UNITED STATES NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

TUESDAY,

OCTOBER 23, 2007

+ + + + +

The meeting was convened in Room T2B3, 11455 Rockville Pike, Rockville, MD, at 8:10 a.m., Leon Malmud, Chair, presiding.

ACMUI MEMBERS PRESENT:

DOUGLAS EGGLI, M.D.	Nuclear Medicine Physician
DARRELL FISHER, Ph.D.	Patient's Rights Advocate
DEBBIE GILLEY	State Government Rep
RALPH LIETO	Medical Physicist
LEON MALMUD, M.D.	Healthcare Administrator
SUBIR NAG, M.D.	Radiation Oncologist
ORHAN SULEIMAN, Ph.D.	FDA Representative
SALLY SCHWARZ	Nuclear Pharmacist
BRUCE THOMADSEN, Ph.D.	Therapy Medical Physicist
WILLIAM VAN DECKER, M.D.	Nuclear Cardiologist
RICHARD VETTER, Ph.D.	Radiation Safety Officer
JAMES WELSH, M.D.	Radiation Oncologist

STAFF PRESENT:

CINDY FLANNERY (alt DFO)

DONNA-BETH HOWE, Ph.D.

ANGELA McINTOSH

JANET SCHLUETER

ASHLEY TULL

SANDRA WASTLER (DFO)

RON ZELAC, Ph.D.

DUANE WHITE

MOHAMMAD SABA

TABLE OF CONTENTS

P R O C E E D I N G S

(8:11 a.m.)

CHAIRMAN MALMUD: During the course of the morning session it will be necessary for me to leave briefly and to meet with one of the Commissioners, as you know. And, therefore, at that point Dr. Vetter has agreed to chair the Committee in my absence. And I very much appreciate that.

In addition, if I may, I would like to review with you, which is not on the agenda, the items that we did discuss yesterday so that you'll be reminded of the items that you asked me to speak to the Commissioner about if the opportunity arises.

They were:

One, the issue of T&E, training and experience which relates to a de facto establishment of a curriculum for residents re: the alternate pathway which has constrained the Boards' flexibility in establishing their own academic criteria;

Two, the objection to the word "competence" because of a potential legal liability associated with that regarding the training supervisor in cases that might occur later on involving the trainee and our preference for "successful completion

of residency" instead of competence;

Three, the issue of sentinel node biopsies and our desire to separate the removal of a sentinel node from the process of the injection of the radiopharmaceutical so that sentinel nodes could be removed at small hospitals that are not licensed to handle radiopharmaceuticals. The patients often are insured by companies that will not allow them to be operated on in the hospitals that are certified, but in their region, the patients only have access to hospitals that are not certified to handle the isotope.

And the last issue that you asked me to present was the issue of the potential cost and time involved in fingerprinting, using as an example the very large institution up to 500 people or more may be required to be fingerprinted, if they are to continue to have access to blood irradiators.

Those are the issues that you asked me to present, and I will do so, if we'll have the opportunity.

Apparently, I'm meeting with the Commissioner with other committee chairmen and, therefore, I'm not certain that I'll have the opportunity. But if I don't then and I'm invited to

discuss the issues later on, I'll make another appointment to do so.

MS. TULL: Dr. Malmud, this is Ashley.

It's just you.

CHAIRMAN MALMUD: Oh, it's just me?

MS. TULL: He's meeting with all of the chairs, but individually.

CHAIRMAN MALMUD: Ah, okay. I didn't understand that from the way the letter was drafted.

MS. TULL: It's just you.

CHAIRMAN MALMUD: Very good. Then in that case I may have the opportunity. Thanks.

Sandra, do you need to do another comment? I see official officer?

MS. WASTLER: No, I don't believe so. We just do it at the beginning of the meeting, and then that suffices.

CHAIRMAN MALMUD: Very good.

We're privileged to have with us this morning Michele Burgess from the NRC who will discuss the NMED overview.

MS. BURGESS: I'm going to be over in this corner. Since we're going to do the demo, I need to be connected to the Internet. So if you can bear with us just for a few slides in the beginning, and then we

can get down to the demo.

CHAIRMAN MALMUD: Yes.

MS. BURGESS: I'm the NMED Project Manager. I work on the contract and keep the data in the NMED database. Hopefully supplying you guys with all the information that you need to take a look at all the medical events that occur.

What we'd like to do today is to do an overview of the NMED database. Some of you may have already been familiar with it and have used it. Some may not. Part of the overview is to introduce to you guys that haven't used it in the past a tool that you might find useful in looking at, experiencing the events that have occurred and the types of failure modes, the things that are happening out there in the hospitals, hopefully showing you how NMED could be a tool.

The secondary part of this presentation, and we'll do that at the end, is addressing some specific comments that were made in an early ACMUI meeting about the use of NMED and some of the searches that were done and some recommendations that were made in that earlier presentation.

In general, NMED starts with licensees. They have requirements to report events, both

immediate, which are the higher significant ones, and 30-day reports, which are follow-ups or the less significant events, to the NRC and to the agreement states.

There are also inspections. We end up with inspection reports and we can gain data from that. But NMED really starts with the licensees doing something, something happening at that stage.

We then collect all of these event reports and inspection reports and glean from that information to help us understand what's been going on in the world.

The data are supplied to NMED, the database, via a contractor that codes for us or the Op Center, who then supplies the information to the contractor. We capture the data there.

The national data is put into one database. It's collected from all the states as well as the NRC, and that's the database that you've got some access to. You should all have passwords. And if somebody doesn't have a password and wants one or their password has expired or they've forgotten it, just give me an E-mail. It's very easy to reset you and we can get you started again.

And if you'll notice the address though,

it's https. It's a secure socket. That's usually the reason people can't get on; they've forgotten the "s". And it has no "www" since it's a secure socket.

Essentially the national website allows access to national data. Having all the individual agreement states collect data is good on a statewide basis, but we need some kind of central repository so we can put all of the events together. Fortunately, we don't have a lot of events. So having things on a state-by-state basis or even just NRC by itself, it's hard to do trending and studies because you don't have a lot of data on it. Consider that a good thing.

If we pull it together into a national database though, now we have enough data to be able to see if we can find any similarities. It helps us identify more patterns, not necessarily patterns from state-to-state, but just more data points to be able to see all the different modes of operation, different loads of failure.

We can use it as a tool to look at generic issues. Is there a particular product that seems to be failing repeatedly? Again, trying to do this on a state-by-state basis or NRC only you could have three events, but they were in three different states. You'd never identify that there was a repeat or a

pattern, or some kind of design flaw if you didn't pool all of your data together. You have a much better chance of seeing those types of things.

And we can look for trends in general. Are we having a lot of events that have to do with human failure versus design flaws, for example, is one we can look at it. It doesn't have to be specific to a particular product. It could simply be a kind of failure.

The national database we post quarterly reports on the website itself, and they're very high level reports. We put them there as a starting place. We use it as a trigger point for looking where change has occurred so that we can dig further.

It's useful in looking at one type of event against a different type of event. Do we see failures in one area versus another area?

To get down into each individual area, we have the quarterly report pie charts where we break out the different types of failures. Is it equipment versus human factors for example is a big one that we look at.

We have the different types of reporting requirements, for example, in the medical section. Is it overexposures? Are we looking at extremities

versus whole body dose? We try to break up the data in ways that is meaningful looking for failure modes.

If as you're using the database you think that there's another way we can break up the data that would be useful for you, we always welcome input. Send me an E-mail and if there's another way that you think would be more useful to break up the data on a regular basis to see changes from time-to-time, then send me an E-mail and we can consider adding that in, too.

The whole purpose of having NMED is the tool and so it's useful for someone. The whole purpose for the quarterly report is so that we can monitor the things that we think are important. So we're always looking for things that will make the report more useful.

We post newsletters each quarter. And in there they're directed towards the user. We don't discuss so much technical issues as system use issues: how to log on, problems that have been encountered in logging on, hints on how to create your new passwords under the new scheme. I see smiles around the table, or maybe they were grimaces.

Different searches that others have done with the idea that if we tell you some of the searches

that have been useful for people in the past, it may trigger something for you and you can modify it to suit something that you might need. Just trying to give you helpful hints.

If you run across something that you think would be useful for other users to know, again, send that to us and we'll put it in our newsletter. A lot of times what we use as the basis for some of our articles are the questions that you call INL with. "I was trying to do a search and I can't figure out how." That oftentimes ends up as a hint or tip in our newsletters later.

So you guys may be ghost writers and not realize it by the questions you're sending to us.

There's also an online tutorial. It's the basics of how to use the website. It's a good place to get started. It shows you how to navigate. We think that the website is pretty self-explanatory. We tried to make it as user friendly as we could so that you don't need a manual. We didn't want to have to put a manual. We don't want me to have to have something next to you while you use it. We want everything on the screen for you.

But the tutorial, if you're not familiar with the website, is a quick way to run through it and

get some ideas about what's on the website.

Now, I'm going to sit down here and holler if you have any questions as we go through. I'm just going to do a quick walk-through showing you some of the features. Again, the purpose is to get you familiar and comfortable with it. It's not going to show you everything you can do on it, but it's hopefully prompting some basic knowledge of the website, and then you guys can take that to customize particular searches that might meet your needs.

If, as you go through and you're using the website on your own -- I realize that what we're going to do here is really high level and that you might have specific questions on how to do particular searches. Again, give us a call. Let us help, especially in the beginning as you're getting used to it. There are some of the fields that are on there. Understanding some of the difference between some of the fields to make sure that you're really getting the search out that you think you're getting out. We can help with those.

And you can either contact me or Ashley as your coordinator can help get you in contact with somebody or you can call the contractor themselves.

Okay. This is the basic website. This is

after you log on. The NRC home button will take you back to NRC home page. NMED Home takes you to this front page for NMED. I'm just pointing that out because the NRC home page is new, and if you get surprised because all of a sudden it looks like it dumped you out of the website, that's probably what you hit instead of NMED home.

For access and log on, again, remember that the log on has its https and there is no www. That's often the reason that people are having trouble finding the website. You can also navigate. If you go to the NRC public webpage and you go to nuclear materials and you go to the materials quick link and you go partway down the screen, there's the NMED database under "Operational Experience." And there you get to your report.

All of the ACMUI members should already have access. So you guys should already have this information, and you should have your IDs and passwords, but again, if there's anybody that doesn't have one or that has forgotten their password, if you need a password you can contact Ashley and she can arrange for me to set one up for you, and if you just need your password reset, then you can E-mail me or INL directly.

Are there any questions?

One thing that is important to remember, and this was probably told to you when you first got your password, is that NMED access is restricted to federal and state regulators or their contractors or advisory committees through a sponsor, and it is to be used only for work pursuant to your advisory committee or for contractors for the contract that they're working under.

Talk a little bit about the main page. We tried to set it up so that it's easy to navigate through. You have your tool bar at the top with the main options, but you also have some items on the top here.

You have a data updated date. This tells you how current the data is. It's not a bad idea to look at it when you log on just to make sure that you are not reaching a cache, for example, that you're actually getting to new data and there's no problem with your system.

If you print out any of the reports, it does show the date at the bottom of your printouts. So if you're printing things out, archiving and doing studies, it should have the dates on there for you. Your search results pages that you print out would

have those results.

Not that there's a delay in how often the data is updated. If an event occurs, it's going to take at least three days for it to show up in NMED because there's at least one day for the event to be posted to the public web from the Op Center, and then INL has two days to be able to get the data into NMED.

So just keep that in mind when you're doing your studies, and then for updates and 30-day reportable events, again, there's a delay involved there. There's 30 days for the licensee to report to the, for example, agreement states and the agreement state gets 30 more days to tell us, and then INL gets two weeks to put it in the database.

So you're looking at two and a half months there. In most cases it's not going to affect a lot of the studies, but if you're looking for things that are recent, that might be the reason that you're not finding data in there.

We wait for annual reports until February to do our studies because then we know we've had enough time for all of this data to process through and be in the database, and then we're getting more accurate results. You had raised that point, I believe. Staging the time of your studies sometimes

is important, especially if you're looking at the most recent fiscal year or most recent physical quarter, especially.

The next thing we can look at is the publications. I'm going to skip the basic searches and advanced searches for a minute. I want to show you these two. The publications, this is where you get to the newsletters and the quarterly reports. You can find the most recent copies for all of these.

We're in the process right now of working on a summary report, putting together an annual summary report. So once that's created, you'll start seeing a third column on here where you'll see that year end wrap-up. We'll still have the quarterly reports. They will be in slightly different format, but it will have the same type of level of detail, but you'll have the annual reports that will be added to it.

Yes.

MR. LIETO: Michele, the annual report, are you talking in terms of the fiscal year or calendar year?

MS. BURGESS: Fiscal year.

We're going to maintain the fiscal since that's what all of our performance metrics are still

based on.

The next one we'll look at then is the basic searches. A lot of people have avoided the advanced search because they think that basic means easy and advanced means hard, but really it's the basic searches are limited and the advanced searches gives you the most flexibility. The basic searches are just some canned searches that people do a lot. For example, a particular item number, a particular -- whether or not all of the events are closed or not. You can see that you only have a few fields to choose from. These are your only selections in these.

You still get the same kind of printout for each. You just have limited search fields. The only one in this list is this lost, abandoned, stolen material. All of the other ones are simply shortened choices of the advanced search. The lost, abandoned and stolen material actually has a different kind of printout than the rest of them. It's a table. It's the only one that we have in here that's a summary printout, and you'll notice that it's both by sources and numbers of events.

Every other printout that we have is all by numbers of events. It's not by numbers of patients. It's not by numbers of procedures. It's

not by numbers of individual users. It's only by numbers of events. This is the only place that we break it down into another format.

I just wanted to point this one out. This is the only part of NMED basic searches that you can't reproduce on your own using the advanced search because this does a lot of the adding for you.

The advanced searches, this is probably what you'll use the most. This is what I use all the time. Aside from that one search under basic, this is the only one I really use.

One thing I want to remind you is give it some time to work. Sometimes NMED makes you pull a lot of data, especially if you've used a lot of fields to filter. So give it time to process. The blue bar at the bottom, for example, watch whatever it is that your browser uses to show that it's still working.

There are a couple of places in here where it's pulling data out that it does take a little bit of time to process. There are over 16,000 records in the database. So sometimes it takes a little bit of time for it to sort through.

The big thing about this one is the power and the flexibility. What we've done in this one is essentially it's almost every field in the database,

but every field in the database would be a little cluttered on the screen. So what we've done is we've divided it up into main topics. Any of these topics, you can click on them and expand them.

For example, general information breaks down all of those fields that are the basics of a record, who it was, when it was, who's responsible, for example, whether or not it's reportable to the NRC. The alternative is the agreement states. Who the responsible region is if you're trying to break it down into areas. Maybe you're trying to see if there's anything different between hospitals in the northeast versus hospitals in the west of the country, if there's any kind of difference in patterns from one area of the country to the other.

Almost every field is searchable, and you can put your cursor on a field and click, and it will give you a description of that field along with some help in how to input. We did this instead of having a manual because we figured it was a whole lot easier for you to see it on the screen.

For example, the use of wild cards. If you don't know exactly what you're looking for, you know an idea. You know something that was entered in 2004. It was an event that would have been entered in

2004. You can enter wild cards and pull out everything or you can do the same search by date so that you can see that there's multiple ways sometimes to get to the same end point.

For each of these searches you may end up with slightly different results. So, again, if you're not sure what the field specifically is, go ahead and click on it and make sure that you know what the results mean when they come out the other end.

We have event date, discovery date, report date, and update date. Make sure that depending upon what you're trying to do, if you want to know everything that was reported in a certain time frame versus everything that happened, that actually occurred in the time frame, be careful which set of dates you use.

We often will have events that two, three years ago, but they were just discovered. So they'll have an event date of a couple of years ago, but the report date and the discovery date will be this year. So just tailor the dates that you'll use to what you're actually looking for.

The same thing down here between state and site of event. State is actually the state of record for the reporting party. It's where they hold their

license. However, the site of event may be different than the state of record because they could have been operating in another jurisdiction under reciprocity, for example.

So, again, you're looking for licensees that reside in a certain area or are you looking for events that occurred in a certain location?

Again, if you have any questions as you're trying to design particular searches, you can contact us.

The only one that we have an and/or that's associated with is the event type. Everything else you enter data in them, and it's anded. If you enter six different fields, you and all of that data so that you're narrowing your search.

This one here you can choose equipment and medical. If it's or, it means it gives you all of your equipment failures, for example, radiography equipment failure, as well as all of the medical things even if it didn't involve equipment if they input the information incorrectly into the system. If you use and, you end up with a limited search and you only get medical events that involved equipment failure. So that's one thing to keep an eye on. The default is or, which is the larger search. That's

where you get more records.

NRC reportable, this is an important field. We often have reports that come to us and get into the database where we don't know yet. We're not sure if it's reportable, but our practice in NMED is once it reaches the database, we don't take it out. We don't like things to disappear. We would rather change it to no and at least if you're going back in to find the status of something that you had looked at previously, it's still in there for you to find.

So if you're doing searches, if you simply want to know of all the possible failures, all of the possible modes of failure, all of the reported events, you could choose all, but if you're doing a study or a trend and trying to do comparisons of numbers, you should use reportable yes because they're the ones that are confirmed, and they're also the ones that are consistently reported.

If you include all, you're including all of the ones that are not reportable, and some states are reporting some things to us and they end up in the database, and again, because we don't remove them they stay as part of the data set which would be pulled out, which would skew your data if you're trying to compare one area to the next because that kind of data

is not consistent from state to state.

One thing, let me see if I can get back to the top. Can you get me back to the top of the screen?

Up in here you can save searches. If there's a search that you do a lot, maybe you perform it quarterly or monthly. You can save it in here, for example. If I want to save this search about all equipment, medical equipment failures, I can go up here and choose safe criteria. I want to name it, and now that search will be there for me any time I need it in the future. See, I've already saved quite a few of them. So I can always go back and I don't have to take the time, one, take the time to repeat the search criteria and, two, risk the chance of having inadvertently changed my search criteria and end up with differing results, not realizing it's because I changed the criteria.

If you have very simple searches, it might not be an issue, but if you have things that are more complex, this can be a good QC tool for you to use so that you don't inadvertently end up with a different data set only because of the differing criteria.

One thing I want to show you is the printout. I'm hitting the search button and taking us

to the printout. This is the standard printout. This is the summary report. It's a list of all of the events.

You can click on any of the headings and you see it re-sorts. Now it's beginning with '07, the most recent. Click again, and it's beginning with the oldest. The arrow here tells you which direction it is sorted in. You can do that on any of these fields. If I'm looking for something in a particular city, I can go here and click it there.

We have two other printouts that show more detail. Both of them take sometimes up to several minutes, depending upon how many records you have for the events to come back up. I'm just going to click on this one here, the partial detail. This one is a quick summary. If you're trying to print out the results of your data to do a quick read-through, this one, the partial detail, is usually the easiest one to go through because it gives you the whole abstract plus some of the basic information, the event dates, who was involved, where it happened, and then a list of all the reference documents.

DR. HOWE: Michele, I just want to point out that we had this particular report specifically designed for the ACMUI so that when we went in and did

the medical events or the other reports, you would essentially on one sheet of paper have a description of the event and all the references so that if you wanted more information we could go back and get that additional information.

So this one was specifically designed for you.

MS. BURGESS: Thanks, Donna-Beth.

And one thing to notice here for the reference documents, if it has the ML number, then that's in the ADAMS system and you should be able to obtain a copy of that through that system.

The PNs are preliminary notifications. Again, they're posted on the NRC's Website. The same thing for ENs, event notifications.

Any of the other formats, however, if you want a copy of those, you need to contact the coordinator, Ashley, and request copies because those have to be obtained through the contractor. They're essentially reports that have come directly from the states as opposed to something that is processed through NRC.

One thing to note on the top of the screen. We have 58 events. However, it only shows a certain number per screen. If I were to print this

screen, only the 20 are going to show. So a good hint for printing this is simply to click on here, type in the number of events, apply, and now if I print this screen, it prints all of them. I don't have to print page by page.

However, if you want to work page by page, that works, too. You just need to remember to print each one. We have these navigating buttons so that you can move around, say, if you have multiple screens or you can simply tell it what screen number you want, select which one, and go to whatever page you were looking for.

Let's get back.

So essentially this screen, the basic searches and the advanced searches are the two screens that you'll probably use the most often. We can add things to the basic searches if there's something that you think that ACMUI as a group need as opposed to saving individual searches. If you save a search, you're going to be the only one that can see that search. So if there's something that you guys need as a group, we can create a basic search and post it here, and then all of you would then be able to use it. So that's a possibility also.

That's the end of our brief tour through

NMED. Is there any specific question on how to use the system or the types of data that's in the system?

DR. VETTER: Thank you, Michele, for that excellent presentation.

Questions? Ralph.

MR. LIETO: Michele, could you go back to the advanced search screen?

MS. BURGESS: Sure.

MR. LIETO: Yeah, do you have the screen for like the general event information expanded? Well, two things that I've noticed. If you wanted to do a narrative search, is it still that you can only use one word? In other words, you can't do a search for multiple words like medical and hospital.

MS. BURGESS: Correct.

MR. LIETO: So still it's only limited to one word.

MS. BURGESS: It's one string at a time.

MR. LIETO: Okay. The other thing that I just wanted to point out that I've learned sort of inadvertently is that if you could just go down just a little bit there, when I was trying to do searches, I just wanted the reportable events, not the things that had been determined not needing to be reported, and in capturing both NRC reportable and agreement state

reportable, what I've learned is that -- and I think you mentioned this -- is that if NRC puts in that it's reportable and an agreement state says, no, it's not for, say a medical event, it will not capture that event in your search

MS. BURGESS: Essentially there are two separate fields. We have some agreement states that regulations aren't interpreted entirely the same. So we do respect the agreement states so that they can use this, too. We put that in there with what they designated the event as.

However, aside from that, we review the event when it's coded, and by the NRC criteria, we also code it per our -- go down to the bottom. Also there's the reporting requirements at the bottom. We'll list the equivalent NRC reporting requirement knowing very well that it was reported under an agreement state, but will also then code it reportable, yes or no, per the NRC's definition, and the reason for that is being able to pull the data out in a consistent set.

So if what you're trying to do is pull everything out using the reporting requirements and using the NRC reportable gets you that consistent data across all states. That gets you the most consistent

data set across all states. You would not use the NRC reportable and the agreement state reportable together as fields in most cases. Simply use the NRC reportable because that gets coded for all of events, including agreement state events.

MR. LIETO: Right, but my point is that if you click yes and NRC reportable, okay, you just want the reportable events.

MS. BURGESS: Right.

MR. LIETO: Okay. If the NRC determined that, yes, it was reportable, and if the NRC indicates no for the same events --

MS. BURGESS: If the NRC said no for an event?

MR. LIETO: I'm sorry. The agreement state says no.

MS. BURGESS: Right.

MR. LIETO: Okay. It will not be captured as a reportable event in your search.

MS. BURGESS: If you do not --

MR. LIETO: Because it's an and. Both the NRC and the agreement state both have to say it's yes. So even though it meets the criteria of NRC reportable, if the agreement state puts in there no, it will not be captured in the search. I think that's

just a --

MS. BURGESS: Only if you include this as part of your search. I would suggest that you don't include this as --

MR. LIETO: That you always say "all"?

MS. BURGESS: Yes, that you leave agreement state reportable as all, and you only search on one or you search on the agreement state reportable if that's your focus, but don't search on both. Don't use both as your criteria. Only use one as your criteria, and you avoid those kinds of complexes.

MR. LIETO: But will you also capture the agreement state events?

MS. BURGESS: Yes, because it captures all agreement states regardless of how it's reported. With the agreement state reportable, it will get all whether it's yes or no or uncertain.

MR. LIETO: Okay.

MS. BURGESS: So only narrow, one side or the other to avoid conflicts.

Yes, Donna-Beth.

DR. VETTER: Dr. Nag -- oh, just a second. Sorry, Dr. Nag. Dr. Howe has a comment.

DR. HOWE: Just a quick comment. When Ralph and I were doing the searches, we had a problem

with a Veterans Affair medical event, and it was coded as NRC yes, agreement state no because it wasn't an agreement state licensee. So that created a problem.

I don't know how many of those types of things we have in NMED.

MS. BURGESS: Specifically I'm not sure what the event is, but if you bring the event to me, we can look at it and see if there was an error in coding or if there is an anomaly there. I'm not aware of any, but we can look into it.

DR. HOWE: Okay. WE have it.

DR. VETTER: Dr. Nag.

DR. NAG: Michele, you said your E-mail. What is your initial on the E-mail?

BURGESS: My E-mail is mlb5.

DR. NAG: Okay. Mlb5.

The radiation oncology community is interested in technical analysis. Now, if we knew from the NCI what the new radiation oncology medical events are, is it something that after analysis and taking the names out and so forth, is it something that can be published in a medical journal so that we can, you know, analyze and say, well, for prostate implant these were the problems. There are at the root cause. These are a way to minimize. For HDR

these are the main problems.

Is that something that can be done and still not go into any confidentiality issues?

MS. BURGESS: Any use of the data other than to directly support ACMUI activities for NMED would need to be cleared through the ACMUI coordinator. You clear each of those individually with her.

DR. NAG: Well, if the ACMUI is here, why do you do that? Because I know that there's a lot of interest from the radiation oncology community not to have difficult things important, but an overall idea of where the main problems are, what are the events.

MS. TULL: This is Ashley.

For something like this I would ask management. I would defer to Sandi or Janet. Is this something that we would see as beneficial to NRC or --

MS. WASTLER: I think we'd have to look at it from a broad perspective, but, yes, I think it would be something that we would definitely consider, but then we may have to raise it up to higher up in the management chain just to let them know that this is taking place.

DR. NAG: Right. I mean, one of the reasons you are going to do it is to try and see how

you can minimize the events. Now, the ones who are responsibility for the event are the users. Now, if the users don't get to hear what the major problems are, then you know, part of this benefit is lost. So --

MS. WASTLER: And if it comes through ACMUI as, you know, if you do an analysis, for example, in that community and you come up with an analysis, I would think you might want to bring it to ACMUI to review.

DR. NAG: Right.

MS. WASTLER: It's an ACMUI product.

MS. TULL: Right. If it's in the ACMUI report, there's no issue. We would vote and you could make a recommendation that we --

DR. NAG: That this be published.

MS. TULL: -- put out a generic communication or that, you know, you're going to use that information in a publication of sorts, and you know, we would follow it that way.

DR. NAG: I just wanted to know the logistics of doing it. Okay.

MS. TULL: Great.

DR. VETTER: Dr. Thomadsen.

DR. THOMADSEN: Right now the AAPM is

establishing an event database, and they're negotiating with ROSIS to try and have a joint American-European database to capture everything, and it would be very nice if there would be some way to cleanse this data, the medical data, and be able to share that together with the AAPM's database. Would that be something that the NRC would think about negotiating with?

MS. WASTLER: I mean, we do work with other organizations, for example, IAEA reporting certain events to the international database. I think we'd need more information, but we'd definitely consider it, yeah.

DR. THOMADSEN: Well, this is early enough in the APPM. There's very little data or information to give you, but that's because it's at a formative stage, which would be the best place to start working together.

MS. WASTLER: Right. I think it's definitely something that we would, you know, be willing to sit down and talk about.

DR. NAG: On similar lines, I think in 2004 I know the National Commission on Radiation Protection had a meeting report on HDR and the HDR medical events, and I remember that we did get the

data from NMED to see what were the HDR problems, and then we used that information somehow and ten we could have used that at least other ways to minimize.

So I know logistically, you know, how we did it, but I know it was done in your similar mechanism and your AAPM.

DR. VETTER: Other questions?

MS. BURGESS: So that's the end of the demo. I'll finish the rest of the slides quickly.

DR. THOMADSEN: I would just like to say I think it was very nice. Nice work.

MS. BURGESS: Thank you.

MS. TULL: This is Ashley.

I had one quick comment. I know there are several members that are new, and I haven't given you a user name or a password or set up your account with INL yet. So if you don't have one, I'll be doing that shortly after the meeting. But I thought it would be beneficial for you to see this first to understand what you're getting into other than getting an E-mail that says, "Here's a user name and password," and have no idea why you have this.

DR. NAG: The user name and password is not the same as our NRC user name and password.

MS. WASTLER: The user name is, but the

password is not.

MS. TULL: For anybody, when we set up a password because remember we set it up for NRC people as well as some DOE, some agreement states, if you have an NRC LAN, we use that. Then your password will be different. You'll have to set up a separate password, but your ID will be the same.

But if there's some password or some ID in particular that you'd prefer, if you send that in your E-mail, we can make the ID anything you want it to be. We just default to your NRC LAN ID when there is one.

DR. NAG: And that's through which IC?

MS. TULL: Your LAN, L-A-N, your Internet --

MS. WASTLER: It's the NRC Web.

MS. TULL: Yeah, local area network.

PARTICIPANTS: We don't have access.

MS. TULL: Correct.

MS. BURGESS: So we can set up any ID that you want if you send it to us. Your password will be randomly generated, and then you'll generate your own once you log on the first time.

DR. VETTER: And some of the reports say, quote, something like this: the INL requested additional information regarding this event, end

quote.

When that information is obtained, is the data entry updated?

MS. BURGESS: Yes. That's a place hold we use so that you know we're still asking questions and so we know we're still asking questions.

DR. VETTER: And one other question. Has there ever been an attempt to establish a denominator for these events so that we could calculate rates?

MS. BURGESS: In our annual report, the AARM report that we do each year, we have tried to establish a denominator. It's difficult. We tried to use the industry Website to try to figure out what that denominator might be both for diagnostic and for therapeutic events, and we have not been very successful in being able to find that. The denominator is really not something that NRC has control over or a handle on. It's something that we would need to get from the industry. It's the number of things that happen without there being a problem.

They're barely required to tell us when there's a problem, not every time they do an event. So we tried to make some educated guesses, but that's one thing we struggle with, and if you have something for us or a way that we can come up with that type of

number, it's something we look at, too

DR. VETTER: Dr. Suleiman.

DR. SULEIMAN: Yeah, I think that some of those numbers are available in terms of use by device. I mean certain procedures or exams. I mean, that's information that the health care and like CMS or whatever has. So I think you could come up with some. It's utilization data, but I think certain types of procedures either with certain types of equipment or with certain radionuclides, I think that reasonable estimates could be made.

DR. EGGLI: But you can't with CMS. This is Eggli.

In our population, CMS as a payer represents a third. In some populations CMS as a pair represents 80 percent. So you can know the answer if you knew on the average across the country what percent of total is CMS, the payer.

And then also because of restricted rules from insurance companies on what's reimbursable and what's not, the fact that CMS will pay CPT code doesn't mean the Blues will. As a matter of fact, I can give you specific examples where CMS will pay and the Blues don't.

So I think it would be very, very

difficult to come up with a denominator unless you actually required every medical licensee to report the number of procedures every year, and that would be the only way you'd ever get that denominator. The rest of it is society's only guess.

DR. VETTER: Okay. Thank you.

MS. BURGESS: Just in general, when you're doing your searches remember that if you're looking at events that are the longer time frame reportable like the 30-day, be careful of your search results if you're looking for things that are very recent. You're not likely to find them in there right away, and that might be something that has to be pursued through the individual states or through NRC if you're looking for information on the status of a particular event that has just recently occurred.

