I guess if a licensee is that unscrupulous that they're not going to do a written directive where it's required, and then kind of cover it up by not -- upon discovery not doing any type of corrective action, I would think there would be a lot of other issues that

you'd need to worry about than not having a written directive. To me, there's just -- I guess I would ask where is the evidence that you're basing this on for the fact that there's a suspicion that medical events are occurring, but they're getting around it because there was no written directive at the time prior to administration.

I would think that there would be, one, there would be licensing violations and citations because you violated other parts of Part 35 already. The other thing is that this applies to all applications applying a written directive. The situation you're trying to address is the ones with the sealed sources, but it's going to apply to all the unsealed radiopharmaceutical therapy administrations, as well. And I think in the examples that are given in the Subcommittee report, it actually uses the radiopharmaceutical therapies as a sort of substantiation for that. I really don't think this needs to be made a medical -- this violation needs to be made a medical event.

And then I think, also, I think it's a very slippery slope to start that if you're going to make certain regulation violations relating to written directive compliance a medical event, I just don't see

the justification.

CHAIRMAN MALMUD: Excuse me. I just wanted to clarify what you were saying, Ralph. So you're saying that you think that currently there is not a need to make this kind of dosimetry a medical event, because it already is being handled otherwise.

MR. LIETO: Right. It's a regulatory violation already.

CHAIRMAN MALMUD: Thank you. Dr. Nag.

DR. NAG: Yes. The other point I had is that this whole issue is on permanent implant; whereas, the part about having a written directive, or not having a written directive is not specific to permanent implant. This applies to any type of implant, including HDR and so forth. If I do an HDR, and I don't have a written directive, it's not specific to permanent brachytherapy. And my preference would be that since this is a rulemaking on permanent brachytherapy, we restrict it only to permanent brachytherapy, and instead of muddling up the issue somewhat when you're having an overall question, because the written directive -- doing a procedure without a written directive is the broad base that applies to every form of brachytherapy. And that is separate regulation that says you cannot do

brachytherapy without a written directive, because that covers it broadly.

CHAIRMAN MALMUD: I think that Rob Lewis is going to make a comment.

MR. LEWIS: Well, I guess I do see a circular argument. If we eliminate the word "pre-implantation" from written directive, and we only do the written directive after -- an example of a situation where the new criteria you propose would be tripped to become a medical event. And I think it hinges on the definition of planning target volume, which brings me back to why isn't that defined pre-implementation?

DR. NAG: Right. Well, I would say that we do this in the operating room all the time. So our planning target would be to say that we are going to implant this organ, and when you do this, you have a diagram that you are planning on the operating room on the computer. And that is printed out, so our plan would be to say implant like I showed you. And at the end, when we do the x-ray, we found half of those seeds were not in the planning target volume, was below, or on the side, or posterior, or in the rectum, then it will be definitely become a medical event. So you do have a written directive that you can go back

to, but that written directive was done when you had just finished doing your implant. Because until such time as you have completed your implant, you can keep on changing as you are seeing change in the shape. So the point where you are completing the implant is when you say well, now I have implanted the target the way I want to, and now we are going to stop.

The mistakes are usual -- I mean, I have examined quite a few of the misadministrations. The mistakes were made not because they went outside of what they were planning, but what happened is they misidentified the plan. They thought that the bladder was the prostate, and they put a lot of the seed into the bladder, or they thought that the bladder or the prostate was some other organ, and the sub-urethral area was the prostate, and they put the seed there. So those would be caught because your planning target on your diagram was the prostate with the margin. And when you came back, and all the seeds are outside, that is very easily identifiable as a misadministration.

CHAIRMAN MALMUD: Dr. Howe, I think you wanted to make a comment.

DR. HOWE: Yes. This is Dr. Howe. I'd like to clarify two points, and one is that if

comments are coming back that not having a written directive is a medical event, will affect in any way the nuclear medicine therapy medical events. That's not true, because the medical event definition for unsealed material is based on dosage.

Dosage is defined in Part 35 as, "The activity or range of activity of unsealed byproduct material as documented in a written directive, or in accordance with the directions of the authorized user for procedures performed pursuant to 100 and 200." So if you were -- if you have a procedure manual, and you are intending to give one of the diagnostic procedures, then you have the procedural manual number that gives you the doses. And if you made a mistake and you gave a therapy, something requiring a written directive, we have a means of identifying that as a written directive. So we won't be increasing any written directives for the unsealed material, because we already have a means of determining what the dose is, if there's no written directive.

The only one we don't have is the one for the sealed source. Have we had an example of that? Yes, we have. We had intervascular brachytherapy that was given to a patient that was not -- did not have a written directive provided for them. Are we -

DR. NAG: Permanent implant?

DR. HOWE: In this case, it was not permanent implant, but it could be for other cases, because if there isn't a written directive for that person, then you've got a medical event.

The other issue is, we're not -- medical events are not violations, and so a medical event is when -- is an event that NRC wants reported to us. They don't have to injure the patient. That's not our criteria. Our criteria is very, very low. It's almost a precursor type of thing. We get triggered at very low levels, so that we get the precursor events, but we also get the really high events. So we capture both of them. So in this case, the argument that this is already a violation isn't really relevant to the situation, because yes, it's a violation, but NRC wants these things reported to it up front so that if we have trends, we can then take some kind of effective action. And that would be to notify all licensees, not just the violation for the one licensee.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

DR. NAG: In the old days, there was something called reporting criteria and misadministration or medical event. In that case,

there's a difference between the two, and it would probably make sense to make not having a written directive a reportable event, but not a misadministration or medical event.

Although you are saying that medical event per se does not have to be harmful to the patient, I agree with that. But the moment you have a medical event in a hospital, it leads to a tremendous amount of paperwork, tremendous amount of anxiety, reporting to the patient where even though you can tell them it's not harmful, the moment you have to report it to the patient separately and to the referring physician separately that there was a medical event, it creates a tremendous amount of anxiety and paperwork for all concerned, the hospital, the NRC, and everyone. Because any of those will then have to be investigated and so forth.

CHAIRMAN MALMUD: Dr. Howe.

DR. HOWE: I had forgotten, I also had a third point, and that was with regard to the pre-implantation. Okay? And the treatment site. Well, the treatment site right now is written in a very global manner, in which the authorized user gets to define the treatment site. Whether he uses your terms or uses some other terms, he gets to define it. So

the gold standard is the physician sets his own standard.

Your description of changing from the pre-implantation, what you're inferring is maybe a week or so before. In this case, pre-implantation is right up to the moment that you implant, so your latest computer diagram the day you're doing the implantation, two minutes before you put the needle in, 30 seconds before you put the needle in, is always pre-implantation, because we don't distinguish it being a week or some other time, just pre-implantation.

Have we had medical events where the physician has used our regulations to avoid having to report serious errors? And the answer is yes, and in permanent brachytherapy, and in prostate brachytherapy. We had two cases where the physician was going to implant, and I don't have the numbers in front of me, say 70 seeds. The seeds went into the bladder, the seeds were pulled out of the bladder in a timely manner so there was no dose to the wrong treatment site. The physician rewrote the permanent prostate brachytherapy to say the first fraction I wanted to give 30 seeds, and I will follow-up with a second fraction. The second fraction was never

followed up. There was an error.

In another case, the same thing happened, where recognizing that the patient hadn't left the surgery, the physician changed the number of seeds that they were going to give from a reasonable amount of seeds to a very low fraction of that. And neither one of those were medical events, because the physician changed the written directive prior to completion of the procedure. That's what we were trying to go for, the errors.

DR. NAG: I need to respond to that. This -- what you are referring to is not particularly for permanent brachytherapy only. You can do the same thing in your removable brachytherapy, and in removable brachytherapy you can write your directive and say well, I'm giving four implants instead of three, and so you could do the same thing, as well. And that would not be a medical event in removable brachytherapy, so why would that be a medical event in permanent brachytherapy?

But more important than that, whenever the word "pre-implantation" is written in here, the way it is interpreted by most people, and I would say including many of the NRC officials, the amount you write before you go to the OR. Before you go to the

OR, you say certain millicurie. That is the pre-implantation that most people refer to. And then when you went to the OR, you did your ultrasound, and you saw you need 45, that would be then considered a post-implantation, and you are not allowed to change your pre-implantation written directive. And, therefore, would be considered a medical event. So that's what we are trying to prevent, so the actual number that we should go by is the number that we are planning when we are doing the implant. We have put our seeds, we have looked at the dosimetry, because the dosimetry available almost instantaneously within a few seconds. We don't like it, so we need to put a few more seeds here, a few more seeds there, so the written directive from which you have to calculate your deviation is basically the written directive when the whole procedure is done, and the physician has certified that he has done a good implant. So you have to calculate the deviation from that point in time which is basically before the patient is leaving the operating room. This is what our definition is, not leaving the post-procedural area.

I know it's a very fine matter of debate, but it's -- we are trying to prevent frivolous medical events, basically.

CHAIRMAN MALMUD: Dr. Zelac has his hand raised, but I have a question for you, Dr. Nag. It wasn't clear to me, how would you deal with the issue that Dr. Howe just described in order to bring attention to the fact that there was a misadministration or a significant problem in treating the patient that she cited? How would you propose dealing with it?

DR. NAG: Well, in any other treatment, let's even forget permanent implant, in the removable implant, if you haven't given enough, what do you do? You say well, we can -- this is not a misadministration because we can give more. We find that the dose is not enough, so you put your needle in, and you find that with the needle that you have, you cannot give a good enough dose, you say all right, we are going to give a separate dose, and you change your administration to say instead of three plats in, four plats in. So I think this is something being done on-line by the physician as they are seeing it, and I think that is not a misadministration, because they are seeing it as they are going. And if they feel they cannot give the full dose -- let's say I'm doing an implant. In the middle of the implant, I find the tumor is much bigger, and I don't have enough

seeds with me. Then it is up to the judgment of the physician as to whether they should stop the implant at that point, or let implant completed and say needs an additional implant to do the job properly.

CHAIRMAN MALMUD: But my understanding, and perhaps I misheard, but I thought I heard Dr. Howe describe a situation in which the physician having made the error, said that the physician was satisfied with giving the smaller number, but would complete the dose with an additional number, which were never administered. Did I hear you correctly, Dr. Howe?

DR. HOWE: That's correct.

DR. NAG: Yes. So in that case -

DR. HOWE: And in the second case, they changed the number from a significant number - once again, I may not have the right number - 70 seeds down to 30 seeds, and said that's what I wanted to give. And it was because most of the seeds went into the bladder.

CHAIRMAN MALMUD: So how would you propose dealing with that with the proposed -- excuse me, Dr. Nag. How would your recommendation deal with a situation such as that?

DR. NAG: Then that situation is something that would be a problem for the hospital

administration, because you can rightly -- you can do an incorrect calculation and say I'm going to give 20 millicurie, when really I was doing that, I was going to give 40 millicurie, let's say. Some other physician said okay, I'm going to give 20 millicurie. He wrote it in the pre-implantation directive, 20 millicurie. He ended up giving 20 millicurie. That patient is not cured. He's going to have a number of those -- there's no regulation from NRC that can catch that. However, over a period of years, he's going to have a lot of recurrences, and he will be caught.

On the other hand, another physician is doing wrong planning and putting half the seed in the rectum, he's going to have -- like a fistula. He's going to have lawsuits on their hands, but he's correctly doing what he's saying he's prescribing. So this is not something I think you can solve by changing the way you are writing the prescription, because in the prescription he could put 20 millicurie, all the 20 millicurie would be in the prostate, and within the 2 cm of the prostate. Half of them may be in the rectum. They would still not be considered a medical event. So I think there are some methods that really no matter how you put in the regulation, you cannot rectify.

Whereas, the example you mentioned, your objective was to give so many, and your prescription, you said he modified to say two implantations, and a second implantation he's going to do to make up for it. If he didn't do that second implant, well, then it would be a medical event, because he didn't do it, because he had two accidents.

CHAIRMAN MALMUD: Perhaps not being a radiation oncologist, I'm asking some very naive questions. Excuse me.

DR. NAG: No, it's not naive. It's something we deal with every time, too.

CHAIRMAN MALMUD: Say that the patient was to have received 60 seeds as the calculated pre-treatment dose. And 30 of those seeds went into the bladder, and, therefore are going to be voided out with urine.

DR. NAG: Right.

CHAIRMAN MALMUD: Therefore, the patient had received 30, which was rewritten to be the correct dose by the physician who administered it in the example that Dr. Howe cited. The 30 that would be urinated out, what's their fate, how were they accounted for? What happens? Is there a recording of the fact that they were voided?

DR. NAG: They are recorded in the place where we say -- where we plat the radioactive source. We receive X number of millicurie of radioactive source, then we say Y went into the patient, and number Z was not used or returned back to the manufacturer.

CHAIRMAN MALMUD: Will they have been returned? When does the patient void these, the ones that are in the bladder?

DR. NAG: The ones in the bladder are voided -- there are two ways. One is immediately after the implant before the patient leaves the operating room, we do a cystoscopy, and if we see a lot of seeds in the bladder, usually we do see one or two. In my experience, I have seen one or two. We then pull that one or two seeds out, and then they are stored for decay. And at the end, we would write there are five seeds stored for decay, and 20 seeds or 80 seeds placed in the patient.

CHAIRMAN MALMUD: So that in the case cited, if 60 were prescribed as the total dose, 30 were theoretically in the bladder, and then voided and retrieved by cystoscopy while the patient was still in the suite, there would be a disconnect; namely, that the dose was to have been X rads, or whatever, and the

number of seeds retrieved is one-half of what that would have been.

DR. NAG: Right.

CHAIRMAN MALMUD: But now the dose has been rewritten to be what the patient received retrospectively after having realized that 30 went into the bladder, and no more therapy is being offered. How would that come to the attention of the hospital itself? Is each of these cases reviewed individually?

DR. NAG: Well, when you do quality assurance, one of the things we do in quality assurance is to say what doses are being given to patients. Same thing in other kinds of implants. I mean, if you -- let's pick out a permanent implant. If we did a removable HDR patient, and you're consistently giving your patient half the dose that the rest of the country is giving, it is not a misadministration, because that's what you wanted to give, but it is below what the recommended, or the standard dose that's been given by the rest of the country. You had something. Right?

CHAIRMAN MALMUD: I understand your explanation. I'm sorry, who was going to raise a question? Please.

DR. WELSH: I was just going to comment on -- Jim Welsh, commenting on the question, as well. In this particular case Dr. Howe brings up, if a number of seeds were placed into the bladder, by the proposed new definition, these would be outside the PTV. Twenty percent would be outside the PTV, and, therefore, it would be potentially categorizable as a medical event. And the reason why this might be is that the PTV, or the bladder, rather, is a critical organ outside of the expansion that would include the PTV, as Dr. Nag's illustration clearly demonstrated.

Therefore, if there's an under-dose to the prostate because X number of seeds have wound up in the bladder, you would recognize that, too, because the normal dose is 145 to 150 gray. If you wind up putting 20 seeds in the bladder, whether they're urinated out, extracted out through cystoscopy, or remain embedded within the bladder wall, it's a medical event because they're outside the PTV. And it's also an under-dosing of the prostate, because instead of the 145 gray, you might be getting half that, and there would be a lot of explaining to do on that account alone.

DR. SULELMAN: So who would pick that up, sir?

CHAIRMAN MALMUD: Dr. Sulelman asks who would pick that up.

DR. SULELMAN: Yes. Let me regress just a little bit more. You've got a tumor. You want to deliver how many gray, 145 to 150? That's the target calculation. You then back -- then you say I need so many seeds of so much activity to deliver that target -- to deliver the dose there. I mean, that's the thinking that's got to go away before you even start. So then you go in, this is the practice of medicine. You've got a certain uncertainty, you put it in there. And for some reason either the seeds migrate, you don't deliver the -- the tumor is bigger. You finish the procedure. You realize that you're not going to deliver 150 gray. You realize with the amount of seeds you've delivered you've placed, some of whom are now outside the target area, and maybe elsewhere, you really have to go through a recalculation of what the actual absorbed dose is to both the tumor and whatever. At that point, you're just -- the procedure isn't completed as far as I would be concerned, because you do a reassessment, and then you say we need to go back in and deliver more dose. We need -- you don't just say finished, that's it. This is what we delivered. We gave 100 gray.

DR. NAG: I wish to correct you there. Actually, that process is going on even before that. When you are putting your needle and you start putting your seeds, you are recalculating as the seeds are going in. You don't wait until you finished everything, and then recalculate.

DR. SULELMAN: You can actually do that?

DR. NAG: Yes. This is what the on-line -

DR. SULELMAN: Software.

DR. NAG: Yes. That is what the real time implantation is, that we are at that thing as we are going, so if we put the needle in and we find it different from the pre-plan, so that's one area where you're adapting. Halfway through the implant, if we see that one area is getting too much, one area is getting too little, we replan -- because all of these are now almost instantaneous.

DR. SULELMAN: So you're doing real time dosimetry.

DR. NAG: This is all real time, yes.

DR. SULELMAN: In a manner of speaking.

DR. NAG: Right. And as you're putting the seed in, the computer is constantly updating the dosimetry. Actually, I have a paper which is the

ABA's recommendation on real time planning. I think I had given it in one of the place here, but I think I have given it in the -- the reference to that is given in the report, not in the slide. But that's the basis, that you're constantly updating your dosimetry as you're placing, and, therefore, correcting.

DR. SULELMAN: That's what you do.

DR. NAG: No. That's what I -- a few of us started doing five to ten years ago. Now, more than half the people are doing it by the real time. So the proportion of people -

DR. SULELMAN: Well, then how does Dr. Howe's scenario happen then?

DR. WELSH: I would find that -- this is Jim Welsh. I'd find it less and less likely to happen. Again, I personally know of no one who is using the old pre-implant dosimetry any more. And in my career, I did it once, and once you have had a taste of real time intraoperative dosimetry, you can't go back to that approach any longer. So I don't think that too many people are going to be using the pre-planning approach any longer.

DR. NAG: There's still a lot of people doing pre-plan, but the proportion keeps on changing. And when the rules were promulgated, the basis of

that was in 2002, a large proportion was doing it pre-plan, small proportion was doing it real time. Although, the report I was in was 2002. But now, that ratio is changing, more people are doing real time, less people are doing pre-plan.

CHAIRMAN MALMUD: I see a hand of NRC staff. Is that right?

MS. BHALLA: Yes.

CHAIRMAN MALMUD: Could you come to the microphone, please.

MS. BHALLA: Sure.

CHAIRMAN MALMUD: Thank you.

MS. BHALLA: Yes. Dr. Malmud and the Committee, my name is Neelham Bhalla, and I'm in the Rulemaking branch of the Division of Rulemaking and Intergovernmental Liaison. So, anyway, we have done this proposed rule, and it started under my -- as my project. But then with other competing projects going on, my colleague, who is here, Ed Lord, he finished this proposed rule.

The whole basis of this proposed rule came from what ACMUI had given to us maybe about three or four years ago, very nicely written paper titled something like the Guiding Principles for Permanent Brachytherapy Implant, and then we -- Dr. Zelac is

here, and this was taken to the Commission, as this is what the ACMUI has been advising us to do. And their problems with the brachy implants specifically, I think the concentration had been for prostate implants, because that has been -- that's where most of these procedures are being done.

So we did the proposed rule. Basically, the working group worked very hard, and there were all these parameters given to us in terms of three centimeters from the target volume, in terms of -- there were these specifics. And that's what we based -- the whole proposed rule is based on.

Two things I would like to go into a detail a little bit about this. So this concept that now Dr. Nag is proposing, and about talking the real time implantation, perhaps it's happening now, but at the same time, there are institutions out there which are still using the old methodology. So when we are doing the regulations, they pretty cover a broader range, so that we are covering people who are on the cutting edge of the practice, as well as those who are still using the old methodologies. So that would be one of our reasons to really say how we have done it, what we have done it. Okay? So that's one.

And two is, I would like to know from Dr.

Nag the difference between the source strength, as opposed to activity, because, to me, pretty much activity is a multiplication of source strength times the number of sources. So these are my two questions, and I would like to have an answer.

DR. NAG: Yes. The first thing, I was a member of that Subcommittee of the ACMUI that had made all the recommendations based on which the NRC recommendation was made. And that is why the first thing I said was had the NRC came back to us first, and said these are the recommendations you made. Based on your recommendations, these are how we are formulating the rules. Some of these things would have been modified at that stage. That's one.

Secondly, in terms of the difference between activity and source strength -- we have gone over many times, so I would like Dr. Thomadsen, who is an expert on this, to clarify.

CHAIRMAN MALMUD: Please do, Dr. Thomadsen.

DR. THOMADSEN: The source strength is a term to express the air kerma strength for the sources. This is a measured quantity for the sources. Activity is ambiguous, first, because it's not clear what is meant by the activity, since it probably is

not the activity that's contained in the sources, because there's no way to really know that.

DR. NAG: Apparent activity.

DR. THOMADSEN: What's that?

DR. NAG: Apparent activity. There's a difference between apparent activity and real activity.

DR. THOMADSEN: Right. The other option is it may be apparent activity, as opposed to what activity is contained in the source. The apparent activity is taking the air kerma strength from the source, which you can measure, dividing it by the exposure rate constant, or air kerma strength's constant for a naked point source of the same radionuclide. And so, the apparent activity is a derivative calculated value that has no real bearing on activity as we think of it, how much activity is in the source. So the air kerma strength, or the source strength as it would be termed, is a much more direct and appropriate quantity for use, if you're trying to be precise about the strength of the source.

CHAIRMAN MALMUD: Thank you, Dr. Thomadsen.

DR. FISHER: However, when you purchase seeds, you purchase seeds in units of activity,

millicurie, becquerel. You don't purchase these seeds in terms of air kerma strength.

DR. NAG: No, you can do it both ways. You can either specify -

DR. FISHER: I'm not quite finished. Both units are typically specified. The air kerma strength is the unit used in treatment plan in software, but typically you look at seeds, you purchase seeds in terms of their unit activity in millicurie or becquerel, so I'm not sure that I agree with the statement that you made, that we can only specify this in terms of source strength or source activity. I'm not sure I agree with that yet.

I think that the regulations can just as well be written in terms of a seed activity, or a total seed activity for a given patient treatment.

CHAIRMAN MALMUD: Thank you, Dr. Fisher. Dr. Thomadsen, you were going to say something.

DR. THOMADSEN: I was going to say that increasingly, the orders for brachytherapy sources are in terms of source strength, as opposed to activity because all the treatment planning softwares in terms of that, the base for the dosimetry algorithm, the TG43 is in terms of source strength. The AAPM and the AVS have both recommended that the term activity not

be used in brachytherapy, that source strength is used, so the activity designations are decreasing as far as their use in ordering. The companies can handle orders in either. They maintain the ability to do either source strength or activity orders, but increasingly, the source strength is what's being used.

Also, the well chambers that are used in assaying the brachytherapy sources come with calibrations in terms of source strength, not in terms of activity, which the calibration labs do not provide.

CHAIRMAN MALMUD: Thank you, Dr. Thomadsen.

DR. NAG: I would like to add to that. From the American Brachytherapy Society, and from ASCO, we have given recommendations to the manufacturers to report and send the sources in source strength in air kerma. Some of them are lagging behind, but it is a tendency, and slowly changeovers have been made. And I think if the NRC also has source strength, that will push even more manufacturers to go towards source strength reporting, and that is the direction we want to go to, anyway. So I would strongly recommend putting source strength

there. If you put activity and source strength interchangeably, this changeover will not happen as quickly.

CHAIRMAN MALMUD: Dr. Sulelman.

DR. SULELMAN: I have a clarification. Are all of these seeds the same nuclide?

DR. NAG: No. We are talking about Iodine-125.

DR. SULELMAN: That's why you don't want activity, because depending on the nuclide -

DR. NAG: No.

DR. FISHER: If you're going to talk -- I'm sorry. This is Darrell Fisher. If you're going to speak in terms of units of millicuries, or becquerel, as you did in your discussion, then you're speaking in units of activity.

CHAIRMAN MALMUD: Debbie Gilley.

MS. GILLEY: Yes. I just have some questions about scope of practice. Do you not look at a CT or ultrasound prior to ordering the seeds to determine how many seeds you need, and the activity, or the source strength?

DR. WELSH: Sometimes, no. This is Jim Welsh. The answer is no.

MS. GILLEY: Oh, okay. So that's still -

how would you determine what you were going to need prior to the implant? This is a surgical procedure.

DR. NAG: Okay. Different centers do it a little differently. Most centers do it, do the order by the patient so that they would have more likely than not either a CT or a pre-implantation ultrasound to give some idea, not necessarily to place exactly on that many seeds, and they order a certain percentage more than that. So that is just to have in stock, that is not what they want to implant, so that's a big difference. We have in stock a certain number of seeds more than what we need. Then when we are doing our implant, and you are doing it real time, you have put your probe in, you have determined the volume, then you say well, I'm going to be starting to put X number from that.