The NMED data is more looking back on a longer time frame or allowing it some time to catch up, not for immediate information. So keep that in mind when you're doing your searches, and especially if you['re trying to use numbers and do a comparative analysis, making sure you've waited long enough for the data to mature.

Like I said, when we do our fiscal year data, we essentially wait until February to close that

out because of the recognized delays in the 30-day reportable events and updates to those events. So we wait until the date of matures until that point to start trying to make statements or drawing conclusions based on the data.

And then it's a tool for analysis, not conclusions. You can't do a search in NMED and it tell you the answer. It can only give you numbers and then you have to add to it exactly what's coming up, the denominator. Well, I know numbers now, but what do the numbers mean? NMED can give you the numbers, but then you have to use all of the other facts that go with it to determine what do the numbers actually mean. Are they significant or are they not, based on the denominators, what you're looking for?

I guess in wrap-up, we hope that you find the database easy to use. We spent a lot of time trying to make it self-apparent so that you didn't need a manual, having everything there for you, but if there's ever anything that you think would make the Website more useful, especially some search that you're going to do on a periodic basis, if you let us know, then we can consider that in a future upgrade to, one, make the search easier for you to do, but, two, improve the consistency.

It's a QC. When you do something and you have a canned search, you know that you all will be doing the search the same way every time, and you eliminate the potential for errors that way, not to say that you can't take that search and then customize it, but if you are doing something and you're trying to compare from month to month or quarter to quarter, making sure your search results or your search criteria are the same from time to time is an important part of it, and saving your searches can be a way to do that at your own desk.

Real quick since we're getting very close to nine o'clock and the time they'll probably pull the cord on me here, I wanted to make sure that I at least touched base on a few things that came up in that earlier ACMUI presentation when you were raising some questions.

I think I have answered most of them in the basic presentation regarding doing different searches and coming up with different criteria, and some of the particular fields that can really make a difference in what the results are that you get with the site of event versus the state, and then the different dates, the use of NRC reportable versus agreement state reportable.

I think that some of the comments that were made in that earlier presentation were a result of some of those kinds of uses of the fields.

One other question that was raised was capturing landfill alarms. We do capture voluntary reports from the agreement states and from the non-agreement states regarding landfill. We do that per request from CRCPD. One of the recommendations was not to continue that because that data is not consistently reported to us. Therefore, there was question whether or not it was of much use.

What we're going to continue to do is we're going to capture that data because the reason that we're keeping it is not because it's reportable, but because it's by request of a sister group that is trying to look at that data, whether it's consistently reported or not. They were trying to look at that data, and we're going to keep the data in there for them at this point at any rate to at least give them the ability to try to look at it.

I think a lot of the issue goes away because NARM now will start capturing on a consistent basis because it will belong to NRC, and some of those events that were not reportable or not consistently being reported to the NRC now will be because it will

be NARM events.

That still means there are going to be quite a few landfill trips where you don't even have the isotope, but it is data that CRCPD was looking at to kind of keep an eye on what was going on and at least be aware of what was out there.

I think all of the rest of the issues we addressed. We created the short report for ACMUI, essentially is what drove it when Donna-Beth was putting together the presentation materials a couple of years ago. We came up with a short report as a quick way to get all of the information without all of the extraneous pages of detail that you didn't necessarily need.

So I think we already addressed that one. If there was anything else that you -- Dr. Lieto, I think you had some of the suggestions that were there -- if there's anything in particular that I had missed or if anything occurs to anybody in the future, then just give me a call.

DR. VETTER: Thank you, Ms. Burgess.

Are there any final questions? Yes, Ms. Gilley.

MS. GILLEY: I just have a comment. When it comes to the agreement states, there is some

Freedom of Information Act walls in each of the agreement states that might prohibit reporting or allowing the reporting of certain activities until that inspection or investigation has been completed.

So when you're looking at doing searches on the date of an event, if it looks like there's a lag in time before there's conclusions to that event, part of that is that we don't release that information until we're through with the entire investigation.

DR. VETTER: Mr. Lieto, did you have a question?

MR. LIETO: No.

DR. VETTER: Okay. Other questions?

(No response.)

DR. VETTER: Thank you very much, Ms. Burgess. Excellent report.

MS. BURGESS: Thank you.

DR. VETTER: We appreciate it, and if we have any questions we have your E-mail.

Okay. The next item on the agenda, Mr. Lieto and Dr. Howe will provide a summary of recent medical events and seek our advice, recommendations and insights.

DR. HOWE: This is the presentation where you see the results of the NMED searches, and what I

do is I've done it every six months, but the best one is in October because we look at essentially a whole year's data of what's been going on, and we try to go the fiscal year, October 1st to September 30th.

And what I've done, I'll get the NMED data, and then I'll kind of use it as a deck of cards, and I'll split out so that I have all of the diamonds and all of the spades and try to group things together and present them to you by parts of the regulations so that you can see common threads as they're developing.

The first slide is just pretty much a background. This is where we were a year ago, and I thought this year it might be good to see what the difference is from year to year. You have to keep in mind that we have so few medical events that none of this data is statistical. It just shows you relative trends.

And this is how we compared FY 2007 with 2008. We have essentially a slight decrease in the number of diagnostic medical events. We never expect very many diagnostic medical events. They normally are where you are expecting to give less than 30 microcuries of I-131 and you give greater than 30, or they are where you have a generator, a technetium generator, and you have a new technologist, and the

technologist elutes the generator and gives the entire elution to the patient, and those are generally what we got diagnostic medical events.

Three hundred is generally our iodine. We have a slight decrease in those this time. Four hundred are generally our prostates. We have a few gynecological ones. In this case we've got 24 patients involved. So we had ten medical events, and we had two medical events with six patients and one with ten patients.

Six hundred, I broke it down by HDR. I'm also breaking it down with the Mammosite because we seem to have a trend of medical events that are unique to the Mammosite. So we're just kind of monitoring that.

In this particular year, most of the Mammosite events really weren't unique to the Mammosite. So they'll be added back into the HDR, and gamma knife, we've got two.

A big increase this year was in the Yttrium-90 microsphere area where we had seven more events than we had last year.

DR. NAG: Donna, can you explain again what you meant by on the 35,400 24, number of patients and ten, number of events? I thought each patient

would be one event. Can you clarify that?

DR. HOWE: No, sometimes we have a medical event that is recognized as an error, and it's generally recognized after the fact, and we go back and we find out there are a whole lot of patients or there are a number of patients that were affected by that one error. And so it --

DR. NAG: But that is one event, but ten patients. I see.

DR. HOWE: Other times we may have the same error, but it's picked up at different points. So we may count them separately. So it depends on how we get the data.

So in this particular case, our 35,200 was where the facility asked for 30 microcuries. The pharmacy drew up 33 millicuries. The dose was sent to the hospital or to the clinic, and two nuclear medicine technologists measured it in a dose calibrator and really didn't register what the units were. They saw a number. The number was about the right number, but they didn't pay attention to the units, and they went ahead and administered it to the patient.

So we had errors at the commercial pharmacy and we had errors at the medical facility

that led to this medical event.

For the 35,300, which are those requiring a written directive, we had six events. Four of them are our typical sodium iodide where in two of them they ordered the wrong procedure. Either they ordered a thyroid scan and they got a whole body dose or they ordered a whole body dose and got a therapeutic dose instead.

We also saw two monoclonal antibodies. The Bexxar had a medical event because the delivery system set-up had problems with it and leaked and the patient did not receive the full dose, and in Zevalin we had a problem with the commercial pharmacy doing a calibration for the Yttrium-90 and they made errors in the calibration, but they also calibrated the hospital's dose calibrator, and so they incorrectly calibrated both their own dose calibrator and the hospital, and it took a discrepancy in the dose coming in for them to realize what the problem was.

An Yttrium-90 is difficult to measure in dose calibrators, and unfortunately I think FDA was depending upon the users to measure the Yttrium-90, and it's not holding the manufacturers to be the definitive answer.

Orhan?

DR. SULEIMAN: Yes, I've been very concerned about that. I think FDA's label sort of passes responsibility on the user, and I've talked with some companies or whatever, and I would be hesitant to call it a calibration factor. Apparently it's a quality check that's traceable, but it's not really calibratable, and I think there are some real technical issues and some papers recently that sort of suggested the radiation absorbed doses are far from accurate, and it also deals back to the calibration.

So it's an issue I've been concerned about. I think I'm pursuing it from within FDA, but --

DR. HOWE: Well, this was a case where FDA approved the drug, but they really didn't talk to us, and so when they approved the drug, they said, well, the medical licensees are required to measure it, and so we'll depend on the medical licensee, and if they had talked to us first, we would have told them that our medical licensees have a great deal of difficulty measuring betas.

And so they should not be the ones that you're depending on. The manufacturer really needs to go through the expensive effort of actually figuring out what it is they're supplying.

DR. SULEIMAN: I understand, and regardless of what may have happened in the past, I said this, I think, at the previous meeting. If these radiotherapeutics are to succeed in terms of improved efficacy, I think how the dose is calculated from the dose calibration from the administered activity, from the internal dose calculation has to be improved significantly. I think I have had some colleagues tell me maybe 30 to 50 percent.

I've come away recently convinced that maybe -- I've had somebody tell me forget 30 to 50. Three hundred to 500 percent. So the doses are really guesstimates in the largest way possible.

So unfortunately these have been approved for refractory patients, patients who are very ill. They have been approved for humanitarian uses. So this is not a patient population where you may see the benefit of much more accurate dosimetry over a longer period of time, but I think radiotherapeutics as a class in my professional opinion may have major impact in therapy in the future, but I think not the way it's being done right now, and this could be the tip of the iceberg in terms of some of the problems associated with accurate dosimetry, not just the dose calibrators, but the whole methodology.

DR. HOWE: Yes, and I know some of these are very narrow ranges between therapeutic and throwing the patient over the edge, but we still believe it's the manufacturer that has the resources for trying to figure out how to measure these things accurately, have accurate labels.

Dr. Thomadsen.

DR. THOMADSEN: Good news on the calibration is the accredited dosimetry calibration labs are coming out with Yttrium-90 standards that people can use to calibrate their dose calibrators.

DR. HOWE: When we look at 35,400, we basically have two patient populations. We have the gynecological patients, and we have the prostates. The gynecological, we have the continuing problem of entering the wrong units into the system, entering milligram equivalents into the program, but the program required air kerma.

And we also have kind of a uniform thing where the distance isn't right. In this case, the tandem insert was shorter than it was supposed to be, and so the sources were not where they were supposed to be. These are common types of problems we see a lot of.

And then in prostate, this is where we had

eight medical events, and we had 22 patients. We had six patients where the dose rate constant was in error. I don't have additional information as to what the problem was, but that could also be our air kerma type of problem.

And then we had ten where they used air kerma instead of milligram rating equivalent. And those were found after the fact. They were found about a year after the procedures were done.

One of our largest trends for the number of medical events, not necessarily patients, but numbers, is failure to correctly visualize the prostate, and in this case we see it repeatedly that the physicians are using ultrasound, and they're not able to visualize the prostate, and they get the seeds into the wrong part of the anatomy. And I think that certainly is something we would like for you to take up because we see it over and over and over again.

We also have two MICK applicable failures. In this case my data is a little funny because one of them wasn't NRC reportable and the other was a palladium seed, which is not reportable to NRC yet, but will be after November 30th, but I included it here because it happened to be the MICK applicator where the seeds get jammed in, and then when you're

trying to release the seeds, they generally end up with a leaking seed, a crushed seed, or they're unable to deliver the rest of the seeds. So I grouped those two together.

Dr. Nag.

DR. NAG: This is a group that I'm very much interested in in the chance that having these data is very important to the radiation oncologist, and this is what I was alluding to before, and it's something that we need to transfer this information, needs to be transferred back to the users.

For example, failure to collect data for like the prostate, I have investigated some of these in detail, and one of the problems is the fact that radiation oncologists are radiation oncologists and not ultrasound technicians. But the problem is we have to be doing the ultrasound, and it's very hard sometimes to recognize what's prostate and what's bladder and what's just fuzzy snow. Sometimes you just see the whole area as snow.

The MICK applicator is really something we have seen and, again, due to lack of training. So it needs root causes can be transferred back through the user, would be very helpful.

Now, you mentioned in the MICK applicator

failure there was one that was a non-reportable implant. What did you mean by that?

DR. HOWE: For NRC purposes, it was not an NRC radionuclide. It was a --

DR. NAG: For palladium.

DR. HOWE: Yes. It was a palladium

DR. NAG: Okay.

DR. HOWE: After November 30th, we will have palladium --

DR. NAG: No, but you said two. One was because of the palladium and the other one was?

DR. HOWE: Is our source. It's, I think, an I-125 source.

DR. NAG: Oh. Oh, you mean Cesium-131 then.

DR. THOMADSEN: No, no, no.

DR. HOWE: No, no.

DR. THOMADSEN: One was iodine; one was palladium. One was not reportable because it was palladium, but they reported it anyway.

DR. NAG: Right, but the other one?

DR. THOMADSEN: So they're all set.

The other one was the iodine. It was reported.

DR. NAG: But you say it was not an NRC

one.

DR. THOMADSEN: Oh, it's the palladium

DR. HOWE: The palladium one was not NRC at this particular point.

DR. NAG: Okay.

DR. HOWE: Yes, Sally.

MS. SCHWARZ: I just had a question. I know you explained this. The 22 patients.

DR. HOWE: Yes.

MS. SCHWARZ: Why are they not individual events even if there's multiple events?

DR. HOWE: In this case they, after the fact, like the new medical physicist came aboard and was going back over records and discovered that there was a problem in entering data into the treatment plan. Then they went back and reviewed records and so at one time, they reported that they had an error in entering the data in and it affected ten patients or it affected six patients. So this is one medical event, but it is also a number of patients.

We've had those on a lot of our retrospective problems where after the fact they go back and they see they've got an error, and then they have to go back through patient records and they find that it didn't happen just once. There's a group of

patients.

So it's not unusual for us to have that. I think a number of years ago we had eye applicator problems in Puerto Rico and Hawaii, and we had to report the patients involved, but the cause was one cause and it was a retrospective going back into the records, and so it was reported as one medical event and not was 500 medical events.

MS. SCHWARZ: But actually it is the 500 events. I mean, what I'm thinking about in terms of reporting individual occurrences, for example, in terms of safety, I mean, you've affected because it wasn't noticed essentially those numbers of patients, which would be individual events for each one.

DR. HOWE: We don't require you to report for each patient if you tell us how many patients were involved with this particular error. This was the error we made, and it affected N treatments. So we still capture the number of patients, but we don't have ten individual reports going in.

MS. SCHWARZ: I understand.

MS. SCHLUETER: I guess, Donna-Beth, just for clarity, so we're basing our statistics on the number of events, not patients involved, right?

DR. HOWE: Generally, it's one event, one

patient. But in cases that --

MS. WASTLER: That event may include -- it normally is an individual, but there are cases where in retrospective events it can have multiple patients, yes. So, you know, when you're doing a study, you're looking at events.

MS. SCHWARZ: Events and not individual patients.

MS. WASTLER: Not individuals.

MS. SCHWARZ: For statistical purposes, it would be better for individual persons.

DR. NAG: In terms of the air kerma milligram equivalent/millicurie, in one of our previous ACMUI, I think the recommendation used the air kerma. Has that been implemented? Where are we with that? Do we know?

I know that the recommendation was that we ought to also be using air kerma, and we had quite a long discussion especially with Jeff Williamson in that discussion. And where are we?

MS. TULL: This is Ashley.

We actually do have an IN on that drafted. It's in concurrence, and, Cindy, we're waiting on input from AAPM?

MS. FLANNERY: Yes, and it's in the

concurrence process.

DR. NAG: And what do you mean by that?

PARTICIPANT: The AAPM hasn't received it yet.

MS. FLANNERY: It doesn't go out for public comment. So right now where we are with the IN is it's drafted, all but one paragraph, which is going to describe the recommendations of AAPM and transmit the information.

We are waiting for that, and once that's done, it'll go through the normal concurrence process.

MS. TULL: Concurrence process is us up through management signing off and OGC taking a look at it. Then it gets published. It will go out on the medical listserver.

DR. NAG: So in plain English, it means that the public so far still have not received the directive --

MS. WASTLER: Correct.

DR. NAG: -- that is supposed to be reported in air kerma.

MS. WASTLER: Because the one issue that I think we were -- one of the discussions with ACMUI was that not only should we put it together, but we should coordinate with AAPM on the one aspect, which we're

trying to do right now.

DR. NAG: I think Bruce is on the committee in AAPM.

MS. WASTLER: Well, I'm not sure.

DR. NAG: He's right here.

MS. WASTLER: I'm not sure who Cindy is in contact with.

MS. FLANNERY: Okay, and when I was talking about the concurrence process before, so far it has gone to the previous ACMUI member who filled the therapy medical physicist position because we wanted to get Dr. Williamson's input before he left. Okay?

And once we get the AAPM's recommendation into that where it's more of a finalized draft, then it will go to ACMUI for review.

DR. VETTER: Ms. Schwarz.

MS. SCHWARZ: What would be the time frame that you're talking about?

MS. SCHLUETER: For publishing it?

MS. SCHWARZ: Until it actually will get to the end users, the public, yes.

MS. FLANNERY: If I had to guess, I would say maybe a couple of months. The concurrence process usually takes about a month, but I think it's going to

be a little bit longer in this case because we're still waiting for some more information. We don't even have the draft finalized yet.

DR. VETTER: Okay. Back to you, Dr. Howe.

DR. HOWE: And then we go into 35.600. Thirty-five, six hundred is the HDR gamma knife and teletherapy. We only have, we think, three teletherapy units in NRC space, and we're not sure how many are in the agreement state. So we very rarely, if ever, have a teletherapy medical event. So we didn't have one this year.

We have two major manufacturers for HDRs, and we just happened to break them out by the Varian weather Nucletron to see if we have any device specific medical events. Generally we don't have any really -- anything that's very specific for Nucletron. It's just an easy way to look at the data.

And in this particular case, I've included the Mammosite data in with the Varian or the Nucletron because the Mammosite can be used with either device, and if it is not something that is unique to the Mammosite, then we might as well put it in with the HDR unit.

And you'll see that we had 12 HDR events, six of them with a Varian, and we ended up with there

were end caps that were removed before surgery, and so you had blood fluid that went in and got into the connector and then caused the equipment to fail.

We had a number of cases where physicians and medical physicists picked the wrong isodose curve and put that data into the treatment plan and, therefore, ended up with medical events. This happened with Varian and with Nucletron and also, I think maybe with some Mammosites.

We also have problems with people not getting the distances right. Either they put the wrong catheter length, they write the wrong distance in, they enter the wrong length. In some cases they use the wrong length. In other cases they enter the wrong length, and so I think I've got maybe about seven of those.

DR. NAG: I think if you are going to describe a manufacturer, you should divide -- Varian has two different ones, one with the original Varian; the other is a Gammamed that was bought by Varian, but yet a highly different machine. If you want to do it separately, you should Varian, Gammamed, and -- Varisource, Gammamed, and Nucletron, or from a functional viewpoint you have all of the similar problems anyway. You can just have it -- my

recommendation would be you have it just at HDR, and again, Mammosite has nothing really specific to it. It's still an APR with a single source. So the Mammosite should be part of HDR.

DR. HOWE: Well, in the past, we've seen Mammosite specific problems where the Mammosite manufacturer has not told the users what catheters are compatible with its unit, and so the user has picked the wrong catheter.

We've also had Mammosite specific problems where they can aspirate the area and they puncture the balloon for the Mammosite. So that's one reason we're kind of monitoring the Mammosite, and that's why in this particular case I didn't see that it was a Mammosite specific one. So I'm throwing it back in.

DR. NAG: Now, I think what ACMUI members just for explanation, what happens is that you have an applicator that you enter into the patient. So that applicator is usually of a fixed length, and then you connect it to the HDL machine. You have a connector. Now, the overall length is what the machine sees. The machine doesn't know what is the applicator length and what the connector length and so forth. The machine only knows what the total length is.

And so if you are using a catheter where

you have to cut the catheter, then you have to make sure that your overall length is what the machine is seeing, and that way you should measure out the overall length. Sometimes people who are not thinking about it just put the default at 120, but the overall length by now may be less or more, and that is where a very strong source of error is.

And, again, this is a message that, you know, I think ACMUI should send out to the end users who are the radiation oncologists or the authorized user. So, again, this is an example of the message that I wish to funnel back to the end user.

DR. HOWE: Another reason that we also kind of break it down with Varian and Nucletron but not into individual devices is the two manufacturers have a different way of doing things. I think Nucletron -- and I may have them backwards -- Nucletron sends it out to the end. Varian goes all the way out to the end and then retracts. So we end up with physician with experience with one device and they flip over to the other device and they end up building in some errors because of the way that they think of doing the treatment plan before they realize the differences.

Dr. Thomadsen.

DR. THOMADSEN: On the Gammamed, which is also now Varian, it like the Nucletron goes out and steps back. So you can't say we'll group Varian because they all behave the same. They don't. Gammamed is more like the Nucletron.

DR. NAG: Right. Again, I think that goes to what I was telling before, that the Varian had two different ones. But again, whether it sends out first and comes back is not the major reason for the error. The major reason for the error is because on the Varian you can put any length. You don't have to go to a specific length of 120. You can make it 118, 115, 200 or, no, 150, anywhere between 80 and 150 for the variable one, whereas on the Gammamed it's fixed at a certain length, 130, and the only way you can treat is at 130.

So those are some of the minute differences between them, but again, this information is important to go back to the end user.

DR. HOWE: Yeah, and I think one of the things we're finding is because Varian took over Gammamed we're not necessarily getting the Gammameds identified at the larger manufacturer named.

DR. VETTER: So before we move on, Dr. Nag has made a suggestion that end users need to hear

about something about this group of errors that involve wrong catheter length, travel distance, catheter length entered into the computer, and so forth.

Is there a mechanism to do that through information notice or something of that sort?

MS. WASTLER: Yes, there is the ability to do that, yes.

DR. VETTER: Okay. Have you considered doing that?

DR. HOWE: We haven't. Normally -- I don't want to say "normally." What I'm hoping is as I present the data to the ACMUI if they find something of particular interest, you guys may set up maybe a subcommittee and really look into it in more detail and come back to us with a good analysis that has the additional professional experience added to it.

But we could certainly put something with a summary like this out and say our newsletter on a short basis.

DR. NAG: May I make a motion?

DR. VETTER: Sure.

DR. NAG: So that we can give it as an action item and keep it rolling?

I'd like to make a motion that a small

subcommittee be formed that would look into this, not just for the six months, but for a longer prior of time, and then report it back to the end user, and the most effective way of doing that, I think, would be to publish it in a peer reviewed journal.

And so my motion would be that the small subcommittee be formed, analyzing this, and then prepare a report that first comes back to the ACMUI and it from that point can be published in a peer reviewed journal.

DR. VETTER: Is there a second?

DR. WELSH: Second.

DR. VETTER: Okay. Dr. Welsh seconds.

Are there some volunteers to serve on that subcommittee? Discussion.

MS. WASTLER: Discussion?

DR. THOMADSEN: I think that's very limited. Could we maybe -- because there's another motion that's been tabled -- could we wait 'til all of this presentation is done because there are some things that also I think should be included in this motion.

DR. VETTER: Okay.

DR. THOMADSEN: And maybe it might just be best to wait 'til we both get done and then we can --

DR. NAG: I will table it.

DR. VETTER: So you withdraw your motion for --

DR. NAG: I withdraw the motion pending --

DR. THOMADSEN: I think you're tabling the motion, not withdrawing it.

DR. NAG: Tabling it, yeah, tabling it until the end of the presentation.

DR. VETTER: Okay, all right. Any other discussion on that point at this point in time?

Yes, Dr. Welsh.

MR. WELSH: Would we have permission to do this? Is there any obstacle in the way that would prevent us from using this information and conveying it to the end user?

MS. WASTLER: No. I think it's --

MS. TULL: This is Ashley.

No, as long as it's an ACMUI report, that's ACMUI business. The problem is just taking it on your own, one person, and then getting with a group of individuals who are not ACMUI members and then using the information to benefit that group.

Does that make sense?

DR. WELSH: Yes. As a physician I'm always thinking about IRB and all kinds of

restrictions that involve patient confidentiality, and so I'm always hesitant and ask for permission.

DR. NAG: Another point. Next week, later this week we are having the annual radiation oncology meeting, and part of my duty to report back to ASTRO, and I think not the, you know, detail, but can I just give an overall overview as part of my report to ASTRO that these are some of the problems that end users have?

DR. VETTER: Well, this is a public meeting. So anything that has been discussed here --

MS. WASTLER: Is public.

DR. VETTER: Sorry?

MS. WASTLER: It's a public meeting. This is a public meeting right here.

DR. VETTER: Right. That's what I was saying. So anything that's discussed here certainly could be echoed at ASTRO.

MS. WASTLER: I think I'd just point out, you know, you may want to run whatever information by other ACMUI members, you know, if you're saying this is, you know, ACMUI's position, you want to make sure.

DR. NAG: I mean, that is right. One is a broader one, which I have labeled. The other one is a rather limited scope of some of this information that

has been presented I'd like to summarize and report back to ACMUI.

MS. WASTLER: So this is a public meeting. So the information is available.

DR. VETTER: Dr. Howe.

DR. HOWE: And actually the total number on the last slide is not right. On the second slide it was right. There were 13 total, and so we had seven for Nucletron, and you're seeing some common errors. Again, the wrong catheter length was entered. The reference position entry error. Once again I have an isodose line where they picked the wrong isodose line and then put it in and it didn't match the written directive. And then we have one where they just entered the wrong dose.

Mammosite, there was a wrong film magnification. I don't know if that's specific to Mammosite in this particular type of procedure.

We had two where they entered the wrong treatment plan, and another one is they imported the wrong treatment plan. So those were pretty serious human errors.

And then moving into another group in 600 was the gamma knife and we had two gamma knife medical events. One was they prescribed at a given percent of

the maximum dose equivalent, but they calculated it based on another dose equivalent.

And then we also had unauthorized user that entered the wrong dose into the treatment plan, and it was a significant error from I think it was supposed to be 18 gray and he entered 28 gray. So that was a problem.

Now, we also have 35 1,000 events, and in this particular case all of our 35 1,000s this time were in microspheres. We had two with SIR-spheres. One was actually a manufacturing problem in manufacturing the delivery system, and they had to do a recall on the delivery system, and they found the person that was putting the delivery system together was not following the right procedures.

So that was a systematic problem with the manufacturer, and then we had another where about 20 percent of the dose went to the gall bladders. That was probably in the actual delivery phase.

We had six Thera-spheres.

DR. NAG: Can you go back to the previous one? I think I do want to comment that 20 percent in the gall bladder, that's usually because you have a vessel, and in that case, technically I don't think it should be a medical event.

DR. HOWE: Wrong treatment site.

DR. NAG: No, but the thing is you inject it into the artery and then the flow goes to wherever the blood flow is. So it's not something that is controllable and, therefore, some of it goes into the lung. Some of it goes into the stomach, you know, depending on where the blood flow is.

One of the ways of using it is to embolize the vessel, but you know, you cannot always embolize the vessel. So this is a patient specific blood flow issue, and technical I don't think unless by mistake if they put the catheter into the raw data artery --

DR. VETTER: Then it would be 100 percent.

DR. NAG: Then it would have been 100 percent. But technically I don't think it should be. If I were analyzing it, I would not have called it a medical event.

DR. HOWE: It reached our criteria for a medical event. The authorized user, in the guidance we tell the authorized user that they have an option of indicating how much of a dose they want to give to another treatment area, and if they don't specify that and it goes to that area, then it ends up being a medical --

DR. NAG: I realize all that, but what I

was trying to say that medically there is some things that are not controllable, and therefore, with the patient specific vasculature issue, if that is not a medical event, it's more of a vasculature issue.

DR. VETTER: Ms. Schwarz.

MS. SCHWARZ: I'm curious on the administration of therapy. Are you checking your blood flow initially to make sure your flow is --

DR. NAG: What happened is you put the catheter into whether it's the main hepatic artery or one of the low hepatic arteries and then you inject a dye and you look and see where the dye is going, and there is always a little blood flow to other organs which is, you know, acceptable.

Now, then you start injecting the spheres. However, backflow changes over time, over a few minutes depending on how much has been embolized and, therefore you start getting back flow.

You know, you stop at certain points and it's a judgment when to stop on the backflow. If it's a slight backflow and you stop you are not going to give enough dose to the tumor. So you try to strike a balance between when to stop, and that's a judgment call.

You are not going to know I'm now at 19

percent here until the judgment is called. This is part of the procedure, and I'm trying to differentiate was it something that's part of a procedure versus if by mistake someone put the catheter no in the hepatic artery but into some other -- gastric uretonal artery and inject it there. That's a misadministration.

DR. VETTER: Dr. Eggli. We have several questions. First Dr. Eggli.

DR. EGGLI: It sounds like this is a written directive issue rather than a medical problem. If the authorized user had said that it was acceptable in the written directive for us up to 20 percent of the dose to go to the gall bladder, then I assume that would not have been a reportable event.

DR. HOWE: That's correct.

DR. EGGLI: So the issue seems to be training of the physicians administering the dose to put limits on where the spheres can go.

DR. NAG: I would like to continue part of this discussion during the microsphere session because that whole one hour or so on microspheres, and you know, I have some of my own thoughts about how to do the prescription activity versus those and so forth.

So I think this part of it should be postponed until the microsphere session.

DR. VETTER: Dr. Thomadsen.

DR. THOMADSEN: Responding to you, the narrative on this particular case does not give enough information that we could make any conclusions about any of this, and further discussion on what this actually means or what the cause was is useless. We just don't have the information.

DR. VETTER: Dr. Welsh.

DR. WELSH: I would like to follow up on Dr. Thomadsen's point because I looked at the specific narrative, and it says after review of CT images on 7/12/07, the physicist believes that 20 percent of the dose went to the gall bladder, and I'm not clear how the physicist can ascertain something of that nature based on a CT scan at all.

DR. HOWE: And we have the right person on the ACMUI. This was a case from Florida, and so --

(Laughter.)

DR. HOWE: -- we would go back to the agreement state and find out the additional details.

MS. GILLEY: And I'll need to go back to the State of Florida to get those details for you. I didn't bring them with me.

DR. VETTER: So in conclusion, basically as Dr. Thomadsen pointed out, there's not enough

information here for us to really draw any conclusions on this particular event.

Dr. Welsh, did you have another comment?

DR. WELSH: No, I agree with that, and I wonder how CT images can help reconstruct dose in any way in this setting. It doesn't sound like --

DR. NAG: You're right.

MS. GILLEY: It could very well be.

DR. VETTER: Okay. Other questions? And then we'll move on.

Okay. Dr. Howe.

DR. HOWE: In the Thera-spheres we seem to have a rash of stopcock orientation errors. They weren't in the right place and so the dose would not go into the patient. We have had assembly errors where either the tube was too tight or the tube was too loose, and so you had leakage.

The very bottom one was also where they decided that there was leakage or the catheter failure.

We ended up with a failure to verify that the dose was delivered. In that case I believe they completed the procedure and it wasn't until it was after that that they went back and discovered that the dose was still in possibly the catheters.

And then there was a difference in what was prescribed and what was received in Nordion, and we're following up to find out a little bit more on that.

So those are the types of errors that we've had with the Thera-spheres and the SIR-spheres. In your books I also have another section which are NMED reports on events that NRC does not consider reportable events under our criteria, but I included because I thought they may be of interest to you.

And two of them were non-reports that will eventually become medical event reports. One was with I-123 and the other was with palladium which had wrong units were given and the wrong doses, but even though the wrong units were given, the dose was below the reportable requirements and so that wasn't.

There was a case where the microspheres and these were SIR-spheres, the physician stopped the procedure because he thought they were clumping, and they were supposed to be sending the sample back to SIR-spheres for evaluation, but SIR-spheres said we don't want to receive them until they have decayed, and so we never found out the final results of whether there was a problem with that particular group of spheres, and the clumping was very noticeable in the

pictures that they sent us in the CAP.

Dr. Thomadsen.

DR. THOMADSEN: We've seen clumping problems with those, too. It's probably nothing abnormal but very likely is either due to mixing of the contrast that they might have used for imaging in with the tubing, which the macrotubes will clump instantly if they hit the contrast, or just taking too long with visualizing with the contrast and flushing the line in which the microspheres sitting in the stopcock will clump. Those are normal situations as opposed to a problem.

DR. NAG: And, again, I think just as a follow-up to that, what is normally done is in between -- you are constantly putting dye or contrast dye in, and then you're putting the microspheres in, but in between you wash it with saline, and if you haven't washed with enough saline it --

DR. THOMADSEN: Water, water, not saline. Water.

DR. NAG: Water, and if in between you haven't spent enough time cleaning it, you could have clumping, and again, I think that part is a -- mechanism and not really a failure.

DR. HOWE: And then I guess the biggest

one that involved like 145 patients were for a problem that was identified in Europe and that was a linear accelerator using an Elekta stereotactic head frame, and the reference point for zero for the head frame was off from the linear accelerator, and so there were a lot of potential events, and those were identified in Munich and in France.

And they have nothing to do with the NRC. We originally thought because they were Elekta and we didn't have enough information that it may be something with the gamma knife. We found out later it was the linear accelerator, but we just included it here for your information. It's not anything that NRC regulates.

So I think that completes my presentation.

DR. VETTER: I have a question about the cause, the procedure for identifying the cause. I think, as I recall --

DR. HOWE: The linear accelerator with the --

DR. VETTER: No, I'm just speaking in general. I think the licensee is told when they create this report to identify the cause, but I'm wondering whether or not the rigor with which licensees identify the cause is adequate and whether

or not we shouldn't discuss whether it would be advisable to require a more rigorous root cause analysis, such as involving five whys (phonetic) or one of the typical quality measures for identifying root cause.

As an example, sometimes human error is designated as the cause. Well, you're not even close to the cause when you simply say it was human error. What was the error and why did it occur and so forth?

I don't know whether the agency has thought about that, trying to drive the process to specifically identify what the root cause or root causes were.

DR. HOWE: Our reporting requirements are in 35,345, and that's a very sensitive area, and the ACMUI generally is pretty sensitive about asking licensees to provide additional things.

MS. WASTLER: Actually the reporting, you know, that just tells what needs to be reported, but on the inspection side is where you get into the rigor, where they'll go in. They'll look at what the licensee has done, and that's one of the reasons, again, why it takes some time before you have complete information.

It depends on what it is, and then they

may send an inspector out to look at the analysis done, and in some cases, you know, we've been asked to assist agreement states on doing some of the analysis by providing consultants.

So it's kind of a two-sided thing. It's not just this is what is reported in. What comes out the other end eventually has a process, and where investigations are conducted. We don't normally though tell a licensee how to conduct the root cause analysis. We will look at it and might scratch our head and ask additional questions that will, you know, push for a more robust answer because like you, I agree. Human error is not an answer, you know.

DR. VETTER: Dr. Nag and then Dr. Thomadsen.

DR. NAG: I have been involved in a number of these, and basically if it is in the NRC's states, then many of them would come back and one of us, usually one of the -- many times one of the ACMUI members would be asked to serve as a consultant.

And so we look at their report, but then we don't necessarily have to agree with that. They might say this was an error in, you know, the manufacture, and we might look at it and say, well, no, because you had to do this and you didn't do that.

So what is initially and the final report don't always agree. Many times they do.

DR. VETTER: Dr. Thomadsen.

DR. THOMADSEN: We did a study that was on contract by --

DR. VETTER: I'm sorry. Who is "we"?

DR. THOMADSEN: University of Wisconsin did a study on contract with the NRC and the IAEA early in the millennium. We published it, I think, in 2004 where we looked through all of the reported misadministrations and isolated the ones for brachytherapy, where we took the reports and actually at the time we did something that we probably couldn't do now. I talked personally with the physicist involved in each of them, and I think we had 215 events, and I only had three physicists who wouldn't talk about it.

Actually most people were very happy to talk about it. They wanted to get it off their chest, and then we did a root cause analysis. The team consisted of several industrial engineers who do this and several medical persons.

One of the conclusions that we came to was most of the causes given in the events were wrong and were probably irrelevant, and there were several very

good reasons why that would be the case. Dealing with the information that people were giving to the NRC is not always complete since they're dealing with regulators and sometimes possibly even misleading.

The other thing that we found was early on in this process when we looked at the events and looked at the root causes and analyzed that and then went back, the early events we did we decided we had done wrong. There was a learning curve, and after a while we found that we were being consistent.

And if you look at people who do this, have an event at a hospital and do the root cause, chances are they've done it wrong just because there is a great deal of skill involved and learning with that.

So just going from what's in the reports and what people have said not only may not be correct, but may be very misleading.

DR. VETTER: Has that been published?

DR. THOMADSEN: Yes, it was in the International Journal of Radiation Oncology, Biology and Physics, 2004, I think.

DR. VETTER: Okay, and who was the principal author?

DR. THOMADSEN: That was me.

DR. VETTER: Okay. Ms. Schwarz.

MS. SCHWARZ: Dr. Thomadsen, I was just wondering on that analysis are there questions that have subsequently come out that would be better in terms of how you begin looking into an event, you know, the kinds of questions that will get you more accurate information rather than, say, the traditional questions?

DR. THOMADSEN: There's a process, yeah, definitely.

MS. SCHWARZ: Is that something that would be helpful to be shared with the NRC in terms of how they proceed to ask the questions?

DR. THOMADSEN: I'd be happy to discuss that some time.

DR. NAG: Well, at the next meeting we can have that in the agenda.

MS. WASTLER: We would definitely be interested in hearing it if you would be willing to present it at the next meeting.

DR. THOMADSEN: Sure.

DR. VETTER: Perhaps the coordinator could make a note of that.

DR. NAG: Action item.

DR. VETTER: Okay. Back to Dr. Howe or

Mr. Lieto.

MR. LIETO: Are you done?

DR. HOWE: Yes.

DR. VETTER: And I will turn the chair back to Dr. Malmud who has just returned from visiting with the Commissioner.

CHAIRMAN MALMUD: Thank you very much, Dr. Vetter.

If I may take a few minutes, how is the schedule? Are we okay?

MS. WASTLER: Actually we're behind schedule. We're in the middle of the medical event presentation, which is a two-parter.

CHAIRMAN MALMUD: Okay. Do you want --

MS. WASTLER: But it's a natural break. So I mean, we can take a break here.

CHAIRMAN MALMUD: Then I'll do this in two parts. First we'll deal with the medical event issue. First of all, the meeting with Commissioner Lyons was very collegial, and as an outgrowth of this meeting we will meet again intermittently. He has indicated that he will be available to meet with me, and I indicated that when issues arose that were more relevant to radiation oncology or so, that I would feel free to also ask if we could bring in a radiation oncologist

and/or radiation oncologist-physicist to discuss specific issues, and he was responsive to that.

He's up to date with what we're doing, and the question that he asked which is why I wanted to mention this right now is is there a need for any regulatory change regarding the number of incidents that are occurring or is there some other means that we might have of reducing the number of incidents. He was also curious as to what the denominator was.

And I said that we were not certain. We could try and get those data for him, but that we all felt that the numerator should be as close to zero as possible, regardless of the denominator, but clearly, the last question was did I believe any regulatory changes were necessary, and I said I did not.

However, with respect to specific issues we could discuss those in the future with the specialists from those areas.

The rest of my meeting with him I'll defer until you continue on with the business of this meeting unless you wish me to continue. I'm here at your pleasure. Do you want me to fill you in on the rest of the meeting with Commissioner Lyons?

MR. LIETO: Well, I'm just wondering because we've got 15 minutes before the break, and I'm

feeling that the presentation-discussion may last longer than that.

CHAIRMAN MALMUD: I'll defer that 'til later.

DR. NAG: The other way would be why don't you finish it out and have a break.

MR. LIETO: I was going to say go ahead and finish, take a break, and then we come back.

CHAIRMAN MALMUD: Okay. I told Commissioner Lyons that there were four issues that you wanted me to bring before him, and I went through each of the four. I'll do the last one first.

The issue of fingerprinting is not under the control of the NRC and, therefore, we're going to have to just live with that. It comes at a higher level and, therefore, we have to accept it.

He was not aware of the sentinel node biopsy issue, and I informed him about it, about the separation of the injection from the biopsy and the ability and the need to have those separated because there are some patients who cannot be seen in the hospitals where they do the injection but only can have the surgery at other places, and he was interested in that and wondered why he hadn't heard about it before, and I assume that it will be resolved

in some fashion before we meet again if we can bring it for discussion here and with a recommendation.

DR. VETTER: Excuse me. I'm sorry. We've already made a recommendation.

CHAIRMAN MALMUD: And the recommendation was that we separate them, and I told him that, and I explained why and how this peculiar circumstance occurs. He hadn't been informed about why the circumstance occurred and so on and so forth, but he seemed sympathetic to it, and we can bring that to him again for closure, I suspect, the next time we meet if we're able to get some closure here between staff and the committee members.

I explained the issue of the word "competence" and why the directors of training programs were so concerned about the word and what it could mean in a legal proceeding, and he understood it. He understood our concern. There was no conclusion to that. We'll meet again and discuss some of these issues at greater length.

He does have a tight schedule, and we actually filled a full hour discussing some of these things.

And the other one was our concern about the de facto establishment of a curriculum for

residents via the alternate pathway. He expressed initial concern as to why we would want to give more responsibility to residents who had not passed the Boards, and I explained that this is not an uncommon phenomenon. Ten percent of the American Board of Radiology residents, according to the director of the ABR, don't pass it the first time and then there are repeats. So there might be between ten and 20 percent of candidates not having passed the Boards. Hence they cannot be authorized users, except via the alternate pathway, and this requires certification, letters of attestation, and in addition, the curriculum therefore is established de facto by the alternate pathway for the residencies themselves.

DR. NAG: In addition to that, you cannot even take your oral boards until you are one year in your practice. The new requirement is that you don't even get your Board until your first year. You have to go by the alternate pathway. Otherwise you cannot practice the first year.

CHAIRMAN MALMUD: Yes, I remembered what you had said yesterday. I didn't get into the details. I just wanted to point out to him that this was preventing specialists in radiology, radiation oncology, and physics, among others, from practicing

in areas which are in most need because they cannot be authorized users. Hence they're not employable in those situations, and it's an issue of patient care.

So he's aware of that. He's most interested in what we do, most supportive of what we do, and interested in hearing from us more frequently in the future. His door is always open.

I said to him I'm not that far away. I can hop down here by train, but I would ask if it was okay to bring with me those individuals who are most knowledgeable about specific issues as they relate to their specialties, and he said yes, and I have the card of his staff person to call and make an appointment, and he would welcome us.

So I thought it was as positive a meeting as could be. I indicated that our general feeling was that over the years that I've been on the committee, not because of me, but observing, that the relationship between the committee members and the NRC staff had improved; that there was a better understanding of our mutual concern, which is the concern for patient welfare and for health care and for the well-being of our employees and the public at large; that everyone involved was concerned with that, and with that common concern, we often have differing

opinions as to how we would achieve those goals, but that the relationship between NRC staff and this committee I thought had improved immeasurably.

And you've been with the committee a long time, too, Dr. Nag, and you agree.

DR. NAG: Yes, definitely.

CHAIRMAN MALMUD: So we're moving in the right direction, but we did hope that things could be brought to his attention more quickly than in the past, and for that he said that his door is open, and that's all the time I'll take with that.

Now we can move on if you wish.

DR. VETTER: Or we could take a ten-minute break.

CHAIRMAN MALMUD: Oh, we'll take a ten-minute break and be back here at 10:15. How does that sound?

Thank you all.

(Whereupon, the foregoing matter went off the record at 10:07 a.m. and went back on the record at 10:31 a.m.)

CHAIRMAN MALMUD: Mr. Lieto will continue with the meeting. And the topic for discussion is medical radioactive material events.

MEMBER LIETO: Thank you, Mr. Chairman.

12. MEDICAL EVENTS

MEMBER LIETO: You have in your notebooks a copy of the slides as well as the narratives that go with the events that will be discussed. I am going to look at those events which were not determined to be medical events but, yet, relate to the medical use of radioactive materials and events that were reported.

The time period was the fiscal year 2007, and the source, as you all know, was from NMED. As Donna Beth reported, I think there were 30 or 40 medical events involving patients. I have a question mark here because we still I think disagree on the issue about the palladium patient being reported.

Even though it meets all the dose criteria for a medical event, the fact that it was a NARM material was not included in that statistic of the prostate patients, although it probably should be pointed out that there were regarding the mick applicators that did include a medical event with NARM. But I think it's probably a little bit of a moot argument right now since the NARM will all come under reporting to this Committee starting in November. But I think as we look at historical information, we definitely want to be sure that we include those events.

So I am going to report on other reportable medical use related material events. There were 31 in total. Since this is I think the second time I have presented this discussion or this information, the categories that I broke the events into were lost sources, both sealed and unsealed; leaking; landfill alarms; and a report on what was decay and storage waste, which was disposed of inappropriately or got out of licensee control and reached the landfill or was unknown origins. We don't know if it was inappropriately or if it was waste that came from, say, a released patient, which is acceptable waste that could get into the waste stream for patients who have been released; and then miscellaneous events, which is basically the catch-all for everything else, which has some I think interesting events.

Regarding lost sources, I think there were 15 events. The narratives are in your handout. The first event involved two shipments of cesium-131 seeds going to a medical facility which were damaged at the airport by handling equipment.

There was a total of 63 seeds in one package, only 3 of which were recovered, the others were damaged and resulted in contamination of airport

areas; and a second package, in which all of the seeds were found intact, although the outer container was pretty badly ripped up.

Another event was a cesium-137 brachytherapy source removed from a patient by two radiation oncology residents. At the end of the treatment period, sometime between after removal and return to the storage location, it was lost but was ultimately found in the hospital laundry.

Another event was an iodine-125 seed, actually was the two-patient shipments that were overpacked together involving 153 seeds, 138 millicuries total, which did not show up and was reported lost at the Chicago airport and ultimately was found 4 days later at Boston airport intact. And the seeds ultimately reached the hospital facility.

The next event involved a radiopharmacy delivery vehicle, which was carjacked, involved a total of 540 millicuries of various technetium agents. The containers were ultimately found four days later intact. Obviously they decayed to background because of the technetium agents, but the containers were found intact and the sources themselves also intact.

The next event involved a moly-technetium generator, which was six curies I think at

calibration, which was reported stolen by the courier vehicle at the airport. Actually, what had happened was that the back of the vehicle was unsecured. During delivery, the package fell out.

An observing citizen saw the package fall out and tried to get it returned. They called the courier. No response by the courier. The citizen then took it to the local police department, which then also was unsuccessful in contacting the courier and actually delivered the generator to the hospital. I don't think there was an assessment on ALARA in doses from this generator made in the report.

Another event was three nuclear medicine quality control sources. two were cesium. One was a decayed cobalt-57 vial source, less than 200 microcuries total, which was found in an abandoned but locked hospital X-ray room cabinet.

From the narrative, it's not clear where these came from. And it appears that the sources are that there was not nuclear medicine at the hospital where these sources were found. And so it's basically a source of unknown origin.

Another event involved the loss of an iodine-125 seed that was used for a temporary breast tumor localization. The tumor was removed with the

seed, localization implant with it. And sometime between removal of the tumor and when the facility, I believe it was nuclear medicine staff, went to retrieve the seed, it was lost and to date was not recovered.

Another event involved the shipment of palladium-103 seeds. A hundred seeds involving 132 millicuries that were being shipped or transported by the licensee, I believe the radiation safety officer, in an acceptable lockbox configuration in a vehicle, was stolen. And the sources were never recovered.

The next involved another delivery container in a centralized radiopharmacy delivery truck, fell out of the back of the vehicle. Again, I believe someone observed it falling out. They caught up with the delivery truck, told him what had happened. By the time they circled back and to the location, the container was gone. It ultimately was found completely intact six weeks later in a different location.

Another event again involving a radiopharmacy delivery vehicle, there were six containers involving a total of almost 1.8 curies of technetium agents were stolen from a delivery vehicle. None of the containers were ultimately found.

The individual involved in here obviously had to be of some strength because these are about 15-20 pounds each. And so it's not something that you very easily go running down the street with but obviously was able to do that.

Another event involved a loss of a I-125 seed following a prostate implant. There were seeds left over from the implant. These are, the number of seeds were, counted. They were recounted later in the storage location. And one seed was found to be missing and was not ever found after a search by the facility staff.

The next one involved a report in which a -- I believe this was an HDR iridium-192 source that had been exchanged out from the licensee and being returned to the source vendor's facility.

The vendor reported that it had not shown up when it was supposed to in the container that it was identified to be in. Ultimately it was found the next day at the vendor's location intact and secured.

Again we have another radiopharmacy delivery vehicle incident. This was a vehicle accident, evidently a serious accident, in which 18 delivery containers were ejected out the back of the vehicles.

Some of these rolled down, I guess, at the location. It was near an embankment, where several of these did roll down into the water. All but one container was found. That container had in it a fluorine-18 source with an activity of 271 millicuries. Underwater search, search with metal detectors, did not recover the container from the water.

The next event involved two I-125 seeds. There was a group of seeds, a group, about a half a dozen or more, seeds taken for sterilization prior to implant. When they were counted upon return, two seeds were lost. A search did not find these lost seeds.

And, again, this is similar to an event I just reported. A number of leftover seeds were put into storage. When these were recounted at a later date, there was one seed missing. A search entailed. Again, it was not found. And so the seed was lost.

The next group of sources involved leaking sealed sources. Now, I did not include sources that were reported under the medical event discussion that Donna-Beth presented earlier.

There were three events. Two reports actually were from the same licensee at different time

periods. All of the events involved iodine-125 brachytherapy seeds.

In the first two incidents, the source container containing the brachytherapy seeds was wipe tested after the sources were removed and assayed. Removable contamination was found above reporting levels. And, as a result, in both cases, the therapies were postponed and the sources returned.

In one of the narratives that did indicate that in analysis by the vendor, that a faulty weld in one of the seeds was found. I guess the presumption or assumption is that this was the cause of the contamination in one of the events.

In another, the seeds were leak tested before implant. This was an event that I found. I think this tends to get to a little bit of what Michele Burgess reported earlier in the search criteria and how you identify the criteria as you are searching because originally this was not something that we originally found in our searches and in the information that was originally sent out to the Committee for the packets.

This involved iodine seeds that were tested before implant. A wipe test resulted in removable contamination. It was four times the

reportable level. And so the seeds were returned to the vendor and not used.

We reported landfill alarms in the past, I think regarding those events that involved waste of medical origin or could strongly be suspected to have medical origin but also because we weren't sure if we could capture landfill events that resulted in loss of control of radioactive sources.

The number of events reported in this time period is significantly reduced from the previous year. There were six events that had been reported into the NMED database. They all involved iodine-131 waste.

Three of the events the waste was of unknown origin. And analysis at the landfill determined that it was I-131. And two other events involved improper disposal of the medical waste from a licensee who subsequently recovered the waste from the landfill and returned it to their storage. And the last event was waste that was medical waste from a residence, from a patient who had been released in accordance with 10 CFR part 35.

All of these events were from agreement states. I think, as, again, Michele indicated earlier, anything that goes into the databases is kept

and is available for reporting. But I think this reflects that a lot of sites are not reporting it because of the case of in many cases it's waste that can simply be left for decay and/or may come from individuals who have been released from medical studies.

There were I think several reports of what I'll call a miscellaneous nature that don't fall into the other categories. One event involved a cobalt-60 teletherapy machine source, failed to retract during treatment.

Operator emergency intervention returned the source to the shield. And the subsequent investigation determined that no medical event occurred, which reflects, I think, on the training of the staff to properly respond to these incidents. There were mechanical problems that were subsequently fixed and the machine returned to patient treatment use.

There were two events that involved I-131 administrations to pregnant women. The first involved 15 millicuries to a patient who was found to be subsequent 13 to 15 weeks pregnant at the time of administration. It doesn't appear that a pregnancy test was done but simply a verbal assessment as to the

pregnancy status of the patient.

Dose estimates were provided in the narrative. And, as you can see, they were quite significant since at this time it's expected that the fetal thyroid is functioning.

This has already been categorized as an abnormal occurrence event. These are events that will subsequently be reported at the end of the year to Congress in their -- "they" being the NRC as a part of their abnormal occurrence events and so obviously as they fall above a significant threshold.

The next event -- well, I guess I will just go to the last one here regarding the pregnant patients here. The second event involved a patient who was administered 125 millicuries.

She did have a pregnancy test. The test was negative. The test was done a week before the therapy. It was estimated that she was four to five weeks pregnant at the time. A dose estimate was done. And it's estimated that the fetal dose was 25 to 34 rem whole body.

The next miscellaneous event involved an agreement state, where a number of individuals were given diagnostic agents, fluorine-18, various technetium-99m agents for various non-diagnostic

purposes. This was done as a part of training employees and testing new equipment, some of which I believe involved PET imaging.

It was subsequently determined that 15 of these individuals received more than 100 millirems whole body doses. And the dose ranges from the fluorine-18 and the technetium agents is given in the slide here and, as you can see, was significantly above the 100-millirem dose limit for members of the general public.

Lastly, the miscellaneous events. There were three events that involved the same licensee receiving shipments from centralized nuclear pharmacies -- actually, I think it was more than one -- and found surface contamination exceeding reportable limits in all three cases. The events occurred, I believe, at different time periods. So it was like three shipments received at the same time.

Comparing the events reported for fiscal year 2006 versus this report, as you can see, there was a significant increase in lost sources, a marginal decrease in leaking sealed sources that were reported, a significant decrease in landfill alarm reports and about the same number of miscellaneous events that had been reported over the same time period.

Lastly, I think some of these events, these issues regarding the searches and so forth, have been addressed in Michele's previous discussion. Probably one of the things that as a recommendation would be able to do searches with multiple words that could be found in the narrative because some of the narratives regarding medical events may only contain the word "hospital." Another event may report just have it with the word "medicine" or "nuclear medicine" or "medical."

So I think it would be advantageous to sort of have the ability to do sort of like a Google-type search, where you could have searches on multiple words in the narrative. Some of the discrepancies I think, again, we have already talked about previously.

I guess what I would like to do, Mr. Chairman, there are outstanding, I think, a couple of recommendations that were tabled from yesterday. And I think, actually, there was a motion when we were discussing medical events, which I think was a variation of the motion from yesterday. I would like to go back to that motion from yesterday. And so that we could kind of act on that, get that off the agenda, if you will.

There was a motion that basically stemmed from an action item from our June meeting, which stated that "NRC staff should engage ACMUI regarding the review of operational events and data and work towards a goal of minimizing therapeutic medical events and, if necessary, to generate a final staff requirements memorandum."

I would like to kind of modify that in line of what I think Dr. Nag was suggesting that we establish either a standing working group or subcommittee that would annually review these material events, not just medical events but all the material events, and report at the spring meeting.

The reason I am suggesting the spring meeting is, as Michele discussed, some of these events, even though they may have occurred, have not completely drawn through the steps necessary to get into the NMED database.

And I think our October meeting misses sort of some of those end date reports, if you will, and that also any updated information would be available and inputted into these events, such that doing this at the spring meeting would allow us to have maybe more complete reporting in that the working group include obviously members from ACMUI but also

maybe from the FSME staff as well as I would recommend or someone that Michele may recommend that had the NMED expertise for doing these searches and that the working group or subcommittee make recommendations to ACMUI as a result of the search and data that we have discovered.

I think when you reported back to the ACMUI this morning, you indicated that Commissioner Lyons was wondering were there events that required regulatory change or action by NRC. And I think having this standing group with a charge of making recommendations based on the information received from the NMED plus also working with the NMED staff to improve the information that's contained in the event reports might also go towards improving some of these goals.

CHAIRMAN MALMUD: This is Malmud.

So Mr. Lieto is making a motion that a subcommittee be established of the ACMUI to review all medical events at the annual spring meeting. And we will take that as a motion. And the members of that committee would be made up of members of ACMUI and invited other participants. Is that correct?

MEMBER LIETO: Could I change just one word?

CHAIRMAN MALMUD: Yes.

MEMBER LIETO: Instead of "medical events" to --

CHAIRMAN MALMUD: "Medical"?

MEMBER LIETO: -- "radioactive material events" because there may be issues that we may start seeing with these --

CHAIRMAN MALMUD: Absolutely.

MEMBER LIETO: -- lost sources and so forth.

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

MEMBER NAG: Second and supplement. I would like to supplement that motion.

CHAIRMAN MALMUD: In what way?

MEMBER NAG: The supplementation would be that this subcommittee -- I agree with the formation of that subcommittee, but the task of the subcommittee would include analyzing these events. And then the important part is that the report of this goes to the end user. Otherwise we have the report to discuss amongst us, but it does not go back to the end user.

So part of the task would be to then have this report either published in a peer review journal or published in a forum so that the end user has

direct access to them.

So the modification would be this subcommittee would report back to the ACMUI and, when appropriate, to prepare a report that could be published in peer-reviewed journals when appropriate.

CHAIRMAN MALMUD: Do you accept that amendment?

MEMBER LIETO: I have some difficulty with that.

MEMBER NAG: Maybe we can do --

CHAIRMAN MALMUD: So is there a second to your motion as it stands? Is there a second to Mr. Lieto's motion as it stands?

MEMBER WELSH: Second.

MEMBER NAG: I'll second, and I'll make a separate motion.

CHAIRMAN MALMUD: So we'll discuss. It's been seconded. So we can now -- all right.

MEMBER LIETO: I was just going to add I don't think the goal that Dr. Nag wants to achieve is precluded from this. I think that as a subcommittee, it needs to come back to the ACMUI. How we decide what that information -- you know, whether it goes to a peer-reviewed report or information notice or RIS or newsletter, I think that would be the discussion of

each report.

I think if we are going to say that each report has to go into the peer-reviewed literature or whatever, I think we are being overly restrictive.

MEMBER NAG: No, no. My motion was when appropriate. I did not say all of them have to go. I said when appropriate.

CHAIRMAN MALMUD: Gentlemen, the motion on the table now, though, is the motion that you made and that you had seconded. So is there any discussion of that motion? Dr. Suleiman?

MEMBER SULEIMAN: I think it's a great idea. I have concerns about is that within the purview of ACMUI? Are we doing the NRC's work for them? Are we working with their medical events review staff already? Do we need a subcommittee?

I mean, I see us going off on a tangent. I think looking at these reports is extremely important. I am just wondering. I am just wondering. It doesn't mean I am opposing it, but I am raising the question.

Is it within the purview of this Committee? Are we inserting ourselves into an area where maybe the NRC doesn't want us to be that involved? I don't know.

CHAIRMAN MALMUD: Dr. Vetter?

MEMBER VETTER: I like the idea. We have done this sort of thing in the past when we think of it or when the staff asks us to. I like this because it suggests it is an important issue that we should keep on top of on a regular basis. So I support the motion.

CHAIRMAN MALMUD: Any further discussion of the motion? Sandi?

MS. WASTLER: I think the question was raised whether it was in the purview of this Committee. And I would say we had two presentations at this meeting, and we have tried to do it at every meeting with the goal of getting ACMUI's advice and guidance on recognizing maybe some trends or to analyze the information and make recommendations, just like you're proposing, on where it might be beneficial to have a generic communication or some other type of notice to go back to the license community, where you could improve. So the goal always is to reduce the number of events. So I think it's well within the keeping of the Committee.

CHAIRMAN MALMUD: I have a question. And this is, how would this interrelate with the data that Dr. Howe presents to us annually?

MEMBER LIETO: This would be putting both of what she did and I did together in one report back to ACMUI and establishing, you know, consistent ways of looking at it so that we can do trends.

Like Donna-Beth indicated, when she did a search on medical events, she came up with a certain number of events. And I did it a different way and came up with a different number and different events. And so I think --

CHAIRMAN MALMUD: You coordinated?

MEMBER LIETO: So the idea is to coordinate it and include the expertise of the NMED people and other interested members of ACMUI so that we're doing things consistently at the same time period and reporting back and making recommendations.

CHAIRMAN MALMUD: Thank you.

Any other questions? Dr. Howe?

DR. HOWE: Just for your consideration, you may want to keep the same presentation in October, which is understood that it's not as complete as far as the NMED data. And then you can pick up focused areas for your spring meeting so that once you see what the raw data looks like, you may have more focus on what you want to really work on for spring.

CHAIRMAN MALMUD: Mr. Lieto, what do you

think of that?

MEMBER LIETO: I have no objection. I don't know if the Committee would want sort of the same data presented, you know, twice in a row, but --

CHAIRMAN MALMUD: From what I understand from your recommendation, Dr. Howe, it wouldn't be presented twice. It would be presented in October. The results of grouping it together and highlighting the important issues would be what we heard in the spring. Is that --

MEMBER LIETO: Oh, I see.

DR. HOWE: That's correct.

MEMBER LIETO: I see.

DR. HOWE: It would be a more in-depth review in spring of certain key areas.

CHAIRMAN MALMUD: Sally Schwarz?

MEMBER SCHWARZ: Well, and I think what Ralph was saying, too, is that since the close of fiscal year is the end of September, first of October, that the spring would be preferable in terms of the total package --

CHAIRMAN MALMUD: Yes.

MEMBER SCHWARZ: -- but that in the in-between meeting, certainly it seems like things like Dr. Thomadsen's review of how to deal with issues

that have come up as a result of Donna-Beth's presentation that he is going to present next meeting, I mean, again, it could be focused from the subcommittee but not necessarily just be the same data reported at each meeting --

CHAIRMAN MALMUD: Yes.

MEMBER SCHWARZ: -- but the overall grouping together in the spring.

CHAIRMAN MALMUD: So the motion presented by Mr. Lieto has been moved and seconded. And would you wish to accept Dr. Howe's suggestion as an amendment that it would be presented in preliminary form in the October meeting and then in final form in the spring? It is an important issue for us. So it's worth -- great. And who seconded your motion? Do you accept the amendment?

MEMBER LIETO: Yes.