MS. GILLEY: But you're at large medical institutions. What does the surgical centers do that do one or two implants every week? I mean, I have a lot of out-patient surgical centers in my state, so what is the standard of practice?

DR. NAG: They usually will order about 10, 15 percent more than what they think they will. And then when they are doing the implant, if it is 10 percent larger, they have those seeds, because

otherwise they will under-dose.

MS. GILLEY: So I suggest to you that there is already some pretreatment planning as far as a written directive goes at the time you order the seeds.

DR. NAG: It is not really a pre-implant planning, because what they do is they use a normal gram that X volume will require about Y number, or Y source strength to give approximately so much of dose. It is a very rudimentary planning, it's not really a treatment planning.

CHAIRMAN MALMUD: May I just pause for a moment. It seems to me that what we're looking at is a technique which is in transition from a -- you had given us a superb presentation, I believe it was you, several years ago about prostate therapy with photos and so on, which I remember vividly. I think every male in the room remembers it vividly.

(Laughter.)

CHAIRMAN MALMUD: So we're going through a transition in which the pre-implantation therapy planning with ultrasound pre-therapy is now fading, and in its place is coming real time CT implantation therapy. Is that correct?

DR. NAG: The ratio is changing.

CHAIRMAN MALMUD: But it is transitioning.

DR. NAG: It is, yes.

CHAIRMAN MALMUD: And so some patients -- after all, the patients are not knowledgeable about this, some of us are not knowledgeable, are being treated in departments in which they use ultrasound pre-implantation planning, and others are going to departments where they're using real time CT therapy.

DR. NAG: No, real time ultrasound planning.

CHAIRMAN MALMUD: Real time ultrasound planning.

DR. NAG: A few centers are doing real time MRI planning.

CHAIRMAN MALMUD: All right. So now we have three types of therapy, real time MRI, real time ultrasound, and real time -- and pre-treatment ultrasound.

DR. NAG: And also a few centers are doing now real time CT. So, basically, real time imaging based planning. That is the whole criteria, real time imaging based, whatever imaging method you want to use.

CHAIRMAN MALMUD: The question arises, this having been brought to our attention by you and

by Dr. Howe, how do we, as a responsible consulting committee, protect the patient who is being treated in a therapy unit which uses pre-implantation ultrasound to base the therapy dosimetry, winds up in the hands of a therapist who has accidentally delivered half of the dose into the urinary bladder, which will be excreted promptly, and then does not follow through. Is that simply that would be picked up in the hospital's routine review of radiation oncology, or is this something that the hospital would miss, and the NRC should be concerned about, because this is technically a misadministration, if only half the dose was delivered, and the rest of the dose was not delivered?

DR. NAG: Well, if he is doing a pre-implantation technique, then he's not using the real time method, then he would have been writing the dose before he went, because he's doing it pre-implant. That would already be in there, how many millicurie he wanted to place.

CHAIRMAN MALMUD: But he changed his dose. In the example cited by Dr. Howe, the therapist, I don't know if it was a male or female, changed the dose. Therefore, how would this be picked up, and how would that patient be protected? Would that patient

be protected under the practice of medicine guidelines, with a review within the hospital, or is the only way that that would be flagged, through the NRC mechanism? That's my question.

DR. NAG: Right. But the problem with trying to flag -- you are trying to use an inappropriate method to do it, because then you are going to be putting -- to try to get that one person who tried to deviate the rule, you are now going to be getting say 100 good implants, because they are now considered a medical event.

CHAIRMAN MALMUD: I understand. But if I'm that one patient who naively is in the hands of that one therapist, and has received an inadequate dose for my prostate cancer, it is a critically important issue to me. And having been brought before the NRC, if it hadn't come before the NRC, it wouldn't have been an issue to the NRC, but having been brought to the NRC, can we turn our backs on this for fear of additional paperwork, which we all are generally opposed to, anyway, and abandon that patient? That's the question. It's a moral question that is raised. We're not a moral group, we're a legal group, but we're still moral human beings. What do we do about that patient, having been brought to our attention?

Can it be dealt with? And I ask you, I ask this of the radiation therapists, and the radiation therapy physicists, is there a mechanism already existent in your hospitals, and in out-patient therapy units that will address this issue on behalf of that patient, or is this something that falls to the NRC because there is no current method to deal with that issue? Ralph.

MR. LIETO: Two points. One, the issue about pre-implantation seems to be driving this, and that's why the Subcommittee recommended that that be dropped. The recommendation that's in the body of the report, and I believe still in the regulation, is that the written -- that the medical event would be based on the source strength in the patient upon release. So that the authorized user would have the ability that after implanting, based on their judgment, if they had to add or subtract number of seeds from their pre-implantation directive, or planning, that that would be the final determination of what the dose was to the patient. Okay? So it's going to be the point upon release from the recovery room, or post-procedural room, I forget the terms that's used. That's what would be determining whether the written directive was violated or not.

The issue about who finds this, the

written -- violations or medical events are self-identified events. It's extremely rare, I don't know of any right off the top of my head, but maybe it does occur, where the NRC comes in and looks at the treatment plans, and compares this written directive versus the pre-implantation treatment plan, pulls patient records, and so forth. They may spot check a patient record, but in terms of the medical event reporting, it's a self-identifying process, and so it's really the licensee who goes back, looks at these administrations, and identifies the events. And if they're outside the written -- outside the medical event reporting criteria, reports that to the NRC. So that's, to answer your question, is it the NRC that's identifying this, or is the -- it's the licensee that's actually identifying the events upon review.

CHAIRMAN MALMUD: So it is the licensee who identifies it. And, Dr. Howe, was it the licensee who identified this problem to the NRC?

DR. HOWE: The physician that changed the written directive identified it but I would also say that NRC in its inspection program, does identify written medical events that the licensee had not identified in the past.

CHAIRMAN MALMUD: So in this case, the

physician himself identified the problem.

DR. HOWE: And he changed the written directive so he would not have a medical event.

DR. NAG: But he correct it by doing a second implant.

DR. HOWE: But he didn't.

CHAIRMAN MALMUD: He didn't.

DR. NAG: Okay, but that the method -- I mean, the community rule for such an implant you need the grade. Now if you have now done your planning and said it's now six for a 30 minute, you are not going to get grade. You are falling below the medical standard, that would be reported by the medical standards.

CHAIRMAN MALMUD: So it's a medical practice issue. And this physician identified the fact that he only delivered one-half of the does, let's say that he intended.

DR. NAG: Right.

CHAIRMAN MALMUD: Now, that being the case, was the patient informed that the patient only received one half a dose? This is really a medical practice issue.

DR. SULELMAN: Is it?

DR. HOWE: Yes, and no.

DR. SULELMAN: Where is it stated in medical practice that the doses got -- well, here's the standard that you flag the person at.

DR. NAG: Most of the standards that are developed are written by the ABS and most of them were primarily authored either by one of the committee members or one of the principal authors and we do give those guidelines, so those guidelines -- it's like any other medicine, you know, who many milligrams do you take when you have --

DR. SULELMAN: You know, I've been bragging on the therapy, on the radiation therapy, the brachytherapy community, big time to my colleagues in FDA, especially, because I think radiation -- radio-therapeutics right now are still in the dark ages relative to that of in terms of dosimetry but if somebody is supposed to get 150 gray and that patient winds up getting 110 or 120, forget the source strength and the activity, you want to know that the dose that was delivered to the tumor was what it should have been. How is that going to get flagged?

CHAIRMAN MALMUD: Dr. Welsh?

DR. SULELMAN: How is that going to get flagged?

CHAIRMAN MALMUD: How is it going to get

flagged?

DR. WELSH: As I was trying to say earlier, the routine standard recommendation is to do formal post-implant dosimetry and have that documented somewhere in the medical record.

DR. SULELMAN: I can't see any physician walking away with an incomplete dose. I mean, that would bother me immensely. I mean, I would think that -- now, maybe the procedure wound up not giving a complete dose, therefore, the procedure -- the total treatment is not finished. They've got to go back and do it right.

DR. WELSH: There are formal recommendations made by our society, the American Brachytherapy Society, for example, that state that post-implant dosimetry should be done and it should be documented in the chart that, for example, if the dose prescribed was 135 gray, what did the prostate actually receive. This way you can get some feedback on what to tell your patient in terms of prognosis, risk of side effects, based on the quality of that implant using parameters such as the D90 et cetera which are normally used.

And this is, in my opinion, standard of care and as mentioned, something that should be done

so that an implant can be judged on the quality, how complete was the job really achieved. So, yes, the answer is that there is a procedure that gives post-implant dosimetry to all prostate implants as an example.

CHAIRMAN MALMUD: Dr. Eggli?

DR. EGGLI? I think we're way down in the weeds and we need to bring it up to a higher level for just a second. The regulatory process will never keep pace with changes in medicine. Regulations have to be written thoughtfully to allow changes that occur in the practice of medicine. And we're assessing here harm versus good done. And our goal is to prevent harm, although there are some -- there is no way to prevent all harm, because no regulation can be written such that someone can't sneak by and create harm undetected. But if the community perceives the regulation as oppressive and stays away from a therapy which would benefit patients, then harm has been done and there has to be a balance in the overall risk versus benefit.

If the bad actors are few and far between and thousands and thousands of patients don't get leading edge therapy because the regulation discourages physicians from providing that therapy and

I can tell you having to call the patient and tell them that a medical event occurred when a perfectly good therapy happened, will, in fact, discourage physicians from engaging in those therapies because it puts them at medical/legal risk that they are unwilling and rightfully unwilling to endure.

So we need to look at the balance of good versus harm and we are concentrating on a few outliers who create harm and potentially throwing out the baby with the bath water and allowing state of the art treatments to be delayed in their adoption simply because we want to catch everyone who does harm, which will never happen.

CHAIRMAN MALMUD: Dr. Welsh?

DR. WELSH: Yes, I would like to reiterate Dr. Eggli's sentiment about our big picture here. The subcommittee, the committee here and the staff should be reminded that the primary purpose of our subcommittee was to focus on the definition of treatment site and what constitutes a medical event. And that is relevant with Dr. Nag's wording and suggestions. It is relevant and works for whether we use pre-implantation approaches or real time intra-operative methods.

The administration of radio-isotope

material without a written directive constituting a medical event was considered a less important subject and was thrown in here at the very last slide as a sort of footnote. And it seems like we've focused too much on that aspect and perhaps that is worthy of a complete separate discussion and topic, but I would like to get back to the important point that Dr. Nag brought up, which was the definition of the treatment site and what constitutes a medical event because that was really the core of our subcommittee's goal and this last aspect about whether administration without a written directive would constitute a medical event was really a footnote in all of this.

CHAIRMAN MALMUD: Dr. --

DR. VETTER: I just wanted to point out there are members of the public who have been waiting some time to comment.

CHAIRMAN MALMUD: All right. Hello, please introduce yourself.

MR. LOHR: Hi, I'm Ed Lohr. I'm with the NRC rulemaking and I have this rulemaking, if you will, I'm the project manager. What I want to point out is a document that was sent to the NRC by your committee and signed by you, sir, Dr. Malmud, that makes a recommendation to the NRC and I'm quoting

here. It says, "Implants in which more than 20 percent of the total source strength documented in the pre-implantation written directive is implanted in tissue organs adjacent to the treatment site, should be classified as a medical event".

That is the official position from the committee. I just wanted that to be brought out because your subcommittee is now recommending reversing that. My only comment.

DR. NAG: Yes, and I was one of the principal ones who looked at the subcommittee report. There were two of us, Jeff Williamson and myself were the main ones. But that is why I'm saying some of the unintended consequences that came after we looked at that how exactly we should word it to that unintended consequences do not creep in.

CHAIRMAN MALMUD: I saw another hand. Ralph?

MR. LIETO: I was just going to say, Mr. Lohr's point is well-taken but the suggested change by the current subcommittee is also consistent with the approach that we've taking regarding the Y 90 microsphere brachytherapy device in that the total dose or activity administered is based on the administration before the patient leaves the post-

procedural room. So we're just recommending also to be consistent with approach that we've taken more recently.

CHAIRMAN MALMUD: Is there another hand? Dr. Zelac?

DR. ZELAC: I'm not exactly sure where to jump because there have been a number of things said that I would like to comment on. However, I'll try to keep it as specific as possible to the particular point that's being discussed now. And this is in the form of a question not a statement. As has been made clear, before a procedure is done, seeds have to be ordered and there is some expectation on the part of the therapist as to how many seeds are going to be required to treat this particular case, not the exact number but approximate number.

My question is, does the number of seeds which might be implanted differ by more than 20 percent from that expected number for implantation very often or not at all?

DR. NAG: I wouldn't say very often but I would say often enough. If you want like a percentage, I don't know, maybe 30, 40 percent we do defer quite a lot from what we thought we might need. So I can't give you an exact number but it happens

quite a lot, but what I'm saying is that the point from which you should judge the deviation should not be the point from the number of seeds that were ordered but from the number of seeds that we finally plan to put in.

If the tumor, for example, happens to be much less then, you know, we might lower the number or might lower source and still be justified. So it does have some relation but you cannot coordinate one with the other.

DR. ZELAC: Thank you.

CHAIRMAN MALMUD: That was your first question, Dr. Zelac. You said you had others.

DR. ZELAC: Not in the way of a question but just a statement I think might have some bearing here. The whole point of having written directives is to provide some reasonable assurance that what a physician intends is in fact, what's carried out. That's the whole point of it, otherwise, we don't need a written directive. And a medical event is supposed to be and indication that what the physician had planned wasn't carried out. It was outside of the scope of what the original plan had been.

And the point about that is that it's important essentially to identify these lapses in

procedures where the physician's directions were not carried out. That's the whole point of having medical events.

DR. NAG: And I agree with you completely, and your second part is also very important that, you know, that there was a deviation. Now, here the point is that my plan is to give -- There are two considerations I have. One is what dose I want to give and secondly, what number of source plan we need that it was that dose which is dependent on volume and many other things. So I have a certain plan before but when I go in and I see that it is somewhat different because of the shape and size, then I am, in real time, changing what I'm planning to give because that will -- that actually one is what I'm finally planning on the table based on what I see on the table.

So we adjust my deviation based on what I'm seeing on the table, not based on something that I have ordered. And sometimes I'll order 10, 20 percent, 30 percent, more if I'm not sure of what I'm planning to implant.

And then the second part of it, and here, and you can go back to the subcommittee report from four or five years ago, that there is a small

subparagraph in there that says that the NRC should note that implantation done at other sites, other than prostate, where the boundaries are not so well defined, and there has to be a leeway or words to that effect. So we did recognize even at that time that there are different organs that have to be implanted where the degree of number of seeds placed in the margin are different.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: Let me ask a follow-up question then. If you've made this determination, when you go into the OR based on the treatment planning system and the visualization system is there, that the number of seeds that you anticipate at that point in time needing to implant properly that patient differs significantly from what you had thought before, what would prevent you from simply issuing an oral written directive at that point, before you start the implantation, that says, "I expect to implant so much source strength or so much activity" and then deviations from that would constitute if outside the boundaries, a medical event?

DR. NAG: Yes, I think that would be coming a little closer to my actual intent because there are two or three places where I'm changing the

plan. One is when I'm in the OR and I'm doing my first planning of the site. Then I have some idea which maybe now quite different from the first, and then as you are doing an implant, remember the dynamic phenomena, the site is changing, where we are planning to put the seeds is changing.

So now if I'm seeing that there are areas of under dosage, I am having another one or two doses changes as I'm going. So at the beginning of the implant, the number or the plan that I have would be closer to the truth but still quite far from my initial plan but as I'm going closer and closer to the end of the implant, I'm getting closer to what my actual number should be.

CHAIRMAN MALMUD: Thank you, Dr. Nag. Dr. Zelac?

DR. ZELAC: I could ask then a follow-up question; if you were making a comparison to what was actually implanted to what you anticipated needing at the beginning of the procedure, not the prior, not a pre-implant, but at the beginning, would you have variations of more than 20 percent often or not at all?

DR. NAG: Okay, a very good question. The feeling is that it's going to be less but I would not

say it would never happen but I would say it would happen less often.

CHAIRMAN MALMUD: We have Dr. Eggli.

DR. EGGLI: I think an interesting comment is Ron's last one, Dr. Zelac's last comment on the purpose of a written directive. In many cases therapies are provided by a physician other than -- or a person other than the physician actually ordering it. It's true in the nuclear medicine therapies. It's true with a linear accelerator where a therapist delivers the therapy that the physician ordered. The intent of the written directive, you said, and I tried to quote you as close as I can, is to make sure that the patient is given what the physician intended.

In the case of brachytherapy, here, it is in fact, that same physician who is administering that dose and their intention is changing dynamically over the course of the procedure are they are more reliably able to determine the volume to be treated.

Somehow that concept of the written directive then, needs to encompass the dynamic nature of treatment planning in brachytherapy so that it accommodates the real time treatment planning that occurs that says that I don't need as many seeds as I thought, and maybe 30 percent less or I'm going to

need 40 percent more seeds than I thought because in the real time planning process, as I'm here in the OR, I see that and it turns out I have seeds in stock and I can accommodate it.

But there's -- so I see a difference between -- or a subtlety in the concept of the intent of the written directive in a therapy where, in fact, the physician writing the therapy is also administering the therapy. I see the issue. I understand the issue of wanting to make sure that you can't just cover up an error by changing the directive, but you need to be able -- the concept of the written directive has to be dynamic enough to encompass these dynamic changes that occur over the process of treatment.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. I think next was, yes, Dr. Sulelman.

DR. SULELMAN: I've gone 360 degrees on this. The real true clinical end point or surrogate end point would be the dose in gray and the fact that the activity or source strength or whatever may vary is -- it's a quality control thing. It's an intermediary thing and trying to lock in on that as a metric is causing problems and it's causing unnecessary, you know, record keeping.

Ultimately, you know what the dose should be, what the absorbed dose ought to be and when it's all finished, when it's all finished, you need to come up with a final number and show that to total delivered dose was pretty close to what you had planned in the first place. And you can dispense with all the intermediary stuff because that's up to the skill of the physician and all the support he's getting or she's getting.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: The main reason why -- what we are expecting now at the second part but the first part, the main reason why we had to change the way we could have interactive for permanent implants is that as opposed to a removable implant, in a permanent implant you cannot control the dose. You can control the source plant you're putting in but the user cannot control the dose because the dose is the dependent on what happened afterward, the where the seed will end up, where the seed moved afterwards and how the organ, for example, the prostate, expands or contracts after the implant because you're doing a post-operating implant dosimetry -- that's what the reason --

DR. SULELMAN: That is real uncertainty due to --

DR. NAG: That was the reason why we wanted to change from a dose based prescription to a source like based prescription because that's what the -- one of the major reasons for the change. Now, when we make those change, some of these unintended consequences are creeping up because the major reason of the change was to change from a dose based perception which is controllable to a source plan based prescription which we can control.

CHAIRMAN MALMUD: Mr. Lieto and then Dr. Howe.

MR. LIETO: It seems to me the issue, if I can just attempt to boil this down, is does the committee accept the subcommittee's position that the medical event should be based on the activity implanted --

DR. NAG: Source strength.

MR. LIETO: -- source strength implanted at -- when the patient is released from the recovery room or is the medical event going to be based on the pre-implantation activity source strength? It seems we're going back and forth about this because that's what was currently written in the proposed rules and gets to most of the points, I think, that Dr. Zelac is driving at.

And I think we need to, you know, go from there.

CHAIRMAN MALMUD: What is your recommendation in this subcommittee report? Just remind the committee what your recommendation is, which of the two options?

MR. LIETO: The option recommended is that the basis for the medical event should, quote from the report, "The basis of the medical event should be the total source strength implanted after administration but before the patient needs the post-treatment recovery area", end quote.

CHAIRMAN MALMUD: And that is the recommendation that this subcommittee of the ACMUI is making now in order to correct the unintended consequence of what a similar subcommittee of this committee made before; is that correct? Do you and Dr. Nag agree with what I just said?

DR. NAG: Yes, that and the definition of the treatment site because the two are somewhat related.

CHAIRMAN MALMUD: May we take that as a motion?

MR. LIETO: So moved.

DR. EGGLI: Second.

CHAIRMAN MALMUD: And it's been seconded. All in favor? Oh, discussion? Discussion, sorry.

MR. LIETO: Can anyone provide, if there is such a thing, a summary of the position of EBS or AAPM on this particular issue?

DR. NAG: Yes, EBS and AAPM have both made the recommendation in writing to the NRC which is available on the NRC website which AdLaw has which I have seen and they're exactly the same as this.

CHAIRMAN MALMUD: I assumed that because you last slide said that your presentation was with the approval of these groups.

DR. NAG: Right.

CHAIRMAN MALMUD: The input of these groups.

DR. NAG: And the one thing is, basically, the same, and I mean, AdLaw is a public document. If you can, you know -- if you can print out that portion of the letter --

MR. LOHR: If you will, sir, what he's referring to is the comments that are received on the proposed rule, they are public documents. They are available at the NRC website. They're also available at regulations.gov. I only have one hard copy and I have not reviewed them. I simply have them, nor has

the working group reviewed them or analyzed them in any manner. So I cannot say anything except that we have them here and they're available publicly.

DR. NAG: I have reviewed them. I can say that they are exactly the same.

CHAIRMAN MALMUD: So the committee, having heard that you have reviewed them, and that from your perspective, they are in agreement, we'll vote based upon your motion and your statement. All in favor. Any opposed? Three opposed, how many in favor again? One, two, three, four, five, six, seven, eight. Eight for, three opposed. Motion carries. Okay, now -- okay, go ahead, Dr. Thomadsen.

DR. THOMADSEN: I might ask if it might be useful for the NRC staff if there were a subcommittee to look at possible ways to help the staff evaluate whether there have been misadministrations based on this recommendation.

CHAIRMAN MALMUD: A retrospective study you mean?

DR. THOMADSEN: No, no, a prospective study so to speak based on these guidelines, the problem that you've brought up, how do you record misadministrations in some of these egregious cases? And it sounds like it may be helpful if we were to

think about that, too, not that I'm positive that a subcommittee could come up with recommendations, but at least they might be able to contemplate the issue and provide some guidance.

CHAIRMAN MALMUD: Someone from NRC wish to respond to Dr. Thomadsen's question?

DR. HOWE: Clearly those that people decided weren't medical events because they changed things and it never came to our attention, we're not going to be able to address but we do have a few cases where, two cases in particular where changes were made to avoid a medical event. And using what we consider to be kind of a loophole of before completion of the procedure to rewrite the written directive to something that wasn't intended in any way. It was to cover up -- not to cover up, but to essentially, not to have an error even though the error was there.

MR. LEWIS: I would suggest that maybe we have to let the working group on the rulemaking do their work to analyze the comments and we'll be in a more informed position of all the options and part of looking at the final rule language will be to determine any regulatory impacts that the new language might entail. And so I guess what I'm saying is we're not there yet. Thank you for the offer.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Yes. There are basically three major recommendations. In the last basic recommendation summary there are three major recommendations of the subcommittee and then the fourth one is basically more like a word thing about activity with the source plan and it's a recommendation but, you know, basically more nomenclature.

The fifth one about administration without working directive and regulation violation and not a medical event per se, is not a permanent implant specific recommendation. It needs to be something that can be solved for all type of brachytherapy and if that is postponed and not considered as part of this recommendation, that's fine with us. But the first three are specific for permanent brachytherapy and we would like those to be recommendations.

Now, if they are going to be delayed or if there are some -- what I would say is we would take a motion of each of these points separately and have a yes/no vote for each of this rather than a whole vote of the whole document.

CHAIRMAN MALMUD: So what you're saying is that what the committee has just voted on --

DR. NAG: Was the first part.

CHAIRMAN MALMUD: I beg your pardon?

DR. NAG: Was part one.

CHAIRMAN MALMUD: Were the three paragraphs that begin -- the three bullet points that begin with Paragraph 35.3045.

DR. NAG: No, what the committee voted just now was Part One which is that implantation should be deleted with pre-implantation with the new directive. We did not talk about treatment site and so forth. The whole thing was on Part One. What I'm saying is to make it clear, we should vote on each of those sub-parts separately.

DR. THOMADSEN: Clarification?

CHAIRMAN MALMUD: Dr. Thomadsen?

DR. THOMADSEN: I want to ask Mr. Lieto, I think you made the motion, what his motion actually was.

CHAIRMAN MALMUD: Ralph, you're being asked to re --

MR. LIETO: You mean the one we just voted on?

CHAIRMAN MALMUD: Yes.

DR. THOMADSEN: What was it that we approved? It would be nice to know.