CHAIRMAN MALMUD: And Dr. Welsh accepts the amendment. All in favor of the motion?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: It carries unanimously.

Thank you.

I have a question for you.

MEMBER SULEIMAN: I was trying to ask some questions.

CHAIRMAN MALMUD: Oh, okay. That's what I like. The Chair asks his questions last. So you, therefore, go.

MEMBER SULEIMAN: I was trying to ask some questions on your presentation before you went in and decided to make a motion.

(Laughter.)

CHAIRMAN MALMUD: Absolutely.

MEMBER SULEIMAN: The use of the PET nuclides on the staff, I know that is not allowed.

(Laughter.)

MEMBER SULEIMAN: Obviously this is interesting. Is this the sole example of that? Is this more prevalent than I would be afraid of? This just fascinates me.

MS. WASTLER: There have been other issues in other -- it is not common, but it has --

MS. FLANNERY: You can talk about it.

MEMBER EGGLI: I can talk about the --

(Laughter.)

MEMBER EGGLI: I believe that it is

actually far more common. I believe that there are a lot of licensees who actually don't realize that it's a problem and that in our practice when we evaluate new equipment, we use patients who have medical indication. We sometimes give the studies away free when we are evaluating new equipment, but we always have medical indication.

I don't believe that everybody knows that you can't do it without medical indication. Otherwise you're in violation of the regulation. And I think that is information that needs to get disseminated.

And then the question always comes down to the benefits versus risk of self-reporting these kinds of things.

(Laughter.)

MEMBER EGGLI: I think that clearly, clearly this is not isolated.

MS. WASTLER: Correct me if I'm wrong, but didn't we put an -- there was an IN that went out?

MS. FLANNERY: There are actually two RISes on this topic.

MS. WASTLER: Okay. On the topic?

MS. FLANNERY: One from like a year and a half ago and another one from like three years ago.

MEMBER SULEIMAN: So what happened with

it? Are they fine? What --

MS. WASTLER: This particular case, if my memory serves me, this was California. And I would have to go back and look. I don't know the specifics.

MEMBER LIETO: The narrative describes the events, the action that they took. My impression was sort of a slap on their wrist response.

CHAIRMAN MALMUD: Dr. Van Decker?

MEMBER VAN DECKER: I'm going to shift topics, though. Do you have something on this piece of it?

MEMBER EGGLI: One final comment.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I think the fact that it's in a RIS doesn't really mean that down in the trenches, where the decisions get made to do these things, that the information has become disseminated.

Most clinical physicians probably don't look at the Web site. I think the radiation safety officers do, but I doubt that clinical physicians do very often. And this can happen and come and go. And the radiation safety officer may never discover it.

MS. WASTLER: Just to build on that, that is one of the reasons why we put together the medical list server, was so that -- because we were finding

out that in cases where we put out a RIS or an IN or even our newsletter article, it would never get down to the actual hands-on staff. You know, it might stop in the RSO's office. It might stop in maybe the company had -- whoever is on the mailing list.

So that is one of the reasons why we did the medical list server. But we would be very, very interested if you have recommendations on how we can get the information to the individuals that need it.

I mean, we try. We are willing to make presentations. We have had outreach at the medical communities, organizations, ASTRO and the like. I mean, we are willing to do whatever we can. So if there are additional things that could be done, we would love to hear it.

MEMBER SULEIMAN: As a follow-up, the person reporting that, are they protected like a whistle-blower? I mean, if somebody comes -- I have been in certain situations where there are --

MS. WASTLER: There are no names usually in the events.

MEMBER SULEIMAN: No, no, no. Somebody reported this to you.

MS. WASTLER: Yes.

MEMBER SULEIMAN: Is that person

protected? In order to make a formal complaint, in order to make a formal complaint, do they have to put their name down? And so they're vulnerable to --

DR. HOWE: Orhan, if I could answer that?

MEMBER SULEIMAN: Yes.

DR. HOWE: If we get the information through an allegation, we have a formal allegation process. We don't necessarily always protect whistle-blowers, but we do have a whistle-blower policy and we also have an allegation policy.

MS. WASTLER: But most of the events are required to be reported by the licensee. So the reporting medical physicist, it depends on the situation.

MEMBER SULEIMAN: Well, the licensee reported this themselves? This wasn't an allegation that you followed up?

MS. WASTLER: I haven't read that one recently.

MEMBER LIETO: This was found during an inspection by the state agency.

MS. WASTLER: Okay.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Clarification that the cesium-131 and cesium-137 -- they sound very similar.

However, cesium-131 is a very low energy, short half-life material. And, therefore, the degree of danger presented to the public is far less.

The cesium-137 is a very high energy and usually also high activity material. And that will present a lot of danger to the public. And usually it is not easily suitable. So I just want to make that clarification for the group.

And I would like to follow it up with a follow-up motion, if I can. The follow-up motion is that one of the problems sometimes I see is that we are discussing this. And this has been presented in ACMUI meetings in the past. However, the end user does not necessarily get to hear about that.

And, therefore, a supplementing motion or second motion I am making is that once the supplementary report has been generated, when appropriate, a publication be done that can be published in a peer-reviewed journal shows that the end user gets to know about some of this when appropriate, which is a separate motion from Dr. Lieto's motion.

CHAIRMAN MALMUD: Is there a second to that motion?

MEMBER WELSH: Second.

CHAIRMAN MALMUD: I would like to speak against the motion, if I may. To obligate a peer-reviewed publication is to obligate someone to write something up in a form which is acceptable to a peer-reviewed publication.

And, in theory, it's wonderful, but in practice, it is unlikely to occur in most situations since many individuals regard the preparation of an article for a peer-reviewed publication as considerable effort.

I would suggest a more direct means of communicating because putting a peer-reviewed publication as a requirement means that it won't get done most often.

MEMBER NAG: No. I'm not saying the requirement. I said when appropriate, you know, will be done. And the subcommittee doesn't have to publish it, but if appropriate, if they felt the -- you know, one of the things that we said was what's the most appropriate way of getting it to the end user. So this would be one way of getting it to the end user.

There are a number of us who are publishing quite a lot. And we can extract the data required from the subcommittee report.

CHAIRMAN MALMUD: This is Malmud again.

I am not opposed to getting it to the end user. I am just suggesting that the mechanism of a peer-reviewed publication will most often not work, though it is ideal. But there are other ways as well of achieving the same goal.

I'm sorry. Who was next? Dr. Welsh?

MEMBER WELSH: I would like to say that I support Dr. Nag's concept wholeheartedly. I understand Dr. Malmud's concern. And I would perhaps like to change the motion, instead of saying "peer-reviewed literature," to say "peer-reviewed literature or other appropriate venue," which opens it up to using the internet, presenting at a national meeting, or other effective means.

MEMBER NAG: I was saying I will rewrite mine to say "for public dissemination," "for public dissemination." I'm not going to say, "peer-reviewed journal." Peer-reviewed journal could be one avenue, but, as Dr. Welsh suggested, in a public meeting, ASTRO meeting, you know, in internet, and whatever other mechanism to get it to the public.

CHAIRMAN MALMUD: Malmud.

I enthusiastically support that. Was there another comment? Sally Schwarz?

MEMBER SCHWARZ: This is going back to the

actual narrative that was described on dosing the workers. I think that one of the groups that needs to be reached probably is the technologists, the nuclear medicine technologists as a group.

And I think that certainly they have an organization. And it would be worthwhile to begin trying -- I mean, I understand that they are not the persons who directed the orders, but at least if they are aware that this is inappropriate practice and it can be presented appropriately, at least they are aware of and not just unknowingly agreeing to inappropriate practice that may not have been designed to be inappropriate practice.

CHAIRMAN MALMUD: Right. Dr. Eggli?

MEMBER EGGLI: Eggli.

I think one of the other sources for NRC to get at and maybe FDA as well is the vendors. I can cite you a recent incident, not in the NRC sphere but in the device sphere, where we had a new 64 slice CT scanner installed.

And the vendor's application specialist suggested to us that we needed to go out and round up normal volunteers for coronary artery CTA so we could learn to run the machine. And I told the vendor, "We can't do that."

And they said, "Why? We tell everybody to do it, and they do it."

I said, "Are you aware that that is illegal in the State of Pennsylvania?" And they looked at me like it was a blank look on their face.

I think a lot of these suggestions to take this approach of studying normal volunteers for new equipment actually comes from the vendor sphere.

And reaching the vendors so that their application specialists don't go out to sites and say, "Round up 25 normal volunteers. We are going to do PET scans this week because you have a new scanner coming in" would probably have a very significant impact.

MS. WASTLER: Good idea. That may well --

MEMBER EGGLI: My experience has been that is where most of the suggestion to do this actually comes from.

MS. WASTLER: We always make sure that the vendors are on our list of --

CHAIRMAN MALMUD: There is a motion on the table. It has been moved and seconded. Any further discussion?

(No response.)

CHAIRMAN MALMUD: All in favor?

MEMBER SULEIMAN: Hold on.

CHAIRMAN MALMUD: Oh, there is further discussion?

MEMBER SULEIMAN: The only point I want to make is we'll talk to the vendors, but it's their field people who are doing --

MEMBER EGGLI: But they need to disseminate that to their field people loud and clear.

MEMBER SULEIMAN: Yes.

CHAIRMAN MALMUD: We still have a motion on the table. All in favor?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: Carries unanimously. Thank you, Mr. Lieto.

Dr. Van Decker?

MEMBER VAN DECKER: I hate to prolong this too much further, but I have a question on the content of the presentation. I was actually a little bit impressed by the amount of HazMat transportation issues that showed up.

And I guess my questions revolve around:

one, do we have any sense that this is any different than any other HazMat material that happens? Number two, do we have a sense from the data reported that these people followed what would be considered normal HazMat reporting for this type of stuff? You know, not responding to a phone call is not quite great sounding.

And then does the Department of Transportation have some overview in some of this as well? And what is the mix in all of that, I guess?

MEMBER LIETO: Those are good questions that --

(Laughter.)

MEMBER LIETO: I do agree with you that there was a significant number of these involving radiopharmacy delivery vehicles.

CHAIRMAN MALMUD: I must say as an editorial comment I was astonished to read these because in the city, every delivery truck that handles baked goods or beverages, carbonated or alcoholic, has a lock on it. And when the man, usually a man, unloads the truck, he then relocks it as he goes into the store to deliver the goods.

And if they can do this for cake, why can't they do this for radioactive material and also

the other things that they are carrying? I mean, I am astonished. I thought that they did this routinely.

MS. WASTLER: This is similar to -- you know, if you look at the events that we get for stolen trucks, it's not the Troxler Gauge. It's the truck that they're in that they do. And then they figure out that this big piece of equipment covered in yellow isn't a Skill saw or some other piece of information. And it's found on the side of the road.

CHAIRMAN MALMUD: Dr. Fisher?

MEMBER FISHER: Just an aside. I had a shipment of 400 curies of cesium-137 at a FedEx warehouse that was inside a locked chain link fence area that was broken into during the night. I guess someone thought that these shielded containers contained coins or other valuables and, therefore, was going after them.

When they found they only contained sources, they put them back and left.

(Laughter.)

MEMBER FISHER: I think the process of protecting radioactive nuclear material in transit is fraught with all sorts of unknown events due to someone's desire to steal something, not knowing what they're dealing with, that is pretty hard to

anticipate any single event.

And I am not sure there is a generic solution, but we must recognize that these things are going to continue to happen and probably cannot be adequately regulated.

CHAIRMAN MALMUD: I recognize that these things can always happen. I am just astonished that an ordinary bakery truck, an ordinary beer delivery truck has a lock and key and that some of these vendors don't even have that with regard to entering out their vans while they're delivering goods.

Dr. Eggli?

MEMBER EGGLI: The whole thing is accident-ridden, but a number of these were simple failures to close the tailgate. I personally have observed a yellow 2 labeled package fall off the back of a Federal Express truck on our campus because the tailgate was up. I managed to retrieve the package and return it to the Federal Express driver at his next stop. I followed him, but he was unconcerned about the fact that his tailgate was up.

MEMBER VAN DECKER: Are you HazMat-certified? No. I'm just --

(Laughter.)

CHAIRMAN MALMUD: This is Malmud again.

We will look forward to the subcommittee's -- oh, excuse me.

MEMBER GILLEY: Just to put it in perspective, there are thousands and thousands of containers of radioactive material being transported on our highways every day. This is very small. We are back to this denominator/numerator issue.

These issues seem bizarre, but they are a very, very small number if you put it in perspective of the amount of radioactive materials that are on our highways every day.

CHAIRMAN MALMUD: We agree that they are a small number. There is no argument about them being a small number. The question is, how do we address the issue without putting in additional burdens that would discourage common carriers from handling radiopharmaceuticals or other radioactive material?

And we will wait for the committee's report and see what recommendations we can come up with that at least eliminate some of these events from occurring without an undue expense.

I still remain astonished that we could protect a bakery truck but not a FedEx truck or other -- I shouldn't choose FedEx -- or other common carrier truck.

Dr. Suleiman?

MEMBER SULEIMAN: One, I think it's a major point I just want to make. I have experienced this throughout my career, but most of the people at this table represent a very high level of professionalism. And you people really don't have the opportunity to see what is going on out there sometimes in the real world.

(Laughter.)

MEMBER SULEIMAN: And so these events may be representing a broad spectrum, although under-reported. And so what I am telling you is that probably these may be the tip of the iceberg and these may be more prevalent and not necessarily typical of your facility.

So I think you have to exercise some common sense when you say, "I'm not experienced with it." None of this surprises me. Okay? None of this surprises me.

(Laughter.)

MEMBER SULEIMAN: And I don't think a lot of you should be surprised that this happens probably a lot more frequently than you would suspect. And that is why sometimes you need regulations and sometimes you have to spell things out.

It's not for the people at this table. It's for the people out there who get away with anything they can. Just a small point but I think to put things in perspective.

CHAIRMAN MALMUD: Thank you, Dr. Suleiman.

We will look forward to the spring meeting when we will see a list of these events and perhaps at that time discuss some recommendations for reducing them as much as possible without putting undue restrictions on their movement.

I think the next item on the agenda is Ashley Tull, if I might take us forward. I'm thanking Mr. Lieto for his --

MEMBER NAG: One second.

CHAIRMAN MALMUD: Oh, Dr. Nag?

MEMBER NAG: We talked about the subcommittee. Was that subcommittee appointed or --

CHAIRMAN MALMUD: No, it was not yet appointed. Now, thank you for reminding me. The subcommittee was recommended by Dr. Nag, if I remember correctly. Do I not remember correctly?

MEMBER NAG: Dr. Lieto here, we --

CHAIRMAN MALMUD: Is either of you currently chairing another subcommittee for this committee?

MS. TULL: Nag is.

CHAIRMAN MALMUD: Not yet?

MS. TULL: Nag is.

CHAIRMAN MALMUD: Dr. Nag is.

MS. TULL: One that you recommended yesterday.

CHAIRMAN MALMUD: I seem to remember that. All right. So, Mr. Lieto, would you be willing to chair this subcommittee?

MEMBER LIETO: If it would make the Chairman happy, yes.

(Laughter.)

CHAIRMAN MALMUD: If the Chairman's happy, this is unimportant. If the Committee is happy, that is what we are concerned about. And the Committee would very much appreciate your assuming that responsibility.

And, Dr. Nag, would you be willing to serve on that committee?

MEMBER NAG: Yes, I would.

CHAIRMAN MALMUD: Now, may I ask you as chair to appoint the other members of the committee? Recommend.

MEMBER LIETO: I would recommend probably Bruce and Michele Burgess. And I don't know. And Dr.

Suleiman?

CHAIRMAN MALMUD: And Dr. Suleiman.

MEMBER GILLEY: May I speak up?

CHAIRMAN MALMUD: And Debbie Gilley?

MEMBER GILLEY: Since the majority of the medical events are from agreement states, I would think agreement state recommendation would be important.

CHAIRMAN MALMUD: All right. Now, who is from Dr. Howe's staff who will be with you? Dr. Howe is I think doing the data collection, are you not?

DR. HOWE: Well, it comes out of NMED, but I --

MEMBER LIETO: I would say whoever Janet would --

MS. WASTLER: Provide the appropriate staff to support the Committee.

MS. TULL: I would just make one comment. They can consult with Ms. Gilley at this time, but since she is not a full ACMUI member, she can't officially be a subcommittee member. They can consult with her. She can participate.

CHAIRMAN MALMUD: Thank you, for clarifying that for us. So you will be a participant.

MEMBER GILLEY: Thank you.

CHAIRMAN MALMUD: Does that complete? So would you just for the minutes tell us who the members of the committee are? The chair is Lieto.

MEMBER LIETO: Yes. Members would be Dr. Thomadsen, Dr. Nag, Dr. Suleiman, staff appointed by Ms. Schlueter. And consultant would be Debbie Gilley.

CHAIRMAN MALMUD: Thank you. We'll now move back to the agenda. And it's microsphere use guidance with Ashley Tull.

13. MICROSPHERE GUIDANCE

MS. TULL: Yes. And I have an additional presentation that Dr. Kennedy will be presenting here in just a minute. So I am going to pass this around. It's two pages. And there are copies in the back for members of the public.

Okay. So the overview for today, as I mentioned, Dr. Kennedy is speaking on behalf of Sirtex. And Dr. Nag wanted to make some comments as well. I believe they have collaborated. So they should have a message for us.

And then their topics will go straight into my presentation, which is a proposed change to the guidance. I have several other changes that I would like to get to. And I will get ACMUI input on all of those.

And then I will do the same thing I did last time: take the guidance back, revise it, send it to the office of General Counsel, get no legal objection, and put it back up on the Web site. So we will have a second revision to the microspheres guidance.

Before we started, I wanted to pull up a couple definitions. We are going to be talking about dose versus activity or dose versus dosage. And as we are having our discussion, I would remind you of the actual definitions when you are talking about dose, talking about total dose, Grays rad, when we are talking about prescribed dosage, talking about activity, millicuries. So when we're in the middle of a discussion, try to keep that in mind as you are throwing terms around because we think we will have a lengthy discussion on it.

So with that, I would like to introduce Dr. Andrew Kennedy on behalf of Sirtex Medical. Although he does not work for the company, Sirtex felt that a well-published practicing clinician with extensive experience in the use of yttrium-90 microspheres would be an appropriate speaker.

Sirtex's key concern in trying to evaluate the effect of NRC's revised guidance relates to the

clinical processes involved in treating patients.

I am pleased to welcome Dr. Andrew Kennedy.

DR. KENNEDY: Thank you, Ashley. Well, thank you very much for having me. In speaking with Dr. Nag last week, he was very generous in giving me some recommendations on how best to serve the Committee.

And so I have tried to limit it to just a few slides for the question at hand, which I understand to be a proposed changes in how one of the microsphere agents that we use would be prescribed.

I do want to disclose that, although I don't have any relationship with the two vendors of these products, I have received honoraria for doing continuing medical education programs for them. And I am a director in a research and development company which does radioactive micro particle research and development.

This diagram is to set the stage for the discussion, I hope, in that looking at MRIs, CT, angiographic data, PET CT scans, we can come up with a lot of objective data on what the tumor volume is, its distribution, its shape, vascular flow, et cetera.

And for one of the two products, the glass

microspheres, which is commonly known as Thera-Sphere, it is assumed that the entire vial of activity that you are given will be distributed in the tumors. And the MIRD calculation is used to give an estimate of what the absorbed dose would be over the lifetime of that isotope.

The exact same case being approached with the resin microspheres, commonly known as SIR-Spheres, although it is calculated many different ways, the assumption that you are going to deliver that whole calculated dose does not pan out for you many times.

And so there is a fundamental difference in these two products when they are used clinically. One you almost always -- in fact, I can't remember a time in several hundred cases that I have done that I didn't deliver the whole dose of glass microspheres. And, yet, for the resin microspheres, no matter which way you calculate it, there are other factors involved which would prevent you from safely delivering what you calculated.

Just one of those reasons could be that the tumor appears to be a certain size in vascularity when, in fact, when you are delivering a large number of microspheres, the vascular capacity is less. And there is no way to know that ahead of time.

A quick comparison chart of the two products on the first column, or the glass microspheres. And the first column is number of spheres per treatment.

Now, there was a variety of different activities that you can preorder to treat a patient with glass microspheres. The assumption is every one of those spheres will be embedded in the tumor without any problem of stasis or near stasis.

However, you can see quite a difference in the resin microsphere column with 40 to 80 million spheres. And before patients receive any chemotherapy or anti-VEGF or antiangiogenic drugs, they perhaps could receive that many spheres.

But the reality is for the indication that resin microspheres have, which is metastatic colorectal cancer, those patients are heavily pretreated. And the ability to put in 40 to 80 million spheres is somewhat limited.

The reason there are so many spheres for the resins microsphere product is that they have very low activity. So the therapeutic approach is to uniformly coat or embed microspheres in a tumor with lots of low-activity microspheres, as opposed to the glass microsphere approach, which is many fewer but

much higher activity. It is about a 50 times higher activity for the glass microspheres.

So what I have termed "stasis-related issues," which I think is the overwhelming question of the day, is there are none for one product. And that product can have a written directive, which quotes gray or dose. But the other product would appear inappropriate to do so because there is really a high proportion. And this is 20 to 50 percent of all cases among skilled users, where what you thought you could deliver just can't physically be given safely.

The difference in dose calculation is a minor point but one I thought would be helpful in background. For glass microspheres, the mass of the liver is used as one of the calculation points. And the dose that you delivered is given by the lower equation.

You will notice that there are no factors in there for vascularity, for distribution in the liver, et cetera. So it's independent of factors that are going to alter your delivery.

And you can simply order the activity that you feel is most appropriate for your patient for your schedule. What you see here in green is just a simple Excel worksheet that I have used for years. And the

green areas are where I felt comfortable delivering the entire dose to that patient. And the other colors are variable degrees of comfort. Yellow, yes, we could probably do it and orange probably not.

It comes as a one-use vial with that total dose. But, just to summarize the glass spheres, based on a nuclear medicine paradigm of MIRD model calculation, even though we know microspheres are not distributed uniformly throughout the mass, all of the clinical data to this point in time has borne out that this is a safe and very effective way of doing that particular product.

The actual absorbed dose is not known and is probably irrelevant, but it is not based on physical factors in the liver other than the liver mass.

For resin calculations, resin spheres, there are a variety of approaches. Three approaches were commonly used several years ago. And which one is currently used really isn't important because research has shown us that, no matter which one you choose, physicians wind up lowering their activity calculation based on their experience.

Once they do 10-12 cases, they realize that they're bringing too much radioactive

microspheres to the interventional suite to deliver. And each different tumor type has a different factor to look at.

So I just wanted to point out that it's not a MIRD-based calculation. It is something other than that. Empiric is probably the easiest way to look at it, that whatever calculation method you use, that's your first order calculation. And then the clinician weighs in all the other factors to lower the dose further.

Activity that you have calculated to be delivered on average is 50 percent of the time you are not able to deliver that to a metastatic colorectal cancer patient. In a first-line patient of a different tumor type, perhaps.

This is the empiric calculation that most physicians would start with. And I would caution you to read this as if the percentage of the whole liver is tumor and 25 percent or less, the maximum dose you would want to consider is two gigabequerels, not that this the dose you should give but the maximum. And experience has taught us, both in looking at complications and at outcomes, that a much lower dose is actually preferred.

Here is a hypothetical patient for today's

discussion. This patient actually did receive microspheres, but this is a CT scan reconstructed in three dimensions with tumor in red, a light purple outline for the actual volume that is liver. You can see it in axial and sagittal cuts here.

So the authorized user would calculate this dose. And I'm going to skip over this one to here. Twenty-two percent of this patient perhaps has liver tumor, metastatic colorectal, and determines that 1.8 gigabequerels is the dose they want to bring to the interventional suite.

Here are three very common outcomes that I see weekly. If the patient has had one year of modern chemotherapy, maybe even had a liver-directed radiofrequency ablation procedure or partial surgery, and they have also had some of the newer biologic agents, which attack blood vessel formation, that patient is unlikely to receive more than 1.1 gigabequerels on the day of treatment.

Now, that same patient, who hasn't had biologic agents, -- and there are some that do not, surprisingly. Either they couldn't tolerate them or there are tumor-specific factors, suggesting it wouldn't be helpful. You could probably get a 1.5 out of the 2 that the empiric suggested were out of the

1.8 that you thought you could do.

And then patients which have colorectal cancer metastasis who were first-line patients without biologics or early second-line patients -- maybe they have only had three months of chemotherapy -- you likely could get that whole dose in.

I would caution that in other diseases, such as hepatocellular carcinoma, neuroendocrine tumors, metastatic breast cancer, these numbers are different. But the indication, the FDA indication, for the resin microspheres is colorectal. So I am sticking with that.

In my opinion, the main reason why it is not possible for me to prescribe a dose when I am using resin microspheres is that I have no way to determine whether that number has any validity.

I am going to change it on the fly usually in the interventional suite. There is no software imaging that I can do beforehand that gets me any closer. There is no way to verify once it is in the patient exactly what the dose is. So, without a way to predict it, I would essentially be making up a number.

There is currently a technology gap, but it is a gap that affects both agents, both products.

It is just the other product has a different way of doing it and a number that for many years now has proven to be reliable.

There is no such equivalent with resin microspheres in that activity that has always been prescribed. And there are many peer-reviewed journal articles on resin microspheres using activity as the way it was prescribed.

And those are all the comments I have. Thank you.

CHAIRMAN MALMUD: Thank you. Questions for Dr. Kennedy?

DR. NAG: Yes.

CHAIRMAN MALMUD: Professor Nag?

DR. NAG: A question -- well, it's really a comment. And I think to put this into perspective there are different ways of prescribing. In a removable -- in manual brachytherapy, we prescribe a certain dose to an organ, or to the target, and we then place the radioactive material, and then there are discreet sources that we can image, and then we can verify the dose based on the dose given by those sources.

For permanent implants, we can verify the dose, because we can image the sources, but many times

we cannot control the dose that we are going to give, and, therefore, if you remember, our recommendation was that for permanent prostate implants we would prescribe in terms of activity rather than in terms of dose, which can change depending on many factors.

In microspheres we have an additional problem that not only can you not know ahead of time, but even retrospectively you cannot image the source, and, therefore, you have no way of verifying what that dose is. So if you prescribe in terms of dose, you can prescribe 100 Gray, you have no way of knowing whether you have 100, 200, or even 50 Gray.

You have no way of controlling, once you have released the microsphere into the hepatic artery, you have no way of controlling it. It goes where the blood is flowing. And, therefore, for these reasons it -- even if you are taking the differences between the two microspheres aside, you still cannot control the dose. You can control what activity you are releasing into the hepatic artery. That is something you can control, but not anything else.

Now, in addition, of course, there are the differences, as Dr. Kennedy pointed out, between the two microspheres that in the glass microsphere if you are planning to give X GBq, you usually can give X

GBq, whereas in the resin microsphere if you are -- even if you are planning to give X, you may give X minus certain amount, depending on the blood flow, and so forth, of the tumor.

You know, I just wanted to clarify the differences in various methods of brachytherapy.

CHAIRMAN MALMUD: Yes, Dr. Fisher.

DR. FISHER: Thank you, Dr. Kennedy, for the really interesting presentation. And I know you've got a lot of experience in this area.

However, I -- if I may, and with the permission of the Chair, and not -- not to sound that I'm an expert, but I do have 14 years of experience on the MIRD Committee and the Society of Nuclear Medicine, or SNM. And I would like to correct a couple of pieces of information, because it's relevant to this discussion on dosimetry.

First of all, there is a common misinterpretation that the MIRD system implies the target tissue is always the whole organ, and that's really not correct. The target tissue could be the tumor, the lining of a hollow volume, such as a bladder wall. It could be a slice of tissue. It could be a mass of cells at the cellular or sub-cellular or nuclear level of organization. It could

also be at a nanoscale. The same physics principles apply at any of perhaps five different levels of organization.

So to say that a dosimetry approach is either a MIRD approach or not a MIRD approach is not correct.

Secondly, MIRD can account for both the uniform or the non-uniform dose distribution. We have dosimetric tools, and the MIRD Committee recommends dosimetric tools for dealing with special situations such as that.

Third, I think that -- it's my own opinion that resin sphere dosimetry is determinable. It's not something that is indeterminate. One simply needs to know -- one simply needs to define what is your target tissue and what is the distribution of the sources with respect to the tissue.

The third or the fourth determinants are specific activity, of course, of the source and density of the tissue mass affecting the dose distribution. Maybe a fifth parameter is energy, but that's well known for Yttrium-90.

And so I -- might I suggest that -- that these factors be taken into account. And what we're really lacking is a higher level of sophistication in

the determination of dose and perhaps markers that can assist in the determination of dose.

CHAIRMAN MALMUD: Thank you for your comments, Dr. Fisher.

Dr. Welsh, then Dr. Suleiman.

DR. WELSH: I understand and appreciate what Dr. Fisher has just stated, but I have to side with Dr. Nag's points here about this being an unusual situation in which we have permanent brachytherapy. But unlike classic permanent brachytherapy with Iodine-125 seeds, for example, where you can image those seems and retrospectively tell what the dose to that target truly is, you don't have that option here. We cannot image these Yttrium-90 microspheres after the procedure has been done.

Therefore, we don't know what the exact dose -- the exact distribution of those microspheres truly is, and that -- therein lies the problem.

CHAIRMAN MALMUD: Dr. Suleiman?

DR. SULEIMAN: I haven't heard anything that's wrong up until now. I think it is always people's perception, but I think -- I agree with Darrell in that when you said MIRD -- that MIRD is perceived as a standard, simple reference model, and simply absorbed energy per unit mass, but it -- but it

has gotten much more sophisticated.

The critical problem here clinically is: where is the tumor? Is it in fact the liver? And what's the amount of administered radioactivity that's going to result in a radiation-absorbed dose. So it's classical energy absorbed per mass of target tissue. And how do you differentiate between the tumor and the healthy tissue? Therein lies the problem.

Conventional standard brachytherapy -- you have a good idea where the tumor is. You physically place these sources, these seeds, whatever, and you get some sort of -- you get a level of precision and accuracy that is just not attainable right now in terms of state of practice for these seeds, which I challenge in terms of -- it's not conventional brachytherapy, because you've got millions and millions of these little things floating around.

So how do you deliver the dose? Unless you have a smart probe, like a monoclonal antibody that is going to go exactly where you want it. The challenge is: where's the tumor? How do you image it? And how do you deliver the dose?

Aside from that, it's just a case of getting the science there. But I think this is a case where medicine is going to have to dominate over

science, because there is no -- the science is just not capable right now of allowing you to predict the tumor mass and target the tumor mass with some sort of radioactivity.

DR. KENNEDY: Let me make just one comment. I'm not a MIRD expert, and I didn't mean to in the presentation suggest that MIRD was incorrect, only that for 20 years now the glass microsphere approach has been to use a very simplified MIRD model, not that there aren't very sophisticated ones. And so we have 20 years of data based on that.

I completely agree with you that more sophistication should be brought to bear on this question, but only where things sit now. But I didn't mean to malign MIRD at all.

CHAIRMAN MALMUD: Thank you.

Dr. Welsh?

DR. WELSH: Well, I would like to thank Dr. Kennedy for this excellent presentation. I believe what was trying to be conveyed in this was that one uses a MIRD concept, namely the therasphere/glass spheres, for dosimetric purposes, whereas the other uses a very different strategy to determine the activity to be administered to the patient.

And one of the questions at hand today is: can we continue to use dosage or activity versus absorbed dose? And I think that we are hearing quite clearly that with the resin microspheres at least absorbed dose is impractical, and the accuracy is highly questionable.

The science is behind, as Dr. Suleiman pointed out, but the medical data is something that is available. And we know that using the methods that have been utilized in the past provide medical results which have been published, and there's no arguing with that in terms of efficacy and safety.

And, therefore, I would recommend that for at least the resin microsphere that absorbed dose might be fine, but we should also allow the prescription to be based on dosage or activity.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Yes. Further, to Dr. Welsh -- and, first of all, Dr. Fisher, I agree with all your comments about MIRD calculations. However, there are a number of missing pieces of information, and that is, yes, you can do MIRD calculation on hemoglobin alone. However, you do not know what ratio of flow will be going to the tumor versus normal tissue. You can estimate, but you really do not know ahead of

time.

You are injecting the microsphere into the main hepatic artery, or into one of the lower arteries. You know, you do not know that ahead of time.

And technically, Dr. Welsh, you are suggesting it for a reason -- to do by the activity. but even in the case of the glass microsphere, even though you say, "I am going to prescribe a certain hepatic dose," you really do not know it because you are assuming that the entire liver is absorbing uniformly when we know very well that is totally incorrect. It definitely is not absorbing it equally in whole liver.

If it were, I would never do microsphere treatment into a liver, because you don't want it to go to the whole liver. You want it to go substantially to the tumor. Therefore, even for the glass microsphere, it is wrong to prescribe it by saying I'm giving a certain dose to the liver.

CHAIRMAN MALMUD: Thank you.

Dr. Welsh?

DR. WELSH: I just want to follow up with Dr. Nag's point, and I don't disagree with anything that he said. I think the bottom line here is that we

have systems that are in place as far as prescription. We have been using dose with glass microspheres, and even though we could argue that maybe it's not accurate, maybe we are truly not delivering this dose to the whole liver, which is what we're saying is happening, nevertheless, we have a system in place.

Similarly, we have a system in place for resin microspheres, which does not include absorbed dose, but refers to administered activity. And it seems to work. And, therefore, I would propose that both systems continue to be allowed, which I think is the point of today's discussion, because the new guidance favors one approach over the other.

DR. NAG: I would like to make a motion.

CHAIRMAN MALMUD: Dr. Zelac had his hand up as next.

DR. ZELAC: Just a quick question I would ask to the assembled group, Dr. Kennedy as well as the Committee. Clearly, you're not treating a standardized patient. You have a particular individual that's going to receive the treatment. The history of that person in terms of the treatments prior to their disease are known.

On that basis, my question is: is it possible to predict the amount of activity which in

fact is expected to enter the patient -- activity -- based on the treatment within 20 percent?

DR. KENNEDY: I can comment on an active research protocol that our center has been undertaking to answer just that point. In the last 185 cases, in the last two-plus years, we became more accurate than 50 percent, very often within 20 percent, but I would say it's probably around 20 percent now. And I'm a fairly experienced user, and I'm continually scratching my head in the interventional suite saying, "I thought we had it this time."

There are disease types that are easier than others, but for metastatic colorectal cancer it is the most difficult, given the past history. The Avastin or Bevacizumab drug that changes blood vessels is highly variable in its effect, and that's the main problem for that disease. But other diseases where -- for instance, neuroendocrine cancers, we pretty much are in the five percent error range.

DR. ZELAC: So if I can just follow up on that very quickly. So if you needed to fill out a written directive -- the prescription -- for a particular patient, it would be possible you're telling me, if I understand correctly, to indicate the amount of radioactivity that you expected to infuse,

and that the actual amount that you would be delivering should be within 20 percent of that.

DR. KENNEDY: On a research protocol we're getting that close.

DR. ZELAC: Yes.

DR. KENNEDY: I would say in clinical practice that would be very difficult to do.

DR. ZELAC: What would be a more reasonable number, do you think, for clinical practice?

DR. KENNEDY: Without any hard data to back it up --

DR. ZELAC: Yes.

DR. KENNEDY: -- like 50 percent.

DR. ZELAC: Thank you.

DR. NAG: I would like to --

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Yes, I would like to make a motion that while microsphere prescription of -- while microsphere is in the directive, the written directive can be made in terms of absorbed dose to be deliberate to the target organ, or -- or the activity to be delivered, period.

Stasis would be -- stasis, which is what we have there -- stasis is an acceptable endpoint to

the prescription. I forget the exact wording, but you can pull that exact wording from --

DR. THOMADSEN: Or to stasis.

DR. NAG: What?

DR. THOMADSEN: Or to stasis.

DR. NAG: Yes, or to stasis.

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

DR. THOMADSEN: Second.

CHAIRMAN MALMUD: Dr. Thomadsen seconds the motion. The motion is open for discussion. Dr. Suleiman?

DR. SULEIMAN: Again, as I've said many times, I think this radio -- I think all radiotherapeutics, the precision is far, far, far worse than conventional external beam or brachytherapy.

And clearly, I think right now technology hasn't reached the level of the practice of medicine, so I think we need to give the community the opportunity, be flexible, but I also think you've got to be sufficiently prescriptive when you write these directives, and not just get very sloppy about it, because, again, I came away from the Society of Nuclear Medicine meeting this past year -- I was

surprised, because one of the presenters got up and said, "We give 150 millicuries of I-131 for our thyroids regardless of patient size." And I thought that Iodine thyroid therapy was sort of the only bastian of credibility in terms of radiotherapeutics.

(Laughter.)

And so that blew that argument out of the water, so I've come away very, very much concerned that there is such a level of imprecision in terms of the science, in terms of the radiotherapeutics, that whatever is going to push us in that direction I'm all for.

I don't buy the resin/glass argument, because in either case I don't -- whether you're delivering activity that you've calculated the -- to deliver a certain dose for a certain mass, the distributions are not uniform in either case. And so I just say I see there's a lot that needs to be done, and I think the last thing we want to do is restrict that and basically allow flexibility.

And I think the article that Dr. Nag has in the handouts, you know, is a major step in that direction in terms of getting the community to be more synchronized.

CHAIRMAN MALMUD: Dr. Welsh?

DR. WELSH: I'd just like to comment that I -- I support Dr. Nag's motion, but isn't this the topic of Ashley's presentation that's --

MS. TULL: Yes. I just went ahead and put it up there.

DR. WELSH: So perhaps we can --

MS. TULL: Put on the first slide.

DR. WELSH: -- hold off on voting until --

MS. TULL: This is the discussion we would have had.

DR. WELSH: Without your presentation?

MS. TULL: This is my presentation. Should NRC staff revise the microspheres guidance to state that activity administered may be used in the written directive?

DR. WELSH: Well, I've read what's in here, and I am ready to vote. I just wanted to make sure that everybody else was.

MS. TULL: Yes, I wanted to make sure the discussion continued.

DR. NAG: That's why I made the motion, so that we could have that discussion. You have the international multi-specialty recommendations in your handout, and, you know, look through that. We spent about two years, you know, getting that out. And we

had the discussion from Dr. Kennedy who very ably pointed out, you know, how the microspheres are given, so we can have any further discussion on that.

CHAIRMAN MALMUD: And we are having a discussion, and the motion was moved and seconded. I think Dr. Howe has a comment now.

DR. HOWE: I have more of a question. I think it's clear when we have stasis that you're not going to deliver the entire activity or the entire dose that you were planning. The question comes down to: when you do deliver the entire amount, how do you decide how much that total amount that you really want to get in is? Is it -- is your decision based on a dose to normal tissue, etcetera, or is it 40 millicuries is it? 60 millicuries is it? 100 millicuries is it?

So what is your decision based on for that 100 percent going in? Is it a dose consideration, or is it an activity? And how do you -- how do you translate that activity in something meaningful?

DR. NAG: Since Dr. Kennedy is there, I would like him to answer. I can --

DR. KENNEDY: Sorry. I prematurely walked away. It's actually -- you're on the right track. If you think of the tumor as a prostate, you're wanting

to get uniform distribution of high activity in that target. We don't know what the right dose is -- or the reactivity, sorry. Throwing the wrong word out.

We don't know what the reactivity is, but there is a clinical sense when you're implanting it that if you started out with a certain amount of assumptions that a mass that size with this kind of vascularity should accept 36 millicuries. What you're really trying to say is that I can completely implant that structure. You know, it's going to take about 36 millicuries to do it with this microsphere.

To only have 25 in, or 20 in, I perhaps get in the -- the correct implant, but perhaps not, because I thought I needed 36 or 38. So we're not really looking for a dose or an activity that should be implanted, but it's more of a uniform coverage of that tumor.

DR. HOWE: So you're -- to some extent you're looking at the total number of microspheres you can get in with that particular product, understanding what its low activity per sphere is.

DR. KENNEDY: Precisely.

DR. HOWE: And that's where you're making your decision on how many microspheres I can get in, and I can get so many microspheres in this

millicuries.

DR. KENNEDY: Correct. And they're estimates, broad estimates.

DR. HOWE: Very broad.

DR. NAG: In addition -- you are correct, but in addition you have to keep in mind that you want to limit the amount that you can give to the lung, because there are more -- let's say that certain amount I need to give to the tumor would give more than the lung can tolerate. Then, I'll have to back it down. That's one.

And, number two, let me -- even if I want to give X millicuries to the tumor, I cannot, because the vascularity is shutting down. Then, you know, I have to back it to even lower. So we have one target amount we want to give, which is then lowered by normal tissue toxicity and the restriction of the vascularity, and, thirdly, any backflow to other organs.

DR. HOWE: And if I can follow up on that, your decision on what you're giving the lung is based on dose, because at a certain dose you're going to have certain effects on the lung that are not good. Your decision on what you're going to try to get into the liver is based on number of particles, because

you're not -- you're not sure you're going to get it all in, but if you do get it all in, then you want to make sure it's not going to wipe the person out, because you got too much activity in.

DR. KENNEDY: I think one of the things, if I may --

DR. HOWE: So you have both concepts. You have both dose and you have an activity concept.

DR. KENNEDY: That's correct. And the -- there are some published papers on taking tumors out of livers that have been treated, and looking at three-dimensional dose calculations. And we know that, back to the particle number, that when the particles are correct, when you have coverage of the tumor, there is a minimum amount to the normal tissue that's adjacent to the tumor, but in excess of 3,000 Gray absorbed dose to some portion centrally.

So we have 100 Gray to 3,000 Gray gradient in some tumors. But the stasis -- and it may be implicit, and it may be not -- but when we say "stasis" what we're -- what we're meaning, what I mean when I say that, is if the tumor is no longer accepting free-flowing microspheres, it's now going to embed -- any more that I give it will embed in normal liver, and that's plenty of radiation to cause death

in that portion of the liver. So stasis is a late sign that you've overshot the runway.

If you ever get to stasis, you have already filled the tumors, and you're now shunting -- already shunting into the normal liver. So approaching stasis is what we sort of mean, but we've shortened it for a safety reason.

DR. HOWE: Yes. And I think I want to make it clear that when we did the guidance we recognized stasis was a legitimate endpoint, and we wrote the guidance to -- to ensure we didn't have a lot of medical events, because physicians were getting to stasis. So we built that into the guidance, so we didn't have medical events. You got to the endpoint you wanted to get to. That's fine.

DR. KENNEDY: Correct.

DR. HOWE: Okay.

CHAIRMAN MALMUD: Dr. Thomadsen?

DR. THOMADSEN: I think there's a simpler answer to your question. That is, the prescriptions that are being written are based empirically on what has worked. That's really all that is. It's not based on dose. It's not really based on anything other than these have worked, and they're trying to duplicate what has worked in your patient.

There are a very small number of variables that are involved. They fit in as the prescriptions have been discussed in the presentation, and that's it. It's fiction to think that we're dealing with dose at all. All we're -- and it's really not even that we're speaking so much in activity as what has worked. That's all.

CHAIRMAN MALMUD: Dr. Welsh?

DR. WELSH: This is Jim Welsh. I'd like to just provide an answer to Dr. Zelac's question about whether or not he would be within 20 percent. I think the short answer is clearly no. The proof might be in Dr. Kennedy's second-to-last slide where he talks about stasis-related issues. And if the physician thinks that 1.8 GBq is the right amount to infuse, presented three different scenarios ranging from 1.8, 1.5, and 1.1, and I think 1.1 might be more common actual activity to be administered once stasis is reached.

And this information is coming from perhaps the most experienced individual in the country, and it's not within 20 percent.

DR. ZELAC: Well, that's why I asked the question the way I did, because what I said was -- and, Dr. Kennedy, correct me if I'm wrong -- the 1.8

was to represent the percentage of the liver, to be a response to the percentage of the liver that was tumor, correct? And the lower amounts that were actually delivered were based on the prior treatments that the patient -- particular patient had received.

DR. KENNEDY: That's correct.

DR. ZELAC: More damage to the vascular system meant less of what was -- what you like to have could actually be delivered.

DR. KENNEDY: That's correct. And those factors were not quantifiable ahead of time.

DR. KENNEDY: Right.

DR. WELSH: But I would say that my point is that these might be average figures from an experienced clinician, and it would vary significantly from any one individual to another. And I think 20 percent is unlikely to be a treatable --

DR. ZELAC: I accept -- that's why I asked the question.

CHAIRMAN MALMUD: Dr. Suleiman?

DR. SULEIMAN: Would it be premature if we basically leaned more towards administered radioactivity, and even dispensed with the concept of absorbed dose, since we really have no idea what the tumor mass is and where the radioactivity is going?

And that would at least tell people up front that, why go through this facade of calculating a radiation-absorbed dose when it could be off 20 percent? I told you, somebody told me -- they said, "No, I've got an exhibit that shows 500 percent." So it depends on the tumor mass and the administered activity.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Well, I -- you know, at least the administered activity is something you can calculate, you can -- you should. But even the administered activity has to have a place in stasis, because you can shoot for a certain amount, but if there's stasis you do not want to continue giving it. It should be -- that is why I paraphrased my written directive the way I did.

CHAIRMAN MALMUD: Dr. Welsh?

DR. WELSH: I'd like to answer Dr. Suleiman's point, and bring the -- draw the analogy to the other Yttrium-90 therapy that is commonly used -- namely, Zevalin -- where we have gone to prescribed activities rather than absorbed dose.

And part of that is because of the inherent difficulties with radioimmunotherapy and calculating doses with such treatment, but also because of the isotope, because it's a pure beta

emitter that you cannot verify exactly where it went and what the dose is. And, therefore, activity is commonly used clinically, and I think that's part of the reason why I'm favoring activity or dosage rather than absorbed dose in this context as well.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: Yes. I just want to make one thing clear. Stasis is off the table. We understand stasis -- that's staying, so that's out of the debate. It also sounds like this is a 35.1,000 use. It is an emerging technology. The manufacturer came in and got approval based on a very small number of patients in a very restricted patient pool. And so we really haven't had time to figure out how to use it, and I think that's the bottom line.

CHAIRMAN MALMUD: This is Malmud again. I'm still puzzled by all of this.

(Laughter.)

It seems to me that, putting aside the regulatory issue, getting -- just getting to the medical issue for a moment, the goal is to deliver a certain dose to the tumor, but not to exceed the dose elsewhere that would result in harm to the patient, meaning normal liver or other organs. Okay. That much I've got.

Why can't the patient first have an injection via the same route of Technetium-99 MAA in a flow study with imaging to determine where the stuff is going, and then do the rough calculation from that, then determine from that, as best as possible, that this is the ideal dose, which you already know, and this is the maximum risk that we calculate from where the MAA has gone? And then, the dose is calculated accordingly.

Then, at that point, define the dose as the administered activity, in which case everyone is satisfied. I'm not saying it's optimal, but everyone should be satisfied, because you've given the activity based upon the calculation from the estimation from the Technetium MAA flow and imaging.

Dr. Thomadsen?

DR. THOMADSEN: We've done quite a bit of work looking into such models. We found that MAA is a very bad algorithm for the microspheres. It is used to estimate the dose to the lung right now. It is a very bad estimate of the dose to the lung, and overestimates the dose significantly. It does not go in the blood vasculature, in the tumor, where the microspheres will go. It tends to break down.

CHAIRMAN MALMUD: Okay. What else might

go in the same direction?

DR. THOMADSEN: We have, actually, a publication coming out showing that PET-labeled microspheres would do a very good job of allowing us to localize ahead of time, and after time, too, what the dose distribution would be. But this is a technology that's not out there yet.

CHAIRMAN MALMUD: So that the answer may be coming to us in the future, and in the meantime putting together the data that you just gave us, which is preliminary, we might just go along with the suggestion that I believe you and Dr. Zelac or Dr. Howe made with regard to the administered dose and the acceptability of that for NRC requirements.

Dr. Welsh I think was -- no, no, Dr. Schwarz was --

DR. THOMADSEN: We didn't hear what you just said.

CHAIRMAN MALMUD: Didn't either -- one of you talked about the -- was questioning the 20 percent rule. We realized that that did not apply here. But then, there was a discussion of the administered dose as being the measure that the NRC would accept. If you said you were going to give --

DR. THOMADSEN: Do you mean dose or

dosage?

CHAIRMAN MALMUD: Activity.

DR. NAG: Well, that is what I have in my motion.

CHAIRMAN MALMUD: The administered activity.

DR. NAG: We have that in my motion.

CHAIRMAN MALMUD: That would -- since once you determine the administered activity as imprecisely as we are able to calculate it, then with -- from the NRC viewpoint they're not interfering in the practice of medicine. If you say that's the activity you want to give, and that activity is given within 20 percent of your recommended -- your recommendation, the NRC should be satisfied.

DR. NAG: Yes.

CHAIRMAN MALMUD: Is that a fair statement? I would ask that of an NRC staff person.

DR. ZELAC: It is for me.

(Laughter.)

CHAIRMAN MALMUD: It is for Dr. Zelac.

DR. HOWE: It is. And also understanding that we allow stasis. So if you only give 10 percent, that's fine, as long as your written directive said stasis.

CHAIRMAN MALMUD: So, Dr. Nag, your motion with regard to the activity sounds like the optimal solution for the moment. Is that the motion that's currently on the table?

DR. NAG: Yes, that is the motion on the table.

CHAIRMAN MALMUD: Can we call the motion now, or is there any -- Dr. Schwarz, did you want to make a recommendation?

MS. SCHWARZ: Well, I'm -- I have a couple of questions. One, I'm wondering -- Dr. Nag had mentioned about administering a dye to look at the blood flow to the tumor, and that is done. And even after that is done, and the radioactivity is administered, it sometimes doesn't go where you're predicting --

DR. NAG: It goes where you're predicting, but once -- the way it works, once the microspheres are going in, you are altering the blood flow and you are altering the vasculature. So now, although at the beginning they were flowing, by now your vasculature flow stops partially or completely, and you can no longer, you know, give further -- yes.

CHAIRMAN MALMUD: We have a member of the public who wishes to make a statement before the vote

is taken. Can you please introduce yourself?

DR. SALEM: Thank you, Mr. Chairman. Riad Salem, Interventional Radiology at Northwestern. I'm just trying to clarify what the motion is exactly. If the motion is to eliminate the entire concept of dose, because of its limitation, and just accept activity, the one thing I wanted to point --

DR. NAG: No. No. I'm telling you that is not the motion.

DR. SALEM: -- out -- that is not. It is just to accept both dosage and dose.

DR. NAG: That's what I had -- that's was my motion, that for microsphere written directives you prescribe in terms of either the dose to your target organ or prescribe activity and the stasis can also be the endpoint, or still stasis. So you are going to allow both, and you are going to allow stasis.

CHAIRMAN MALMUD: Did that answer your question?

DR. SALEM: It did. I was concerned that dose was going to be eliminated.

PARTICIPANT: Sir?

CHAIRMAN MALMUD: I beg your pardon?

PARTICIPANT: Name?

CHAIRMAN MALMUD: I'm sorry. Someone said

something. I didn't know who.

PARTICIPANT: No. The speaker needs to identify himself for the recorder.

PARTICIPANT: Oh.

PARTICIPANT: That's Dr. Riad Salem.

PARTICIPANT: He wasn't on a microphone. He wasn't using the microphone.

CHAIRMAN MALMUD: Oh. Would you please come up to the microphone again, and will you reidentify yourself and spell your names for the court record.

DR. SALEM: Riad Salem, R-I-A-D, S-A-L-E-M.

CHAIRMAN MALMUD: Thank you very much.

MS. FLANNERY: And can you repeat your last comment that was made to Dr. Malmud, so we can --

DR. SALEM: I said I was just concerned that dose, as in Gray, was going to be eliminated from the written directive. And I wanted to make sure that wasn't going to happen.

Thank you.

CHAIRMAN MALMUD: Thank you.

All in favor of the motion? Any opposed? Any abstentions? Two abstentions. Otherwise, all positive.

Thank you, Dr. Nag. Thank you, Ashley Tull.

(Laughter.)

MS. TULL: We have five more.

(Laughter.)

Okay. So the next issue has to do with medical event reporting. When we looked at the guidance, we realized we didn't have any reference to reporting. So for this -- obviously, this is pending, the dose versus activity issue that we just discussed. Currently, 35.3045 is going to reference dose. That's what medical event reporting is based on. So we would use similar wording to 35.3045 to say either dose or activity. Is that acceptable to ACMUI?

DR. NAG: Yes. It's acceptable to me. That's the same way we worded the I-125 permanent implants.

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

DR. VETTER: Second.

CHAIRMAN MALMUD: Dr. Vetter seconds the motion. Any discussion?

(No response.)

All in favor? Any opposed? Any abstentions? One abstention. Thank you.

Next?

MS. WASTLER: That's got to be historical.

(Laughter.)

CHAIRMAN MALMUD: No. We had a more rapid sequence --

MS. WASTLER: You did.

CHAIRMAN MALMUD: -- last time with Dr. Howe's recommendation.

MS. WASTLER: That's right. I apologize. I had forgotten.

CHAIRMAN MALMUD: Then, the rifle was an automatic.

MS. WASTLER: This wasn't your best.

(Laughter.)

CHAIRMAN MALMUD: Yes.

MS. TULL: Okay. The next one, quantifying dose. This is the paragraph that was in the original guidance that was in advertently in the thousands of revisions that I did -- deleted. And so we propose that we add it back.

And it states, "Procedures for administrations requiring a written directive should for Yttrium-90 microsphere administrations describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon

completion of the administration to confirm that the administration is in accordance with the written directive." Obviously, we would add something about activity into this as well to make both acceptable.

DR. NAG: How are you going to quantify the total dose to the treatment site? Again, unless you have a way of determining how many microspheres went to those sites, you are again -- basically, you are still saying, "I gave so many GBq to the hepatic artery." Again, I don't see how you can put it back.

CHAIRMAN MALMUD: Dr. Suleiman?

DR. SULEIMAN: Dr. Nag is completely right. I mean, you can quantify, you can say 10 percent, 20 percent, 50 percent, in terms of administered activity, which we're defining as dosage. But the distribution of the administered activity internally and where it lands in -- and whether it's overkilling, I mean, that's where the radiation-absorbed dose can vary several hundred percent.

So that's going to trigger a medical event every single time. So the uncertainty is the issue here -- what is the uncertainty associated with the state of the practice? And then, you could say, if it's more than that, then it's serious. But I think for this specific situation I think administered

activity would be the trigger, and I'd back off on the -- because you -- I'll bet you if you brought in 10 different people and they independently calculated the radiation-absorbed dose, I'd bet you not a single one of them would agree.

CHAIRMAN MALMUD: This is Malmud. Would you prefer that, if it just said, "Procedures for administrations requiring a written directive should, for Y-90 microsphere administration, describe that the administration is in accordance with the written directive," period, leaving out the --

DR. NAG: Yes.

CHAIRMAN MALMUD: Is that acceptable?

DR. NAG: Yes.

CHAIRMAN MALMUD: Would someone care to make that motion?

DR. THOMADSEN: So moved.

CHAIRMAN MALMUD: Dr. Thomadsen. Who seconds it?

PARTICIPANT: Second.

CHAIRMAN MALMUD: Seconded. All in favor -- any discussion? Dr. Howe?

DR. HOWE: You still have the issue of wrong treatment site, and so just that you have pushed through so many millicuries into the catheter doesn't

mean it's not a medical event if you didn't end up in the -- if you ended up in the wrong treatment site. So --

DR. NAG: How would you --

DR. HOWE: -- we'd like to make sure we capture the wrong treatment site.

DR. NAG: How would you know that?

DR. HOWE: Well, I mean, you have -- you have things in your written directive about the acceptable dose to other sites, like the lung, etcetera. If you put all of the activity in and it goes to the lung, you're going to say it's not a medical event.

DR. NAG: I would like to have Dr. Kennedy and Dr. Riad both, you know, back to answer some of these questions. But for example, if there's stasis, or if there's no stasis, if there's a backflow and part of the backflow goes to the lungs, part of it will go to the lungs, part of it can go to the gastrointestinal, and so forth, that is not the wrong site. It's a backflow.

Now, it is a wrong site if the catheter was not placed in the right place and was placed in a different artery altogether. That would be a wrong site. But there is really no way of calculating in

detail where the -- where the microsphere went once it was deposited at the right site.

CHAIRMAN MALMUD: Dr. Salem?

DR. SALEM: Yes, please. Obviously, recognizing the inefficiencies and sort of the learning curve that exists with the Tech MAA, that portion was really designed years ago to look at liver dosimetry, either specific to the tumor or the lobe treated, and also the shunting that occurs to the lung for the proper lung dosimetry.

I specifically received phone calls about this point from my RSO, because people are interpreting this as meaning if you see -- you are supposed to pre-treatment calculate dose to the gastrointestinal tract or anywhere else before you treat. And, really, that should never happen. If there is uptake in the GI tract, it needs to be corrected, embolized, etcetera. So you should never have pre-treatment dosimetry that includes the gut. It should be the liver and the lung, and that's where the dosimetry stops.

People I think have gotten a little bit confused by this, and are now trying to determine GI uptake from free Tech, etcetera, from the MAA, and then calculate a dose to the GI tract which should be

zero in every case. So I just wanted to clarify that.

DR. NAG: Right. And, for example, this morning you had the gall bladder of 20 percent. Again, you don't know exactly what the gall bladder got. You have some idea that there was some backflow, and you really cannot calculate that.

CHAIRMAN MALMUD: Dr. Schwarz?

MR. SCHWARZ: Actually, I'd like to follow up on the misadministration that was reported today by Ralph Lieto. How did they determine that there was 20 percent in the gall bladder, as to make it a misadministration?

MS. WASTLER: I believe at the time we said we didn't have the detailed information. We should be getting it.

MS. FLANNERY: We said it came from Florida, and so we were expecting --

(Laughter.)

-- our state representative from Florida to find out more information.

MS. WASTLER: We just didn't have the detailed information in the -- all we had was a summary. I don't now.

DR. NAG: Dr. Kennedy, can you -- you are the expert, one of the experts --

DR. SALEM: If I could just make one comment on the gall bladder. You know, anatomically, it's nearly physically impossible to avoid the gall bladder when you infuse the hepatic artery. The blood flow to the gall bladder is indeed from the hepatic artery. So in every case, when there's a patient who has their gall bladder, the gall bladder will get some radiation.

That's not non-target radiation. That's part of the treatment, and the radiation cholecystitis rate is less than one percent. So radiation can't -- sorry, the gall bladder can't tolerate radiation, so the gall bladder shouldn't really count, to make it practical, as non-target radiation.

CHAIRMAN MALMUD: Mr. Lieto, you had your hand up.

MR. LIETO: Well, I'd like to try to go -- get back to the issue at hand here. And I would like to ask Dr. Kennedy and Dr. Salem this question. A patient presented, and I get this therapy. Okay? Afterwards, we're done, whatever, how do I know that what you intended got done? And I think that's the point that they're trying to drive at. When is there this -- what -- and what should that action level be, and how do you determine it, that an event -- a

medical event -- has occurred? And I'd like your comments.

DR. KENNEDY: This is Kennedy. The standard of care is to do a nuclear medicine scan after the treatment, which we call a bremsstralung scan, which is a very coarse quality image. So that's what we use to assure that we've deposited the radiation in the liver.

We don't use it to do a dose calculation of any organs. We don't think it's accurate enough for that. If we were to see a lot of activity not in the liver, then we would know there is a problem. We can't take the spheres back, but we could do some medical interventions to prevent further damage.

So the only quality control check, so to speak, that I'm comfortable recommending is what we all do anyway, which is do the gamma scan or bremsstralung scan after the procedure.

CHAIRMAN MALMUD: Thank you.

DR. NAG: May I add something to that? But that bremsstralung scan, although it's done, cannot be used to determine if that were the misadministration or not. It can be done to do a qualitative assessment on where the majority of the particle went, but not a quantitative determination

that 20 percent went here or 30 percent went somewhere else. Am I right, Dr. Kennedy?

DR. KENNEDY: Absolutely correct. And I think Dr. Thomadsen could say it much more eloquently, but there is no way that I know of that a bremsstralung scan could be used for any accurate dose calculation.

CHAIRMAN MALMUD: Let the record indicate that Dr. Thomadsen was nodding his head affirmatively.

(Laughter.)

In agreement.

Dr. Suleiman?

DR. SULEIMAN: What if it was administered? What if it didn't go where it was supposed to because the chemical complex somehow disassociated, all right, and you take a bremsstralung scan and you see that it's everywhere it wasn't supposed to be. Why wouldn't that be a misadministration?

CHAIRMAN MALMUD: That is a question for whom?

DR. SULEIMAN: I guess Dr. Nag. You were saying it shouldn't be used to define a misadministration, but I'm giving you a case where the -- and the -- I'll cheat, I'll tell you why.

Something happened chemically, and so the drug changed and it wasn't what you thought it was. The complexes you administered and it winds up someplace it doesn't belong.

CHAIRMAN MALMUD: Dr. Thomadsen, do you want to answer that?

DR. THOMADSEN: We've done a lot of work with that question and found for the glass microspheres that cannot happen, because the glass -- the radioactive material is in part of the glass infused in the glass. For the resin microspheres, conceivably that could happen, that does not happen. And we've put them through quite a bit of use to try to dissociate them.

Were that to happen, that would be a misadministration. The probability of it happening is very small. That could very well be one of the ways you could have a reportable event.

DR. SULEIMAN: Well, let me stand corrected, because actually this is a physical -- it's a device, so it shouldn't happen. I mean, because there's no drug here.

DR. THOMADSEN: Hmm?

DR. SULEIMAN: There's no change in chemical complex where it would behave differently.

DR. THOMADSEN: No, but it would be just like planting an iodine seed in the prostate that leaks. It could conceivably have a leak. And you always have some Yttrium-90 coming off. That's part of the device. But you don't have -- you don't have much. It's very hard to get it off.

DR. SULEIMAN: But the intent there, it should be reported anyway and figure out, why did this behave the way it did?

DR. THOMADSEN: Yes.

DR. NAG: Yes.

DR. THOMADSEN: But that would be perfectly compatible with what we're talking about. I mean, that's one of the things you would report.