MR. LIETO: It was one of the recommendations of the subcommittee was that the pre-implantation piece be -- or excuse me, the medical event should be based on the total source strength implanted after administration but before the patient is released from the post-treatment recovery.

DR. THOMADSEN: So your motion is --

MR. LIETO: Basically, it's removing the pre-implantation --

DR. THOMADSEN: -- you were intending to just move that first.

DR. NAG: Yes.

MR. LIETO: I'm sorry, just to move that what?

DR. THOMADSEN: The first recommendation.

CHAIRMAN MALMUD: Take a look at next to the last slide.

MR. LIETO: It was to get us off what I thought was the sort of the merry-go-round of the issues that we were discussing.

DR. NAG: What I'm suggesting are put those up on the board and therefore you can vote each of those -- that is why I had made them in bullet points. The last slide --

CHAIRMAN MALMUD: It's the last slide

before the roses and it's the first bullet point.

DR. THOMADSEN: I guess it really gets down to just asking the committee do they accept the subcommittee's report or they don't. I mean, that was what I thought your motion said.

CHAIRMAN MALMUD: Well, that's what I thought your motion was, too, that we accepted your report.

DR. NAG: But the way the motion was made, it was only that first paragraph.

MR. LIETO: Well, I will so move that the ACMUI accept the subcommittee's report as submitted in the ACMUI's packet.

CHAIRMAN MALMUD: That's a motion.

MR. LIETO: That's a motion.

DR. THOMADSEN: I second that motion also.

CHAIRMAN MALMUD: Seconded again. Is there discussion if this? Yes, Dr. Welsh?

DR. WELSH: I would be in favor of this with the exception of the second to last one where administrations without written directive be cited as regulation violation and are not medical events per se. I think that could dilute the overall message and that is such a controversial point which is different in spirit from the first three, which are very clear

and fully supported by ASTRO, ABS and ACRO that penultimate one was not discussed by ACRO, ASTRO and ABS and therefore, I would suggest excluding that particular paragraph.

CHAIRMAN MALMUD: Dr. Welsh, I will editorialize. I am extremely pleased that you have raised this point because I'm very concerned about the case example cited by Dr. Howe which would have escaped any kind of action by approving the fifth bullet point. Mr. Lieto?

MR. LIETO: I take exception with that. The example she giving would not be effected by this whatsoever. The issue that Dr. Howe has been raising is the fact that the individual changed the other written directive and then changed it afterwards based on their poor implantation procedure.

The point about not having a written directive applies to all written directives, not just brachytherapy, HDR. I mean, it applies to HDR, brachytherapy, radio-pharmaceutical therapies. And so it also is a part of the proposed rules on permanent implants. This subcommittee was directed to address the proposed rules as they were addressing the permanent implant -- permanent implant medical event definition. That's part of those proposed rules and

that's why it was commented on.

DR. SULELMAN: So you're saying that that's an absolute violation of the regulation. It shouldn't be factored in as a medical event.

MR. LIETO: Correct. I don't believe that it should be considered a medical event. It's a violation of the regulations already.

CHAIRMAN MALMUD: So they would still be flagged for this.

MR. LIETO: Absolutely.

CHAIRMAN MALMUD: Is that what you were going to say, Dr. Nag?

DR. NAG: No, what I was going to say is the first four points have been discussed by many scientific organizations including ASTRO, ACRO and ABS and therefore, that -- those four can be taken together. The fourth point about the administration without written directive applies to permanent implant as well as other types of implants. They are -- it's a slightly different issue, although it is linked to this issue but it's a slightly different issue. It has a much broader implication. It has not been discussed by the other scientific boards like the first four have been and therefore, if we need to make a yes or no vote, it could potentially have some

conflicts if you try to make a yes and no vote of all of them together. So I would prefer the first four points to be as block vote and then the fifth point to be a separate vote and, you know, the two can be -- both of them may be yes and yes or yes -- or no and no, but they should be voted separately.

CHAIRMAN MALMUD: I understand your point. Mr. Lieto?

MR. LIETO: Well, I've got to voice my strongest objection. This is not an ASTRO report. It's not an ABS report, okay. The fact that they supported it is terrific, but this is a report from the subcommittee of the ACMUI, okay, and if ASTRO has a problem with it, ABS has a problem with it, APM has a problem with it, or Society of Nuclear Medicine has a problem with it, then they can put their comments in and reject to that point if they so believe. I don't think they will but this was a report from the subcommittee of the ACMUI, not ASTRO, ABS or any other group and I think the fact that it wasn't -- you know, prescreened and approved by the other organizations, I don't think has any bearing on the subcommittee's report.

CHAIRMAN MALMUD: Thank you, Mr. Lieto. I interpreted Dr. Nag's comment to clarify his response

to my earlier question which was, did it have the approval of all and it turns out that the first bullet -- the first four bullet points had the approval of all but not the entire. That's how I understood your comment. It --

DR. NAG: Yes, right.

CHAIRMAN MALMUD: He was not rejecting his own motion. He was just clarifying his earlier response.

MR. LIETO: But I think the point that is being made is that that should be pulled off as being a part of where the report is -- the recommendations of the subcommittee is addressed is the fact that these other agencies or other organizations didn't approve it and I have an objection to that.

DR. NAG: Not didn't approve. They didn't discuss it.

CHAIRMAN MALMUD: They didn't discuss it.

DR. NAG: They did not discuss that last one.

CHAIRMAN MALMUD: They only discussed the first four bullets.

DR. NAG: Right, because that was not on the agenda.

CHAIRMAN MALMUD: Thank you for clarifying

that. Dr. Zelac, you had your hand up.

DR. ZELAC: Just so that perhaps that I'm perfectly clear before a vote is actually taken, with the two events that Dr. Howe described under current regulations the ones that are on the books right now, those were not medical events. Under what is out as the proposed rule, they would be medical events. Under what is being proposed now by the advisory committee's subcommittee, it would not be medical events. Am I correct?

DR. NAG: I don't --

MR. LIETO: I don't -- my opinion, they would be because --

DR. ZELAC: But if the physician has the opportunity to essentially change the written directive, up until the point where the patient is released, what would preclude exactly what these physicians did?

MR. LIETO: It would get right back, I think, to what Dr. Eggli I think stated before, that's the practice of medicine. I mean, if that is his clinical call that he needs to change that --

DR. SULELMAN: It's modifying it because of the way the procedure went because of the physiology and whatever. That's just -- I would

consider that a modification. If that had lied, if they had adulterated -- if they messed -- if they did something, record something that was not correct, that's -- that crosses over into an ethical situation. I mean, modifying because a car is going off on the shoulder and you bring it on is one thing, but if you've run over somebody, if you change the numbers because you screwed up --

CHAIRMAN MALMUD: Well, may I ask a question? In nuclear medicine, if we prescribe 100 millicuries of I-131 for thyroid cancer, and it comes in two capsules, and the patients is given the capsules to swallow. Swallows one capsule and then the bottle is put back into the pig and they don't realize the patient didn't get the whole dose. That's considered a misadministration.

Why is it not a misadministration if a whole dose of radiation therapy, which was ordered by the radiation therapist but under the standard practice of his or her therapy, gets into the wrong organ, why is that not administration, particularly when there is mendacity with telling the patient that the patient didn't get what the patient was supposed to get and is not going to get it? Mr. Lieto?

MR. LIETO: In your example, if the

patient had been discharged and left the facility, it would be a medical event. But if the tech went back, assayed the vial, found that the other capsule was still in there, went back and gave the patient that other capsule before they left, it would not be a medical event.

CHAIRMAN MALMUD: That's correct.

MR. LIETO: And that's what we're saying in this example, in this scenario here, with the seeds. It's the same thing. Once they leave the licensee's control from the treatment area, then that's when the medical event is determined.

CHAIRMAN MALMUD: That's not the analogous situation. The one that Dr. Howe described was one in which the dose -- I'll give the nuclear medicine. I ordered 100 millicuries. We gave the patient 50 by mistake. The other 50 went back to the pharmacy in a pig because it was thought that the patient had swallowed both capsules and we changed the order to say 50 millicuries instead of 100. Thank you and goodbye. That's the equivalent of what she described in the patient who was to have gotten seeds into the prostate for cancer.

And I wonder why is one situation treated differently from the other? Dr. Nag?

DR. NAG: The reason for that is for the implantation procedure is a dynamic procedure, so in your case, you are not going to change whether the patient is going to need 50 millicuries or 100 millicuries, depending on when he's swallowing and every minute when he's swallowing is it changing something? Well in our case, it means changing minute by minute. So it is a dynamic procedure and we want to be able to be able to have the written directive in such a way that it understands or it takes into account that brachytherapy is a dynamic procedure and not aesthetic procedure.

CHAIRMAN MALMUD: Oh, I'm not debating that. I'm not debating that. I'm in favor of what you want. I'm still questioning -- I'm still concerned about this patient who thought he was getting fully treated for his prostate cancer, got a fraction of the dose and then was told everything is fine, and the doctor changed the dose that he had ordered previously and now there's no follow-up. That's of concern to me and I wonder how will it be picked up?

Will it be picked up in a tumor committee, will it be picked up in the ordinary process of medical care and therefore, it's strictly and issue of

medical practice or is the fact that the NRC has this oversight ability, the only means that it will be picked up and dealt with? It has to be dealt with. This patient can't be allowed to think that he was adequately treated when the physician himself who planned the therapy knows he didn't treat the patient adequately. That's my concern. Dr. Welsh?

DR. WELSH: I might argue that in Dr. Howe's presented case that using Dr. Nag's proposed nomenclature this would be classified as a medical event and the reason is that if 20 seeds wound up in the bladder, 20 seeds are outside the PTV, because by Dr. Nag's proposed definitions, critical organs are not part of the PTV. Therefore, if you have a whole slew of seeds in the rectum, a whole slew of seeds in the bladder, regardless of whether they are subsequently removed, urinated out, or remain in place, it is outside of the PTV and potentially an administration or medical event.

So I think that it would satisfy the concern for the patient and when you do the post-implant dosimetry, as a backup check, it would be verified that these seeds are not in the position they're supposed to be.

DR. HOWE: Could I make a follow-up --

DR. WELSH: I do think we need to have some checks and balances though.

DR. HOWE: Could I make a follow-up to that comment?

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: If you're permitted to change the written directive before the patient leaves, in this particular case they would have just said, "Oh, I intended to give 30 to the -- put 30 in the bladder and take them out". There's nothing that holds you to the treatment site. You can change the treatment site, too. As long as you can change the written directive, you can change any element of the written directive no matter how strange it appears, because in these cases, we're not really talking about you, Dr. Nag, or you, Dr. Welsh. We're talking about somebody that doesn't want to be held accountable for a medical event and they're using the regulation to not be held accountable for a medical event.

In this particular case, subsequent patients found by NRC had lots of medical events.

DR. NAG: And let me -- yes, how are you going to write a recommendation for someone who is incompetent? He has determined that he wants to implant again in a prostate and in his calculation,

he's totally wrong and he calculated he needs only 10 millicuries when you need 100 millicuries. He implants that 10 millicuries, and then he has prescribed 10 millicuries, pre-implantation, post-implantation was 10 millicuries. That patient is bound to fail. That definitely is not a medical event because he said he wanted 10 millicuries.

So how is that different from what this unscrupulous physician is to what is an incompetent physician, the other is an unscrupulous physician. How are you going to catch them?

CHAIRMAN MALMUD: I would ask you that question since you are the radio-therapist and I am not.

DR. NAG: And the way we -- the way we catch them is by the medical board. If a patient -- if a physician is having a large number of recurrences, we -- you know, we do review the outcome results. That is an incompetent physician. If the patient is having a rectal morbidity and having a fistula, most likely he will end up with a lawsuit. So you know, I think you know, you cannot catch everything just by the definition of regulation.

So the way we are trying to do it is to catch all the usual ones, have a definition that will

catch the bad actor, at the same time, it's not going to catch dose-setting post-implant because it's like a sieve, how small do you make the sieve without letting everything out and yet getting the good ones.

CHAIRMAN MALMUD: Thank you. So you say that the medical board does review the outcomes of the therapies?

DR. NAG: Of the patient and also when you're having the dosimetry, it consistently if someone is giving, you know, half of what the ABS has recommended, you know, they are going to be -- they are going to be caught. That's why we have peer reviews and peer reviews, every -- not every implant, every treatment plan is peer reviewed by your peers and --

CHAIRMAN MALMUD: No.

DR. NAG: You're supposed to have a peer review. That's what the charts are meant for.

DR. THOMADSEN: But it doesn't have to be every case. This is Thomadsen. There's no specification of a percentage of the cases. So you can't say every implant gets reviewed. They don't.

MR. LEWIS: Dr. Malmud, if I could -- this, to me brings us back almost full circle, to a point that Dr. Zelac made that what's important to us

is at some point in time even in a dynamic procedure, a physician makes a decision that, "This is what I intend to have".

DR. NAG: Yes.

MR. LEWIS: And the medical event then becomes locked in, is contingent upon that decision and if the decision is made after the fact, then what you intend to happen becomes a variable, and you can out of medical events. The current regulation and the as proposed regulation will close that loop but maybe not in a way that appreciates the dynamic procedure.

The proposal by the subcommittee, I think you're hearing a lot of concern from the NRC staff, goes too far in the other direction, that you can redefine after the fact and we have a very specific example that's an ongoing event right now, that illustrates that that regulation could be abused. And so maybe I'm stating the obvious but what we need, I guess, is a consensus point where medical event is locked in, variation from what was intended at some point and as we said, it could be right up until the procedure is being done. It doesn't have to be, you know, days or weeks in advance but we do need a firm decision as regulated.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Yes, we do have our intention. You know, our intention is those in the region of 120 gray, let's say. So that is a dose that is not to be measured by that plus or minus 20 percent but an intention of approximately what we are trying to achieve. And then we have a number of millicuries that we start with to hopefully get that dose and then we are changing from that, so if there's a huge deviation from our initial intended dose in line with -- you know, if you had what is in your case, that patient obviously was less than 50 percent of the intended dose. So maybe we can have both, that you know, that there would be some relation to the dose that was intended and then -- but the 20 percent would be plus, minus, you know, final -- you know final source plan that you wanted to come up with.

So, you know, someone -- I'm saying that well, you know, I wanted only you know -- because in your situation he would end up -- instead of 140, he will end up with 70 gray or somewhere in that range. So we may have to do something like that if you want -- you had some point with that, or --

CHAIRMAN MALMUD: Who had a comment, Dr. Welsh?

I did. There was -- I don't remember who brought it

up here, but there was a suggestion I think, if I recall correctly, or a question about what would we do or what do we think about an oral written directive put down at the time of the real time dosimetry. If we were to accept that proposed solution, whoever, it still could be consistent with Dr. Nag's principles and what he has written down and it might satisfy the concerns of those who are wary of post-procedure written directive changes.

So whoever brought that question up, that point up, could you perhaps reiterate what you said before?

DR. ZELAC: I did. The current regulation having to do with written directives permits the physician to make changes when it's in the interest of the patient. It's basically a result of changes in the condition of the patient such that there can be a change in the written directive orally as long as it's put down in writing within 48 hours.

Now, if it were possible and I'm not saying it is under the current written directive regulations, to massage that a little bit to accommodate this situation so that you could essentially come up with a pre-implantation written directive, 10 seconds before you start your

implantation, and that may solve much of the problem associated with this.

DR. WELSH: So if I might reply then, it appears that that solution may be a viable solution with the understanding as Dr. Nag has pointed out, that intra-procedure, intra-operatively, there is a dynamic process wherein the volume is changing and you may want to make some subtle changes here and there but it might still be a viable solution that would be acceptable to all.

DR. ZELAC: Because again the criteria that we're looking at were changes from what is in the pre-implantation directive by more than 20 percent being a medical event. I mean, that's why I asked the question before if it's just before you start the procedure would you expect variations of more than 20 percent from that number in terms of the anticipated source strength to be implanted? And the answer I got was rarely.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Yes, but the suggestion you're making would not help to catch the really unscrupulous person because after the fact when he implanted and he implanted only 50 percent, he can then make a verbal written directive that I am now giving --

DR. SULELMAN: No, the current -- the definition of the written directive is that it must be created before the procedure begins.

DR. NAG: Right. But then it wouldn't allow intra-operative changes; whereas if you're allowing the written directive to be verbally changed, then you could verbally change it after and say 50 percent. So it doesn't solve that problem either.

DR. FISHER: No, that's not correct.

DR. NAG: Why?

CHAIRMAN MALMUD: Who is speaking? Dr. Fisher.

DR. FISHER: If you have a written directive that states the physician intent to achieve a certain outcome, and during that procedure you're making those adjustments that you need to make to achieve the original intent, then you're not violating that written directive.

DR. NAG: Let me -- with a dynamic procedure, your written directive before what you say you need 15 millicuries or 50 at normal strength.

DR. SULELMAN: See, but that's where the problem is because those are variables. The final dose is the one that's the more static, the more finite, the more targeted thing and so that -- you're

not going to mess that up often.

DR. NAG: You will, but that was the reason why we changed from those -- now, we are going back, and saying none of these things will occur. Because now you're going back to the old method of doing it dose-based rather than source-strength based and we said that source-strength based would not work because -- I mean, the dose-based doesn't work in brachytherapy because many of the things are not under the physician's control. So that's why we go back to a dose-based prescription.

DR. SULELMAN: I disagree.

CHAIRMAN MALMUD: There is disagreement from a number of the members. It's now 1:15. The cafeteria begins closing at 1:30. So in order for us to get some lunch, we'll have to interrupt this discussion if we may and then return to it. So what I suggest is that we meet back here at 2:00 o'clock. Is that okay? 2:00? And then if we have to we'll adjust the schedule later, because we have some people here for the next presentation who have a return flight and we'll -- so we'll come back to this. I apologize for the interruption but we do not control the cafeteria.

(Whereupon at 1:18 p.m. a luncheon recess was taken.)

CHAIRMAN MALMUD: Ladies and gentlemen, I'm going to change the order of the presentations today. Because our 2:45 p.m. schedule would delay the departure of those who have flown in just to discuss the Yttrium-90 with your indulgence we'll pick up the topic of Yttrium-90 Microsphere Licensing Guidance now and then come back to the subject we were discussing before.

I asked of Dr. Nag and he's agreeable with that. So that we'll move ahead on the next item which will be the Yttrium-90 Microsphere Licensing Guidance. But I think we need an AV person here. Do we have one?

He's there. I see him. Okay. Great. I didn't see you back there. Hi. Okay. So Dr. Salem will do the present and we'll skip a minute to get those slides in there because we have changed the order of things.

So the next item on the agenda is Yttrium-90 Microsphere Licensing Guidance. When we have completed that, we will then come back to a discussion of Permanent Implant Brachytherapy Rulemaking and then move on depending upon what the time allows. Dr. Zelac indicates that it may not be necessary for him to use the total time allowed for him. So we may be

able to get back on our schedule again.

With that, I'll introduce a face familiar to most of you and that's Dr. Salem from Northwestern. Dr. Salem.

8. YTTRIUM-90 MICROSPHERE LICENSING GUIDANCE

DR. SALEM: Thank you, Mr. Chairman. Thank you for the ability to change the schedule and accommodate some of our earlier flights.

MS. TULL: Here are the handouts for Dr. Salem's slides.

DR. SALEM: Thank you.

MS. TULL: So please take two pages at a time.

DR. SALEM: All right. So I'd like to take about ten minutes or so to discuss some ideas we have about the next steps in involving Y-90 therapy at the NRC guidance level. As everybody knows on the Committee, we've worked with the NRC and the ACMUI and had 490 and 390 now represented for AU eligible for Yttrium microspheres and I'd like to spend a few minutes talking about that and some of the issues that have come up. I'd also like to point out that we do have representation from the Society of Interventional Radiology here and the American Board of Radiology to discuss any issues that NRC or ACMUI might have.

As a brief review, this therapy has been around for about eight to ten years or so in this country and I think it's fair to say there is a steady increase in adoption of this therapy as a treatment option for many patients. I think conservatively over 5,000 patients have been treated in the U.S. in the last ten years or so. I think that's a conservative estimate.

The status for a long time was the 35.490 and recently with the September revisions of the NRC document it's now under 390 and some of the work that we did with the NRC on this was for interventional radiologists to fall under 390 or at least meet some of the requirements to become authorized user eligible for Y-90 under 390.

In parallel over the last five to ten years or so, I would like to point out there have been several collaborative efforts between the societies on this therapy. The first one was spearheaded by Dr. Nag. This is the Rebok document published in Rad Journal of 2006 really reviewing this therapy, the status of this therapy. It was very well represented and, in this document, it did recommend that radiation oncology, nuclear medicine and interventional radiologists were all qualified to be authorized

users.

Also at the American College of Radiology level, another document has been published, the guidance document, practice guidelines in 2008. Also very well represented by several members of ASTRO, ACRO, SIR and the American Board of Radiology and it did go through several committees, the Radiation Oncology Committee, Interventional Committee, obviously the comments reconciliation and again several types of conclusion that specifically to AUs, this document also agreed that all three subspecialties were qualified to be authorized users.

So the scope of the issue that we have today that I would like to address is that under 390 there are many states and local radiation safety committees or safety officers that are uncertain if interventional radiology fulfill the requirements of 35.390 and the reality of it is that it has created some confusion and certainly an impedance of the ability of interventional radiologists to gain authorized user status and unfortunately this does limit in some cases the ability of patients to therapeutic options.

Now ideally, you would want to work collaboratively with nuclear medicine, radiation

oncology and IR. Unfortunately, that is not practical or plausible in several centers. Hence some of the confusion that's been created and hence one of the topics of discussion today.

I would like to review for the Committee what interventional radiology training is about. It's five years of diagnostic radiology with anywhere from 700 to 960 clinical hours in nuclear medicine of which there are 80 hours of classroom and laboratory training. There is a formal written radiation physics examination that reviews safety and biology, etc. There's a formal written radiology examination and a formal oral board examination. Interventional radiologists then complete added fellowships in interventional radiology in catheter-based techniques.

Of the 80 hours that interventional radiologists now have, I just sort of underlined some of the salient features of the training that's included: the radiation biology, radiation protection, safe handling and administration and, of course, quality control of radiopharmaceuticals.

If I could have the slides displayed in the front. I apologize. That's been changed.

(Off the record comment.)

So again also under the 80 hours, other

subjects are surveying dose calibration, managing radiation spills and accidents and, of course, prevention and management of medical events.

Qualifications for authorized user status by interventional radiologists, I think it is well known and well recognized by most, if not all, knowledgeable of this therapy that Y-90 today is performed safely and effectively at institutions with IRs and non IRs as authorized users. And one of the critical aspects of this therapy does revolve around patient selection criteria for liver-directed therapy and the safety delivery of this therapy using advanced catheterization techniques which is in the realm of interventional radiology.

Interventionals have also worked very extensively with Yttrium therapies since the beginning and have organized courses and workshops and symposia. A lot of the research is being performed by interventional radiology on this therapy. And again, as I described before, there are several consensus documents.

One, I think, of the most powerful arguments for interventionalists having a road to authorized users is that authorized users today are being proctored by interventional radiologists. So

they are being given their credentials by interventional radiologists.

So the proposal to be discussed here today, the above line talks about 35.390 and 490 which is the status today. One of the things I'd like to discuss and proposed for the Committee is to permit interventional radiologists that are under 35.290 with the appropriate examination administered by the American Board of Radiology and this has been approved by the American Board of Radiology to then provide a road or pathway to authorized user status for Y-90.

The Society of Interventional Radiology and the American Board would most likely provide a course of CME hours to be determined, taught by experts involved in Y-90 microsphere therapy and the two largest aspects of the course would involve first of all patient selection of preparation at the IR specific subjects, so therapy planning and dosimetry, techniques of MAA and vascular mapping, the IR-specific portions of the procedure and also the dose selection and preparation of Y-90 and specific radiation physics and dosimetry as it applies to Y-90. This would not prevent people that are going to become authorized user from the vendor-specific training that is already in the NRC guidance

documents. So no change in that.

So to summarize right now authorized user approach is 35.390 or 490 with vendor training per the guidance document. We would like to propose or at least open up a discussion on the possibility of having 290 plus an ABR primary clinical certificate for Y-90 and, of course, vendor training as a possibility for consideration for IRs as authorized users. The American Board of Radiology has already agreed to this approach to grant this primary AU certificate and, as I mentioned before, would not preclude other recognized and standard vendor training and onsite support from the manufacturers of Y-90 microspheres.

Open for discussion.

DR. NAG: One quick question. Who grants the primary AU certificate? I thought it was not within the jurisdiction of American Board of Radiology. Authorized user is an NRC term and therefore can only be granted by the NRC, not by the ABR. Am I right or am I wrong, someone from NRC?

DR. GUIBERTEAU: Mickey Guiberteau. I am the trustee of the American Board of Radiology, primarily for nuclear medicine and other issues. That's the way we perceive it. We give AU eligible

certificates. That means that a person who is a diagnostic radiologist, a candidate, who becomes a diplomat by receiving a certificate by going through our exam process that's been approved by the NRC then becomes AU eligible. That is presuming that they have been attested to us that they've completed that training and they've had their examinations. They become -- They basically have achieved deemed status through that certificate for 290 and 392 portions of the rule. But, yes, we don't grant AU.

DR. SALEM: I think the correct item would be AU eligibles. Is that it?

DR. GUIBERTEAU: That's the term.

DR. SALEM: Or AU eligible.

CHAIRMAN MALMUD: Dr. Howe.

DR. HOWE: Dr. Nag, I think the important thing is we asked the American Board of Radiology to put some kind of distinguishing mark on their certification that we could tell that these individuals met NRC's requirements versus other individuals that didn't. They happened to select the term "AU eligible." It does not mean they're AUs. It just means that's how we distinguish them.

DR. NAG: Thanks for that clarification.

CHAIRMAN MALMUD: Thank you. Dr. Eggli.

DR. EGGLI: Could this proposed pathway to be implemented without a rule change?

DR. HOWE: No.

CHAIRMAN MALMUD: Dr. Eggli.

DR. EGGLI: If it requires a rule --

DR. HOWE: I'm sorry. I'm sorry about that. It's 35.1000. So 35.1000 is not in 35 as one of the regular modalities. So this is guidance on the website. So we would not need a rule change.

DR. EGGLI: Okay.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: Jim Welsh. Thanks, Dr. Salem, for that excellent presentation. Right now, 390 users are required to have 700 hours of total training, 200 hours of classroom and laboratory training to be AU eligible, documenting that they have the appropriate safety training. How would you propose that this certification procedure goes? In your presentation, you said a number of hours to be determined. What can you tell us that would assure the Committee that IRs would have the requisite level of training and experience particularly in safety status?

DR. SALEM: So I think it's important to recognize that when we talk about AU status here the request is for AU status for Y-90 primarily. And the

discussions we've had right now revolve around some type of training course which would be co-sponsored by the SIR and the ABR. And this would be in the vicinity of 20 to 40 additional CME credits where participants would come and attend and really get very in-depth Y-90 only type training.

And so this would leave most AU eligible radiologists with their portion that they received in diagnostic radiology to 80 hours plus a number of hours that we deem are acceptable, not too short but also not too long that makes providing this kind of training prohibitive and, in fact, impossible in many ways. From there, the idea is that person might then be able to sit for this examination and from there then become AU eligible for Y-90.

CHAIRMAN MALMUD: Dr. Eggli.

DR. EGGLI: Most of the therapeutic uses come under part 300 and the training and experience requirements are in 390 with the exception that the use of radioactive iodine has slightly different requirements and is covered in 392 and 394.

I guess for some consistency in therapy, although I guess here we would be into rulemaking, I would personally prefer to see something like a 396 or something like that that dealt specifically with a

therapeutic application limited to Y-90. If you essentially grant 390 style authorizations to folks trained to 290 I guess the question would be do you open up some kind of a wide range of therapeutic possibilities because actually I actually heard Dr. Salem say it would be predominantly limited to Y-90. So again, I would prefer to see something like a 396 limiting the therapeutic use to Y-90.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: Yes. Two points. First of all, you can't use 396 because 396 was the pathway for radiation oncologists to be in unsealed sources if they were radiation oncologists and they had to --

DR. EGGLI: That didn't exist then.

DR. NAG: But I mean something similar.

DR. EGGLI: Something like that.

DR. NAG: Something similar. But secondly, if we were to have a pathway like that, what would then that interventional radiologist to say, "Now I'm authorized user and now I'm going to use it to do Yttrium-90 or I want -- brachytherapy" or some other thing?

DR. EGGLI: Again, if you wrote it as a subpart it would be limited to Y-90.

DR. NAG: That is if it was a subpart.

But if it was the way Dr. Salem is requesting that they would therefore gain authorized status with 20 hours, wouldn't that prevent that person from now saying, "Well, I am an authorized user. I'm going to put in a catheter and use XYZ isotope"?

DR. SALEM: Can I reply to some of that? The intent is certainly not that and, in fact, I specifically stated in the training course that this was specifically for Y-90. The reason I said predominantly Y-90 is because the concept here is transarterial microsphere brachytherapy and there is research being done in P-32 and other types of similarly administered microspheres. This is not a mechanism to have wide scope ability to perform brachytherapy. This is a transvascular micro brachytherapy. This is what this is. So that's the explanation.

CHAIRMAN MALMUD: Dr. Thomadsen.

DR. THOMADSEN: A precedent for something like that would be 491 which is the strontium 90 ophthalmic applicators which only a user there is only approved for that use.

But I would throw a question to my radiation oncologists colleagues here and as well Dr. Salem has pointed out that the interventional

radiologists train the radiation oncologists on that. They really don't train the radiation oncologists on that. They train them in the procedure, but the radiation oncologists don't do the procedure. They write a prescription issuably because they are the ones who are familiar with radiation reactions at high doses in various parts of the body and the question to my colleagues would be what would you think would be the minimum requirements necessary for somebody to have enough training and experience in such reactions and expectations and doses necessary for control of tumor in order to qualify as an authorized user.

DR. NAG: I think for that you would require training on oncology. You would require training on the adverse effects of radiation and how cancer spreads and how cancer is controlled and basically you would require like a semi-radiation oncology residency. In fact, I don't know how you can learn only about liver cancer oncology without having some general oncology expertise.

Now talking about that the report that was sent out says that the radioembolization team requires expertise in medical management, someone who has medical management of the cancer patient, someone who can perform the scan which is an interventional

radiologist, someone who can perform a scan with an interventional radiology scan and then assume responsibility for the delivery of the microsphere and be the authorized user and then monitor radiation safety.

So that person would therefore have to be a radiologist as well maybe have training in medical management of the cancer patient if they are going to be one and the same. Otherwise this function can be done by two people. So actually we have five functions that are mentioned here probably best managed by at least three or four people. So we have five different individual kinds of management that are needed. Now whether it's performed by -- Can all those five be performed by one person? Almost impossible. By three or four, definitely. Whether someone has -- whether two people can share and show competency in all those five functions, that's something we have to see.

CHAIRMAN MALMUD: Dr. Salem.

DR. SALEM: Just a few comments. First, I think interventional radiologists who have been performing and focused on oncologic therapies are extremely well trained and extremely well competent and able to handle and deal with all of the issues

that Dr. Nag has mentioned when it comes to diagnosis and management, etc.

I think it's also important to recognize that we are not asking to take over the cancer management of the patient. This is an administrative request for authorized user status. Of course, the patient is also managed by his surgeon and his medical oncologist and his radiation oncologist.

The request here is for authorized user status without implication that this will be done solo by interventional radiologists without really the multidisciplinary team which is very well laid out in all guidance documents.

CHAIRMAN MALMUD: Other comments or questions of Dr. Salem?

DR. NAG: I think a similar request --

CHAIRMAN MALMUD: I think Mr. Lieto was next.

MR. LIETO: Along that line of the comment that you just made about the team approach, aren't at least one of those an authorized user to begin with and has been involved either radiation oncology and/or nuclear medicine? So wouldn't one or both of those team members be an authorized user? Because what you're saying is that you would have potentially a

team member or a team approach in which none of them have nuclear or say radiopharmaceutical or radioactive material experience and training and it's only going to be the IR that's going to have this. That's why he needs to be the AU. That was a question I guess more.

DR. SALEM: Yes. First of all, there are many different models where this therapy is being applied because it depends on local practice patterns, size of the hospital, the referral base, etc. And it is not the norm to have as you stated everybody be an authorized user.

However, in some centers, the radiation oncologist is an AU. In some centers, the nuclear medicine and in some centers, the IR. And there are very successful and well-run practices where in fact only the IR is the authorized user not because of by choice but because of the inability of other disciplines to participate, maybe too clinically busy. It's not often that easy to have everybody join and meet to work with this therapy. But everybody is involved in some way and the interventional radiologist is the common denominator in all practices.

DR. NAG: Therefore, in these uncommon circumstances where you do not have a radiation

oncologist or a nuclear medicine in this modern hospital you are suggesting that the therapy would then be done by interventional radiologists with a surgeon and that's the only involvement that would be there. Is that what you're suggesting?

DR. SALEM: I'm suggesting that there are places where this, in fact, happens and has been going on for many, many years.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: Jim Welsh. I'm not sure I could agree with that because wouldn't -- I understand and agree with the idea that the IR is the common denominator. But isn't nuclear medicine always present, too, if you're doing the imaging? So you have to have nuclear medicine as well and therefore you would have an AU available in the institution. Correct me if I misinterpret that.

DR. SALEM: Yes. So we need to make sure that we're talking about the same thing when we talk about present or the AU or there is some terminology I think that we differ with. At our institution, for example, neither radiation oncologists nor nuclear medicine physicians are authorized users.

MS. GILLEY: Wait. But you're a broad scope academic.

DR. SALEM: Yes.

MS. GILLEY: Okay. A different set of rules here.

DR. SALEM: Well -- What is that?

MS. TULL: This is Ashley. I said and agreement states. This is guidance so the agreement states can follow whatever the agreement state feels they need to follow.

DR. SALEM: So Dr. Welsh is correct. There is always also nuclear medicine involved in the imaging assessment of lung shunting and extrahepatic flow. That is correct. But that does not necessarily mean that the nuclear medicine physician is an authorized user.

DR. GUIBERTEAU: For Y-90 microspheres.

DR. SALEM: For Y-90 microspheres.

MS. TULL: Dr. Malmud, this is Ashley. There are interventional radiologists named as authorized users in agreement states.

The state can regulate under its own jurisdiction. This is not regulation. There is no level of compatibility with Part 1000. It's Compatibility D. So we write this guidance. We do send this guidance to the agreement states so that the state regulators can look at it. But if they choose

to on a case-by-case basis approval an interventional radiologist as an authorized user we found this is I don't want to say a common practice, but it is out there.

CHAIRMAN MALMUD: Mr. Lieto.

MR. LIETO: I have a question for our agreement state member across the table.

(Laughter.)

MS. GILLEY: Not important.

MR. LIETO: How frequently does or do agreement states not follow NRC guidance? In other words, do they take that as their template and they go from there? Or do they just -- Or is it hit and miss? Some agreement states follow it explicitly or?

MS. GILLEY: Some. It depends on the skill level and the number of employees. Some follow NRC agreement guidance documents verbatim. Other states that have larger programs with more people that can do development of regulations and guidance do not.

MR. LIETO: Thank you.

CHAIRMAN MALMUD: Other comments or questions?

DR. VETTER: Question.

CHAIRMAN MALMUD: Please do.

DR. VETTER: This is Rick Vetter. Could

Ashley or someone review for us the qualifications of those authorized users in general? In a state where an IR is an authorized user, what are their qualifications that allow them to be an authorized user?

MS. TULL: That is completely up to the state.

DR. WELSH: Can I ask a follow-up question?

CHAIRMAN MALMUD: Dr. Welsh and a member of the public.

DR. WELSH: Okay. On the same thinking, what would disqualify a radiation oncologist or a nuclear medicine physician who has gone through all the training and is AU eligible but now is not an authorized user?

DR. VETTER: Yes, I'm confused about that as well.

MS. TULL: I'm sorry. Repeat the question.

DR. WELSH: So if somebody is a radiation oncologist or nuclear medicine physician and has gone through all the training and has board certification and is AU eligible, a state can say that you're not an authorized user.

MS. TULL: They could have more stringent criteria, yes. I can't imagine it being anything more than a radiation oncologist, I mean.

DR. NAG: The only -- If he wanted to apply and if he could, if he took the training of that three cases, the three cases and the vendor training. So if he doesn't want to do -- If a radiation oncologist doesn't want to do a vendor training and doesn't want to do the three cases then he couldn't apply.

MS. GILLEY: May I?

CHAIRMAN MALMUD: Please.

MS. GILLEY: I'm Debbie Gilley. Part 1000 is a unique animal and because of the way it's set up it's meant for the innovated new technology to come on board. We would be able to get some experience with that and then the intent I thought was once it became a common practice out there we would roll it out of partner -- and put it into the 200, 300 or 400 or 600 or which ever one it best fit and what we have here is a gap.

The agreement states, some of them have more experience with this technology than others just by the nature of their size and the number of medical institutions within their state. So they have

flexibility to do that and that's part of the reason it's Part 1000 is to give the agreement states some of that flexibility. So you're going to find it to be across the board. There are 35 different agreement states. There are going to be 35 different ways they handle Part 1000.

CHAIRMAN MALMUD: Ashley.

MS. TULL: Another point to make is for the broad scopes. This is going to be driven by the Radiation Safety Committee. So it's going to be institution by institution. That's how you could very easily have a interventional radiologist as the authorized user.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: So then, in summary, Dr. Salem, it sounds like you're proposing that IRs be authorized users because there is a shortage of AUs and because you feel that IRs can be qualified for this type of therapy.

DR. SALEM: I mean fundamentally I believe and this has never changed that radiation oncology and nuclear medicine and IRs are qualified and have the qualifications to be authorized users for this very unique technology. This is I think one of the very important aspects. Is there a shortage of AUs? There

are at times as I have been told because I'm a representative here of the SIR and the ABR that there are at times a lot of confusion on the qualifications and the ability of IRs to meet the AU standard that the NRC has just put out and so this is why this discussion is being initiated is to find solutions to this. But it is in all honesty part of the problem but certainly not the majority of the problem.

CHAIRMAN MALMUD: Member of the Public, would you please introduce yourself?

MR. SOULEN: Hi, I'm Dr. Michael Soulen. I'm a Professor of Radiology and Surgery at the University of Pennsylvania and I run the interventional oncology program at the University of Pennsylvania. I'm using Yttrium before actually it was introduced to the United States. I guess the original TheraSphere trial for HCC almost ten years ago.

Just to give you sort of a perspective on the IR as an AU, when we started doing this at Penn one of our nuclear medicine, actually a couple of nuclear medicine attending were the authorized users for Yttrium-90. And the problems that ensued were that although one might conceive that a nuclear medicine physician or a radiation oncologist might be

instrumental in the management, diagnosis and prescription for the patient.

In fact, the patients are referred to the radiology clinic. They're assessed by us. We make the treatment plan. We review the diagnostic images and analyze them. All the factors that go into the plan, the treatment dose, are actually determined by the interventional radiologist and then we fill out a spreadsheet which we would then hand our authorized user to sign so then the material can be administered. So, in fact, all the treatment planning and the data necessary to do the treatment planning and the image analysis of the treatment planning with the exception of calculation of lung shunts by nuclear medicine on the diagnostic MAA study was already being done by the image radiologist. He was essentially doing all the work and admitting the patient, treating the patient and doing all the follow-up care of the patient afterward in terms of response evaluation and management of any complications including issues relative with liver function which is something we've been managing frankly for many years. So essentially we're doing almost all the work.

Now if we had an AU who was present and active and available to make the patient's access to

care smooth and easy that would be fine. But we would be sitting in a room with a catheter in a patient wondering where our nuclear medicine attending was to show up so we could actually administer the dose and sign the treatment plan. Or we would have a nuclear medicine attending come in and inject the dose himself into the wrong catheter because they didn't really understand the mechanics of what was going on in this particular instance.

So finally and I think it relates to the comment you just made, our institution came to us. Our radiation safety officers came to us and said, "We want the IR to be the AU for this because you guys really know what's going on and you guys are doing all the work and trying to get these other people involved is actually inhibiting us, slowing down the process and making it less efficient in our institution."

So I think even in major medical centers where there is lots of expertise the care of the patient goes to the people who are willing and able and we do delivery brachytherapy. We work with our radiation oncologists to get the catheters and do the mapping, get the anatomy and get the delivery systems in the right place. But they make the treatment plan to the delivery because that's what they do in taking

an active role in the management of the patient.

And if you're not therapy, the image radiologists are doing all the work for the treatment planning and the treatment administration and the clinical care and so if you don't have in that institution even though we had a nuclear medicine authorized user they weren't serving a helpful function if, in fact, they were inhibiting access to care by not being an active role in the care of the patient.

So I think as we were saying there's really sort of a fairly compelling argument for making possible for image radiologists who are actually providing the care and the treatment of the patients to have authorized user status in situations where there is not someone else who has authorized user status available to be involved in that care. Again, this is sort of a single institution perspective on --

Again I didn't go seeking authorized user status. My physicians came to me and said, "We want you to do this because you do a better job than if we have someone else doing that who is not actively involved in treating liver cancer." Again, I think this applies uniquely to this application of brachytherapy in the liver.

CHAIRMAN MALMUD: Thank you. Dr. Nag.

DR. NAG: Yttrium-90 microsphere is under 1,000. It does not require the physical presence of the authorized user. Am I right? It requires to be involved in the planning. You know, the comment that we are waiting for the authorized user to be able to put it in cannot be true because you don't need the physical presence. Am I right?

MS. TULL: This is Ashley. You're correct. There is no physical presence requirement in the guidance right now. However, I believe from talking to the manufacturers the current practice is to wait for the AU to show up.

I would ask either one of the manufacturers to address that. Sam Putnam.

MR. PUTNAM: I can speak to that. Sam Putnam from Sirtex, Medical Director. That's true and I think most places across the country when they do have radiation oncologists, nuclear medicine docs, as the authorized user they would appreciate having them actually present in the room. They often and usually do wait for those physicians to show up.

So I wouldn't say, Dr. Welsh, that there's a shortage of radiation oncologists or nuclear medicine docs who could be the authorized users. But

I think there's a shortage of interest among those doctors to be the AUs and to actually be part of the therapy.

DR. NAG: Yes, but radiation is not stopping you because it is unique to have user in the planning but the authorized user does not have to be physically present. So it's not hindering the administration of radiation.

MR. PUTNAM: Well, it does. At the two institutions I provide this therapy, they don't buy into that and we do have to wait for the authorized users to be present.

DR. NAG: But that is not a radiati0on issue.

MR. PUTNAM: I understand.

DR. NAG: That is an institution issue.

MR. PUTNAM: It is an institution issue. That's right. But we still wait.

CHAIRMAN MALMUD: Dr. Thomadsen.

DR. THOMADSEN: I think a sampling of the institutions that the AAPM's task group on microspheres would indicate that the authorized user is seldom present for these therapies.

CHAIRMAN MALMUD: Thank you. Other comments? Yes, Debbie.

MS. GILLEY: Just for clarification, there are no regulations on Part 1000. They are guidance documents and you had mentioned the regulations and they simply -- So there's a big difference between guidance documents and regulations when it comes to the agreement states.

DR. NAG: So in that -- there is nothing like regulation guidance. There's nothing that is stopping the interventional radiologist from going ahead so long as they have an authorized user in their planning committee. Am I right or not?

DR. SALEM: I think Dr. Nag is correct. I mean it depends on the location of where you're at, but I think in terms of best medical practice, I think there are some people that have some inherent resistance to just signing off on written directives that then again in the spirit of medical legal issues that were discussed previously, the previous session, might come into play if a program is run such that an authorized user is never physically present in an area and I would point out that I believe one of the rationales for stating that the authorized user doesn't have to be there was because of the very issue that the interventionalist could not be an authorized user. This was the origin of this. So I think good

medical practice if the authorized user can be there whether the radiation oncologist, the nuclear medicine physician or the IR, I think best medical practice would dictate that that would be the best way to do it.

CHAIRMAN MALMUD: Other comments? Dr. Vetter.

DR. VETTER: A question. Maybe I'm just getting foggier. But what problem are we trying to solve?

CHAIRMAN MALMUD: I think the issue before us is the request of the interventional radiologists to move ahead with one of two pathways to achieve authorized user status or specifically for the Yttrium-90. Am I correct?

DR. SALEM: Yes.

DR. VETTER: That's the solution. What's the problem?

CHAIRMAN MALMUD: The problem is that they feel that they do not have that process in place currently and they're seeking NRC approval for it.

DR. WELSH: If I may?

CHAIRMAN MALMUD: Yes, Dr. Welsh.

DR. WELSH: This is Dr. Welsh here. This is why I asked Dr. Salem earlier if you perceive that

there's a shortage of Aus. Because if the answer is no, then perhaps there is no reason to change things. But from what I'm hearing where radiation oncologists and nuclear medicine physicians were Board certified are not AUs there very well could be a shortage of AUs for this therapy and therefore there is a problem that needs a solution. So we're hearing the solution. But the question may be is there truly a shortage of AUs to provide this therapy nationwide.

CHAIRMAN MALMUD: We have another member of the public.

DR. FACCHINI: Good morning. Thank you, Mr. Chairman. My name is Frank Facchini. I'm an interventional radiologist just outside of Chicago. I'm in an agreement state and a very experienced agreement state due to Dr. Salem's work. Because of my practice, we cover five hospitals. I am an authorized user at only one of those hospitals and our radiation oncologist also covers that said five hospitals.

So truly it's very, very difficult for me to have him in the room with me and that is why I sought out AU status personally. I did it post September. I work very closely with our IEMA and I did it by providing my ABR certificate, showing my

classroom work and my experience and then under the guidance of our RSO I did the material handling as Dr. Salem has proposed. I provided actually seven patients. I involved all of the planning that went into it, the treatment planning, the receipt of the radionuclide, the disposal and I gained approval that way.

But the entire impetus was that it was just near impossible for us to get all of these people in the same room at the same time and it actually compromised in my opinion patient safety because as you have a microcatheter in the artery and you're waiting and waiting that catheter can get clogged. There can be issues. So how efficient we are is absolutely relevant to patient care. Thank you for your time.

CHAIRMAN MALMUD: Thank you. Dr. Nag.

DR. NAG: Thank you for that statement, but that still the same issue I had before. You don't have to wait for the authorized user to be in the room. Why are you waiting for the authorized user to be in the room if that's not required for their presence? It requires that they be involved in the planning and so forth. So you don't have to wait in the room with the microcatheter in place. So that's

an argument that you're bringing in that's not relevant.

CHAIRMAN MALMUD: Thank you, Dr. Nag. May I ask a member of the staff? Is it correct that we do not need to have an authorized user in the room at the time of the injection of the radioactive product into the catheterized vessel in the liver?

DR. HOWE: This is Dr. Howe. When we were first developing the guidance for the Yttrium microspheres we modeled after the manual brachytherapy and manual brachytherapy did not require the physical presence. The only sections that required the physical presence were HDR and Gamma Knife. So we did not require the physical presence. There was an understanding that you normally had the manual brachytherapy authorized user there, but that was not a strict requirement.

CHAIRMAN MALMUD: Thank you. So your question is answered, Dr. Nag, that it's not required. May I ask a question of the public that's here and also Dr. Salem? Who calculates, who checks, the dose when it's delivered currently?

DR. SALEM: Checks the dose or calibrates the dose?

CHAIRMAN MALMUD: Yes.

DR. SALEM: Pretreatment or post treatment.

CHAIRMAN MALMUD: Pretreatment.

DR. SALEM: So pretreatment all the doses are calibrated in nuclear medicine.

CHAIRMAN MALMUD: By a nuclear physician or a member of the staff.

DR. SALEM: Correct.

CHAIRMAN MALMUD: Is that true for the other institutions represented here?

DR. SULELMAN: What do you mean by dose?

(Off the record discussion.)

CHAIRMAN MALMUD: The activity in the product? Who makes sure that what you plan is really what you intend is what you receive?

DR. FACCHINI: In my institution, I actually do it personally.

CHAIRMAN MALMUD: And you are Dr.?

DR. FACCHINI: Facchini.

CHAIRMAN MALMUD: Dr. Soulen, how about the University of Pennsylvania?

DR. SOULEN: In my institution, a nuclear medicine technologist checks the initial activity in the vial and then they then check the residual activity. So non nuclear medicine physician, but the

technologist then brings me the worksheet which I sign off on as the AU.

CHAIRMAN MALMUD: Thank you.

DR. SOULEN: Prior to that me being the AU, it got signed off by the nuclear medicine AU.

CHAIRMAN MALMUD: And is there a third institution represented?

DR. VERMEERE: Bill Vermeere from Medical College of Wisconsin. It's the nuclear medicine pharmacist at our institution who calibrates the dose pre and post treatment.

CHAIRMAN MALMUD: Thank you.

DR. NAG: And in the south area --

CHAIRMAN MALMUD: I see a member of the public. Would you go up to the mike? And you are?

DR. HAGERMAN: Jim Hagerman from MDS Norran. I'm involved in training many centers through our vendor certification program and very rarely have I seen an instance where a hospital authorized user, be it radiation oncology or nuclear medicine, will not insist on being in the room in the interventional suite. So there are a lot of pragmatic logistical issues with having an authorized user who is not physically infusing the device and I think when you need two people to make that necessary it does impose

issues.