CHAIRMAN MALMUD: Thank you. Dr --

DR. THOMADSEN: The other thing is, if you would take to the operating room three times the activity that you wanted to inject and inject it.

DR. SULEIMAN: And Ralph's committee would pick up on that the next year, and we would discuss it.

DR. THOMADSEN: That's right. It would give us something to talk about.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: I have basically a question

that I'd like to ask. When the bremsstralung scan is completed, would it be possible to determine what fraction of the total activity that had been administered wound up where it was not intended to go?

DR. KENNEDY: No.

DR. SULEIMAN: No.

DR. KENNEDY: It doesn't provide that data.

PARTICIPANT: Dr. Suleiman, you look puzzled by the question.

DR. SULEIMAN: No, I think the question is valid.

PARTICIPANT: Okay. Thank you.

CHAIRMAN MALMUD: Who answered the question for Dr. Zelac?

DR. KENNEDY: Kennedy.

CHAIRMAN MALMUD: Dr. Kennedy? I'm sorry. What did you say, Dr. Kennedy?

DR. KENNEDY: I said no, it would not be possible to estimate the fraction.

CHAIRMAN MALMUD: Thank you, Dr. Kennedy.

DR. SULEIMAN: Why not?

CHAIRMAN MALMUD: Dr. Suleiman asks, "Why not?"

DR. SULEIMAN: Why not?

DR. KENNEDY: The delivered activity in the liver, I guess my understanding of it, because I tried to do this in the past, was that there was not enough reproducible data to suggest that the pixel intensity in some part of the bremsstralung scan could be attributed to an actual dose. So the Gray scale that you get from the bremsstralung scan cannot be converted into an actual known dose.

DR. SULEIMAN: Maybe not a very precise --

DR. ZELAC: Dosage.

DR. KENNEDY: I'm sorry, dosage.

DR. ZELAC: Thank you.

DR. KENNEDY: Yes, I apologize.

DR. ZELAC: Or dose.

CHAIRMAN MALMUD: Thank you, Dr. Kennedy, Dr. Zelac.

We still -- oh, excuse me. Mr. Lieto?

MR. LIETO: Well, I think you're looking at the same question that I was going to ask, and that is, as -- as the hypothetical patient, I still have no sense of confidence any longer that --

DR. SULEIMAN: But your refractory --

(Laughter.)

MR. LIETO: I don't think we're still -- we're going to be able to answer this question about

the quantification, because what our experts are telling us is that that is not a possibility -- to quantify this endpoint to establish if a medical event has occurred or not.

DR. NAG: But no, I think it -- the same reason why it -- what I-125 permanent implant -- you know, I-125 permanent implant where we have much more control, where we are able to quantify post-implant, we again said that the dose that is finally administered and the so-called intended dose cannot be equated, and, therefore, we went by the dosage, which we can control.

And it's the same thing here, except that in Yttrium microsphere it's even less controllable than Iodine. So that is the limitation of the technique and limitation of the product that we have to, you know, accept. Otherwise, this treatment will not occur.

CHAIRMAN MALMUD: Malmud. Do I understand your question, Ralph, to be as follows -- that if I were a patient, and I were given this therapy, and for reasons that had nothing to do with the doctor's competence, the material was all shunted to my lungs, and I died of lung disease, is that considered a misadministration? Is that your question?

MR. LIETO: Yes. In other words, is there some endpoint that -- threshold that we're saying --

CHAIRMAN MALMUD: There it seems to me that one of the bits of informed consent in treating this patient is to inform the patient and/or the family that this is a statistically small but possible risk.

DR. NAG: That is included in our consent, that --

CHAIRMAN MALMUD: Oh, I haven't finished my statement yet. That this is a small but possible risk in the same way that having any surgical procedure can be associated with a one in X-thousand anesthesia death, that this is one of the risks of the procedure, in which case that event, which is described as a possibility in the informed consent, has been -- that risk has been taken by the patient. It is a -- it's a significant risk, we admit that, but it's part of the medical procedure, not -- not a risk which is unanticipated with this particular therapy. Am I correct in what I'm saying?

MR. LIETO: I don't disagree with anything that you've said, Mr. Chairman. I am just trying -- and maybe I am a bad example -- just trying to get to the issue here of addressing how or -- this paragraph

should be modified in determining the completion -- the proper completion -- I shouldn't say proper, but the --

CHAIRMAN MALMUD: Well --

MR. LIETO: -- the completion of the procedure was done as intended.

CHAIRMAN MALMUD: My suggestion had been -- I'll repeat it, so that you can tackle it again -- procedures for administrations requiring a written directive should, for Yttrium-90 microsphere administrations, describe how to quantify the total dose in accordance with the written directive.

DR. NAG: No. Dosage.

CHAIRMAN MALMUD: Dosage, I'm sorry, in accordance with the written directive. Period. Dr. Nag, is that an acceptable --

DR. NAG: No. It is acceptable. However, since you are not quantifying the dose, because you cannot quantify the dose, I think what Ashley has done and removed that paragraph -- you know, my solve it by just removing that paragraph, but you cannot --

MS. TULL: That was not intentional, though.

(Laughter.)

DR. NAG: But having that paragraph

removed has -- having that paragraph removed worked fine.

CHAIRMAN MALMUD: Sally Schwarz?

MS. SCHWARZ: Can't we confirm that the amount of activity dosage requested was delivered, and not quantify where it went?

CHAIRMAN MALMUD: Yes, that's what I had tried to do this time. So -- and I think I said how to quantify the total activity administered in accordance with the written directive. And then --

MS. TULL: I have a question.

CHAIRMAN MALMUD: -- someone challenged the -- my using the term "activity administered." Yes.

MS. TULL: My notes from the first time you said it -- and this may be wrong -- but I had, "Procedures for administrations requiring a written directive should, for Yttrium-90 microsphere administrations, be performed in accordance with the written directive."

DR. NAG: That's fine. That's excellent.

MS. TULL: We don't say dose, we don't say dosage. Is that okay with NRC staff?

CHAIRMAN MALMUD: That sounds best. Did I say that?

DR. NAG: Yes.

(Laughter.)

MS. TULL: Those were my notes. I'm guessing.

CHAIRMAN MALMUD: Quit while I'm ahead.

DR. NAG: Your first try was your best try.

CHAIRMAN MALMUD: But it was challenged. Then, it's a motion. Who makes that motion? The Chairman does.

MR. LIETO: I would make that motion.

CHAIRMAN MALMUD: Mr. Lieto makes the motion. Who seconds it?

MS. SCHWARZ: Second.

CHAIRMAN MALMUD: Sally Schwarz seconds it. Any further discussion of the motion? Dr. Eggli?

DR. EGGLI: I would just like to make -- I've been uncharacteristically silent. I'd like to make one clarification --

(Laughter.)

-- and ask you why the bremsstralung can't be used. And the answer is that it's not monochromatic radiation, and, therefore, it's variably attenuated in the tissue. And, therefore, you can't quantitate it. It can tell you qualitatively where,

but not quantitatively how much. I thought we needed a little bit more of a scientific spin on why.

DR. NAG: But you are supporting it, basically.

DR. EGGLI: Yes. I'm just explaining why it can't be used.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

PARTICIPANT: I don't buy that completely, but that's okay.

CHAIRMAN MALMUD: All in favor of the motion? Any opposed to the motion?

(Laughter.)

Any abstentions? One abstention.

DR. NAG: Dr. Vetter, would you clarify where you were?

CHAIRMAN MALMUD: Dr. Vetter. So it's all for, none against, one abstention. The motion carries.

Next, Ashley.

This is much more wordy.

MS. TULL: Okay. This is from the last meeting. Last time I put a slide up that said 35.14, which is notification for experienced AUs, that 35.14 did not apply. That's true, because this is a 35.1000 use. So the recommendation that was made last time is

a true statement, we're fine with that. But we want it to apply.

So I'm bringing it back to you to say, "We should add words similar to 35.14 to recognize an AU who does satisfy the T&E listed above," so listed above in the guidance, is currently -- "and is currently listed on a Commission or agreement state license, a permit issued by a Commission master materials license, a permit issued by a Commission or agreement state license of a broad scope, or a permit issued by a Commission master materials license broad scope permittee, may be allowed to work under a different license for the specific microsphere use listed on the license or permit, provided the new licensee submits documentation of satisfactory completion of the T&E listed above and a copy of the license or permit on which the AU was originally listed for the specific microsphere use."

MR. LIETO: So moved.

CHAIRMAN MALMUD: Mr. Lieto moves. Is there --

MS. TULL: These are words from 35.14 that would be specific for microspheres use.

CHAIRMAN MALMUD: Is there a second?

MS. SCHWARZ: Second.

CHAIRMAN MALMUD: Sally Schwarz seconds. Any discussion?

(No response.)

There being no discussion -- who? Oh, I didn't see your hand. Excuse me.

DR. NAG: If you remember, Ashley --

MS. TULL: Yes.

DR. NAG: -- we had said in one of our previous discussions that if someone had experience in one type of microsphere it applies to the other type with training. You know, unless you want them to undergo a full retraining again, this may not be exactly what we intended.

MS. TULL: We considered the ACMUI recommendation last time to do for each type; however, it was a split vote. We decided as NRC staff that it is "for each type of" -- if you do SIR-Spheres®, you are not automatically approved for TheraSpheres®, and vice versa. I believe the manufacturer -- I'm getting nods from manufacturers in the back, and users.

DR. THOMADSEN: That's in the training and experience, not in this -- not in this section.

CHAIRMAN MALMUD: Okay.

DR. THOMADSEN: That's the training and the --

MS. TULL: Right. So if you do theraspheres, and you want to go to a new license, you can do theraspheres. But you can't go to a new license and do SIR-spheres. That's what this is about.

CHAIRMAN MALMUD: It has been moved and seconded. All in favor? Any opposed? Any abstentions? The motion carries. Thank you.

MS. TULL: Okay. The next one --

CHAIRMAN MALMUD: Oh, Donna-Beth, yes.

DR. HOWE: I just wanted to make a general comment, and that is that this is the first time we've added the notification process to a 35.1000 use. And our intent is to add the same type of revision to the other 1000 uses that are currently approved, and we just wanted to make sure that you knew that and appreciated that this was going to be a global change. Okay?

CHAIRMAN MALMUD: Thank you for informing us of that. So this will be a model in a sense for the future.

Next motion?

MS. TULL: Next issue -- training in the manufacturer's procedures. This was a recommendation from one of the NRC regions, and they suggested this

paragraph. "Training in the manufacturer's procedures, commensurate with the individual's duties to be performed, must be provided to the individuals preparing, measuring, performing dosimetry calculations, or implanting microspheres."

DR. NAG: I'm not too sure that I understand.

DR. SULEIMAN: As opposed to what?

MS. TULL: The AU doing all of it. This is making sure the AU -- if someone else is doing any piece of it for the team approach, that they are training that individual in what to do as they're delegating.

CHAIRMAN MALMUD: Does this mean that a manufacturer's representative who has had experience with this could be the instructor?

MS. TULL: Yes.

CHAIRMAN MALMUD: That's what I thought. Thank you. Does anyone wish to make that motion?

MR. LIETO: I'll make the motion.

CHAIRMAN MALMUD: Mr. Lieto makes the motion. Seconded by Sally Schwarz. Any discussion?

(No response.)

All in favor of the motion? Any opposed to the motion? Any abstentions? Two -- three

abstentions. Thank you. The motion carries.

Next?

MS. TULL: This is the last one. Completion of procedure. So we are suggesting deleting the highlighted text here. The written directive should include "after implantation but before completion of the procedure." I believe this terminology was taken from another guidance document where there would need to be the distinction. We understand that that doesn't need to be there for this one.

DR. NAG: Well, clarification -- similar to permanent Iodine-125 implantation where there is really no completion of the procedure, that would be taken as infinity, because the radiation is going on.

CHAIRMAN MALMUD: Someone wish to say something? Dr. Thomadsen, then Mr. Lieto.

DR. THOMADSEN: I assume that the appropriate changes from dose to dosage and dose, etcetera, would be --

MS. TULL: Yes.

DR. THOMADSEN: -- in here, too.

MS. TULL: Yes. That's why I said "text pending dose activity issue."

DR. THOMADSEN: Oh, yes. Okay.

CHAIRMAN MALMUD: Mr. Lieto, does that cover your concern as well?

MR. LIETO: Well, actually, no. I think the intent of this was that, as you're doing the procedure, and the authorized user determines, just like with the I-125 seed implants, they're saying I'm going to put in 100 seeds. They're going through and they find that due to whatever they're only going to put in 80 seeds. Okay?

They can, before the patient is released, because completion was determined when released from the licensee's control, that they could change the written directive to reflect their change in the -- in the administered dosage or activity to the patient.

And I think this was meant to be consistent with that, and maybe kind of actually reflects on the long discussion we had earlier about activity versus dose, and that as they're going through the authorized user has the ability to modify what that written directive is as long as that is done before the patient leaves their licensee's control. And that was determined -- and that was what defined completion of the procedure.

MS. TULL: Dr. Salem?

DR. SALEM: I have a comment -- not answer

this, a comment after, please.

MS. TULL: Oh, okay.

CHAIRMAN MALMUD: Dr. Thomadsen?

DR. THOMADSEN: If that's what you mean by completion of the procedure, I think it would be clearer to state that exclusively here as opposed to referring to what the definitions are somewhere else. As most people would read this, they would think it's when you are finished pushing the fluid into the patient.

CHAIRMAN MALMUD: Dr. Suleiman?

DR. SULEIMAN: I agree. Maybe -- but "before completion of the procedure" should be changed "before the patient leaves the facility."

PARTICIPANT: Patient release.

DR. SULEIMAN: Patient released. Because that's a valid point, Ralph, but I think I interpreted it the same way Dr. Thomadsen interpreted it.

MR. LIETO: I think --

CHAIRMAN MALMUD: Mr. Lieto?

MR. LIETO: Yes. I just wanted to remind the Committee that we had defined "completion of procedure" when we -- because we have the issue with the I-125 seed implants as to, when do you determine that -- if you're doing a dose-based assessment, when

do you determine? And we determined it was going to be activity at time of release.

CHAIRMAN MALMUD: That what was -- Dr. Welsh?

DR. WELSH: I understand what Dr. Lieto is saying here. But I think that, as written, the average RSO might not understand what we have agreed upon and misinterpret that. And, therefore, I would favor the original motion for deletion, or the amended version of -- "before discharge of patient."

PARTICIPANT: Before the patient is released.

DR. WELSH: I can understand those words.

CHAIRMAN MALMUD: And I have a question about this. Is this specifically for the Yttrium microspheres only?

MS. TULL: Yes.

CHAIRMAN MALMUD: It does not apply to I-125 seed implants.

MS. TULL: No.

CHAIRMAN MALMUD: Thank you. Wanted to just make that a matter of record.

Mr. Lieto?

MR. LIETO: Point of clarification. Your question, Dr. Malmud, was regarding this specific item

that's posted before us, correct?

CHAIRMAN MALMUD: That's correct.

MR. LIETO: Because the Committee I think had requested or has already gone on record that it should be in the regulations that completion, okay, of -- for medical directives would be when the licensee leaves -- excuse me, the patient leaves the licensee's control for anything that required a written directive.

MS. TULL: Ron or Donna-Beth?

MR. LIETO: And if there's a question, I'd be glad to --

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: There has been favorable response to the recommendations of the Advisory Committee to change for permanent implant brachytherapy the dose to dosage, and that is part of the rulemaking which is pending at the moment. So this will be -- any additional changes that need to be made to the text will be incorporated at the same time when that rulemaking goes forward.

CHAIRMAN MALMUD: This is Malmud. So, Dr. Zelac, does that mean it would be applicable to I-125 implants?

DR. ZELAC: It can be, and there's no

reason why it couldn't or shouldn't be, when we get to that point in rulemaking for the rule. And, again, we're discussing the guidance for the microspheres here.

CHAIRMAN MALMUD: If it's applicable to the I-125 implants, is it possible for the therapist to have accidentally put 50 implants in the bladder and then order 50 more being delivered to the suite and put in an additional 50 without there ever being a record that anything happened because the directive was changed before the patient left the suite?

DR. HOWE: Dr. Malmud, I'd like to answer that, and the answer is yes. The way the current regulation is interpreted, because there isn't an endpoint for completion of the procedure, then you can change the written directive before the completion of the procedure, and so you could -- you could provide anything you wanted to to cover up a mistake that you made, which was not our intent.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: However, a supplement to what Dr. Howe just said is that this was part of what we had considered, what you had considered or made recommendations on, and this is -- this -- to correct that is being incorporated in the rule change, which

is -- will be taking place.

You made a whole series of recommendations concerning the change from dose to activity, and one of them had to do with variations from the initial --

CHAIRMAN MALMUD: Yes.

DR. ZELAC: -- before procedure as opposed to what had actually occurred in the implantation itself. So if there were significant changes from what the pre-implantation procedure -- written directive said, that would trigger a medical event.

CHAIRMAN MALMUD: Thank you, Dr. Zelac.

Dr. Nag?

DR. NAG: Yes. There was considerable discussion on this subject for permanent iodine implant. And 20 percent who will get -- if you are now adding more than that 20 percent, then it would have triggered a medical event. So that was taken care of.

Now, if you're only adding five percent more, it would not. But if you are adding more than 20 percent, then it would. So that was taken care of.

CHAIRMAN MALMUD: So once this is approved, what happens in the situation that I described? Namely, that let's say 50 seeds were accidentally implanted in the patient's bladder, and

now 50 more seeds were ordered from the stock and implanted correctly in the prostate. Is there a means of identifying the fact that this occurred and that it was untoward, so that the problem could be addressed with respect to future patients who might be exposed to the same practitioner using the same technique? That's my question. What's the protection for the public? Dr. Welsh?

DR. WELSH: I think the answer to your question is clearly, yes, there is a way of determining that a dose to an unintended organ has been administered, and that is at the heart of this discussion. Namely, you have visualizable implants in one situation -- the prostate brachytherapy -- and non-visualizable implants in the microspheres.

You would easily be able to tell after the procedure has been done through an X-ray that I-125 seeds are in the inappropriate location. You would be able to do post-implant dosimetry that would calculate what the dose to that bladder was, and this would be reported.

It depends also -- and I'm not sure about the specifics or the nuances of your question -- if 50 seeds were put in the bladder, and 50 seeds were taken out through the Foley catheter, and then 50 seeds were

put back into the prostate, that's possible, and then there would be no misadministration, no medical event, and the patient would have received exactly what was supposed to have been received.

CHAIRMAN MALMUD: I understand that. But my question is, if they're in the bladder wall, will the patient -- will the patient be informed of this untoward event?

DR. WELSH: Absolutely.

CHAIRMAN MALMUD: Under the existing regulations.

DR. HOWE: Dr. Malmud, under the existing regulations, the authorized user for a permanent implant can change the written directive before completion of the procedure. And since we don't know when completion of the procedure is, the authorized user -- and we have had a case where this happened -- he put most of the seeds in the bladder, and he just put more seeds in the prostate, and he changed the written directive. And we could not call it a misadministration or a medical event.

CHAIRMAN MALMUD: I recall that, which is why I'm asking the questions --

DR. HOWE: Yes.

CHAIRMAN MALMUD: -- with respect to this

change in the text. My concern is: is there some means by which that problem can be addressed? It might be through the NRC regs, it might be through the hospital's standard of care regs. But is there some way that this would be addressed?

Dr. Nag?

DR. NAG: Yes. I think there is some misinterpretation between your exact question and Donna-Beth's answer. Donna-Beth was answering under present rule. However, we have already -- ACMUI has already made a recommendation for the dangers of that rule. So under existing rule, you could not. But under the ACMUI recommended rules, it would be there.

CHAIRMAN MALMUD: Thank you. So under the -- our recommendations from the last meeting, it would be identified.

MS. TULL: That's in the user need memo now for rulemaking.

CHAIRMAN MALMUD: I'm sorry. I didn't hear what you --

MS. TULL: That's in the user need memo now for rulemaking.

CHAIRMAN MALMUD: Thank you.

MS. TULL: So that's in the rulemaking process.

CHAIRMAN MALMUD: Thank you. Thank you.

Mr. Lieto?

MR. LIETO: Well, I just want to -- in this discussion on this agenda item, is the motion -- is there currently a motion to accept this change? Because if it is, we need to make a -- we need to change the motion.

CHAIRMAN MALMUD: I don't think that we --

MS. TULL: I haven't written down anything for a motion.

CHAIRMAN MALMUD: No, there's no motion yet.

MR. LIETO: Okay.

CHAIRMAN MALMUD: Do you wish to make a motion?

MR. LIETO: My motion would be to keep the highlighted text and add after the word "procedure" parenthetically "completion is defined at time of patient release from licensee control," closed parentheses.

DR. NAG: I would like to amend that motion and make it very -- and simplify it. The written directive should include "after implantation but before release of patient from licensee control -- the radionuclide, the manufacturer, the treatment

site, and the total dosage to the treatment -- and the total dosage, really, not even treatment site, and the total dosage."

CHAIRMAN MALMUD: Period?

DR. NAG: Yes.

CHAIRMAN MALMUD: End?

DR. NAG: And then, you continue the other one. The implantation was terminated because of stasis. Then, the total dosage is the value of the total dosage delivered when --

DR. THOMADSEN: That's not necessary, since you said total dosage was --

DR. NAG: Right. Right. It's not necessary.

DR. THOMADSEN: You can end it there.

DR. NAG: Yes.

CHAIRMAN MALMUD: For the purposes of the record, could you just slowly read the motion that you would like to make, with the changes in wording?

DR. NAG: Okay. The written directive should include after implantation but before release from licensee control -- the radionuclide (Y-90 microspheres), the manufacturer, treatment site, and the total dosage to the -- and the total dosage."

DR. WELSH: Dose or dosage.

DR. NAG: And the total dose or dosage. I'm sorry.

CHAIRMAN MALMUD: And the total dose or dosage, period. Everything else is eliminated from that statement?

PARTICIPANT: Yes, it's redundant.

CHAIRMAN MALMUD: All right. So that is the motion, which has been seconded and amended. Is that acceptable to you, Mr. Lieto? I think you made the motion. Dr. Nag seconded it.

MR. LIETO: Yes, that's acceptable.

CHAIRMAN MALMUD: Discussion of this motion?

(No response.)

All in favor? Any opposed? Any abstentions? It carries with one abstention.

Thank you.

MS. WASTLER: There are two abstentions.

CHAIRMAN MALMUD: Oh, two. I'm sorry. Who was the other one? I didn't see it. Were there two abstentions?

MS. TULL: No. Dr. Malmud does not vote.

MS. WASTLER: Oh, he doesn't vote. He just raised his hand, so -- I'm sorry.

CHAIRMAN MALMUD: Comment from a member of

the public. Please reintroduce yourself.

DR. SALEM: Thank you, Mr. Chairman. Salem from Northwestern. I just wanted to thank the Committee. I was here last year representing the Society of Interventional Radiology, and wanted to thank the Committee for the work they did on the revision of the guidelines, especially Ashley Tull that answers the phone surprisingly frequently.

(Laughter.)

I did want to just make one clarification as the -- one of the premises of last year's meeting and presentation by myself representing the Society of Interventional Radiology was that one of the constituencies that was underrepresented in the multi-disciplinary team of microspheres was interventional radiology; hence, leading to possibly a pathway for authorized user status for radiologists and interventional radiologists.

I just wanted to confirm that the Committee was clear or understood or make sure that I understood that in fact one of the constituencies that will be interested in working with this technology, and as long as they complete all of the training and requirements to become authorized users, that radiologists and interventional radiologists represent

that constituency.

Thank you.

CHAIRMAN MALMUD: Thank you.

MS. TULL: If I can speak to this, as a little bit of background, and me answering the phone, I've had a significant number of phone calls in the past month asking if interventional radiologists can become authorized users. My response to that currently is no. We have authorized 390 users being the nuc med physicians, 490 your radiation oncologists.

However, I have told them, if you can meet the training and experience requirements, and you've done the vendor training, you can meet everything in the revised microspheres guidance, and you're an interventional radiologist, then the answer would be yes, you meet the T&E, you meet the requirements.

CHAIRMAN MALMUD: Dr. Eggli?

DR. EGGLI: It certainly is possible for a diagnostic radiologist to be certified under Part 390 currently through the ultimate pathway, since the American Board of Radiology did not ask for a general 390 authorized user status as part of board certification. But it certainly should be possible --

MS. TULL: I've referred them to the 700

hours.

DR. EGGLI: -- under the alternate pathway.

MS. TULL: yes.

CHAIRMAN MALMUD: That is correct. The NRC does not establish credentialing for specialists, but does establish standards for training and experience.

DR. SALEM: Okay. One of the concerns, and I know that you were getting lots of phone calls, because they were all coming to me first --

(Laughter.)

-- from interventional radiology was indeed that. And so I just want to make sure that as we move forward a very interested and important constituency with this therapy is interventional radiology, and I would like to make sure that people recognize sometimes the difficulties in meeting 900 hours or 700 hours, and sometimes the wiggle room in interpretation of regulation.

Again, RSO is calling me -- one interprets it one way, one interprets it another way. So I just want to make sure that we recognize this is an important constituent, and we'd like to participate.

CHAIRMAN MALMUD: Dr. Eggli?

DR. EGGLI: Mr. Chairman, I think unfortunately the threshold for training is clear, and I think that this is an issue at this point probably better addressed to the American Board of Radiology and how they choose to train their diplomats.

CHAIRMAN MALMUD: You are correct. I just wanted to reaffirm to Dr. Salem that we -- we don't get into turf issues with respect to the issues that we've raised, meaning the NRC doesn't. The NRC establishes the T&E requirements. What happens beyond that is in the practice level rather than in the Nuclear Regulatory Commission's interest, from my understanding of their decisions in the past.

And Dr. Eggli, being a board certified radiologist himself, has some familiarity with the issue, and probably gave you the correct advice. But we did recognize -- your complimenting Ashley Tull on being available to answer the phone.

(Laughter.)

You are correct. That has been our experience as well.

DR. NAG: Mr. Chairman?

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Yes. I would also like to notify Dr. Salem and also the ACR representative here

that the person we had yesterday about possibility of diagnostic radiologists being -- possibly even be on the ACMUI directly if they had an interest to the application.

CHAIRMAN MALMUD: Thank you, Dr. Nag.

And we received a mystical message from the cafeteria indicating that they're waiting for us. We're a half hour late for lunch, so we'll take a break. And can we reconvene at 1:45? Is that reasonable? 1:45 we'll meet back here.

Thank you.

(Whereupon, at 1:06 p.m., the proceedings in the foregoing matter went off the record until 1:56 p.m.)

CHAIRMAN MALMUD: The next item on the agenda is specialty boards. And Cindy Flannery will be discussing this with an update on the approval status of the specialty boards.

MS. FLANNERY: Thank you.

14. SPECIALTY BOARDS

MS. FLANNERY: I'm providing this update on the status of the recognition of the specialty boards. There is really only one change since I last gave this talk at the June meeting. For those of you who are kind of new, this has been a standing item on

the agenda for the last couple of years.

The one change since our June meeting is in the last row here, you will see the Canadian College of Physicists in Medicine. They just recently submitted an application about a month ago. They're applying for recognition under 35.51 I have described here.

And it is under review by NRC staff right now. We have not provided any response whatsoever yet because we just received this application about a month ago. So that is under review. And that's really the only change.

Now, besides the Canadian College of Physicists and Medicine, there are two other boards that currently are not recognized that have applied. And that is the American Board of Medical Physicists and the Certification Board of Nuclear Endocrinology.

You will see here near the bottom the ABMP. Their status has remained unchanged for the last two years. When they submitted an application, NRC staff requested additional information. And we are still awaiting their input.

The Certification Board of Nuclear Endocrinology, they submitted an application earlier this year. NRC staff requested some additional

information to complete the review. And we are still awaiting input.

Besides those three that are not currently recognized who have applied, the remaining eight boards that are listed here and are recognized and are listed on NRC's Web site, their status has remained unchanged since we last met.

But I would like to just point out a typo. In the slides that went into your binder, a typo was noted after the slides had already gone out. So I just want to just point that out, and I am sorry if it has caused any confusion for anybody. To the American Board of Radiology portion right there, I believe the June 2007 and June 2006 dates I think are down one line. So the projected slide here has the correct date.

So the American Board of Radiology Radiation Oncology, the recognition date is June 2007. The American Board of Radiology Diagnostic Radiology, the recognition date is June 2006. The last three dates here indicated are for the subspecialties in the physics section.

CHAIRMAN MALMUD: Thank you.

MS. FLANNERY: I just wanted to spend just a minute to describe to you the handling of the

Certification Board of Nuclear Endocrinology because this is being handled slightly different than the other boards that have applied in that the CBNE applied for recognition under 35.190. This is uptake dilution and excretion. They also applied for recognition under 392 and 394, which is your iodine-131 administration's requirement in written directive.

Now, 190 is for uptake dilution and excretion studies. The CBNE is a new board that is still developing the certification process. And they don't really have an interest in dilution and excretion studies. They are really just interested in the uptake.

So when it gets to that point that they are recognizing and get listed and so forth, we are going to list them with a partial recognition under 190. And that would be for uptake. Does that make sense, rather than the entire 190?

And that is all I have.

CHAIRMAN MALMUD: Thank you. Are there any questions for Ms. Flannery?

MEMBER NAG: Yes. Cindy?

CHAIRMAN MALMUD: Yes?

MEMBER NAG: Is anyone applying under 590?

I mean, I hardly ever hear about 590.

MS. FLANNERY: Nobody has applied for 590.

MEMBER NAG: And when you are saying 392 and 394, if someone applied for 390, that means 392 and 394 are automatically included. Am I right?

MS. FLANNERY: That's correct. They need to get their work experience. Like say, for example, 394 is -- you know, they need to have 3 cases greater than 33 millicuries. So yes, they would be listed under 390, but they would have to show that case of strengths, correct.

CHAIRMAN MALMUD: Thank you.

I think Mr. Lieto had a question.

MEMBER LIETO: I just had one question and just one comment. The comment was that the 500 uses are diagnostic sealed sources. And there are just not any devices out there anymore that are available. I think the last thing was the gadolinium 153 bone densitometers, which are I don't think available anymore.

But I did have a question. I did notice that there was not like 396. Were there any notations about 395.396 on either side, either a listing or any status? Is that correct?

MS. FLANNERY: Well, right now there isn't

anybody who -- there aren't any boards that are recognized under 396.

MEMBER NAG: The 396 was that subpart J. That was the one related to subpart J, isn't it? If I remember correctly, 396 was the bypass thing.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: There is no board for 396. Three ninety-six doesn't have a board that stands alone. You get to 396 by being board-certified under 490 or 690 and then having additional training and delivering parental administration. So that's why you're not seeing 396.

MEMBER NAG: And that doesn't apply anymore. That was only for a partial time when --

DR. HOWE: No. It is current. It applies right now.

MEMBER NAG: Okay.

DR. HOWE: But you get there by other boards and other authorizations.

MS. FLANNERY: In other words, there's not a board certification pathway under 396.

DR. HOWE: That's exactly right, that's specific to 396.

CHAIRMAN MALMUD: Any other questions?

(No response.)