CHAIRMAN MALMUD: Thank you.

MR. SALMARINI: I am Joe Salmarini with Sirtex. Regarding your question about the preparation of dose and certification of the activity, I can speak for 20 institutions and it's all done very carefully and precisely in nuclear medicine.

CHAIRMAN MALMUD: By whom in nuclear medicine?

MR. SALMARINI: By the hot lab technician under the guidance of the authorized user or the nuclear medicine physician.

CHAIRMAN MALMUD: Thank you. Dr. Sulelman.

DR. SULELMAN: I'm just going to reveal my thinking. How accurate are the dose calibrators that you calibrate these with? Or are these just checks for activity? When you say calibrated, it means something very special to me and these are Yttrium sources which are beta emitters. And I hear the term that these are calibrated in the hospital. I think a lot of hospitals don't even have the capability of calibrating Yttrium sources. So I think the very sloppy use of the term "calibration" is misinformative and potentially hazardous to the public safety because

it's not an accurate estimate of the activity or the dose.

CHAIRMAN MALMUD: Thank you. I'll ask Dr. Zelac to comment on the accuracy of the calculation of an Yttrium dose in a well counter.

DR. ZELAC: Pass.

(Laughter.)

CHAIRMAN MALMUD: Dr. Howe.

DR. HOWE: Although we haven't come out with anything addressing Yttrium-90 we have in the past experienced a number of medical events where people have thought they could measure accurately P-32, Samarium and other radionuclides in a dose calibrator and it wasn't really true. So we've already recommended that you use the manufacturer's number and then extrapolate using a volume type of thing. Although with the microspheres, you have to keep them up in solution. So volume is not necessarily an accurate way of doing things. So we don't depend on the nuclear medicine technologist to be able to accurately measure Yttrium.

CHAIRMAN MALMUD: Thank you, Dr. Howe. We have another member of the public.

DR. SELWYN: Hi. Dr. Selwyn. My views do not represent the Navy. Let me say that first. All

right. They're my views.

But in terms of calibration of Yttrium-90 in a dose calibrator, they could be upwards of 30 percent. This is research that has been conducted. It's in publications as well based on geometry and dependence of the dose calibrator at the facility. So, yes, I would steer away from saying calibration at all with these. All right. It's really just the manufacturer's stated activity and you're injecting that. Okay.

CHAIRMAN MALMUD: Thank you.

MS. LAIROBENT: Lynn Fairobent with AAPM. Dr. Nag, to your question and the point that NRC may not require the physical presence, it may be a case that it is required under CMS for reimbursement. However, it may be a procedure done under personal supervision and therefore the individual would have to be physically present.

CHAIRMAN MALMUD: Thank you. I see another hand. Dr. Thomadsen.

DR. THOMADSEN: In answer to that at our institution, we just don't charge for the physician's physical presence and if the radiation oncologist isn't there, we don't charge.

But back to your question, I'm not sure

that you were getting the answer to the question that you had intended to ask when you were asking about who prepares the dose in that I was interpreting your question earlier how ever it was stated not in who's preparing the dose, but who's preparing the prescription. Was that what you were asking or were you asking the physical handling of the radioactive material?

CHAIRMAN MALMUD: I was asking about the handling of the radioactive material because the material comes and it settles. And therefore if you're getting, let's just use a number, 10 millicuries and you have to shake it to make sure that the spheres are evenly distributed and then draw out half of it, you're not really getting 50 percent when you draw out half because the spheres are not uniformly distributed exactly. So you're getting something close to it but not exactly. I was just wondering who was doing that.

But your question is one which I think Dr. Salem addressed or one of the members of the public addressed with respect to calculating the dose and that was with the liver geometry and the portion of the liver that needed to be dealt with in terms of calculating the dose. Did you address that or a

member of the public?

DR. SALEM: No, not really, but I can expand on it a little bit.

CHAIRMAN MALMUD: A member of the public addressed that.

DR. SALEM: Again it depends.

CHAIRMAN MALMUD: Dr. Soulen addressed that.

DR. SALEM: So I guess it depends again on who is involved in the team, who the authorized user is. In a radiation oncology authorized users, this is the work of the authorized user and is done by the authorized user. In our institution, this is done by the interventional radiologist authorized user. So it really is that aspect, a critical aspect, is done by the authorized user. So this does not change irrespective of who it is.

CHAIRMAN MALMUD: Thank you. Rob.

MR. LEWIS: Getting back to I think to Dr. Vetter's question on what is the problem, if it is not the NRC requirements or even the agreement state requirements that are causing the presence of the AU but rather the vendor recommendations or facility-specific procedures, I guess, is your premise that or thesis that if NRC were to come out and say that the

IR can be an AU and therefore have the presence that the vendors and the facilities will be more amenable to changing their procedures? I mean, what are we trying -- What regulatory action are you asking?

DR. SALEM: I think that the premise is you've just heard I think several sort of observations about what is working and what is not working and in my opinion unfortunately some solutions are sort of band-aid solutions in terms of this person can be the AU. He doesn't have to be there. And so the request still at its core is irrespective of the practice pattern interventional radiology is requesting and stating that they would like to proceed with a pathway that will permit them to gain authorized user status just like nuclear medicine or radiation oncology and we'd like to develop a program that is acceptable by the Committee and the NRC to allow this pathway with or without the problems that occur at the institutions and so to leave that as an option. That's really the core of the request for today.

CHAIRMAN MALMUD: Thank you. That's clear enough? Yes. Please come up to the microphone.

(Off the record comment.)

Sorry. Did you want to make --

DR. SELWYN: A quick comment again. Dr.

Selwyn.

CHAIRMAN MALMUD: Dr. Selwyn.

DR. SELWYN: On dosimetry versus radiation oncology, dosimetry treatment planning, of brachytherapy treatment planning is much more extensive and we have treatment planning programs that do that. In terms of this treatment, it is very minimum. It is a simple equation. Okay. Technicians can do it. The IR can easily do it. The physicist can easily do it. There's not much to it. It's the liver size. All right. It's the mass of the liver, that's it, versus when you're looking at brachytherapy. So they're not asking the IR to do the job of the radiation oncologist at this point. In the future, that may change and this may have to be revisited in terms of treatment planning. But currently it's very minimal.

CHAIRMAN MALMUD: Excuse me. It's not simply liver size, is it? It's the liver size versus the portion of the liver that's being percused by the vessel that you're injecting and a ratio of that mass over the liver mass and it's calculated by taking slices and then adding them up.

DR. SELWYN: No, that is not true. It's an approximation and there are two different

modalities. There are two different ways from the two different companies and they can address it if they'd like. But a basic answer to that is that one assumption is that the microspheres go to the entire liver. It's very simple. It's the mass of the liver and the activity is assumed to be distributed homogeneously throughout the entire liver which it's not. But this is the modality that's being used for clinical trials.

CHAIRMAN MALMUD: Excuse me. What about shunting? How do you check for shunting?

DR. SELWYN: You can subtract the shunting if you have an accurate number on that. But lots of people don't subtract the shunting at all. But you can and the company does say to do that, one minus F, which is the shunt value. Dr. Salem can also talk very long about this as well. But it is a very simple solution. It is not what I think people think about dosimetry and treatment planning, but it would take longer to go into the details.

CHAIRMAN MALMUD: Thank you.

MS. BHALLA: This is Neelham Bhalla from NRC Rulemaking. With regard to if I understood what the issue is for the interventional radiologist to be authorized user for the 35.1000 procedures and this

one in particular, there is another way and that's how interventional radiologists came to NRC to be the authorized users for perithelial administration of radiopharmaceuticals in terms of Zevalin and two or three other names and they came. They petitioned that these drugs come. They are FDA approved and it's easy. The calibration is easy and therefore they should be allowed to be authorized users.

This petition came to us I think about a year ago or so or two years ago and so there is -- A note, the petition was denied. So I just wanted everyone here to know that that is the process for coming to request the NRC to be authorized users for some things which are not outright in the regulation.

DR. SALEM: I'm sorry. This was a request by interventional radiology.

MS. BHALLA: That is correct.

DR. SALEM: To administer Zevalin.

MS. BHALLA: Correct. It's not only Zevalin but there were three Bexxar, Zevalin and --

DR. SALEM: By interventional radiology?

MS. BHALLA: Yes, the group was the interventional radiologists and it came from -- That is the group that came and it's under Petition No. TRM3519 and you can go into the details of the whole

petition in that regard.

CHAIRMAN MALMUD: Thank you. Dr. Welsh had a comment before you leave the microphone. What were you going to say, Dr. Welsh?

DR. WELSH: I think that there might be a misinterpretation here. I think we're alluding to the Stein petition and the Stein petition was hematology/oncology petitioning to administer Zevalin, Bexxar and Quadromed. Is that what we're talking about here or is this something separate?

DR. SALEM: That I've heard of. I've not heard of interventional radiology giving Zelavin.

MS. BHALLA: Okay. That is correct. It's the Stein petition, but the issue is very similar. It's --

DR. NAG: Medical oncology.

DR. SALEM: It's medical oncology.

MS. BHALLA: It's medical oncologists coming up instead of radiologists. But it's a very similar issue of somebody who wants to be an authorized user which clearly does not meet the requirements spelled out in Part 35.

CHAIRMAN MALMUD: Thank you. Dr. Welsh.

DR. WELSH: A quick reply or comment. There are some superficial analogies, but underlying

this are some very significant differences in the meat of the matter and one of the critical differences is that medical oncologists and hematologists have zero training during their residency and fellowship and another critical difference is that there is no shortage of qualified AUs for the administration of Zevalin, Bexxar and Quadromed and that's why I think there are some big differences here where radiologists have some underlying training and there's a discussion about adding some training that would make them qualified to be safe AUs and I still haven't gotten a clear answer about whether there's a shortage or not.

CHAIRMAN MALMUD: May I just editorialize for a moment? When you say that the medical oncologist have no training, you mean they have no training in the handling of radioactive material.

DR. WELSH: That's correct.

CHAIRMAN MALMUD: Thank you. Because we don't --

(Laughter.)

You would be offending a very large group of people.

Dr. Guiberteau.

DR. GUIBERTEAU: I think from the perspective of diagnostic radiologists that one of the

issues here is the method under which this agent was approved and I think if it was not microbrachytherapy it would clearly be one of the other agents that we have commonly developed and will develop many, many more in molecular medicine in terms of injecting materials that are labeled to peptides for cell surfaces, within the cells, delivered in this case in a mechanical way and I think what the devil is, the radiology community is, the length of time it takes to take a new technology like this from Part 1000 that's clearly being done and integrate it in and making some semblance of fairness to it. That is we have agreement states with apparently a tabula rasa of what they want to do. We train people in our state to do these and they go to another state and they can get licensed.

And so I guess just -- I'm sure you've heard this all before. But the feeling of the community is that we don't know what to do. We're totally confused. IR in terms of the American Board of Radiology is probably in the next five years going to be its own direct pathway and we have to know how to train those people to get this, to get certified, and to get AU status to do these procedures. So I guess my plea is here that it would be very nice if

the Committee would consider some way to move this into part of the rules so that we can have some semblance of understanding of what we're supposed to do.

CHAIRMAN MALMUD: Thank you. Other comments. Dr. Eggli.

DR. EGGLI: I think interventional radiologists make perfectly good authorized users. I think my concern here is mixing the part of the regulation that deals with diagnostic applications versus therapeutic applications and I think that what we need to look for is not a way to add it to 290 as a subclass of 290 but as a subclass of 390 setting up reasonable training and experience requirements that allowed interventional radiologists to do this procedure. But my concern is mixing the definitions of diagnostic applications versus therapeutic applications among sealed sources.

CHAIRMAN MALMUD: Thank you. Therefore you would recommend that this be for a very specific application for the therapeutic application.

DR. EGGLI: Under Part 300.

CHAIRMAN MALMUD: Under Part 300. Thank you. We had two hands showing here.

DR. NAG: I would agree with Dr. Eggli

that this is therapeutic and if you want to either have interventional radiologists that will have similar training so that they would qualify either under 300 or under 390 whatever that would be a more logical way that will, too, ensure enough training and yet allow them to do only that portion of 300.

CHAIRMAN MALMUD: Thank you and, Mr. Lieto, you had a comment as well.

MR. LIETO: Yes. Well, I was also going to echo my support for Dr. Eggli's comment about making a specific category under 300 training and experience because I think it's a therapeutic use whether you call it brachytherapy or what it truly is, a radiopharmaceutical therapy, regardless. It belongs in the therapeutic portion of the regulations.

One of the things in talking about the AU and AU being present and why AUs may not be there and so forth, I think you need to understand that and I think, Dr. Malmud, you gave a perfect example to me earlier today in that when you are the AU and you're going to be giving a therapeutic application to a patient just like you said, "I want to be there." That's the patient. I wrote the written direct for I want to be there and know what's going on and I think it's the same way generally speaking in that the AU is

not just someone who signs the written directive. He is accountable for supervising in all the aspects that go along with that administration. So it's not just filling out the written directive and that's the end all and be all. They are accountable for the supervision of all the people under that written directive.

I'm kind of wondering and they're saying that there's reluctance and some of the colleagues in the back there are saying that getting the multiple parties together may be sometimes problematic. But I'm sure they want to be there because of the fact of their responsibilities that they can't, I shouldn't say that they can't, but they don't want to delegate to someone else. And I think that's why even though Dr. Nag has said the AU doesn't need to be there the AUs want to be there for these administrations.

CHAIRMAN MALMUD: Thank you. I would just comment. We were discussing something different. We were discussing the use of I-131 orally for thyroid disease, either hyperthyroid or cancer. And there it's a simpler process. I see the patient. I make the diagnosis. I calculate the dose. I order the dose. I physically check it in the well counter. I physically hand it to the patient. It's me. It

doesn't require a team and what I understand from Dr. Salem is that this is complicated because it requires a team and getting the team together actually makes the process less efficient than more efficient.

That's the difference between the two situations. I'm not taking a position either way.

MR. LIETO: No, actually it wasn't a point. It was actually a point Dr. Nag was making and his point was that the regulations don't require you to be there.

CHAIRMAN MALMUD: I know that. I wasn't suggesting that they do. I'm just saying it's a similar process.

MR. LIETO: Right and I'm just saying the same thing is that you want to be there because of your responsibilities to the patient having done the written directive and so forth.

CHAIRMAN MALMUD: Yes, but I was not -- The context of our discussion was not meant to be analogous to this discussion. They were totally unrelated.

I'm sorry. Who was next? Someone had a comment. Dr. Sulelman.

DR. SULELMAN: I'm going to take a step back. I'm very troubled by these regulations and I'm

very troubled by everything that's interdisciplinary and I think the whole purpose of the NRC involvement here is radiation safety clearly from a radiation perspective, not the practice of medicine.

I see things very differently from FDA perspective how we approved -- I mean, unfortunately the Yttrium-90 was approved as a medical device. It's a tiny little brachytherapy device. That's because our lawyers got involved and read the laws and said, "This is a brachytherapy source." But the radiation safety characteristic we have, it's more like an unsealed source because there's millions of these little products. Regardless of what people think about the semantics and the definition, the radiation safety handling of it is as you would an unsealed source.

As things get more interdisciplinary and as imaging technologies evolve and they're going to get a whole lot more complicated than we see here, if the NRC is going to try to break these things into more and more subcategories and you have all these evolving, very specialized disciplinary developing for therapy, for diagnostics, for a whole multitude of applications, this approach is going to just get more and more complicated. I think you're seeing that

here.

I would be more than comfortable with somebody who understands the hazards of radiation involved with thing. I would be more than comfortable with a medical practitioner who understood what it was they were doing and somehow we need to solve that, you know, get that. But to throw all these multitude of regulations and is this person doing this and is this a sealed source, an unsealed source, is it a beta emitter or a gamma emitter which clearly raises different issues, I don't know what the solution is. But I think the problem is that we're trying to microcategorize both the users of these products and the way we're classifying them.

I'm really glad this is under 1000 because when you start to try to break it out and put it someplace else where are you going to put it and wherever you put it you can argue that it belongs probably someplace else.

CHAIRMAN MALMUD: Dr. Thomadsen and then Dr. Eggli.

DR. THOMADSEN: I would like to make a motion at this moment.

CHAIRMAN MALMUD: Please.

DR. THOMADSEN: That there is formed a

subcommittee of this group to draft a set of proposed qualifications that if satisfied by an interventional radiologist would qualify them for authorized user status for this application.

DR. VETTER: Is there a second to that motion?

DR. VAN DECKER: Second.

DR. VETTER: Dr. Van Decker seconds. Discussion? You wanted to say something, Dr. Eggli. Is that related to the motion?

DR. EGGLI: Semi.

DR. VETTER: Okay.

DR. EGGLI: I think that as you look at the way things are broken down if you're authorized for a higher level you're typically authorized for a lower level of functionality and I think from the point of view from safety and training there is a clear break point between diagnostic uses and therapeutic uses of radioactive materials with respect to safety and training.

I think that impossible thresholds and the 200 hour threshold for Part 390 is something this Committee argued vociferously against. So I think a 200 hour threshold for those Part 300 uses may be off the wall, but I think the training requirements are

different for diagnostic than for therapeutic uses.

And I would agree with Orhan to the extent that I'm a lumper instead of a splitter. But a mechanism need to be found that allows interventional radiologists to become an authorized user under a portion of the regulation that governs the use of therapeutic radioactive materials. And from that extent I support Dr. Thomadsen's motion that a subcommittee be formed to try to discover this after. But I feel very strongly that it needs to under the regulation that pertains to therapeutic uses not diagnostic uses.

DR. VETTER: Dr. Malmud, I'll turn the chair back to you. Just for your information, there's a motion on the floor now by Dr. Thomadsen to form a subcommittee to develop the recommendations for the training requirements as discussed earlier.

CHAIRMAN MALMUD: Has it be seconded?

DR. VETTER: Yes, it has. We are discussing the motion and Dr. Welsh has his hand up next.

DR. WELSH: So my point is that before we vote on whether there should be a subcommittee to put together some guidelines the question still has to be answered "Do we really need to have interventional

radiologists as authorized users?"

I've heard some comments from the public that one of the reasons for moving in this direction is that the AU at the institution is dragging his feet and getting to the IR suite. We've learned that the physical presence of an AU is not mandatory. So that argument has to be discarded, although I personally as a radiation oncologist find it embarrassing if a radiation oncologist is not there during the procedure. But nevertheless by the current guidelines, the authorized user does not have to physically be present.

Therefore in my mind the only real reason why we would want to IRs as an authorized user is if there is a shortage of qualified AUs and, if the answer is yes, then I will vote in favor of having such a subcommittee. But if the answer is that there is plenty of AUs already, what's the need?

DR. SALEM: I think there is, I mean, as I said before, to a certain extent a shortage. But I also say this sort of representing interventional radiologists that there's a genuine desire to become an authorized user not just to fulfill this shortage but, in fact, out of interest and I think out of best care, out of sort of providing continuity of care. I

think there's a genuine desire to do this, not just to plug up holes basically. But there's a genuine request to do this.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: Yes. I don't think that there's a shortage per se. But I think that it's lack of interest. I think you would agree with me, but there might be a lack of interest in some of the AUs to be leaving their own area that they are busy at that point to then leave and go to some other area. And then there's a reluctance of the hospital to say, "Well, you can go ahead without the AU." So I think that's what I'm hearing. It's not necessarily a physical shortage. Am I correct?

DR. SALEM: Again, the reality is a mixture of all of these things, a little bit of shortage, a little bit of lack of interest, I think, good clinical care, maybe some medical legal issues and again, like I said, the genuine desire. This is an independent, also, request and desire to become authorized users. I think interventional radiologists believe they have the qualifications and can participate and contribute to this therapy equally. That's really, I guess, at the source of the request.

CHAIRMAN MALMUD: Dr. Welsh is next.

DR. WELSH: My question for you, Riad, is I can't speak for all of radiation oncologists and apparently I don't because I apparently think that there's great enthusiasm in the radiation oncology community and what I'm hearing objectively that maybe there is not and perhaps if it's to the point where it's hard to get a physician out of the oncology center and coming up to the IR to what is his responsibility in my mind, then that represents a problem. It's representative of perhaps a lack of genuine interest.

You're telling me that interventionalists in the interest of best patient care and genuine desire to move this treatment forward and to the forefront interventionalists as a whole are in favor of this. Do you think that perhaps you are representing a small minority yourself?

(Laughter.)

DR. SALEM: An excellent question. Very, very worded. Again, I used to think that. I'll be honest with you. I used to think that and I am slowly being convinced otherwise. I see more and more genuine interest, investigation, symposia, courses, publications, genuine curiosity than I thought I would ever see. So I used to think that.

CHAIRMAN MALMUD: You were next, Dr. Eggli.

DR. EGGLI: I support an interventionalist being able to do that. They're the primary drivers on these patients. If I had to go to somebody else to get them to sign off on my high dose iodine patients that I felt I was responsible for, I would be very unhappy about that.

I think the interventional radiologists do take care of patients. I think that's one of the areas where radiation oncology, nuclear medicine and interventional radiology share a common practice pattern in that although for the two interventional radiologists and the nuclear medicine docs we are imagers. We take care of patients every day and basically this is from my point of view the interventional radiologist's patients and I can understand him not wanting me as an interloper in his case.

So I think that the primary driver ought to have a mechanism whereby they can become authorized to do the things that they do. Again, my concern is where we put that authorization. But I firmly believe these guys are taking care of the patients and they ought to be the ones who are driving the bus here.

CHAIRMAN MALMUD: If I may, there's a motion on the floor and seconded to set up subcommittee to try to achieve that goal. Is that correct? Is that the motion?

DR. VETTER: Yes.

DR. NAG: It's still under discussion.

CHAIRMAN MALMUD: You are still discussing the motion.

Dr. Fisher.

DR. FISHER: I would speak against the motion. If this is a workable proposal, then there is no need for this subcommittee to rethink the issue as well as Dr. Salem has presented it here this afternoon. It looks like he has the, at least from my perspective, two possible answers to the question as long as we understand what the question is. But why form a subcommittee when the work has been done already and you have the American Board of Radiology willing to work it.

DR. SALEM: I think 290 is the wrong place for this.

DR. FISHER: Then let them --

DR. SALEM: We could change it to 390 or 300 XX or something I guess.

CHAIRMAN MALMUD: Dr. Thomadsen.

DR. THOMADSEN: And that's what I think part of the subcommittee's work would be to craft what that pathway, what we think that pathway should be. Just because the ABR and the Society of Interventional Radiology have defined what they think doesn't mean that we agree anymore than we may think that the pathway to authorized users might be Board certification and the NRC differs with us on that. There are reasons to differ.

CHAIRMAN MALMUD: Thank you. Dr. Guiberteau. Then Dr. Vetter.

DR. GUIBERTEAU: I just want to say that I have had lengthy discussions with the ABR and we didn't make a specific proposal about how this should be done. I mean we agree that the NRC is the one who has to set up the training requirements and the safety requirements that they feel are necessary. The ABR is in a position since classically for radiologists and most position users you want training, you want attestation, and you want a test and the ABR has committed if the NRC so agrees to a training pathway, an alternative training pathway, for interventional radiologists that we will provide a test to see that the body of knowledge that has been presented to the candidates will be appropriately confirmed.

CHAIRMAN MALMUD: Thank you. And Dr. Vetter.

DR. VETTER: Yes. Just to clarify as I understood the motion, the motion did not presume that the training requirements would fall under 200, 300, 400, 1000, anywhere. That would be all be part of what was developed.

CHAIRMAN MALMUD: That's correct. Dr. Nag.

DR. NAG: I know like Dr. Salem and a few other interventional radiologists who I know really well, they are like a diehard microspheres. They are willing to go through all the training required to be able to do this successfully and safely. Would other interventional radiologists be equally diehard to be able to pursue the training? Let's say that Dr. Thomadsen's subcommittee would be -- For example, if they say the 700 hours and the 200 hours, would they be still having that determination to follow that?

CHAIRMAN MALMUD: The only way we'll get an answer to that question is offering the opportunity and seeing how many people avail themselves of it. I think there is no certain way of predicting. Some radiation oncologists practice in freestanding clinics. It would be impractical for them to leave

the freestanding clinics and go to an in-patient service, spend the time there and then rush back again.

So I don't think we can predict that and given the experience that preceded us with approval of endocrinologists to give I-131 therapy, the majority of them don't do it either. But it's still there for those who wish to. I don't think your question has an answer yet.

However, but we will move on this motion. All in favor of the motion?

All opposed to the motion?

So it's how many? Four again. It's easy to count the against. How many for?

Ten for. One opposed.

(Off the record comment.)

Is there an abstention?

One abstention. So it's 10-1-1.

MS. GILLEY: May I make a comment?

CHAIRMAN MALMUD: Please do.

MS. GILLEY: Okay. My suggestion as a path forward to go would be encourage NRC to begin the rulemaking process to move microspheres out of Part 1000 and move it into regulations and then these issues we have and these gaps with guidelines versus

regulations, T&E can all go through the public review process of the rulemaking. It's already in place.

CHAIRMAN MALMUD: I think for that you have a second. If that's a motion, Dr. Eggli seconds it.

DR. EGGLI: Second.

CHAIRMAN MALMUD: Is there discussion of that motion? That's in addition to the other motion, not instead of the other motion.

MS. GILLEY: That's correct.

MR. LIETO: I just have a question.

CHAIRMAN MALMUD: Yes.

MR. LIETO: May I ask NRC staff how many items in Part 1000 have ever been moved out?

(Off the record comments.)

Part 1000 has been there since what? 2002?

DR. HOWE: This is Dr. Howe. We were going to move intervascular brachytherapy out because we had enough experience with it that we thought we could move it into rulemaking and then it dropped in its use. So it didn't become cost/benefit.

Right now, we have a recommendation to move the perfection into 600. We haven't moved any into 1000 yet because there is a tremendous resource

that's involved in rulemaking. But that doesn't preclude us from moving it.

MR. LIETO: Okay. My answer is none.

CHAIRMAN MALMUD: The number is quite small in other words.

MR. LIETO: None.

CHAIRMAN MALMUD: That's a small number.

(Laughter.)

Dr. Sulelman.

DR. SULELMAN: I'm going to restate what I said earlier. I think by trying to force these in certain holes and whatever, you're going to cause problems. The technologies are changing so fast. In this case, they're either going to drop in use by the time you come out with rules. It may not longer be a valid technology. It may have morphed into a hybrid technology with some other imaging modalities. You're seeing some x-ray applications taking over for some radioactive sources like the Gamma Knife or at least competing with them and I think you have -- I think take a step back and think very carefully.

I kind of like 1000 because it catches everything. Maybe you eliminate all the others and put them all back under 1000 and just address the users in terms of radiation safety qualifications. I

just see this as pretty ugly right now and I don't see it getting cleaner. I see it getting more complicated.

CHAIRMAN MALMUD: Thank you. When something is very ugly, the only thing that can happen to it is it begins to look prettier. So the answer to your request, Dr. Salem, is that this subcommittee --

DR. WELSH: Do we still have a motion?

CHAIRMAN MALMUD: I thought we voted on it.

MS. GILLEY: My motion.

CHAIRMAN MALMUD: Your motion.

DR. WELSH: To move it out of 1000.

MS. GILLEY: And may I make another comment. It takes a long time to go through rulemaking. So I suggest if we're going to solve the gaps between the agreement states and the non agreement states and the variabilities that at some point, Tom, we need to start that clock.

CHAIRMAN MALMUD: So it's been moved and seconded. All in favor?

Any opposed?

(No verbal response.)

Carries unanimously. So we have two motions.

DR. SULELMAN: I am slow.

CHAIRMAN MALMUD: Are you abstaining again?

DR. SULELMAN: What's the motion that was actually on the floor?

MS. GILLEY: Encourage NRC to begin the rulemaking process. Move microspheres out of Part 1000 and into regulation.

DR. SULELMAN: I would vote against that.

CHAIRMAN MALMUD: So it's a 10 or 11. How many hands for?

Eleven for. One opposed.

DR. NAG: Since we made the subcommittee, I would suggest to speed up the procedure, we name members to the subcommittee.

CHAIRMAN MALMUD: All right. We will do that. But I wanted just to -- Because we have a guest today.

DR. SALEM: Thank you for the time for this, but I must be honest that I find myself confused.

(Laughter.)

DR. EGGLI: At least, there's two of us.

DR. SALEM: In terms of -- I understand some of the processes that we may initiate. Is there,

I'm going to ask the Committee, a short-term solution to opening a pathway for interventionalists? The reason I say this is with resources that we have in our communities and our societies a program that is numbered to be determined plus a training course that Dr. Welsh was describing with an examination can be accomplished within six to 12 months.

But if this is not anything that will accomplish anything substantive for interventional radiologists, then it would be nice to know because that's certainly much less work for me. But it would be nice to know if this is really not plausible. That really this has to go through the process and this will take some time.

CHAIRMAN MALMUD: I understand your concern. What I heard here today is that the spirit of this subcommittee is to find the mechanism to grant you what you're requesting.

DR. SALEM: Okay.

CHAIRMAN MALMUD: In addition, there's second motion to get things organized with respect to larger issues that are prevalent. That's separate and that will take a long time. The first one should be as rapid as the subcommittee can get together, meet and then report back to the Committee. But the spirit

of it was to try to achieve the goal that you're trying to achieve.

DR. SALEM: Thank you.

CHAIRMAN MALMUD: And you asked me to appoint a subcommittee. Dr. Zelac.

DR. ZELAC: It's probably worth noting that guidance is something that is adjustable in a relatively short period of time as opposed to rulemaking. So if a determination is made the Committee that it would be appropriate to move in this direction and that's the recommendation that comes from the Committee, then the staff is in the position to consider that recommendation and to move accordingly in short notice.

CHAIRMAN MALMUD: Dr. Zelac speaks for the NRC. So he suggested to do this as guidance and it would be a relatively short turnaround.

DR. SALEM: Thank you.

CHAIRMAN MALMUD: I need to appoint a chair of this committee. Who is intensely interested in this subject?

(Laughter.)

DR. NAG: I estimate that Bruce made the recommendation. He would be the chair, but Dr. Thomadsen is the chair but I would help. I'll be

willing to help him.

CHAIRMAN MALMUD: Dr. Thomadsen, would you please chair?

DR. THOMADSEN: I would, but this may have ramifications on future motions being made by people on this Committee from now on.

CHAIRMAN MALMUD: And I'll ask a nuclear radiologist to be there and that will be Dr. Eggli.

DR. NAG: I have looked at it for a long time.

CHAIRMAN MALMUD: Dr. Nag certainly. And we need a physicist, don't we? Dr. Welsh.

DR. WELSH: You need another member on it.

CHAIRMAN MALMUD: Yes.

DR. WELSH: You have a physicist, the chair.

CHAIRMAN MALMUD: We have physicist as chair.

DR. NAG: Yes, I hope so.

CHAIRMAN MALMUD: So we have it. Do we need a radio -- We don't need a radiopharmacist for this, do we? No. Okay.

DR. THOMADSEN: I think it might be very useful.

CHAIRMAN MALMUD: You think it would be

useful. All right. There we are because the measurements of the Yttrium and the well counter are precise estimates.

(Laughter.)

CHAIRMAN MALMUD: Very well.

DR. NAG: I think Jim also that you want to be on the committee.

DR. WELSH: You're right.

DR. NAG: Dr. Welsh wanted to be on the committee.

CHAIRMAN MALMUD: They are precise, yes. So we have the committee. You are the chair. Do you approve of your membership?

DR. THOMADSEN: I think they're delightful.

CHAIRMAN MALMUD: Could we have done any better?

DR. EGGLI: Is there a person NRC staff liaison for us?

CHAIRMAN MALMUD: The NRC staff liaison.

DR. NAG: Not for the subcommittee though.

CHAIRMAN MALMUD: Not on the subcommittee. All right. Then we'll go to the person on the NRC staff and sitting over to my left are Dr. Howe and Dr. Zelac, both of whom look intensely interested in the

subject. So we'll get it to them and then they will get it to their hierarchy as well.

I hope that that shows some progress with this.

DR. SALEM: Thank you very much. Thank you for the time.

CHAIRMAN MALMUD: Thank you for being here and thank you to the members of the public who spoke today as well.

Do you want to take a short break? Be back at 3:45 p.m. Off the record.

(Whereupon, the above-entitled matter went off the record at 3:34 p.m. and resumed at 3:45 p.m.)

CHAIRMAN MALMUD: It will be necessary at 4:00 o'clock for several members of the Committee to leave so that they can get their badges, which have to be done during this hour. So Ashley will give me a tap on the head to remind me when they have to be taken out.

(Laughter.)

MS. TULL: I thought you liked me.

MEMBER GILLEY: Taken out?

MEMBER NAG: What do you mean? You take them out like the mafia?

CHAIRMAN MALMUD: All right. Let's see.

What are we proceeding with? We're back to Dr. Nag's item. Is that correct?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: And you will recall there were a number of bullet points. The first four are the ones that you wanted us to hopefully agree with and then --

MEMBER NAG: Yes. If I may?

CHAIRMAN MALMUD: You are on. Yes. Go ahead.

MEMBER NAG: Okay. I have thought it would be more efficient to make this more into like a line item, make it into part A and part B. So we will work on part A separate from part B.

Part A is specific recommendations that are specific for limited brachytherapy. And those are the ones before the line that says permanent implantation should be deleted, treatment sites should be clarified, and then A through B will become superfluous. And that one should be eliminated. And the activities should be replaced by source strength.

So my motion is that these are the recommendation of the Subcommittee, and we vote on this. And then I will make a separate recommendation for the next one.

MEMBER THOMADSEN: Do we still have the motion, Mr. Lieto's motion, on the floor?

CHAIRMAN MALMUD: We do.

MEMBER NAG: If we do, I am modifying it to include this all as one.

MS. TULL: This is Ashley. You voted on it.

MEMBER THOMADSEN: It started as an amendment to the --

CHAIRMAN MALMUD: We voted on it.

MEMBER THOMADSEN: Oh, we did vote on it?

CHAIRMAN MALMUD: Yes. We passed that one.

MEMBER THOMADSEN: Then it was moved again.

MS. TULL: The vote was 8:3:0.

MEMBER THOMADSEN: I mean, we had passed it. And then we -- what?

MS. TULL: This is Ashley. The vote was 8:3:0, 8 in favor, 3 opposed, no abstentions.

CHAIRMAN MALMUD: We finished.

MS. TULL: But that was just for the pre-implantation, which I believe is the first thought.

CHAIRMAN MALMUD: That was for the first

bullet point.

MEMBER NAG: Yes. And then we go to the second bullet point that clarifies that the treatment site include the volume plus a very low treatment margin.

CHAIRMAN MALMUD: If that is a motion, will someone second the second bullet point?

MEMBER WELSH: I will second it.

CHAIRMAN MALMUD: It has been seconded. Any further discussion of the second bullet, just the second bullet?

MEMBER FISHER: I am sorry, but I think that when we took our first vote, we voted on this set of recommendations, not the first bullet.

CHAIRMAN MALMUD: Dr. Nag says that his motion was Mr. Lieto, and it was only the first one.

MEMBER NAG: Mr. Lieto's motion on the first --

CHAIRMAN MALMUD: Ralph, do you recall? Was it one or all four? What had you proposed originally?

MEMBER LIETO: Yes.

MS. TULL: This is Ashley. I think that there was a second recommendation.

MEMBER LIETO: We voted on first one,

which was the issue --

MEMBER NAG: Pre-implantation.

MEMBER LIETO: -- which really addressed the first bullet up there. The second --

MEMBER EGGLI: But that wasn't the wording.

MEMBER LIETO: Pardon?

MEMBER EGGLI: That wasn't the wording of your motion, though.

MEMBER LIETO: No.

CHAIRMAN MALMUD: Well, it looks like today is a day of corrections. So do you wish to correct your motion?

MEMBER LIETO: No, but it did the same thing.

MEMBER EGGLI: Right. Your motion said something to the effect that up until the time the person leaves the procedure area, the written directive could be modified was the essence of your first motion that passed.

MEMBER LIETO: Right, that the medical event is based on the written directive at the time the patient leaves the proposed treatment procedure room or whatever the term is used.

MEMBER NAG: I would like to now -- it

means the same thing, alternative --

MEMBER LIETO: It is verbatim out of the report.

MEMBER NAG: Yes. The one that was confirmed said it would be a medical event if the total source strength administered occurred by 20 percent or more from the source strength documented in the pre-implantation written directive.

Okay. The recommendation was that the administration of byproduct material, all radiation from byproduct material results in total source strength administered deploying by 20 percent or more from the total source strength documented in the written directive, that there is delete "pre-implantation." So basically the same thing is a summarized form of the same.

CHAIRMAN MALMUD: Just deleting pre-implantation.

MEMBER NAG: Right.

CHAIRMAN MALMUD: And that is the motion that we had moved on or that you wish us to move on? That is the motion?

MEMBER NAG: That first one was already moved. So I forgot that it had been moved already. So we have to go on to the next two.

CHAIRMAN MALMUD: So the proposer's memory of the first motion was limited to the first bullet point. May we move on to the second bullet point?

MEMBER THOMADSEN: But I believe that that was the case in retrospect. But then did not Mr. Lieto make a second motion to approve the entire report, the recommendations of the entire report?

CHAIRMAN MALMUD: That is correct.

MEMBER THOMADSEN: It was seconded. And in the discussion, it was then --

CHAIRMAN MALMUD: Interrupted.

MEMBER THOMADSEN: -- interrupted.

CHAIRMAN MALMUD: Right.

MEMBER THOMADSEN: And now we are resuming that. So I think we have a motion on the floor. The transcriber could --

CHAIRMAN MALMUD: You are correct. You are correct.

MEMBER THOMADSEN: -- possibly correct me on that.

CHAIRMAN MALMUD: Dr. Thomadsen is correct. The motion is on the floor. Perhaps we should just -- do you want to table it or do you want to move it forward? What would you like?

MEMBER NAG: What is the motion? I would

like to make clear.

CHAIRMAN MALMUD: The motion is to approve everything as it stands on that.

MEMBER NAG: But the first one has already been approved.

MS. TULL: That's okay.

CHAIRMAN MALMUD: Yes, we know that. The issue is not the first one any longer. The issue is what remains on there. You can either table it or you can bring it forward and reject it and then go through each bullet point at a time. Or withdraw it, or you can amend it.

Whose motion is it? Ralph, it is your motion. What would you like to do?

MEMBER LIETO: To approve. My motion was to approve the report.

CHAIRMAN MALMUD: The whole thing?

MEMBER LIETO: Yes, all the recommendations in the report.

CHAIRMAN MALMUD: All right. Any further discussion of that?

MEMBER GILLEY: I would like a definition of what gross tumor, clinical target volume, invariable planning margins are as far as the parameters because that will determine whether or not

we have a medical event per se. I don't have definitions for those in the regulations.

MEMBER NAG: They are not even in the regs. They are in ICIU-52, I believe.

MEMBER THOMADSEN: They updated it to 62. They put some out for the new one, but I'm not sure what that --

MEMBER NAG: In the ICIU regs. It basically says that the gross tumor volume is the volume that contains the tumor. And the minimum target volume is the area of the gross tumor plus the variable margin. That's the margin that contains microscopic tumor. And the planning target volume is the area around that, the area that the radiation oncologists wish to implant. Those are the three volumes.

MEMBER THOMADSEN: It is in the slide.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Hopefully this will help to answer Debbie's question. The regulation addresses treatment site. And the subcommittee is making a recommendation to clarify that definition so that you can more easily determine medical events. And the treatment site is now being clarified to be named the PTV, the planned tumor volume, which is defined in

ICIU. It is an international definition and is clearly understood across the radiological, radiation oncology community.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: I would like to discuss amending the motion by including the bullet points with the exception of the last one because I think the last one is controversial enough that there could be enough dissention that the whole package might not pass and could be throwing the baby out with the bathwater by mixing that last item in here.

The others are clearly very relevant to prostate brachytherapy and are causing a great deal of consternation to active practitioners.

The last issue I think we're going to have a lot different opinions on, but I think the first four items I think we would have a lot of unanimity on. And, therefore, I would propose separating that last one out.

CHAIRMAN MALMUD: Dr. Welsh recommends dropping the last bullet point and voting on the bullet points above with the exception of the first one, which has already been approved.

VICE CHAIRMAN VETTER: Second.

CHAIRMAN MALMUD: It has been seconded by

Dr. Vetter. That's an amendment to the motion.

MEMBER SULEIMAN: You are saying we are voting on the second, third, and fourth bullet points?

CHAIRMAN MALMUD: Second, third, fourth, fifth.

MEMBER THOMADSEN: Everything except the last one.

CHAIRMAN MALMUD: Two, three, four, five.

MEMBER SULEIMAN: And does that mean we are going to discuss the last one separately?

CHAIRMAN MALMUD: That's not being discussed in this motion. The last one is not being addressed in this motion, only the bullet points up to the last one.

MEMBER SULEIMAN: Well, if we are going to limit it just to the bullet points up to that and you're not allowing us to decide if we're going to discuss the last one separately --

MEMBER NAG: The last one would be a separate motion.

CHAIRMAN MALMUD: Dr. Suleiman, I have never disallowed any discussion. No. What I am saying is that the motion that is on the table addresses the bullet points except for the last one. So let's not discuss the last one until we are done

with the motion above.

MEMBER NAG: Again, I would like to amend the motion since the first one has already passed and --

MEMBER THOMADSEN: Don't we have a motion? We have an amended motion on the floor right now.

CHAIRMAN MALMUD: Yes, we do.

MEMBER FISHER: You can amend an amendment.

CHAIRMAN MALMUD: Sure, you can.

MEMBER NAG: I am amending the amendment.

MEMBER THOMADSEN: He is not amending the amendment.

MEMBER NAG: Yes.

MEMBER THOMADSEN: It is a new amendment.

MEMBER GILLEY: A new amendment? Until we vote on this amendment.

VICE CHAIRMAN VETTER: The amendment is the last item.

MEMBER NAG: Right. And I am last. I am eliminating the first and the last. The first has already passed.

VICE CHAIRMAN VETTER: Don't worry about it. You succeeded.

CHAIRMAN MALMUD: We now understand what's

on the table is bullets 2, 3, 4, and 5.

MEMBER THOMADSEN: We haven't voted on that amendment yet, have we?

CHAIRMAN MALMUD: No. That's the amendment. It would be just those four. So all in favor of this amendment, please raise your hand.

Eight.

All opposed?

Two opposed. It's -- oh, three. Where is the third? I'm sorry. Okay.

MEMBER NAG: Now I would like to make a new motion for the --

MEMBER SULEIMAN: Whoa. We haven't finished this one. We just voted on whether we --

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Do you wish to amend your new --

MEMBER NAG: The new motion is now we go to the last bullet point and --

MEMBER THOMADSEN: No, no. We have a motion on the floor.

MEMBER NAG: No. The motion has already been voted.

CHAIRMAN MALMUD: Everyone is going by parliamentary rules now. So we have another amendment

on the floor. And that is to vote on items 2, 3, 4, and 5. Am I correct?

VICE CHAIRMAN VETTER: That is the motion. That is the new motion.

CHAIRMAN MALMUD: That is the new motion. Dr. Vetter says it is so. So it must be so. So it's 2, 3, 4, and 5, not 1. It has already been approved, not the last one. It is not on the table. So is that correct? And it has been moved and seconded. Any further discussion?

(No response.)

CHAIRMAN MALMUD: All in favor of approving items 2, 3, 4, and 5?

Nine.

All opposed?

Two. Nine to two. Okay. Now we'll move on. So we now have approved 1, bullet 1, bullet 2, bullet 3, bullet 4, bullet 5.

Does anyone wish to tackle the last bullet that you wished to be deferred? Dr. --

MEMBER NAG: I will make a separate motion for that.

CHAIRMAN MALMUD: Okay. Make a separate emotion.

MEMBER NAG: My motion now is that

administration without working with written directive should be cited as regulation violations and are not medical events per se.

CHAIRMAN MALMUD: Is there a second to that motion?

MEMBER NAG: That was your motion.

MEMBER LIETO: That is not exactly what --

CHAIRMAN MALMUD: No second to the motion. I beg your motion?

MEMBER WELSH: Second.

CHAIRMAN MALMUD: Dr. Welsh seconds the motion. Is there any further discussion of the motion, which has been moved and seconded?

DR. NAG: I would like Ralph to clarify why that is not what is in the report.

MEMBER LIETO: Thank you. The administration without written directive is a violation of regulations already. I mean, it's not that we're adding or changing anything.

What the body of the report reflects is a discussion to support the fact that they should not be classified as medical events. And this is part of the proposed rules that the subcommittee was asked to address. It's not something new that was brought up.

It's an addition into the definition of

the rules that are under the title of permanent brachytherapy. They encompass all written directives, not just permanent brachytherapy. It also includes temporary brachytherapy as well as radiopharmaceutical as well as the part 1000 therapies.

So I felt that, for the reasons that are described in the report, that making a violation of the regulations a medical event when there was not -- to me, I guess I am also looking for the support as to why not having a written directive needs to be a medical event. Okay?

I'm not saying that it's not a violation that needs to be handled as a violation, but just like any other type of medical event that you find that you self-identify, this would be handled in the same way that you handle any type of self-identified regulation under the licensee's auspices. And that's where I think it should stay. I don't think it needs to be in the medical event reporting.

Contrary to what was said earlier, that the reason for this is so that medical events are not necessarily things that indicate harm to the patient, that's true. But these go into the reporting mechanisms for the medical events, which means it automatically within 24 hours goes into the public

venue.

It's handled just the same way as a reactor event would be in terms of notification to the general public. And I don't think that they warrant that type of reporting.

CHAIRMAN MALMUD: Thank you for clarifying that.

MEMBER NAG: How would you make a motion of that, that we should issue an LIS? Can you state how we can make it into a motion?

MEMBER LIETO: Just as it states here, that that part should be stricken from the proposed rule.

MEMBER NAG: That the LIS be issued emphasizing that administration we thought required written directive of violation of regulation and are not medical events per se, but you must access to identify any deviation from the requirements? That's what mine says.

CHAIRMAN MALMUD: May I make a suggestion to you? What would you think of the wording that says, "Administrations without prior written directives are to be cited as regulation violations," period?

MEMBER LIETO: Well, written directives

are required prior to the administration.

CHAIRMAN MALMUD: Ah, but we heard about written directives that are changed afterwards.

MEMBER LIETO: I mean, that's in the regulation right now if I'm not mistaken that a written directive is required to be signed and dated prior to administration. I mean, that's the way the current rule states. I am not recommending changing that.

CHAIRMAN MALMUD: I didn't recommend a change either. I just recommended that it be reiterated.

Dr. Suleiman?

MEMBER SULEIMAN: If they don't have a written directive, it's a serious violation, correct? Without a written directive, how would you know whether you had a medical event because you wouldn't know whether you have exceeded the area or the quantity or whatever. And it's double jeopardy to both get hit on the lack of written directive violation and then get hit with a medical event when it's an administratively defined medical event.

So I think that is consistent. In other words, the lack of a written directive basically just qualifies them from a medical event, but it is a

heavier penalty. I mean, it is a heavier --

MR. LEWIS: Right. While I agree with what Mr. Lieto said, I think you have to take this slide into context with what it's together with, which is your Committee comments on the proposed rule, not the current rule.

MEMBER SULEIMAN: Correct.

MR. LEWIS: Among your comments is a change in when a written directive occurs, whether it's before or after the actual procedure. I think that to properly give context to the last bullet, you have to consider that fact that it's not always ahead of time the way that you proposed that we changed the proposed rule.

It's not always a pre-procedural written directive. It can be a post-procedural written directive, as we talked about this morning.

MEMBER LIETO: Does that make a difference?

MEMBER SULEIMAN: Wait. I want clarification. You can modify it, but you had to have something on the table in the first place. I mean, you are going in with a target dose. And you then modify. And then you make the corrections.

But going without any written directive,

how do you know if you are on target or not at all? So I think without a written directive to me means no written directive.

CHAIRMAN MALMUD: Please, Dr. Welsh?

MEMBER WELSH: So this morning we discussed issues relevant to this particular topic One of the issues we discussed was how do you solve the dilemma of real-time interoperative planning, where the plan is generated in the operating room and then the written directive is put together after the fact?

Dr. Zelac put together a suggestion that at the time the plan is finished, that is when an oral written directive might be generated. I kind of like that idea because then you do have something that you use as a template, a guide that serves as your pre-procedural written directive and you could still have an adjustment afterwards based on what happens to volume change, size changes in the procedure.

MEMBER SULEIMAN: I would argue that the fact that you are even initiating the software program to start calculating to me is sort of an implicit. I mean, it hasn't been finalized but tells me that there is some planning and thinking going into this process.

So I would argue that that doesn't mean it

doesn't have a -- it may not have a written, in-writing directive, but I think the initiation of the software to do the treatment planning, do the dosimetry --

MEMBER WELSH: In that case, there can never be an administration without a written directive by your definition.

MEMBER SULEIMAN: No because you have said: I want the opportunity to make changes. So you have now committed to having a final directive based on what happened during the procedure.