CHAIRMAN MALMUD: If not, thank you for your report. And we will move on to the next item on the agenda, which is the T&E implementation issues. Actually, you are going to do that one?

MS. TULL: Yes.

CHAIRMAN MALMUD: Thank you.

15. T&E IMPLEMENTATION ISSUES CONT.

MS. TULL: Yes. If everyone wants to turn under tab 5 to the last meeting summary, the motion was "NRC staff should add increased complexity versus additional benefit as an agenda item for the October ACMUI meeting so that ACMUI may continue a discussion on this topic." So here we are.

The summary of the issue is that the ACMUI believes the new 10 CFR Part 35 training and experience requirements do not increase public health and safety and the additional costs and complexity of the new regulations are not justified. Additionally, ACMUI believes the new regulations make it difficult or possibly exclude certain groups of individuals from practicing.

There is a brief paragraph on the discussion that took place during our last teleconference. If anyone else has anything they would like to add, we are open to hear it.

CHAIRMAN MALMUD: Comments? Page 6?

MS. TULL: Tab 5. It starts on page 5 of the meeting summary from the two teleconferences that are put together, the August 16th and September 20th.

CHAIRMAN MALMUD: It's page 5 of 6?

MS. TULL: Yes.

MEMBER NAG: I think for a full discussion of that, we probably have to go back to some of the issues that were discussed the last time. Otherwise it's really hard to pick up the thread of the discussion. I mean, it --

MS. TULL: Do you want me to go through and name some of the --

MEMBER NAG: Yes. Some of the --

MS. TULL: We have nine other issues that were T&E issues. The first one would have been from the June meeting. That had to do with the attestation requirement for board-certified individuals. And ACMUI recommended that this requirement be rewritten so that the attestation requirement for individuals seeking authorization under the alternate pathway --

CHAIRMAN MALMUD: Excuse me. Ashley, could you identify the page and --

MS. TULL: It's a memo dated October 11th, 2007, --

CHAIRMAN MALMUD: Right.

MS. TULL: -- the first page behind the tab. And it's motion number 3.

CHAIRMAN MALMUD: Motion number --

MS. TULL: Two. I'm sorry. It has to do with attestation. That's the first T&E issue.

CHAIRMAN MALMUD: Right. And this was a continuing source of concern?

MS. TULL: Correct. The next motion has to do with grandfathering board-certified individuals.

CHAIRMAN MALMUD: Before we move on, let's just review the discussion that had occurred. It was rather a lengthy discussion. And there were strong feelings about it. The Committee members felt that the attestation requirement was unnecessary if the individual was boarded.

And, in addition, because of the issue of potential liability to the director of the training program, in the event one of the trainees was sued and the trainee's competence was challenged several years down the road, that it might lead to a suit against the director of the training program as well, either by the aggrieved party or by the trainee himself or herself claiming that they had not adequately been trained.

For that reason, the word "competency" has been a word which every accrediting board has opposed. The accrediting boards wish instead for the statement to be, the attestation to be, that the individual has completed the training program.

I believe the term that they prefer is "has successfully completed the residency or has demonstrated successful completion of the residency."

Some of the directors of training programs will not sign off on these attestations. And that means that those individuals, therefore, will not become authorized users. And this will be a problem for smaller institutions who are trying to attract trainees who have completed their residencies, whether they be in the clinical or physics areas, as authorized users.

So there was quite a bit of discussion, which everyone who was on the Committee at the time remembers full well because the discussion had gone on for almost two years.

Sandi? I'm sorry.

MS. WASTLER: I was just going to ask when you were completed what Dr. Nag had requested. I didn't understand what he was leading up to, not that I don't want --

MEMBER NAG: Yes.

MS. WASTLER: -- Dr. Malmud to complete his statement, but --

CHAIRMAN MALMUD: That's okay. I'm finished.

MS. WASTLER: -- to understand what he was looking for with regards to the last issue on the table, which was the --

MEMBER NAG: Increased complexity.

MS. WASTLER: -- complexity issue.

MEMBER NAG: Yes. I mean, I don't think the issue of attestation was necessarily what we were referring to increased complexity and additional benefit.

So that's why I wanted Ashley to briefly summarize what were the things that were included under that topic.

MS. TULL: Right. And --

MEMBER NAG: I believe that with things like making some of the part 35 so complicated is that even though it was complicated, really, it did not add anything to the patient safety. And I just wondered, what were some of the issues that we were talking about so that today we can discuss that in a little more detail?

MS. TULL: I think my point in starting there is we had ten issues listed for T&E and that increased complexity versus additional benefit was the tenth one.

So I went back to the first one to say, "This is the first one. This is the second one." And I was kind of leading up to just to refresh your memory on each T&E issue that we have already talked about at length. You have made a formal recommendation on each and every one of them.

So I was just going to briefly say, you know, seven-year recency of training, just all the different topics, so that we could move to the last one and get a recommendation on that one.

CHAIRMAN MALMUD: Okay. Go ahead. Please go ahead.

MS. TULL: Okay. So the first issue back on the first page of that, first page behind tab 5, was the attestation. The second issue was grandfathering. And then you will have to turn to the next meeting summary, which is the August 16th and September 20th meeting summary. And this is where we picked up on T&E.

And the first issue was unintended consequence of prescriptive requirements on

certification boards resulting in NRC setting the curriculum.

MEMBER NAG: And, again, what page is that?

MS. TULL: That's the first page.

MEMBER NAG: Okay.

MS. TULL: It's page 1 of 6 of the meeting summary from August 16th and September 20th. The next T&E issue was about Canadian-trained AUs not being eligible under the board certification pathway.

Next we talked about compatibility, B versus C, for T&E requirements. Then we also discussed the unavailability of preceptors for authorized individuals. And the last issue we discussed was the seven-year recency of training. And that brought us to increased complexity versus additional benefit. I believe all of those fed into where we are now.

Is there a specific motion that the Committee wanted to make with regards to this or is it just a statement that there is no perceived additional benefit?

MEMBER NAG: Yes. I think, if I remember our discussion directly, I think what we were leading up to at that point when we had to stop was that many

of the new part 35 -- you know, there are a lot of complicated things in there, which does not really add to patient benefit. And, therefore, it is burdensome.

And, you know, was there any way we could use some of those burdensome natures? And if there is a huge benefit, then it is worthwhile going into, you know, that burden, but if it is not going to be additional benefit, then why have things which are burdensome?

CHAIRMAN MALMUD: For purposes of example, if you could give us one illustrative example of that, one component of that?

MEMBER NAG: That's why I was asking if --

MEMBER LIETO: I was just looking at the summary that was done on the meeting and trying to recollect, you know, the eloquent statements of our past member, Dr. Williamson, who made a lot of the discussion and also had a motion, I believe, proposed motion, that -- let's see. He had a proposed motion that "stated that the current revision of the training and experience regulations has not improved public health and safety and has actually diminished safety or possible or potential patient access to health care."

And I think in terms of examples, I think

one that I guess I would maybe like to offer is that I think this whole recognition of the boards process, of the boards themselves I think has gone way beyond I think what was intended in the statements or the proposed rules when we were looking at this stuff versus its implementation.

I mean, it talks about that basically the process be recognized. And I think now we have gotten into looking at, is the curriculum appropriate, established dates of recognition? It doesn't talk about dates of recognition.

And I guess I would have to ask maybe those of you who are involved in teaching physicians or medical physicists, have the training and experience requirements over the last five years changed so significantly that -- or I should say have the training and experience of those individuals over the past five years such that you would have a problem with indicating that that person could function independently?

I mean, an attestation but over and above the attestation statement, is there a problem that these graduates going out from these programs have a problem and become board-certified being recognized as either an AU or an AMP or an RSO in the case of a CHP,

that this process has added to such that we have these dates of recognition, as opposed to just the board certification.

CHAIRMAN MALMUD: Doug, do you want to comment on that?

MEMBER EGGLI: Yes. From the point of view of someone who trains diagnostic radiology residents, I don't think we have added to their knowledge base. What we have added to is the hoops that we have to jump through to get them certified.

And I think that what Jeff was trying to get at here was sort of a cumulative summation of all of these other issues that led up to it. And if you look at all of the motion stealing with various parts of the training and education requirements, the whole thing has become very complex. And then the question is, what benefit have we derived from that increased complexity?

So I am not sure that this addressed a new topic. It may have just been a summation of essentially the frustrations of the professional community with the hoops we have to jump through to get to the same point in space and time that we used to get through without jumping through the hoops.

And in the process -- and we have dealt

with it in other motions -- we have potentially disenfranchised some people. Some of the boards are trying -- the American Board of Radiology is trying to go backwards and create a 50-question exam that they give its diplomates who are caught in the gap.

You know, the gap group, the gap babies was a Social Security thing between 17 and 22, where people got reduced benefits. Well, we have gap babies here, too, in the training and education between when the new requirements went into effect in October 2005 and the boards finally got themselves recognized.

We have a whole bunch of gap babies who are potentially disenfranchised. That's one of the issues where we haven't trained them any differently. But, yet, they go out without credentials.

And so there was a whole summation of all of these issues boiling up into the feeling that we have made it much harder. I guess I am not sure "complexity" is necessarily the right word.

We have made it much harder for people to become authorized users. And at the output end, we haven't made our authorized users any more qualified, any more talented, any more capable than they ever were.

CHAIRMAN MALMUD: Thank you. May I try

and say that even more simply?

MEMBER EGGLI: Oh, please.

(Laughter.)

CHAIRMAN MALMUD: When the rules changed, several of the boards did not submit their data on time. As a result, the graduates of those residencies were left in this gap period so that as they completed their residencies, they could not qualify for authorized user status unless they had completed their board certification. That's one group. And that was one complaint.

The other complaint generated two years of discussion here. And that has to do with the issue of competence. The boards were not supportive of the word "competence." We're disappointed that the word "competence" continued to be included and are still oppositional to inserting the word "competence" since the training program director feels vulnerable in using that word.

The third issue was the attestation. Why should someone who has already qualified to sit for the boards require an additional attestation from the training program director? And, going back, why should it be necessary to get an attestation from a training program director who may have left the face

of the Earth already or be otherwise unreachable for the attestation? So those were the issues of concern.

The other issue of concern was the number of hours of training in specific subjects which were to have been, for lack of a better word, didactic and if they were taken literally as being classroom would have prevented radiologists from having any clinical experience in nuclear medicine because the number of hours required of classroom work consumed a nuclear medicine rotation in the radiology residency. We're speaking of radiology now.

I believe that we resolved the last issue because NRC staff did get an interpretation for us from NRC counsel that the trainees could use their clinical experience, which was related to the delivery of interpretations and clinical work that related to calculations of doses and so on, in addition to their classroom work. So that satisfied -- was it 200 hours or --

MS. SCHLUETER: Seven hundred.

CHAIRMAN MALMUD: -- 700 hours in this case. That took care of that.

The issue of the competence is an issue which I raised with the commissioner this morning. And he and his staff have heard our continuing concern

about the use of the word "competence" because of the medical liability issues that might be surrounding it.

And the establishment of de facto curriculum for residents by dictating the number of hours remains an issue. It will become an even greater issue from what Dr. Nag has reported as there is going to be a possible delay in permitting certain residents to sit for the boards for two years, rather than the year after completion, which means a larger group will be without board certification as the board certification process is altered and, therefore, will not be able to serve as authorized users.

And the departments that will be most severely impacted by this will be the small departments in rural areas throughout the United States. So that problem will escalate if the current pattern continues.

Does that summarize it?

MEMBER EGGLI: Then there is one more little piece I would like to segue again to add to that. The American Board of Radiology when it submitted its application for its diplomates to be certified in part 392 were under the impression that there could be no overlap in the didactic hours between 392 and 394 and, therefore, didn't apply for

394, which is going to ultimately create a severe shortage in physicians available to treat higher-dose thyroid cancer patients as this ripples through the system. It will be limited only to physicians who are intrinsically trained for part 390 uses, which will be American Board of Nuclear Medicine Diplomates.

And, again, the process has become complex enough that the American Board of Radiology did not understand that there was significant overlap in the didactic training hours between part 392 and 394. And, as a result, American Board of Radiology resident diplomates with authorized user status will not be able to treat higher-dose thyroid cancer patients, which is going to create a huge crunch in about five years' time.

CHAIRMAN MALMUD: Thank you. Is that true, even if they have the three required cases?

MEMBER EGGLI: Yes, yes.

CHAIRMAN MALMUD: Because of the absence of a didactic --

MEMBER EGGLI: Because the American Board of Radiology did not submit its board certification status for part 394. Because of a misunderstanding of the training and education requirements, they assumed that there would be no overlap allowed.

CHAIRMAN MALMUD: Thank you for clarifying that point.

MS. TULL: Dr. Malmud, Lynne is standing behind you. Lynne is standing behind you.

MS. FAIROBENT: Dr. Malmud?

CHAIRMAN MALMUD: Oh, there you are. Hello.

MS. FAIROBENT: Lynne Fairobent with AAPM.

I just want to second what Dr. Eggli just said. We have had extensive discussions with ABR on the 392/394 situation. And the one thing that I don't think is clear, I don't believe that there is an alternate pathway for just 394 that these folks can come in versus through the board pathway. Is that correct?

DR. HOWE: No. There is an alternate pathway for 394.

MS. FAIROBENT: But it will also be more cumbersome and complex.

MS. TULL: Dr. Malmud, I have a question.

CHAIRMAN MALMUD: Yes?

MS. TULL: For this particular issue, it doesn't seem like there is going to be a formal recommendation for action for NRC staff. Is there a general statement that the Committee would like to

make or is there a recommendation to revert to the old part 35? Do you know where this is going or does the path forward take all of the previous recommendations, move forward with those, we'll make a statement that --

CHAIRMAN MALMUD: If you wish, I could reduce these to a single statement. And that is that the ACMUI recommends that the NRC accept the board's standards for training with regard to radiation physics issues in each of their programs and, in addition, that the word "competence" be struck from the current regulations and replaced with a statement from the program director that the trainee was successful in completing the residency.

MEMBER NAG: Why are you restricting it to radiation physics? Why not to radiation oncology and radiation physics?

CHAIRMAN MALMUD: I didn't mean to exclude radiation oncology and radiation physics. So you are correct. I said radiology. It should have been radiology, radiation oncology, and radiation physics. It doesn't relate to nuclear pharmacy, as I recall. You're okay. And it doesn't relate to nuclear medicine because their standards exceed those required by the NRC.

All right. So if you could read that back? Excuse me?

MEMBER SCHWARZ: One thing. In your statement, in accepting the board certification, can you make the statement without the attestation statement, essentially as a board-certified individual, there is no need for?

CHAIRMAN MALMUD: Yes. That's a good point in that with board certification, there should not be a need for an attestation statement. The individual could not sit for the boards without the approval of the program director.

MEMBER SCHWARZ: This would be appropriate for all boards.

CHAIRMAN MALMUD: For all boards. And that would keep the academic issues within the tradition of the board certification process and should make things easier for both the NRC and the boards without affecting in any negative way the quality of health care delivery to patients or the safety of health care workers.

MS. TULL: So that statement summarizes all of the previous issues individually?

CHAIRMAN MALMUD: I think it summarizes the important ones. I would have to go back and look

at them word by word to answer your question.

MS. WASTLER: Did you catch it?

MS. TULL: I have most of it. Yes. I have "NRC accepts board standards for training." I have "for each program." I didn't write "radiation." I said "for each program."

CHAIRMAN MALMUD: "The ACMUI recommends that for each training program, including radiology, radiation oncology, radiation physics," --

MEMBER SCHWARZ: Nuclear pharmacy.

CHAIRMAN MALMUD: -- "and nuclear pharmacy, that the curricular requirements be established by those boards." And I think perhaps we should say, "who do recognize the importance of the NRC standards for radiation safety and radiation physics."

I beg your pardon?

MEMBER SCHWARZ: They are approved by the NRC currently, correct?

CHAIRMAN MALMUD: Yes. "In addition, the ACMUI recommends deletion of the term 'competence' and its replacement with a statement regarding the 'successful completion of residency training.'"

MS. TULL: To clarify, that would be the same as motion from the June meeting, "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 minimum training and experience requirements.'"

CHAIRMAN MALMUD: Yes. I don't know why the word "minimum" is in there. Was there a reason for that? I mean, the "training and experience" should be sufficient. "Minimum" suggests a low standard. If you are in agreement, we can eliminate the word "minimum."

Was there a reason for the word "minimum"? Does anybody know? Can we eliminate the word "minimum"? Let's eliminate the word "minimum."

Someone said something. Would you please introduce yourself, a member of the public?

MR. PFEIFFER: I'm Doug Pfeiffer with AAPM. And I just wanted to verify that your statement of including radiological physics in that does include health physicists at the ABHP, American Board of Health Physics, would also be included.

CHAIRMAN MALMUD: Yes. Thank you. It does.

MS. TULL: Was there anything in your new statement that hadn't previously been covered by a motion from another meeting?

CHAIRMAN MALMUD: Everything in my statement was included previously in a group of separate statements. I think this ties it together, --

MS. TULL: Okay.

CHAIRMAN MALMUD: -- hopefully in only two sentences, maybe three.

So is someone making that motion that I just read? I can't.

MEMBER THOMADSEN: So moved.

CHAIRMAN MALMUD: It's been moved by Dr. Thomadsen.

MEMBER NAG: Second.

CHAIRMAN MALMUD: And who seconds it?

MEMBER NAG: I second it.

CHAIRMAN MALMUD: Dr. Nag seconds it. Any further discussion?

(No response.)

CHAIRMAN MALMUD: All in favor?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: It's unanimous, no abstentions. And that's the spirit of the Committee.

MS. TULL: So that concludes T&E.

CHAIRMAN MALMUD: That concludes T&E? Thank you very much.

MS. WASTLER: No we're ahead of schedule.

MS. TULL: Four meetings later.

MS. WASTLER: At this point the next presentation is Dennis Rathbun, who is not currently scheduled to be here until 3:30.

CHAIRMAN MALMUD: All right. If I may?

MS. WASTLER: I would suggest that maybe if we could take a short --

CHAIRMAN MALMUD: Yes. We have a subcommittee report. You recall that this morning we established several subcommittees. The first subcommittee has met and is prepared to give its report.

MS. WASTLER: Okay. In that case, while that is taking place, we will contact Dennis and see if we can have him come down ahead.

CHAIRMAN MALMUD: Dr. Vetter, would you please give the report of the subcommittee?

VICE CHAIRMAN VETTER: I would be happy to. This is the subcommittee that was asked to look at NCRP commentary 11 relative to -- I am looking for the motion yesterday that Dr. Howe made.

Dr. Howe outlined as problem in 10 CFR 35.75 that the limits specified for release of patients was simply based on what they call total effective dose equivalent. I expect that what they really mean by that is a cumulative effective dose equivalent.

It is not likely to exceed five millisieverts. And they said it would be appropriate to change that to five millisieverts per year. We raised the question. Since this recommendation for patient release was based on commentary 11, we raised the question of what exactly it said.

And so the Committee appointed this subcommittee of myself, Dr. Fisher, Dr. Eggli to take a look at commentary 11. We have done so. And, in fact, the limits in here are annual limits. The recommendation in here of five millisieverts is an annual limit.

Consequently, this supports what Dr. Howe was requesting.

CHAIRMAN MALMUD: So the subcommittee has

set a record for the completion of a task by a subcommittee of this Committee. And it also, not unexpectedly, agrees with Dr. Howe's recommendation.

So is there a motion?

VICE CHAIRMAN VETTER: Well, I didn't say we agree.

CHAIRMAN MALMUD: Oh, you didn't say you agree.

(Laughter.)

VICE CHAIRMAN VETTER: That is up to the Committee.

CHAIRMAN MALMUD: I see.

VICE CHAIRMAN VETTER: Our task was to determine whether or not this was an annual limit, that NCRP recommended annual limit, and it does.

PARTICIPANT: Didn't we vote on that yesterday.

MEMBER EGGLI: Yes. It ended up being the subcommittee report back.

CHAIRMAN MALMUD: Dr. Fisher?

MEMBER FISHER: Yes. I was hoping that Dr. Vetter would mention this additional fact. The units are not the same.

CHAIRMAN MALMUD: Yes.

MEMBER FISHER: There is a discrepancy in

the precise dosimetry units. And that could cause some concerns for licensees. We believe that the annual limits specified by commentary 11 is the effective dose equivalent or effective dose.

PARTICIPANT: Effective dose.

MEMBER FISHER: Effective dose; whereas, the unit in part 35 is the total effective dose equivalent, which has complicated some of the internal dose plus the shallow depth external dose. And it's a little bit complicated, maybe an archaic unit in some ways.

CHAIRMAN MALMUD: In orders of magnitude, they are close, are they not?

MEMBER FISHER: Sure. But conceptually they are different. For example --

CHAIRMAN MALMUD: You are correct, of course.

MEMBER FISHER: -- the total effective dose equivalent is not an annual dose by definition.

CHAIRMAN MALMUD: And, therefore, having answered the question, what is the subcommittee's recommendation?

VICE CHAIRMAN VETTER: We did not meet to bring back a recommendation. However, it is my personal feeling that if you were to try to correct

the deficiency that Dr. Fisher has identified, we would be here another day and a half because what he points out is correct. The regulations use a unit called total effective dose equivalent, which is a different unit than what the rest of the world basically uses. The rest of the world is using effective dose these days. And total effective dose equivalent, it's conceptually difficult to provide an annual limit for such a unit.

However, as a practicing radiation safety officer, I think it is workable. I think it could create a little difficulty occasionally, I would say rarely, with some licensees who are bumping up against the limit. And they would have to argue that with inspectors as to whether or not the doses they are attracting are effective dose, effective dose equivalent, or total effective dose equivalent. It's really a little different answer.

I personally think that the individual programs would have to iron that out with their inspector if they were bumping up against this limit.

It also is my personal opinion that it would be rare that a program could not live with this limit of five millisieverts per year total effective dose equivalent for a member of the public exposed to

a patient that was released.

What they basically would have to do is advise that patient in such a way as to change the occupancy factor used in the patient-specific dose calculations. And that is possible to do. It simply means the RSO has to pay attention to detail.

Nuclear medicine has to pay attention to detail. Dr. Eggli knows exactly what I am talking about. He has advised patients to do that. And it can be done successfully.

So, bottom line, I would recommend to the Committee that we approve the request that Dr. Howe brought before the Committee.

CHAIRMAN MALMUD: It's a motion to approve the request that Dr. Howe brought before the Committee. Is there a second to the motion?

MEMBER SULEIMAN: Second.

CHAIRMAN MALMUD: Dr. Suleiman. Any further discussion of the motion? Mr. Lieto, a question?

MEMBER LIETO: Yes. I would like to remind the Committee that what initiated this request was the issue of licensees administering multiple studies for the same patient and releasing them over the course of a year. I'm going to state calendar

year for defining what that time period is.

So one of the ramifications of this is going to be there is now going to be the added burden that licensees are now going to have to assess the dose to a member of the public from that same individual, who gets multiple studies in the course of a year, because that is going to be something that has not I think been done by licensees in terms of this assessment.

I'm sure there is an evaluation in terms of from a clinical standpoint if multiple studies have been done for other reasons, but now there is going to have to be a total effective dose equivalent assessment or calculation when you start to give multiple studies to these same individuals, same patients.

CHAIRMAN MALMUD: Dr. Vetter?

VICE CHAIRMAN VETTER: I appreciate what Mr. Lieto has said. He is certainly correct. And programs will have to be sensitive to that, alert for it, and will have to account for that in their planning when they release those patients.

They will have to anticipate that for monoclonal antibody patients, for example, that these patients are going to be coming back, will be treated

again.

In the case of something like a hypothyroidism patient, where you have to treat a second time, where you didn't anticipate it, that might be a little more problematic, but you simply are going to have to deal with that.

CHAIRMAN MALMUD: I think Dr. Fisher was next and then Dr. Eggli.

MEMBER FISHER: Yes. I think I have a couple of quick thoughts. One, this will be much more complicated if followed in full. It will require a new guidance document, a new NUREG.

And I am concerned from the patient perspective that it will eliminate the opportunity for some protocols that involve fractionated high-dose radionuclide therapy because it will require hospitalization, rather than release.

CHAIRMAN MALMUD: The inverse square law being what it is really does allow for instruction to the patient with regard to the distance that they should keep from other individuals.

MEMBER FISHER: But, see, in the guidance document, those assumptions are already spelled out. You follow a given set of assumptions, regardless of patient behavior. And it's incumbent on the licensee

to follow the guidance, do the calculations, keep the records. And the specific behavior of the patient is not accounted for in that calculation.

CHAIRMAN MALMUD: Nor is it accounted for in the existing regulation --

MEMBER FISHER: Right.

CHAIRMAN MALMUD: -- because we assume that the patient will follow the instruction, et cetera, et cetera. If the patient does not, it is away from the institution, and we are unaware of it. So I'm not sure that the fact that we are unaware of it should be the determining factor. However, it is just a personal opinion.

Dr. Eggli?

MEMBER EGGLI: I have two issues. One of them is the fairly young patient who is getting multiple monoclonal antibody therapies for a lymphoma and is a single parent of young children and has a big problem on their hands.

The second one is, to really follow Dr. Fisher's statement, the guidance suggests an occupancy factor of 25 percent. And basically the only way to round this is to modify either distance or the occupancy factor.

If the question is, is a different

occupancy factor going to be acceptable if in my work-up and my documentation of the patient's treatment I can justify an occupancy factor, for instance, of five percent, recently I had a thyroid cancer patient that I treated with 150 millicuries as an outpatient, who literally spent 4 days in an RV in their driveway to stay away from the rest of their family.

That occupancy factor was zero. Do the treating physicians have the ability to modify the occupancy factor based on the patients' conditions and the counseling given the patient I planning for these additional doses downstream?

CHAIRMAN MALMUD: I have always assumed that we do and that logic would prevail. And some of the patients that I deal with are extremely medically indigent. They, even with young children or young grandchildren in the home, have found ways of either sending the children elsewhere or themselves moving out temporarily and finding another friend or relative to care for the kids in the interim. They have shown extreme concern for radiation. And though they don't comprehend the physics of it, they understand the danger of it.

We don't know, even in the case of the

patient in the trailer, whether the patient remained in the trailer. Patient said the patient remained in the trailer. The patient could have been intimate with somebody else for an hour or two outside the trailer or even in the trailer.

So we make basic assumptions. The question is, shall we obviate everyone's treatment based upon a patient who does not or will not follow instruction? And I would assume the answer is not to that and that as a physician, we would determine whether or not we trusted the patient to follow the rules. If we didn't, we would document in the chart that we didn't feel secure doing that and, therefore, didn't do it.

Dr. Zelac, you were going to make a comment.

DR. ZELAC: To answer both of you, first, Dr. Malmud, your assumption is correct that the actual conditions that are anticipated for the patient can, in fact, and should if the physician wishes to be incorporated into the determination of what the expected dose will be.

What used to be reg guide 8.39, which is now chapter U of 15.56, volume 9, is simply the most conservative approach that one might anticipate. If

these conditions are such that these conservative assumptions do not apply, then you do not have to follow that particular conservative calculation.

The second point is with respect to the single parent that you mentioned of a child, who will be undergoing multiple treats. If, in fact, you went along with this request for per year being added into the requirement, we do, as I mentioned yesterday, have a mechanism in place already whereby a licensee can request and get expedited attention to a request for an exemption from that limit.

So it has been in place. It has been used. It does work. And I don't see any reason why it couldn't continue to do so.

MEMBER EGGLI: I agree, then. Will that be applied from region to region?

DR. ZELAC: Indeed, it is.

CHAIRMAN MALMUD: Thank you for asking the question, Dr. Eggli. And thank you for responding, Dr. Zelac.

Oh, Mr. Lieto?

MEMBER LIETO: Mr. Chairman, the reason I brought this up is I think there might be a point being missed here in my bringing it up in that we're talking just about therapeutic applications. What the

regulation states is for patients who are released who are administered radioactive materials. So it's just not therapeutics but also the diagnostics.

So let's say you had a patient that came in in January, you gave them five millicuries of I-131 for whole body assessment in preparation for an iodine therapy. Then you bring them back for a therapy of 150-plus millicuries for a therapeutic application. A couple of months down the road, patient because of the thyroid condition also has a heart condition. You bring them back for a cardiac stress study, which is not any small activities being administered either. In a year's time, you have given this patient three studies.

MEMBER EGGLI: Don't forget the PET scan.

MEMBER LIETO: Thank you. And the PET scan. So all of these dose assessments to the general public have to be added up and an assessment done. And I think it gets back to the reason, my point, really I think, as Dr. Fisher stated, is that I think that there is going to be an increased potential or increased burden on the licensee, which has not been realized before, plus the potential I think for patients not getting certain studies because they are going to go over that limit.

CHAIRMAN MALMUD: If I may address the second part of your question first? If there is a medical need for the diagnostic procedure or for the therapeutic procedure, it will be done, regardless of whether or not it exceeds an idealized goal, as long as there is documentation and the patient is aware of the risk to the patient from the procedure. We have not put limits on what patients can receive if they are informed of the risk and if the medical procedure is genuinely required.

In the example that you cited, it might be necessary for the patient who had a whole body iodine scan followed by 150 millicuries in less than a year, not much less than a year but in less than a year, have another 150 or 200 if the metastatic disease is still evident and that there is still uptake.

That patient's radiation burden is warranted as long as the patient is adequately informed from the medical perspective of the risks, the cumulative risks, of radiation to the individual.

That patient is also warned with respect to the risks to the family. And it is incumbent upon the treating physician to inform the patient of the risk to the members of the family or whoever lives with the patient from the radiation from the patient.

Now, the first part of your question was not the burden but -- what was the first part again?

MEMBER LIETO: Well, it was the burden on the licensee to keep track of all of the effective dose equivalents from these multiple studies and from the single patient and the potential that licensees may not want to do those studies because of that dose-limiting factor.

CHAIRMAN MALMUD: I don't think that we are required to keep dosimetry for patients who have received diagnostic or therapeutic, routine diagnostic, procedures or I-131 therapies other than the record, which is maintained longitudinally, of their treatment and, of course, the informed consent and explain to the patient what the risks are. Am I incorrect, Dr. --

MEMBER EGGLI: I believe that what Ralph is saying is correct, that the total exposure to a member of the general public from any individual who has undergone either a treatment or a diagnostic study with a radionuclide must not exceed the five millisievert.

And the issue that Mr. Lieto is raising for a licensee to be certain that that is, in fact, going to happen, particularly since for diagnostic

studies, patients don't remember them. And they shop around and get one at Kmart and one at Wal-Mart and one at our place.

And keeping track of the cumulative potential exposure to members of the public from a myriad of diagnostic and therapeutic studies becomes extremely difficult.

And I believe that the regulation as it's sitting in front of Ralph with the book open right now does not specify therapy versus diagnosis.

MEMBER LIETO: No, it does not.

CHAIRMAN MALMUD: This is Malmud again.

I have never been aware of a patient being refused a diagnostic procedure because he or she may in the course of a diagnostic procedure expose the public at large to more radiation than is acceptable.

I am aware of the need to inform the patient that they are temporarily radioactive and, therefore, that they should keep a distance from family members, et cetera, et cetera, et cetera.

Dr. Welsh?

MEMBER WELSH: Jim Welsh.