So you cover yourself. You allow yourself that flexibility that when you're finished, you need to document what happened. And then that --

MEMBER LIETO: I would agree. I mean, the regulations, the current regulations, in force say you have to have a written directive prior to the administration.

What determines the medical event is that written directive that is made before the patient is released. After you have done your changes in your real time and whatever, the medical event is based on the written directive changes before the patient is released.

CHAIRMAN MALMUD: I don't think you want

that because if you had a sound medical reason for changing the written directive, then you would have a medical event, even though you had a sound reason for it? No. You don't want that.

MEMBER LIETO: Why would you have a medical --

CHAIRMAN MALMUD: Because you changed your written directive.

MEMBER LIETO: But you did that before the patient was released from your control. During the course of the treatment, you make these --

CHAIRMAN MALMUD: You modify it.

MEMBER LIETO: -- changes and modify it based on whatever. That then becomes your basis for the medical event determination.

CHAIRMAN MALMUD: All right. Now I understand.

Dr. Howe?

DR. HOWE: This is Dr. Howe. The issue wasn't that you hadn't modified your written directive, and the issue wasn't that you didn't have a complete written directive. The issue was you didn't have a written directive at all.

A person receives a treatment that requires a written directive and there is no written

directive. And it happens rarely, but we have had patients that have gotten therapeutic procedures in which there was no written directive at all. And we wanted those to be reported to the NRC. And the important concept here is reporting.

CHAIRMAN MALMUD: Reported as what, as violations or as medical events?

DR. HOWE: No. As a medical event.

CHAIRMAN MALMUD: Oh, okay.

DR. HOWE: Because you don't have to report violations, but you do have to report medical events.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: And I address that in this report. Let's say you have two scenarios, I mean, there are two scenarios. You have a patient. You do not have a written directive, verbal or written. It's the patient you intended to give the therapy to.

And you give the patient what you intended to, but there is no written directive. Okay? There are no health and safety issues in terms of harm to the patient in that scenario. That patient hasn't been harmed. Okay. You didn't document what you intended to do. I mean, you did what you intended to do. You just didn't document it.

My second scenario is the patient, no written directive or verbal given of what you intended to do. You say you are intended to give a I-123 diagnostic administration and, instead of 200 mics, you give 200 millicuries of I-131. Okay? You obviously have exceeded by ten percent and exceeded all the dose criteria for a medical event. And that has to be reported.

CHAIRMAN MALMUD: Okay. May I ask you a question? Why would anyone give a therapeutic dose without a written directive? What would the circumstances be that would excuse the absence of a written directive?

MEMBER LIETO: I'm not making any excuses for it. I'm just saying --

CHAIRMAN MALMUD: I understand that. That is the first part of my question.

MEMBER SULEIMAN: I can see that.

CHAIRMAN MALMUD: You can see that. Dr. Suleiman from the FDA?

MEMBER SULEIMAN: I would say these are approved for humanitarian use. The patient is not going to live very long. And so you have "Why bother? I'll give this person what I gave the last person" and sort of --

CHAIRMAN MALMUD: Well, you still have a written directive. You write out a prescription for what you are going to do.

MEMBER SULEIMAN: Well, maybe they felt so casual about the thing they forget to write the written directive. You asked me to come up with a scenario. That's all I did.

CHAIRMAN MALMUD: No one on this Committee will vote for that.

Dr. Welsh?

MEMBER WELSH: I can't give you an example, but Dr. Howe says it has happened. So maybe we should ask under what circumstances this has happened.

DR. HOWE: It happened with intervascular brachytherapy, in which there were patients coming in and the authorized user reviewed cases for -- there were like four potential people. They reviewed the cases for three, never reviewed the case for the fourth one.

The first person didn't show up. They gave the intervascular brachytherapy to the remaining three. It was never a written directive for the fourth person. There was never an evaluation for the fourth person. And they received the intervascular

brachytherapy.

CHAIRMAN MALMUD: We would all agree, having heard this story, that we would object to it. There is no one here who would approve of that I don't think.

So, therefore, once again I ask the question, under what circumstances? I mean, after all, this is not emergency room medicine, where quick decisions have to be made, even then thoughtfully.

What would be the reason for giving a patient a therapeutic dose of radioactive material without a written directive?

MEMBER NAG: Even in the emergency is obvious because I forget under what part that it is because of the emergency nature of the procedure, you can have a verbal written directive that you can sign within 48 hours or 34 hours. So even that is that. I have used that provision. So I know that.

CHAIRMAN MALMUD: This is for radiation therapy?

MEMBER NAG: For radiation therapy for brachy dose.

CHAIRMAN MALMUD: So you are saying there are valid reasons not to have a written directive?

MEMBER NAG: No. But, I mean, the

provision is already there for emergency, under emergency conditions, --

CHAIRMAN MALMUD: For emergency.

MEMBER NAG: -- you have to do that.

CHAIRMAN MALMUD: Why would someone be scheduled for -- again I would ask the same question. Can you give me an example?

MEMBER THOMADSEN: I am just curious. Why are you looking for justified examples? I don't think anybody is saying that it is ever justifiable.

CHAIRMAN MALMUD: Then we should reaffirm that it's not justifiable. I am puzzled by --

MEMBER THOMADSEN: That's fine, too. I mean, it says it's a violation. Nobody is arguing that it is not a violation. It's Hynia's the people are wicked and evil, but it's probably not a medical event. That's the only thing that this is saying.

If you wanted to take on an appendix that says, "And we heartily" --

CHAIRMAN MALMUD: I said that was the first part of my question. Okay. So now it's okay not to have a written directive. So now I will play the role of the sloppy practitioner. I didn't have a written directive for the last three. I don't need one for this one.

Give him 100 millicuries. He only needed ten. Where is the evidence that he only needed ten? Where is the evidence that I gave the wrong dose? It isn't there because there was no written directive. Why wasn't there a written directive? Because I didn't need it the last three times. It doesn't get reported to the NRC. Don't worry about it.

Once we go down a slippery slope of not having written directives, I think we enter a world which none of us lives in but which exists. And that is the world of sloppy medicine.

And that's what concerns me. That's why I asked my question in two phases. Once we open the door, who knows what will happen? It's like, you know, look how many prescription errors there are in the United States according to the Institute of Medicine. Why wouldn't the same errors be made with radioactive material?

That's what my concern is. My concern is for the patient who will suffer as a result of laxity in requiring us to write a written directive.

I don't live in the world of emergency medicine. So, therefore, it's easy for me to write a written directive. And I never have not written one.

Dr. Welsh?

MEMBER WELSH: I think that we would all agree that there are no circumstances in which you shouldn't have a written directive. Even if it's an emergency and you have to put it together the day after, you should always have a written directive. And I think everyone would agree with that.

The question at hand is, if a written directive, for whatever heinous reason, was not put there, what do you call that? Is it a medical event or is there another category which would be more appropriate? And is there such thing as a reportable regulation violation?

CHAIRMAN MALMUD: Is there such a thing as a reportable regulation violation?

DR. HOWE: No, there is not. The only thing we have reportable in part 35 is if you have a leak test that exceeds a certain level, if you have a medical event, if you have embryo fetus that receives a dose over a certain level.

So there are very few reportable things in part 35.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: Yes, a quick question. You are talking about amending the regulations. This is rulemaking. Why can't you have a reportable

violation? I mean, I think the resistance against making this a medical event is to make it a medical event so it's reportable.

Well, this is where you take the wrong reason, the wrong reg to get a right solution and downstream this is going to cause other complications. Why call it a medical event when, in fact, it is a failure to write the written directive, you know? And why not make it reportable under the proposed rulemaking?

MEMBER NAG: I would agree to that that --

MEMBER SULEIMAN: Let's call a spade a space.

MEMBER NAG: I mean, having a procedure where a written directive is required, a legal written directive, is a reportable violation. I have no problem with that.

MR. LEWIS: Just for the record, we do have other parts that apply to medical licensees. And those have reportable violations of exposures of personnel, releases to environment, failure of --

MEMBER SULEIMAN: I mean, this is serious. This is a therapy. And they haven't done a written directive. Yes. As soon as they find out, they should have to report it.

CHAIRMAN MALMUD: So there are interim levels between --

MR. LEWIS: Well, there are other regulations that have reporting requirements.

CHAIRMAN MALMUD: Good. Can you give us one that we could all agree upon that's not as severe as a medical event?

MR. LEWIS: Because our system for reporting for the conditions in part 35, patient dose was off by 20 percent or wasn't what was prescribed, those are defined as medical events. And that is our system for reporting.

So, again, I guess one way to look at this is if NRC wants to hear about it, it should be reported as a medical event. Help me out, Donna-Beth, if I am off base, but we don't need another regulatory system of different types of things to report. Let's just have one thing.

CHAIRMAN MALMUD: You see, that's where we have a problem. We recognize as physicians that there may be a variation of more than 20 percent in a dose received by the patient, which is not really a medical event. It can occur in the hands of the best physician. That physician and that institution should not be subjected to what you go through when you have

a "medical event."

We are looking for something in which you will be informed but does not have the course of action following it which actually discourages reporting events.

We would like you to know about these events. We would like you to know how many administrations we are given without a written directive so that you could send somebody in there and say, "Hey, what is going on around this place?" and begin haunting them the way a regulatory agent should haunt a provider that is not adhering to the rules. We are in the spirit of Halloween you raised it. You raised heinous issues before.

So the point is we are looking for something. We are not trying to escape it. On the other hand, the punishment does not fit the crime. The punishment is too severe for a legitimate practitioner whose therapy dose is outside the guidelines for a reason which may be very explainable without it being plastered on the internet and causing embarrassment.

Is there something between a regulatory violation and a medical event that could be reported to the NRC without the sequelae of a medical event?

MR. LEWIS: Not in part 35.

CHAIRMAN MALMUD: Then that is something that we would probably want all to work with you to try to develop over the long haul because I think that would improve the safety of patients by making the incidents not so severe that some parties might decide to try and hide them, rather than report them.

MR. LEWIS: NRC only wants to hear about things we need to hear.

CHAIRMAN MALMUD: Of course.

MR. LEWIS: We are not trying to create something we need to hear about. In the past, we drew the line of things we want to hear about versus things we don't need to hear about at medical event.

CHAIRMAN MALMUD: But you realize traffic has three colored lights: --

MR. LEWIS: Yes.

CHAIRMAN MALMUD: -- a green, an orange, and a red.

MR. LEWIS: I appreciate what you said.

CHAIRMAN MALMUD: I am trying to get the orange in there.

Dr. Zelac?

DR. ZELAC: Actually, in thinking about this, we really have kind of a fundamental problem

here, which has already been alluded to. The whole concept of medical events was to bring out for consideration facilities where there were lapses in procedures so that there could be attention paid to those lapses.

And we have made the point repeatedly that medical events were not violations. Well, here you have got a case where there is something that is being classified a medical event which, in fact, is a violation. So it doesn't really belong in that category.

CHAIRMAN MALMUD: What happens when a medical event is reported to, let's say, district one? What happens?

DR. HOWE: For region one?

CHAIRMAN MALMUD: Region 1.

DR. HOWE: A potential medical event may come into region 1. Region 1 will tell the licensee to report it to the WHO. It becomes an event notification. It can be called a potential medical event if there is still a question or it can become a full medical event.

And then region 1 will either evaluate what it was and decide it is really important for us to go out and schedule a reactive inspection or region

1 may decide that yes, it was a medical event, but it doesn't appear to be a serious problem with your program. We have an inspection coming up at a certain time. We will go on a routine inspection. This is one of the things that we'll ask about.

And so depending on what it is coming in, there will be a value judgment made as to how NRC will react on it.

CHAIRMAN MALMUD: It is not made public, then.

DR. HOWE: The event notification is made public. If we think it is a potential medical event, we're not sure, we'll hold it for about five days. And then it becomes public. If we know it is a medical event, we'll make it public.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: Well, that's not all. There are other notification requirements, including the patient and referring physician. But the medical event is based on a variance from a planned therapy, which implies it's a variance from the written directive. You're redefining now medical event to include the absence of a written directive.

So you are fundamentally changing the definition of the medical event, which is the flip

side of what Dr. Zelac just pointed out, which is that medical events are not considered violations, where in this case we have a violation.

You are changing the definition of a medical event because you now no longer have anything to benchmark against whether or not this really is a medical event without changing the definition to include absence of a written directive. So you are now fundamentally changing the definition of medical event across the board.

It is sneaking in in a subsection of brachytherapy, but it will apply broadly because it doesn't say brachytherapy administrations without written directive. It says administrations without written directive. So you are fundamentally changing the definition in a place where it probably ought not to be fundamentally changed.

MEMBER NAG: And this was another reason why I wanted to separate a discussion of permanent brachytherapy with this because this applies not only to permanent brachytherapy but for other sources, too. I wanted this to be a separate discussion because it implies that there were broad implications.

DR. HOWE: It doesn't really deal with the unsealed sources because the way the rules are

written, we are able to capture those events in which an unsealed therapy is given but there wasn't a written directive because we can go back to the second part of prescribed dosage and we can see that that prescribed dosage is also based on your procedures.

And if your procedure manual includes one of the diagnostic things and you gave a therapeutic, then we say, "This is your diagnostic procedure. You intended to give whatever this was. You gave this that differs from the dose you would have given in the diagnostic by" such and such.

So we have a regulatory basis to get into the unsealed. It's the sealed sources where the dose is dependent on what is in the written directive because no written directive, there's no dose for it to be different from and you weren't supposed to get a dose, but OGC has determined that is not a medical event and it's not reportable.

And so someone gets a therapeutic dose without a written directive. It's not reportable to the NRC.

MEMBER NAG: Right.

DR. HOWE: That's the thing we want to fix.

MEMBER NAG: It's more than permanent

brachytherapy. It includes removable brachytherapy, HDR, and gamma knife but does not include the unsealed source. Let me correct myself.

CHAIRMAN MALMUD: Okay. So where do we stand at the moment?

MEMBER SULEIMAN: I would like to amend if there is a motion on the floor. I don't know if there is a motion on the floor.

MEMBER NAG: I have withdrawn it.

MEMBER SULEIMAN: I was going to say change the wording on that last thing to say "Administrations without a written directive should be cited as a reportable regulatory violation and are not" --

MEMBER NAG: I was going to say the same thing.

MEMBER SULEIMAN: And how the NRC does that is up to -- I mean, you have got other reportable.

CHAIRMAN MALMUD: Was that a motion you just made?

MEMBER SULEIMAN: It was an amendment to a motion I thought was on the floor. Otherwise I will make it a motion.

MS. TULL: There is a motion on the floor,

yes.

CHAIRMAN MALMUD: What is the motion on the floor?

MS. TULL: I had NRC staff should accept the sixth recommendation of the Permanent Implant Brachytherapy Subcommittee report, which would just be the last bullet listed on that slide.

MEMBER NAG: Yes. I would amend that and say administration without a written directive should be classified as a reportable regulatory violation.

CHAIRMAN MALMUD: That is a motion. Is there a second to that motion?

VICE CHAIRMAN VETTER: Second.

CHAIRMAN MALMUD: Dr. Vetter seconds it. Is there any further discussion of that motion?

MEMBER LIETO: As I understand, there is not any mechanism.

VICE CHAIRMAN VETTER: They are writing the rules right now.

MEMBER LIETO: Right, but that --

VICE CHAIRMAN VETTER: That is nonnegotiable.

MEMBER LIETO: That does not get to the gist of the issue in terms of what is being proposed in the current rules. The proposed rule states that

any administration without a written directive. And that is what the subcommittee report asks to be withdrawn.

CHAIRMAN MALMUD: That can be dealt with as a separate motion. First we move on this motion.

MEMBER WELSH: May I ask --

MEMBER NAG: I am confused.

MEMBER WELSH: Before I make --

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: I would like to have some clarification from Ralph about that point. I think that the motion is that administrations without written directive should be cited as reportable regulation violations, period.

How about if we said "and are not medical events"? Would that satisfy what you just brought up?

MR. LEWIS: Or may or may not be medical events because --

MEMBER NAG: That is why the "per se" is there.

MEMBER WELSH: Yes, per se. Would that satisfy what your thought was?

CHAIRMAN MALMUD: You are asking a question of whom, Dr. --

MEMBER LIETO: I believe it would, yes.

MEMBER WELSH: So, therefore, there is an amendment to the motion.

CHAIRMAN MALMUD: The amendment to the motion reads, "Administrations without written directives should be cited as reportable regulation violations and may or may not constitute MEs," period. Is that what you're saying?

VICE CHAIRMAN VETTER: Yes.

CHAIRMAN MALMUD: And that has been seconded. And Dr. Zelac has a comment.

DR. ZELAC: My suggestion would be to add the words "when a written directive is required" because there are many administrations for which a written directive is not required.

CHAIRMAN MALMUD: Thank you.

Dr. Zelac makes that suggestion to your motion. Is that acceptable?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: So that it will read, "When a written directive is required, administrations without written directives should be cited as reportable regulation violations."

DR. HOWE: I don't think you want to say "cited." I think you want to say "reported."

CHAIRMAN MALMUD: It should be reportable?

DR. HOWE: Classified as.

CHAIRMAN MALMUD: "Should be reported as regulation violations" -- you can polish up the words -- "and are not necessarily MEs" or "may or may not be MEs." Is that right, ""may or may not be MEs"? Is that acceptable?

MEMBER SULEIMAN: I just have a question about the last clause, "may or may not." Why not just not say anything?

CHAIRMAN MALMUD: Well, because a patient can come into the hospital for a bone scan and, instead of getting 20 millicuries of technetium on IMDP, they get 20 millicuries of I-131.

MEMBER SULEIMAN: By definition, that would be a medical event you are reporting. Why do you have to have --

CHAIRMAN MALMUD: That will be reported.

VICE CHAIRMAN VETTER: Because there was no written directive.

CHAIRMAN MALMUD: There was no written directive. The patient didn't have a written directive, came in with a referral for a bone scan.

DR. HOWE: In that case you would use the procedures for the diagnostic procedures. And there would be something in writing. It wouldn't be a

written directive. That's your second alternative.

MEMBER SULEIMAN: Standing order dosage activity that they exceeded by --

CHAIRMAN MALMUD: How about Mrs. Smith brings her daughter in for I-131 and the daughter sits there and someone says, "Are you Ms. Smith?" and the mother says, "Yes"? They come in. They give the mother the dose. There was no written directive.

I'm trying to bring up absurd situations in which you may want --

DR. HOWE: It is more or less someone comes in and gets a therapy dose. And they weren't intending to get anything, and they got it.

CHAIRMAN MALMUD: Yes.

DR. HOWE: In some cases like the Smiths, you might consider that wrong patient, wrong person. But it's the sealed source one. There wasn't really any written directive there to give anything, but somebody had extra material and they just gave it to you.

CHAIRMAN MALMUD: Okay. Dr. Zelac?

DR. ZELAC: I think the determination should really be made on the basis of what was delivered. If it was a dose delivered that required a written directive and there wasn't one, that's an

issue.

CHAIRMAN MALMUD: Yes, I agree.

MEMBER SULEIMAN: And the second part of that would be if a dose were given and there wasn't a written directive but it was a dose that was clearly wrong, you know, you were giving them much more than they would have received if you had bothered to write the --

CHAIRMAN MALMUD: Do you want to leave off the last part of that statement, just say that -- it's gone off the board now. We will get it back.

MS. TULL: What I am giving you is your actual recommendation.

CHAIRMAN MALMUD: Oh, wonderful. Thank you. I hope you have improved it.

MS. TULL: So it is this one right here.

CHAIRMAN MALMUD: NRC staff should accept the sixth recommendation. NRC staff should accept the sixth recommendation of the Permanent Implant Brachytherapy Subcommittee report, later amended to read "When a WD is required, administrations without a prior WD are to be reported as regulatory violations that may or may not constitute a medical event."

Is there agreement on that? Debbie, do you agree?

MEMBER GILLEY: I just wanted to know the status of this being a recommendation and the impact on agreement states. Maybe NRC can provide clarification since it is not in regulations and it is not a compatibility issue at this time as a recommendation from ACMUI.

MR. LEWIS: This would be a comment on the proposed rule, which we would refer to the working group. And if the working group for the rulemaking, which would include agreement state people, adopt the final rule, it would be about a year's time. And then the states would have the normal times after that to become compatible.

MEMBER GILLEY: So it would be compatibility B.

MR. LEWIS: Well, I don't want to say that, but --

MEMBER GILLEY: Thank you.

CHAIRMAN MALMUD: All in favor of the motion? Do you want to call the motion? All in favor?

Any opposed?

Two opposed. Any abstentions?

(No response.)

CHAIRMAN MALMUD: May I see the count

again for the number?

Ten in favor, two opposed.

MEMBER GILLEY: I would like to make a comment. I think this is an implementation issue for agreement states. And that's where I come from voting opposing it. It leaves a lot questionable. And I'm not familiar with what goes on in all the agreement states. So that's why I chose to vote against it.

CHAIRMAN MALMUD: Thank you.

Ralph?

MEMBER LIETO: So what happens to the subcommittee report? You basically sort of chopped it up into pieces, but the report in its entirety has never been acted on. Will this go to the working group if there is no formal recommendation for that or is it up to the individual members to take this and send it in as individual comments because, as I am viewing right now, this doesn't leave our packets and it doesn't go to to the working group on the proposed rule?

Any individual can comment on any proposed rule. So if you feel a certain way as an individual about any rule, I would encourage you to comment. That's what we do that process for.

But in terms of this subcommittee report,

it is my understanding that the full Committee was going to consider it and submit it as a comment of the Committee to the rulemaking working group.

CHAIRMAN MALMUD: That's correct.

MEMBER NAG: And based on what I have heard, the way I was planning to modify is to add the way this wording is, that sixth bullet. The way you have that written, that is the way it was supposed to be on that. That last item I had would be like this wording.

CHAIRMAN MALMUD: Yes. That was the sixth bullet. So we passed the first bullet. Then we passed the middle four. Then we passed the sixth. Is that a summary, Dr. Thomadsen?

MEMBER THOMADSEN: I think that is a fair summary. And maybe for Mr. Lewis' peace of mind in passing this along, we could just endorse the entire report to be passed on to the group.

CHAIRMAN MALMUD: Is that a motion?

MEMBER THOMADSEN: That is a motion.

CHAIRMAN MALMUD: Would someone care to second Dr. Thomadsen's recommendation? Thank you, Dr. Nag. And any comments?

(No response.)

CHAIRMAN MALMUD: If not, may I see a show

of hands for moving the report forward? All in favor?

Let's see. We have ten. And how many abstentions?

(Laughter.)

CHAIRMAN MALMUD: I fooled you. I asked for abstentions.

(No response.)

CHAIRMAN MALMUD: How many opposed?

(No response.)

CHAIRMAN MALMUD: Two. Okay. Two opposed. All right. Dr. Nag, we thank you for a lively discussion, brief as it was.

(Laughter.)

MS. TULL: Dr. Malmud, I need to steal the four members to go get badges if you want to take a quick break. And then we'll start right in with the medical isotopes discussion.

CHAIRMAN MALMUD: Very good.

MEMBER NAG: At 5:00 o'clock or 5:15?

MS. TULL: No. Like 4:45-4:50, as soon as we get back.

MEMBER NAG: Well, it's 5:00 now.

MS. TULL: I'll notify you as soon as we get back.

CHAIRMAN MALMUD: And, by the way, we

should thank Dr. Zelac for his graciousness in postponing his two presentations until tomorrow.

(Laughter.)

DR. ZELAC: You are very welcome.

(Whereupon, the above-entitled matter went off the record at 4:40 p.m. and resumed at 4:51 p.m.)

CHAIRMAN MALMUD: I have been asked to open the topic. The topic is medical isotope shortages, and Chris will do the intro.

MR. EINBERG: Very good. Thank you, Dr. Malmud.

11. MEDICAL ISOTOPE SHORTAGES

MR. EINBERG: Recently there have been some shutdowns and some shortages on medical isotopes. The global production of molybdenum-99 is dependent on a small number of processing facilities and aging reactors around the world.

These recent shortages have highlighted this important issue. And we're seeking the ACMUI's input on these shortages, what impact any potential shortages to medical isotopes may have, specifically molybdenum-99.

And, as you may know, the Chalk River reactor in Canada is an aging reactor. It's 52 years

old. There is a reactor in the Netherlands, the high-flux reactor. That is 47 years old. And recently, as I indicated, these two facilities were shut down at the same time.

Combined, these reactors produce 70 percent of the world supply for molybdenum-99. And there is an increased attention being paid to the shortages of molybdenum-99 and what the impacts to the medical community may be.

Recently the Chairman of the NRC was at an IAEA meeting approximately two weeks ago. And this was a topic of intense interest at the IAEA meeting. The spring meeting of NEA in Europe will have medical isotopes and the shortages as a key topic on the agenda there.

So we have put together a series of questions for the ACMUI to solicit your input on what are the potential impacts to medical shortages of isotopes.

Additionally, if there is anything that the ACMUI understands that regulatory relief could be provided or sees that there is regulatory relief needed because of shortages, we would like to understand those issues as well.

Currently two entities in the United

States have expressed interest in developing facilities to produce medical isotopes, but in the best case, these two facilities will be at least four or five years wait before they were being able to produce any type of medical isotopes.

With that, I turn it over to the Committee to address the questions or if you would like, I could read the questions as --

MS. TULL: I'll put the questions on the screen.

CHAIRMAN MALMUD: Okay. Dr. Van Decker?

MEMBER VAN DECKER: Why don't I open up a piece of this since these jogging questions seem to have the word "cardiac" involved in them quite a bit. I'm sure Dr. Eggli, Dr. Gilley, or I will have much more to say as well because obviously, you know, while we have been talking a lot about therapeutics today, the large volume of what goes on in this country is really diagnostic and where a technician kind of fits into. And so these shortages will have volume-wise quite a bit of impact fairly quickly.

You know, we have had two slowdowns already: one in November and December of last year when the Canadian plant had difficulties and was shut down and somehow brought back up relatively quickly.

And then we have had another slowdown just a couple of months ago when Europe had a problem.

I think you well point out that these are all aging plants. And the reliability I think in the future, how we look at them, we need to be a little bit concerned about.

You know, all of the technetium in this country is coming from moly coming in from these outside countries and are then being made into moly generators by industry here in the U.S. but obviously is getting the raw moly from outside.

You know, I don't have the exact numbers to your questions, but I kind of have some sense from some industry surveys and some claims data I have been involved in.

I would probably think that on the diagnostic realm in this country, there are probably between 15 and 20 million diagnostic radiopharmaceutical studies performed in the United States. You know, I would think that probably right now almost 50 percent of them are cardiac or close to that.

And of that, in the marketplace right now -- and these are just gross numbers -- I would think probably about 70 percent of that is being done with

tech radiopharmaceuticals.

You know, there is a small percentage of still thallium and some opportunities and some that is obviously some of the PET tracers. But obviously the ability to get to those in a meaningful financial way and for the volumes that we do this for is a hard thing to say.

So we're not talking about a small issue as far as the diagnostic stuff, especially in the realm of cardiology. And I'm sure my two colleagues will talk about the non-cardiology applications quite a bit.

You know, in the realm of how soon we need this stuff for diagnostic realm, you know, it is not usually the type of thing that we absolutely need something the next day.

I mean, most of that type of stuff if the symptoms are that bad is probably going to cath labs. But, you know, when you are trying to make a relatively straightforward and at least good risk stratification process, I would think that probably the majority of these studies get done, a good chunk, within a week and then another big chunk within two weeks and then only some outliers after that.

So you're talking about a relatively short

period of time where these become germane to a decision-making process on what is going to be done with the patient as far as further workup goes or further meds or further reassurance.

So it's not like we can withstand, you know, several months of slowdowns here and not be in a situations where it will clearly impact care the way patients are used to receiving that care.

You know, obviously at times we have had some slowdown bits. You know, we have had to try to find other ways to kind of make sure that we are taking care of patients the best as possible. I think the fears in people's minds are that, you know, slowdown availability will either lead to some extra people going towards an invasive root to be sure that there is an answer. There might be some people that go to other roots.

You know, obviously perfusion pad is a root but not easily available to the volumes we need. There are some other modalities that can be tried in all of this, but depending on a patient-to-patient basis in their patient characteristics, you know some may not fit quite as well for diagnostic reliability.

And so you come to a realm where you're trying to say, "Well, am I doing something with

slightly less diagnostic possibilities so at least I try to take out the biggest piece of the risk and then retest down the list to look for the intermediate level of risk that I really want to get an answer for.

So am I now layering tests because of what I've gotten to plus some degree of exposure to of some of the population to a more invasive approach?

And I think that all of that, you know, hopefully did not go on too much in these two periods of slowdown because they were relatively short, but I can clearly foresee that if this becomes commonplace and unpredictable in how it happens, that certainly we're going to have to re-deal with paradigms of how we deal with all of this.

You know, thallium kind of filled the role for some of this in the short term in these places, being cyclotron-produced, but thallium can be a piece of the solution here for short terms. But obviously the radiation dosimetry is not the most perfect for a situation that could deal with some of the tech agents.

And I would certainly say that from the world of diagnostic nuclear cardiology anyway, you know, unreliable up and downs when the decision process can have reasonably quick repercussions to it

to some degree does create some problems. You know, certainly we would like to see ways that that can kind of be ameliorated.

You know, obviously I don't know what this answer could possibly be other than a newer source in a more reliable place. And, as you just pointed out, that likelihood, even at its best, would probably be a few years away. But I think that is something that the discussion certainly needs to be dealing with.

I have to say, looking old but probably being a little bit younger, I'm not quite sure of the outplay of the marketplace and the prior for production of medical isotopes within the U.S.

I hear the words Union Carbide sometimes in these discussions, and I picture that on a sign in north Jersey when I was a young kid. I'm not sure what it did back then either.

I am not quite sure why that kind of phased out of this country and became more on other soils, whether it was regulatory environment or whether there were marketplace pressures or what really caused this.

I guess some understanding of that as we try to figure out what is the best thing for stability in access to patients in the future here would

probably be helpful. And I look forward to my other colleagues' comments on that.

So I think I would end my piece of it that way. And I will come back in later. I'm looking to hear some of my other colleagues' comments in all of this. But, you know, I think that obviously the high volume issues that are more diagnostic and have turnover time as a piece of workup certainly get significantly affected by this. And it's something we can handle for short periods of time once in a while, but it's not something I think we want to be at risk for for prolonged periods of time in the future if we could avoid it.

CHAIRMAN MALMUD: Thank you.

Comment, Dr. Welsh?

MEMBER WELSH: Jim Welsh here. I would like to just reiterate a lot of things that we heard from Dr. Van Decker. In my review, I agree with that estimate between 15-20 million cases per year with most of them being cardiology. I've heard estimates of up to 60 percent of the consumption going. We have nuclear cardiology.

Also, there are a number of therapeutic uses of radioisotopes that while, representing a minority of the overall uses of byproduct materials,

though, nevertheless, quite important, I understand that 80 percent of the world's cobalt-60 comes from one reactor. And that places an exceptional vulnerability for those who own and operate gamma knife units.

We had a discussion this afternoon about yttrium-90. There is always discussion about I-131. And new radiopharmaceuticals are going to be using I-131.

Older ones, such as bezar, are perhaps going to have more utility in years to come as data is maturing about the efficacy of these treatments. Therefore, therapeutic uses of byproduct material that is coming from across international boundaries is in the limelight.

Then there are these issues about domestic production versus international shipment and the controversy about highly enriched uranium, which we talked about cesium earlier today. That's a relatively smaller security concern compared to the real risk of highly enriched uranium winding up in the wrong hands.

And we know that there's a Schumer amendment. The Schumer amendment is being ignored. And there is the Burr amendment that is allowing it.

Perhaps by having isotope production in our own country, the Schumer amendment could be abided by. We wouldn't need the Burr amendment, and we would have adequate supply.

But, as I said, it's not as simple as just saying, "Yes, let's do it." It's going to take some time. That's my comment.

CHAIRMAN MALMUD: Thank you.

Dr. Suleiman?

MEMBER SULEIMAN: FDA has a group that actually addresses drug shortages. And with all the press that these supplies have been receiving the last year, we have been in discussions with the manufacturers.

Even though there's a heightened concern and awareness, we continued to be assured by the manufacturers that their supplies are okay.

The last round when the Canadian reactor was shut down, it turned out that the shipments to the U.S. were not curtailed. They were curtailed to Canada and other places. That's just what I understand right now.

CHAIRMAN MALMUD: Steve Mattmuller?

MEMBER MATTMULLER: Steve Mattmuller. Just a quick comment that typically have a Covidien

generator. And we had a Lantheus generator for a while. And then we were affected by that shortage.

But in the interest of time, I would defer my time to the public comments from the SNM, who I know are waiting for us in the audience.

CHAIRMAN MALMUD: Dr. Atcher?

DR. ATCHER: Robert Atcher, radiopharmaceutical chemist by training. I am here as the President of the Society of Nuclear Medicine.

In response to the four questions that you see, we have responded with answers to all four. In addition, we surveyed our members. So that there is some data -- I don't know if it's in your packages, but there is some data available on the impact.

We also have reports that the last outage that Nordion experienced resulted in people not getting generators. So there was some impact in the U.S.

Within the answers to our surveys, there is a lot of the questions that I think I have heard so far in the discussion answered in terms of alternative procedures that might be entertained.

We are probably closer to 20 million than 15 million in terms of the number of procedures done. We are estimating that 90 percent of those procedures

are single photon, as opposed to PET imaging. And of those, about 90 percent of the single photon studies are done with technetium.

So we are at about 70,000 procedures a day that utilize technetium 99M and, therefore, dependent on the availability of the molybdenum-99.

After the outage that occurred about a year ago, we put together a task group in the society to look at the issues associated with short-term, mid-term, and long-term potential solutions to the issue because having a domestic source of this isotope has become more and more important.

And since 9/11 with the potential for the borders to close to shipments of radioisotopes, it has become even more critical over and above the issues associated with the outages that have occurred at the Chalk River facility and the fact that the two new reactors that they assured us were going to be able to supply us in the future have now been canceled.

And we still await the ultimate outcome of that since Nordion has now sued AECL. And the result of whatever happens with that particular lawsuit is still up in the air.

The bottom line is that our membership and, therefore, the nuclear medicine practitioners in

general are significantly impacted by this. The outage that occurred a year ago resulted in some serious scrambling because we were down with the Nordion facility.

About 70 percent of the molybdenum-99 that is supplied to the U.S. was not available. And so there was an attempt to up the production at the reactor in the Netherlands, but it was not able to meet the requirements.

Similarly, in my discussions with Nordion, they try to cover any shortages, although, as we describe what happened a few months ago, the perfect storm of having all the reactors go out at the same time, there was really no option there. So we're looking at in the short term those reactors that are currently producing moly-99 to have material that is qualified for use in the United States and which is mostly an FDA issue.

In the intermediate term, there is the proposal from the University of Missouri. We recently got one from the reactor at McMaster, which is very similar in terms of its scope of using an existing reactor but building a processing facility to process the material. Again, that is going to be something that is going to take a few years for them to be able

to get the licensing and the facility built.

And then in the longer term, probably having a facility that would be constructed to current regulatory standards would probably be the optimal solution.

I just returned from the European Association of Nuclear Medicine, where this problem is much more critical than it is here right now. And they are having the same discussions that we are about the potential for a new facility.

There is a facility that is under construction now in France which is going to come online, but it will not supply all of the needs of the European community.

And so the discussion is, what do we do in the absence of something to replace both the reactor in the Netherlands and the reactor in Belgium that also have been involved in the molybdenum-99 production activity?

And so this is a worldwide problem right now. And we are kind of at this point where one of the questions that come up is, well, what is the lifetime of technetium 99M as a diagnostic agent? It's probably within a reasonable lifetime in terms of the justification for building a new reactor. So

that's one of the things where NRC obviously would be plying a role.

The second one -- and we discussed this at the earlier break -- is that there is a proposal that BWXT has been making for an old reactor design but to use it for a current application. And that is a liquid core reactor in which you could just sample the nuclear fuel as the reactor operates to extract the molybdenum-99, but that is not a research reactor and it's not a power reactor. It's somewhere in the middle. And so there may be some need for some regulatory clarification as far as how that facility would be licensed.

I know the hour is late. So barring any questions that you might have for me, I will stop there.

CHAIRMAN MALMUD: Thank you.

Are there questions? Dr. Eggli?

MEMBER EGGLI: Not so much a question as more a comment. In response to question 2, -- and I think the society has answered it in their letter -- a week is by far the outside that most procedures can be delayed. And many of them that are urgent can't be delayed a week.

And then what it results in is looking for

an alternative diagnostic effort, which is typically either more morbid, higher risk for the patient, or significantly more expensive. So that there is both an economic and a patient care impact.

If you look at something like lymphosentigraphy in lymph node evaluation, breast cancer patients, they will simply go without it if the tech is unavailable for the sentinel lymph node procedure and, as a result, have a high chance of having significant extremity swelling after their more aggressive lymph node dissection than would have otherwise been required.

And although the number of nuclear medicine procedures is high, 20 million, it's only about 5 percent of diagnostic imaging procedures in the United States on an annual basis.

As a result, in the marketplace, I think there isn't room for a whole lot of competition, that the marketplace supports the vendors that exist and not a whole lot more. So there may be disincentive for vendors to get into the business.

We certainly see that on the pharmaceutical side of radiopharmaceuticals, where most radiopharmaceuticals these days have only a single vender. And if the pharmaceutical portion goes

away, you simply do without it for extended periods of time.

DMSA is a classic example of a radiopharmaceutical that seems to have FDA problems every 18 to 24 months and disappears from the market for 6 months at a time. There is just nobody else in the business.

So that even though 20 million seems like a lot of studies, compared to the cost of providing the service, the market is small. And there has to be some economic incentive for someone to get into the business of building a reactor that is going to be produce molybdenum for medical purposes.

If we are going to have one in the United States, it may require some kind of subsidy for the public good to make the technetium radiopharmaceuticals available. Certainly my practice reflects what the society is reporting.

The vast majority of all clinical nuclear medicine procedures is, in fact, done with technetium-labeled radiopharmaceuticals. It's safe and effective, and it can be labeled for lots of things. And nothing else really at this point is a viable substitute for a technetium label.

And so I think that if we are going to

have something in the United States, reactor in the United States, that supplies technetium, there may need to be some form of subsidy, at least on a start-up basis, because the start-up costs are huge and the marketplace is still relatively small.

CHAIRMAN MALMUD: Thank you.

Mr. Guiberteau?

MR. GUIBERTEAU: Well, I think Doug will be happy to know there is a group that is trying to lobby for decreasing our dependent on foreign molybdenum and allowing for drilling for molybdenum offshore.

(Laughter.)

MR. GUIBERTEAU: And so far they haven't really come together. I think there are three things in terms of performing nuclear medicine procedures that molybdenum has really, the lack thereof has really, hurt us in the last two times it has occurred. And, of course, it has been brief, as Bill was saying.

Most nuclear medicine diagnostic procedures other than cardiac procedures are performed by diagnostic radiologists. And what happens is in the nuclear medicine section, when we are not able to perform these tests reliably, the referral patterns

change. And right now it has only been brief.

When that happens to us, some of these people eventually if it keeps happening don't come back. And it harms the whole specialty.

The other thing that Doug brought up that is very important and what we did in our hospital system when this happened because we are within, our nuclear medicine department is within, the diagnostic radiology realm, we tracked the names of those patients that we had to cross off our list and find out what other studies they had within our system.

Almost all of them went to studies such as CT and MR. The expense increased by two to five percent. And this is not a small amount, even with just five percent of the total diagnostic imaging.

So the reliability helps us not only in terms of changing the algorithms for working these patients up. It also makes it much more expensive. And it also can delay the care of patients, which has its own expense.

CHAIRMAN MALMUD: Thank you.

MEMBER THOMADSEN: This is Thomadsen. Just as a matter of information, for the first question, the report from the NCRP on population exposure, which is now out for comment, has several

appendices with fairly good numbers on the number of procedures that are performed each year. The table is for 2005 but probably could just be expanded by about seven percent to get last year.

CHAIRMAN MALMUD: Thank you.

Other comments? Member of the public?

MR. BROWN: Roy Brown with CORAR. In anticipation of this meeting and seeing the questions that the NRC staff posed, CORAR is the radiopharmaceutical manufactures of North America. We turned to our medical resources about a month ago and asked for their most recent data. It takes quite a while to get this information.

I will be passing along -- Dr. Van Decker's numbers were very, very, very accurate. I have 2007 numbers here I will be forwarding on to the Committee, but they go out and sample a few thousand hospitals to get actual numbers of procedures by hospital. And then they expand that out.

So all the marketing gurus in the U.S. use AMR data. That's data that I will forward on to the committee for you. But Dr. Van Decker's numbers are very close.

CHAIRMAN MALMUD: Thank you.

Dr. Welsh?

MEMBER WELSH: Just some follow-up comments for discussion. I was disappointed, of course, to hear that the Maple 1 and Maple 2 reactors have been canceled. And in a way, it was a bit of a relief because we know that they were not compliant with the recommendation that they do not use or require HEU.

So I have read a number of recent reports saying that there are solutions that are technologically feasible in which modern reactors if they were built from scratch with modern technology, as opposed to an old reactor that is trying to be adapted to go from HEU to LEU, these modern reactors, like the aqueous homogenous reactors, could use LEU and in principle be much more cost-efficient because of the decrease in the intensity of the security required for HEU.

And whether or not that is a reality or is a myth remains to be determined. But it does raise the possibility that there could be considerably less cost associated with a new reactor, with a modern design that doesn't require highly enriched uranium because of the security concern.

Also, if we hear that Europe is having this increased need for a radiopharmaceutical and it

is not being met by Belgium, France might supply it. If we could supply it here, that also could justify the cost and could perhaps be more profitable than initial predictions, which were that this would not be economically feasible.

CHAIRMAN MALMUD: Thank you.

Other comments?

MR. EINBERG: Do we have any information on the French reactor or the French initiative to build a new reactor?

MEMBER EGGLI: Let me say nothing about the French reactor, but I was involved with a National Academy of Sciences briefing on this issue as well about a year or so ago, I believe.

At that time there were other countries, like Argentina, Australia that were saying, "Oh, we can provide all sorts of things." I haven't followed up on this.

It was interesting. There were a lot of players who were coming to the table. I had been, I would say, personally a little bit concerned because it seems like it is all foreign reactors.

The elimination of highly enriched uranium as a source is basically being dictated by this country. We are not going to provide actors with

highly enriched uranium as a target anymore and encouraging the use of low enriched uranium because low enriched uranium poses less of a risk. And so a lot of reactors are having to re-tool. And I think some of the stuff that happened in Canada was actually a direct result of some of that.

So I think everything is really in play. I think it's a good effort. It's noble to try to get an assessment of what is going on right now. I am clueless, I mean, except when I hear somebody tell me that the Australians promise that they can provide everybody with everything, though they are not geared up yet.

I haven't heard anything else except for those statements. And there were people from other countries saying, you know, "We are already switched to LEU. And we are already producing."

So I am surprised with all of these promises, you know, we haven't seen anything more tangible. There seems to be a lot of lack of information right now.

MR. EINBERG: Has the initial Canadian study been finalized on the use of --

MEMBER EGGLI: I really don't know.

CHAIRMAN MALMUD: Thank you.

Other comments?

MR. BROWN: Hi. Roy Brown with CORAR again. I can answer some of these questions.

The National Academy study is in the final phase right now. We expect it will be out sometime probably in the December time frame.

We would be glad to provide, CORAR would be glad to provide, some additional information on LEU. Just for your information, the IAEA has an effort underway called -- CORAR did a research project called the CRP to help countries develop their own source of moly.

That has been the source of a lot of the LEU production. That has been in countries like Argentina, Korea, Indonesia, where it has been very, very, very small-scale.

There have been some gel generators in India where they make 50-millicurie generators that really won't do us much good in the U.S. So although there have been some successes with LEU around the world, not only the kind of scale we need in the U.S.

CORAR will be glad to come back and provide any information either NRC or ACMUI would like on this at future meetings.

CHAIRMAN MALMUD: Other comments? Dr.

Fisher?

MEMBER FISHER: For the benefit of the Committee, I wondered, Roy, if you would explain what CORAR is, what it stands for, and its purpose?

MR. BROWN: Roy Brown with CORAR. CORAR is the Council on Radionuclides and Radiopharmaceuticals. It is the North American trade association for the manufacturers of nuclear medicine products that includes companies such as Nordion, Lantheus, Covidien, Bracco. All the major radiopharmaceutical producers in North America are members of CORAR. We also represent companies that produce other types of isotopes for medical research.

CHAIRMAN MALMUD: Other questions or comments? Dr. Welsh?

MEMBER WELSH: Quick comment again about the LEU/HEU issue. The request, the Schumer amendment, came from the United States that around the globe reactors stop using HEU. But since we are by far the largest consumer of radioisotope for medical purposes, there is little financial incentive for Chalk River to switch from HEU to LEU if it is going to come them a lot and there is nothing in it for them other than just being good guys and complying with Americans' request, plus the Burr amendment.

And I don't think that we're ever going to get around this unless we take the lead in the United States and make isotope ourselves with LEU and show the world that it can be done. And if Canada, Belgium, France want to be competitive in this market, they would, too, have to follow this lead.

But until somebody starts generating isotope en masse, not like Argentina, Australia, with a lot of promise but nothing being kept, the United States is probably the only country that can do this. And others will then be forced to follow suit if they want to maintain their share of the market.

CHAIRMAN MALMUD: Other comments?

DR. ZELAC: Dr. Malmud?

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: Just for clarification -- and, anyone, please correct me if I am wrong, but when we are talking about HEU versus LEU, we are not except in the case of the homogeneous liquid reactors talking about the fuel itself. We are talking about the targets which are being irradiated and then moly and others stripped off from the fission products. Is that correct? Okay. Thank you.

CHAIRMAN MALMUD: No other comments?

MEMBER VAN DECKER: Can I ask a question?

CHAIRMAN MALMUD: Yes.

MEMBER VAN DECKER: Since the NRC put this topic on the table, what were the NRC's thoughts on where it saw itself fitting into this?

MR. EINBERG: Well, the NRC would like to have a good assessment as to what the situation is because while we regulate the safe use of medical isotopes, we don't promote the use of isotopes. It's more of along the lines of Department of Energy and other federal agencies.

We want to be fully informed as to what the situation is. We want to be on top of it. And, as such, we're soliciting input. Especially with the medical community, we want to be aware of any shortages and make sure that patient treatment is not adversely impacted.

MR. LUEHMAN: The only thing that I would add is that obviously when there is export of HEU to provide targets, you know, the NRC has to approve all of that export.

And obviously, as I think Dr. Welsh has summarized, that is a very controversial activity. Every time it comes up that there is going to be export of HEU targets, there are diametrically opposed, probably the correct words, views of that in

Congress. And so to the extent that there are other options, that there are other paths that could be explored, I think that the Commission wants to look at those because ultimately the Commission does have to approve exports of high enriched uranium targets for use in this endeavor. And if there were alternatives to that, I think the Commission would like to explore those.

And obviously going to some kind of high-production low enriched scenario would be one of those. I mean, it would probably be preferable even a high enriched as long as it was in the United States and we weren't exporting those targets.

So I think that those are the other things that the Commission is looking at, the perception of a proliferation concern.

CHAIRMAN MALMUD: Public?

MR. BROWN: Roy Brown with CORAR. One more comment on LEU versus HEU. The reactors in Canada and Europe have done a very good job converting the fuel over from HEU to LEU over the last several years.

But you are right. The HEU is currently used for targets. To be able to switch to LEU targets is a very long and lengthy and costly process. All

the major moly manufacturers now are looking at it.

What it requires, it requires a new waste stream. I mean, if you think about it, if you are using less than 20 percent uranium, rather than greater than 80 percent uranium, you produce a lot more mixed fission products.

You produce a lot more plutonium. That needs to be taken out of the moly before it is finished. You need to write new drug master files. You need to go to FDA. The generator manufacturers need to go to FDA with supplements with those new DMFs.

So it's a very lengthy and costly process. That's why it will take a long time to convert from HEU targets to LEU targets. So it is not a simple process.

This is something the National Academy of Sciences addressed in their report. And hopefully it will have a good write-up in that when that report comes out in December.

CHAIRMAN MALMUD: These are informational items only. So there is no action to be taken.

MR. EINBERG: I appreciate everyone's input on this issue. And it will help the NRC and the Commission understand this critical shortage if it

does appear.

CHAIRMAN MALMUD: Thank you.

Ashley has several announcements to make now.

MS. TULL: I just have three quick things. This is Ashley. For members of the public, if you are not coming back tomorrow, if you would please fill out the public feedback forms? They're right there by the red and white box. It's four or five questions. Fill it out. Drop it in the box. You're done. If you're staying tomorrow, you can do it tomorrow.

For ACMUI members, will you please take off your badges and leave them here so I don't have to reprint them? And you can leave your binders and anything else that you want here because this room will be locked as soon as we all leave.

That's it.

CHAIRMAN MALMUD: Thank you. So we will all meet here tomorrow morning at 8:00 o'clock.

(Whereupon, the above-entitled matter was recessed at 5:32 p.m., to be reconvened on Tuesday, October 28, 2008, at 8:00 a.m.)