But I think that's the point that if we change the wording to say "per year," then it becomes incumbent upon the licensees to start to keep records

that we would not have kept at any time in the past.

CHAIRMAN MALMUD: Thank you for clarifying that. We would have to ask NRC staff what they think that the wording means. Dr. Zelac?

DR. ZELAC: The intent and I think the actual practice would be that when an individual was to receive a significant dose, a therapeutic dosage, of material, that at that point a computation would be made as to the dose to others with the circumstances for that person's release from the hospital.

If there was an expectation or a possibility that that person had received additional therapeutic doses within a year, then those certainly should be brought into light in terms of the physician's decision as to meeting or not meeting the requirement if, in fact, there had been previous doses, there had been previous exposures of other individuals, that those would need to be taken into account before this dosage and this release. And if, in fact, the limit of five millisieverts in the year appeared to be possibly exceeded, then an exemption could be sought.

Is there a need to take into account the small diagnostic doses, the small doses to others that result from the diagnostic doses? The answer is no.

And if you wanted to be conservative about it and make some assumption, I'll say that 10 percent of it, 10 percent of my limit, or 50 millirem, could have come from diagnostic doses received over the course of the year. Fine. Then do that. Let's be practical about this.

CHAIRMAN MALMUD: Thank you.

MEMBER WELSH: I have one other thing to say. I'm sorry. With respect to what is actually being discussed -- and that is keeping of records -- when the change from the previous release criteria, the 5 millirem per hour and the 30 millicuries, was made to be performance-based in terms of dosage to others, at that point when it was being proposed, there was a proposal that facilities would have to keep records for exactly this purpose.

And, in fact the proposed rule did have the word in there "per year." It was because of the objections from the medical community and the hospital community that this was removed with the presumption, as I said yesterday, that there would be -- and this was not unreasonable under the circumstances -- one treatment in a given year's time for a given individual, which is no longer the case.

DR. HOWE: Dr. Malmud?

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: If I could just add to that? And that was there was a requirement in the proposed rule to keep records. They removed the recordkeeping requirement.

MEMBER WELSH: I just said that.

DR. HOWE: Right. You indicated they took out the "per year," but you didn't indicate that it was the recordkeeping requirement. They actually did away --

MEMBER WELSH: I had keeping record in there.

DR. HOWE: They took it out, in addition to not putting the "per year" in. So I think the NRC has answered the question of whether we would expect licensees to maintain records.

And the only records that are required are specifically stated in 35.75 that if you don't use the standard way of calculating what a member of the public will obtain and you use some other factors, that you keep a record of those other factors in your calculation. But you do not have to maintain records from exposure to exposure to exposure if you don't trigger this.

CHAIRMAN MALMUD: Thank you for clarifying

that, Dr. Howe.

Did we have a member of the public? Please introduce yourself again.

MR. PFEIFFER: Doug Pfeiffer, AAPM.

In the State of Colorado, we are required to keep records for all of these releases. And it is indeed true that, even for diagnostic exposures, we are required to document that the dose is kept below this 500-millirem limit.

And, for that reason, changing it into a per-year limit is going to be a terrible burden upon us because of all of the shopping around to try to get records from all of these diagnostic and other releases from all of the different institutions that a particular patient might have gone to is going to be untenable for licensees.

CHAIRMAN MALMUD: Thank you.

Dr. Suleiman?

MEMBER SULEIMAN: I think there's a bigger concern in terms of the patient getting multiple therapies. So I think the bigger task is to make sure they know what the dosimetry is for the patient. So I think that would be the bigger burden.

I think the public dose and how many patients proportionately that get therapy are going to

be getting it several times during the course of a year, I think this is a very small proportion.

I also thought the guidance said "not likely to exceed." It's not an absolute. And, again, I feel that the uncertainty in these dose estimates, be it effective dose, effective dose equivalent, or whatever, are much greater than the precision in calculating.

So I think it is attainable. I think it is doable. And the alternative is just to leave it as it is. I think people are still going to have to counsel patients on what to do when they go home.

CHAIRMAN MALMUD: Thank you.

Other comments? Sally?

MEMBER SCHWARZ: Sally Schwarz.

I really think the issue is the patient at hand. That's having to go through these therapies. And I think that the chance to restrict the possibility for these therapies is the biggest problem. I think that the exposure to the public or to the family is the secondary consideration.

I think we shouldn't change the rule as it stands. It will increase burden on the licensees for recording. And I think that the amount of exposure to the public as a whole is really minimal. And

certainly the benefit to the patient is the thing that can't be overlooked that we don't want to restrict the possibility for those therapies if we need them.

And I would recommend not changing the regulation as it is.

CHAIRMAN MALMUD: Thank you for your comment.

Mr. Lieto?

MEMBER LIETO: Sally stated the issue about exemption. I find it kind of ironic in light of the discussion yesterday about granting exemptions. But I think that it's not realistic when you say, you know, that we make practical assumptions and whatever.

The fact that you have somebody from I'm assuming the regions bringing this issue up is to me just a red flag that obviously this is what is going to be done at the inspection and enforcement level.

They are going to come in. And they are going to say, "Boy, you do a lot of iodine therapies." Okay? Okay. Show to me that you have done some assessment on patients X, Y, and Z that they didn't get multiple studies or that the dose for multiple studies does not exceed 500 millirems to a member of the general public.

Right now the assumption has been that for

each individual procedure, as long as it is well below that, in the aggregate, you are below the 500 millirems to a member of the general public. But now what is being asked is that you provide the records to document that that has been done within an annual time period.

CHAIRMAN MALMUD: Thank you. I understand your concern. I am totally unaware of that ever having occurred. Has it occurred?

MEMBER LIETO: Well, it's because we haven't had the time limit imposed. It's always been based on a per-incident or -- excuse me -- per dosage administration that as long as your calculations prove that, you're fine. And you do have to keep calculations for every patient that you release.

So if there is an impression that licensees do not have to keep records for therapeutic applications on patient releases, that's not true.

CHAIRMAN MALMUD: We do keep records for every patient that we treat. We cannot keep records for the people with whom they have contact. We can only instruct the patient as to what the patient should do and the patient's responsibility regarding not irradiating other people around them. Beyond that, we can do nothing.

So that whether it's one treatment of 500 millicuries for metastatic thyroid cancer or whether it's 3 treatments of 150 millicuries, we still have no way of assuring that the patient has followed the directions.

And I have never known -- I haven't been on the Committee as long as some of you have, but I have never known the NRC ever to interfere with the actual delivery of health care to a patient in terms of a diagnostic or a therapeutic procedure. Maybe NRC staff can inform me if that has ever been done.

DR. ZELAC: No, to my knowledge, it has not been done.

CHAIRMAN MALMUD: It has not? No.

DR. ZELAC: I can interject, however, with respect to the recordkeeping requirement that has been bantered around here certainly it is in an individual licensee's best interest to keep records.

But there is not a requirement that records be kept unless -- and this is in 35.2075, the corresponding recordkeeping regulation for 35.75. A record needs to be kept if -- and there are four different considerations, the retained activity, rather than the activity administered was used for the calculation; an occupancy factor of less than .25 at

one meter was used; using the biological or effective half-life, as opposed to the physical half-life; or considering the shielding by a person's tissue. If any of those are part of the computation, then the record has to be kept to show where the result came from. Otherwise, using the standard computational technique, you don't need to keep a record or at least you haven't up until --

MEMBER GILLEY: Could I have the reference again, please?

DR. ZELAC: Yes, 35.207-5(a). In the books, it's on page 607.

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

MEMBER WELSH: It's Jim Welsh.

There's a motion on the table. And initially I was going to vote in favor of it, but after the discussion, I can see that I am now not in favor of including per-year terminology. Dr. Malmud has brought up the fact that there have not been any cases where NRC has interfered with the ability of the patient to receive the diagnostic study or therapeutic dose. And that has been confirmed by what Dr. Zelac just said. But if we change the terminology, it has the potential to occur.

The point I want to bring up now is the question that Dr. Fisher brought up earlier about the terminology, "total effective dose equivalent." Is this the terminology that is most appropriate for 35.75, regardless of whether or not "per year" is added in the end or not?

CHAIRMAN MALMUD: And your question is addressed to Dr. Fisher?

MEMBER WELSH: Specifically, yes.

CHAIRMAN MALMUD: Dr. Fisher, you are invited to respond.

MEMBER FISHER: If I'm correct, I think the basis for that is -- help me remember -- probably based on 10 CFR part 20 terminology. And the 10 CFR part 20 terminology is somewhat old compared to what the rest of the world is using, 1977 ICRP publication 30 and 26. So what that means that in rulemaking, NRC has to be consistent internally with 10 CFR 20, which is what they try to accomplish. So that means that these units in new rulemaking can be archaic as well.

It doesn't mean they are wrong. I mean, there is a good scientific basis for those units. One thing that is interesting, it is a bit complicated to determine this particular unit because of the complex way of calculating the shallow dose equivalent from a

photon emitter, such as iodine-131 to an off-site member of the general public. That is not trivial. So using that unit, rather than effective dose, adds some complication.

Also, then it would force one to consider whether or not the nearest member of the off-site general public had received any internal radionuclide burdens, which contribute to that dose, and we don't do that right now with our standard patient release calculations.

CHAIRMAN MALMUD: Thank you.

Dr. Vetter?

VICE CHAIRMAN VETTER: If we look at part 20 definitions, total effective dose equivalent means the sum of the deep dose equivalent for external exposure --

MEMBER THOMADSEN: Can you give the reference that you are looking at right this second?

VICE CHAIRMAN VETTER: Page 327.

MEMBER THOMADSEN: I'm sorry. Page 327.

VICE CHAIRMAN VETTER: Under definitions of part 20, total effective dose equivalent means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures. That implies that you are going

to measure with an external dosimeter or something. You're not going to be calculating that.

CHAIRMAN MALMUD: We do use an external dosimeter on our therapy patients.

VICE CHAIRMAN VETTER: But you don't use it when you are computing. Let's see. I guess I don't know what the guidance uses. Did it use TEDE in the guidance? That's probably what they use. The formula is a means of estimating the TEDE. And I think the guidance also assumes that there's no dose from internal. So it becomes simply deep dose equivalent.

CHAIRMAN MALMUD: Dr. Welsh, you were next.

MEMBER WELSH: If I could just follow up with this? I understand the appeal of being consistent with part 20, but if you had your druthers, which terminology would you prefer and recommend in 2007 to minimize confusion and improve clarity and make this so that the people will not read this and say, "What do I have to do to make my calculations for the year? What kind of loopholes are in existence with this terminology? What is the clearest terminology right now?"

CHAIRMAN MALMUD: Next was Dr. Suleiman.

And then, Janet, you follow on.

MEMBER SULEIMAN: My understanding, effective dose equivalent was determined by the ICRP in 1977 so that you could relate partial body irradiations with whole body irradiations. That since has morphed into effective dose, which was in 1991.

In terms of the uncertainty and the underlying risk in the organ weighting factors, they are essentially the same. I mean, they are different but not in a significant, plausible way. And the main reason for the changes is because as science moves on, we understand better the risks of different organs to radiation. So the current unit would be effective dose. So, if anything, I would recommend the NRC adopt the most current, you know, definition by the ICRP.

But this is supposed to be simple. And we make it confusing because external X-ray beams came into play or external radiation. So people said, "How do you relate the dosimeter badge to a whole body dose?" That's why you don't worry about internal because you have already gone through this exercise in calculating dose for the organs, and you come up with effective dose or effective dose equivalent.

If you know what the doses are from the

radionuclides or whatever, you don't have to worry about the shallow portion because you have already got those numbers.

And so I think the effort to come up with a shallow dose was intended to make it simpler, and now it sounds like people are trying to come up with the shallow dose interpretation, which is making it a little bit more complicated.

But I think to be a single unit, I think you should go to the most current ICRP definition, which is slightly different than the 1991 version, and use effective dose, which would require a rule change. But, practically speaking, I don't think there's any real difference in the calculated values, no matter which method you use.

So I think there is an awful lot of argument over some real minor issues.

CHAIRMAN MALMUD: Thank you.

Janet?

MS. SCHLUETER: Well, they're all excellent points. And I would make a comment similar to yours, Orhan, in that until the NRC makes a decision to holistically adopt more recent dose methodology through ICRP or other recommendations, I am very concerned with going into just part 35.75 and

making that sort of terminology change to a rule that has been in place for 10 years that we're really not seeing any negative impact because of the use of the older terminology.

CHAIRMAN MALMUD: Thank you.

Yes, Dr. Vetter?

VICE CHAIRMAN VETTER: Getting back to the original question, have we seen any negative impact from the expression of the limit based on a dose, as opposed to a dose rate of five millisievert per year?

MS. SCHLUETER: I'm not aware of it.

VICE CHAIRMAN VETTER: There's a member of the public who has a comment.

MS. SCHLUETER: She's NRC staff. You will have to come to the microphone, Neelam.

CHAIRMAN MALMUD: Please introduce yourself.

MS. BHALLA: Yes. I'm Neelam Bhalla. I'm with the rulemaking Branch in the Division of -- it's FSME.

So going back to the question, I have also been an inspector in Region I. So going back to was there any example, yes, the University of Pennsylvania. In fact, there were people here from that institution.

They did increase the caretakers. They had children who are getting radiation, iodine-131 treatment. And those family members could not just stay with 500 millirem a year dose. And, therefore, they came up for an exemption to the regulation.

And NRC did give that license has been granted up to two rem for family members. And that is because these parents when their children are in the hospital, then the parents come and take care of these. Family members are there.

They are treated almost as radiation employees because they are given all of the training. They are informed of the risk. And then they are able to stay with their children.

So yes, there are examples. And there could be some other licenses, too, but that is one example certainly where we have granted an exemption and the licensee could not work with the 500 mR.

CHAIRMAN MALMUD: Thank you. Does that address your concern?

VICE CHAIRMAN VETTER: No.

CHAIRMAN MALMUD: Dr. Vetter?

VICE CHAIRMAN VETTER: I think that's an example. I think that's an example of what Dr. Zelac mentioned earlier, that, in fact, licensee could go to

their regulator and have the limit changed for a particular procedure.

What I was asking is, has there been demonstrated any negative impact on the public from this limit of .5 rem per year? And I think the answer is no. And so why are we fussing with it basically?

So I guess personally I change my position on this because of the complexities of the issue. I also personally think we ought to go to an annual limit, but I don't think we're ready for that. It's just too complex.

CHAIRMAN MALMUD: Thank you.

So Dr. Welsh?

MEMBER WELSH: If I could respond? I would say to Dr. Vetter's point that the reason why we don't have any examples is because it's not written at a rate currently. It does not say per year. So we don't have any examples because there is no rule to violate here.

As soon as we change it, we might find that we will see situations in which this is going to be a problem.

VICE CHAIRMAN VETTER: I guess the point I was trying to make was if there is a problem with the current limit the way it's expressed, then we ought to

be dealing with it. But there isn't.

CHAIRMAN MALMUD: All right. Now, is there a motion on the floor?

VICE CHAIRMAN VETTER: Yes.

CHAIRMAN MALMUD: And what was the motion? Do you recall?

VICE CHAIRMAN VETTER: The motion was to approve the recommendation that Dr. Howe brought before the Committee yesterday to change the limit from 5 millisievert to 5 millisievert per year.

CHAIRMAN MALMUD: That's a motion which has been moved and seconded.

VICE CHAIRMAN VETTER: Right.

CHAIRMAN MALMUD: I see another hand raised. Was that Dr. Zelac?

DR. ZELAC: If you're into discussion on the motion.

CHAIRMAN MALMUD: Yes, we are.

DR. ZELAC: Okay. You may remember that this came up as an issue because there was a licensee who wanted to give multiple treatments over the course of a calendar year or over the course of a year. And the resultant dose to the most highly exposed other individuals from this patient would have far exceeded the five millisieverts. And the question was, how

should this be handled?

In fact, an exemption was given in that case, too, but the point is that these are coming up, multiple treatments in less than a year, more frequently, much more frequently than had ever been the case before. And these are going to keep coming up. And the same question is going to keep coming up. That's point one.

The second point is we have done it before, we will do it again. But we are out of synch with the rest of the world if you leave it the way it is.

Both the NCRP that Dr. Vetter has mentioned as well as the ICRP have both recommended annual limits. And everybody else is buying into it. Why shouldn't we? Is our ability to provide medical services that much inferior to the rest of the world that we can't do this?

CHAIRMAN MALMUD: Longevity statistics suggest that our delivery of health care is inferior to much of the rest of the Western world.

Any other comments before we take a vote on this issue?

(No response.)

CHAIRMAN MALMUD: All in favor of the

motion, which is to include per year? Vote yes?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: All opposed?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: The nays carry it. Were there any abstentions?

(No response.)

CHAIRMAN MALMUD: It was, what, seven nays?

PARTICIPANT: That sounds good.

CHAIRMAN MALMUD: Seven nays, too yeas. Thank you. We have covered that subject.

Next item on the agenda?

MS. WASTLER: Well, actually, we've managed to come back, all the time that we had. It is now 3:15, where we are scheduled for a break until 3:30. And then Dennis Rathbun is here to make a presentation.

CHAIRMAN MALMUD: We will take a break until 3:30.

MS. WASTLER: So we are back on schedule again.

(Whereupon, the foregoing matter went off the record at 3:20 p.m. and went back on the record at 3:37 p.m.)

CHAIRMAN MALMUD: If we may, before we begin, before we introduce the next speaker, we wanted to make certain that we had the count correctly. We are not looking to change the count, but we were missing one vote. It may have been nine to one or nine to two, instead of what it was.

So can all of you who voted against the motion please raise your hands?

(Whereupon, there was a show of hands.)

MEMBER EGGLI: Including Ralph Lieto. Ralph?

CHAIRMAN MALMUD: Five.

MEMBER EGGLI: And Meg.

CHAIRMAN MALMUD: Eight opposed.

PARTICIPANT: And Ralph.

MEMBER EGGLI: Did you get Ralph?

CHAIRMAN MALMUD: Nine.

MEMBER EGGLI: And Subir? What about Subir?

CHAIRMAN MALMUD: How did Subir vote?

PARTICIPANT: He voted with the majority.

CHAIRMAN MALMUD: That's nine, right?

MEMBER EGGLI: No. Ten.

CHAIRMAN MALMUD: Let's try it again.

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Ten against, two for. Let the record show that the vote was officially ten.

MEMBER THOMADSEN: We can only have 11 votes.

CHAIRMAN MALMUD: Ten for.

PARTICIPANT: Does it make any difference, nine to one or ten to one?

CHAIRMAN MALMUD: Absolutely. We have to be precise. You know, this is a very precise group made up of physicists and mathematicians.

PARTICIPANT: Okay. Now that everyone is here --

MEMBER THOMADSEN: I think we should just add an uncertainty to the vote.

CHAIRMAN MALMUD: Well, we can do that.

PARTICIPANT: Let's take ten votes and take the average.

PARTICIPANT: Nine to two.

MEMBER SCHWARZ: I think you have nine to two.

CHAIRMAN MALMUD: Nine to two? Nine to two.

MEMBER NAG: What was this for?

CHAIRMAN MALMUD: It was the last vote. We were missing one vote. We wanted to make sure that

the entire count was in. It was nine to two.

And are we back on schedule? In that case, we will move forward, and I will spare you the story about the vote, I mean, the joke about a vote, not about this vote.

So we now have Dennis Rathbun, who will talk to us about the NRC petition process. He is from the Division of Intergovernmental Liaison and Rulemaking. Am I correct?

MR. RATHBUN: Yes, sir. Now, thank you, Dr. Malmud.

CHAIRMAN MALMUD: We welcome you here.

MR. RATHBUN: Thank you.

16. PETITION FOR RULEMAKING (PRM 35-20)

MR. RATHBUN: Yes. Let me just describe a little bit of what we do in our petition process. I think, as I understand it, it is somewhat unusual. I don't believe that one of our members of our petition review board has come down here before. I could be wrong.

However, what we do do is after we have received a petition and it's docketed, we will assign a project manager, as we have done for this particular petition. And then we will form a working group, which will review the petition and the public comments

and develop a recommended resolution of the petition, which could be either to -- yes?

MEMBER SULEIMAN: What constitutes a petition? Does it have to be filled out a certain way or can it just be some statement with a bunch of signatures?

MR. RATHBUN: We'll get to that in just a second.

MEMBER SULEIMAN: Okay.

MR. RATHBUN: Anyway, they act in some ways as our agent, the petition review board, and review the material before them. The working group has as its responsibility to review the petition, any supporting information presented by the petitioner, and any public comments received.

They will then on their own motion develop an analysis of that petition independently of the petition review board; identify each of the regulatory issues which the petitioner raises; describe the rationale for each requested action by the petitioner, including any supporting information; identify the key points made by the commenters, which they may summarize as they see fit; and indicate how the petition supports various agency performance goals; and identify the advantages and disadvantages of each

issue and recommend for the petition review board's consideration a course of action.

The working group briefs the petition review board. I have been involved in that for a year now. It is actually sort of an interesting activity. They may, the working group may, deny the petition, recommend that we deny the petition, or grant the petition, or grant in part, or deny in part.

And not on the viewgraph here, but in a number of instances, the petition review board will develop areas where we would like the working group to look further. And we have done that a number of times.

The petition review board is composed of the deputy director of the new Office of Federal and State Materials and Environmental Programs, myself as the division director, and the Division of Intergovernmental Liaison and Rulemaking, Mike Lesar of the Admin Branch, and Janet Schlueter from our Division of MSSA. And then, of course, we will have a lawyer, who is in general Chip Cameron on these activities, Assistant General Counsel for Rulemaking and Fuel Cycling.

The petition review board, as I said earlier, can accept the recommendation of the working

group or refer it back to the working group. That happens a number of times in which we have been involved and have questions where we would like additional thought analysis. We may even ask for a public meeting, which we have done at least on one occasion.

Let's go on to the next one.

MEMBER NAG: You cannot deny the petition. You can only approve, approve in part, or send it back to the working group.

MR. RATHBUN: No, no, no. We can deny.

MEMBER NAG: I don't see that.

MR. RATHBUN: We can deny it.

MEMBER GILLEY: Well, that's the working group.

MR. RATHBUN: Oh, I see.

MEMBER GILLEY: There is a distinction.

DR. HOWE: And then you can accept the working group recommendation.

MR. RATHBUN: Right, right, right. Let's go on to the next one.

The petition review board decision will be considered to be the resolution of the petition, requested action. If the petition is granted, in whole or in part, the proposed rule goes into the

rulemaking process. That has happened in at least one instance, my experience, in the past year.

If the petition is denied, the denial package is prepared for the executive director for operations or the chairman to sign. And then the denial is posted in the Federal Register as a resolution of the petitioner's proposed action.

Now, with respect to the petition from Dr. Russell Ritenour, let's go into this one. Dr. Ritenour wrote, as I recall, in September of 2006. It was docketed by the NRC on September the 13th; i.e., accepted as a legitimate petition for us to consider.

On November the 1st, the Ritenour petition was posted in the Federal Register, our Office of Administration. On January 16th, which I believe is a 75-day public comment period, the comment period closed. And then on April 11th, the working group began its own analysis of the issues raised by the petition.

Dr. Ritenour asked for an amendment to 10 CFR 35.57 which would if granted recognize medical physicists certified either by the ABR or the ABMP on or before October the 24th of 2005; i.e., as grandfathered, for the modalities that they practice as of October the 24th of 2005. And that change would

be independent of whether or not a medical physicist was named on an NRC license or an agreement state license as of October the 24th, 2005.

In addition, the doctor would cause us to recognize all diplomates that were certified by named boards in subpart J for the radiation safety officer, who had relevant timely experience, timely work experience, even if they had not been formally named a an RSO or an assistant or an associate RSO. These diplomates need to be grandfathered as an RSO by virtue of the certification provided the appropriate preceptor statement is submitted.

I'm sure since ACMUI has been involved in this for some time and participated in the revision to the training and experience rule promulgated by NRC in 2002 and then promulgated again in 2005, part 35, subpart J was retained for a two-year transition period in 2002 and extended in 2004. It expired as of October the 24th, 2005.

And the AMP, authorized medical physicist, and radiation safety officers listed on licensees prior to the effective date were grandfathered. The Commission directed that all boards, both new and existing, must meet the new requirements in part 35.

We received 165 public comments. I have

gone through several of them prior to coming down here, 108 form letters, 10 professional association-submitted comments. And most of the comments were in support of the petition.

I am informed that the Committee has approved a resolution and that June 12th, 2007, that the Committee passed a motion, which the NRC staff should revise the regulation so that previously board-certified individuals who were certified prior to the effective date of recognition are grandfathered.

The working group membership consists of the project manager from our Division of Intergovernmental Liaison and Rulemaking, a Medical Safety and Event Assessment Branch representative, a representative from the Office of the General Counsel, a representative from the Office of Information Services, from the Office of Administration, and from NRC Regions III and IV, as well as a representative from the Organization of Agreement States.

Right now the working group is reviewing the petition and the public comments. And they are in the course of analyzing these comments. They expect that they would be making a recommendation to the petition review board by the end of the year.

How the PRB would react to that I don't know. I am a member of the PRB. And I am certainly not in a position to speak for them. I've learned some amount of my own review of the materials here in the course of preparation to come down here.

So that's where we are. I am informed that the Committee asked that someone come before you and explain a status of where we are. I think I have a reasonably good idea of what the sentiments are of the Committee. However, there are probably some things that could be useful in one way or another to inform us with respect to impacted individuals.

I know that a couple of the public commenters were concerned that there would be medical physicists who through the process could have difficulties in continuing to practice their medical physics. I understand that. That was pretty clear from several of the public comments.

MEMBER NAG: Mr. Chairman?

CHAIRMAN MALMUD: Yes?

MEMBER NAG: Obviously a petition process is a more complicated and long-term process. Would you tell me the difference? If the same issue were brought up by ACMUI, what are the differences?

ACMUI, for example, knew about this, knew

about the problems. And if we had brought it up and gave our recommendation to the NRC, what would the differences have been? And would it have less weight or more weight or whatever?

MR. RATHBUN: Well, I can only speculate on that. I mean, as I understand it, you are an advisory committee to the division director, Janet, in MSSA. And that would be a different process than a petition submitted to the Commission from an outside entity, in this case Dr. Ritenour.

I am familiar with our petition review board process, but I am not sure if it would have more weight or less weight or whatever. I mean, if there is merit to the issues which were raised and they have to do with meeting our responsibilities for protection of public, of course, I think they would have to be listened.

MEMBER NAG: Would the time commitment has been a lot less if we were to do it directly from the ACMUI or not? I mean, someone from NRC --

MS. WASTLER: The processes are slightly different. I don't think I would go so far as to say that the time differences would have been tremendously different for various reasons. One, any recommendation that comes from the Committee on making

a change, then we, as staff would take it, evaluate based on the basis that you provided us.

And then we could make -- for example, in this case, we could have said, "All right. We will make a recommendation. Put it in our part 35 user need letter," which would have gone over to Dennis' group and then gone into the rulemaking process. And then you would get into the comment process. All right?

PARTICIPANT: Very similar.

MS. WASTLER: It's very similar, but to say that there are huge differences in time is not necessarily the case because once you get in the rulemaking, it would be more cumbersome.

In the petition sense, you deal with a lot of the questions. You get input from the public up front. All right? A little more. And then you go into rulemaking. And you still have the public process, but some of those have been identified up front as part of the petition process.

So in some cases, it could balance out. It could go either way.

MR. RATHBUN: Yes. Sandi makes a good point. I mean, basically an action for rulemaking could be initiated from inside as well as outside and

could come to you; to MSSA; and then, as you know, a user needs memo; and to us, a call for action. And then it would go through a similar kind of process in which it would be published for public comment and try and enrich ourselves, find out more about what is actually going on.

Does that answer your question?

CHAIRMAN MALMUD: Are there other questions or comments?

MS. SCHLUETER: I just for the record wanted to clarify for Orhan that it's on page 95 in the 10 CFR book here. It's part 2.802, which describes petitions for rulemaking. And it's very prescriptive as to what constitutes the petition for rulemaking.

I mean, essentially, just as this one did from Mr. Ritenour, you must specifically identify a rule or portion of a rule that you believe will warrant some sort of modification and a basis for that change so that it gives us some specifics on which to base a decision and further review by the working group.

It's very narrow. The petitions for a rulemaking are pretty narrowly defined.

MS. WASTLER: And it depends on the

petitioner to make the case.

MS. SCHLUETER: Yes.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Yes. I'm just trying to understand some of the details here. You indicated that the working group analysis began in April. Are they done with their analysis and are ready to present to the petition review group?

MR. RATHBUN: No.

MEMBER LIETO: How much longer in terms of analysis?

MR. RATHBUN: What I am informed is that they were of the mind that they would have something ready for us to consider, you know, I guess by the end of the year.

But, quite frankly, many times we will develop our own based upon their analysis and discussions that we had with them as our agents or working group, some additional issues that we want them to explore. And then we will ask them, "Would you please go back and develop some more information and get some more facts for us to consider?"

And one scenario, which has happened at least once, "We said, "Well, we would actually like to hear some more from the petitioner" or "more from" --

you know, and we do that from the public and what.

So I think it's a fairly laborious and thoughtful process and can be sort of time-consuming, but what we try and do is give a good, honest, independent look from our responsibilities for protection of public health and safety of what is being brought before us for consideration.

MS. SCHLUETER: So the working group may come to the petition review board more than once.

MR. RATHBUN: Right.

MS. SCHLUETER: And the working group members are working on many other items, projects, tasks, but this isn't their full-time job --

MR. RATHBUN: Right.

MS. SCHLUETER: -- or clearly it wouldn't take them until the end of the year. You know, it's our staff that have many other responsibilities, too.

MEMBER LIETO: Are there any things that the regulated community can do to urge this to come to some resolution? Because from what you are telling me, I notice that there are no time lines on how long a working group has to respond or a petition review group has to respond to them and then back and forth.

I mean, from what it looks like, you can do this ping-pong back and forth for years until most

people kind of retire or go away. Some of us don't go away, but the --

CHAIRMAN MALMUD: Don't tempt me.

(Laughter.)

MEMBER LIETO: You had mentioned like the impacted individuals and there might be maybe an increased sensitivity that's needed by the working group as to the impacted individuals. If that information is needed, can they come back to the ACMUI and say, "Listen, you know, this is the type of thing that we need" or would they go directly to the petitioner or how is -- because this is the first we are hearing from it.

We're glad that you're here. And we're wondering why we didn't hear about it previously because I think this affects not only just authorized medical physicists but people who want to become RSOs. And the big problem that this Committee has already addressed in a couple of different situations is that you only have one RSO name to a license. Okay?

So the whole issue of preceptor RSOs and others that can fill this need is a very sorely impacted group.

MR. RATHBUN: Well, you raise several very good issues. First, I have been concerned since I have

been in the Division of Intergovernmental Liaison Rulemaking about pace and tempo and trying to get things done.

Secondly, I do try and have a sensitivity to I guess what I would call order with importance with respect to things that I think are important to the Commission, security perspective or medical or this or that.

But I will say it is difficult to come up with a cookie cutter as to time lines that would be applicable to every petitioner or proposed rule for no other reason than they are not all the same.

I mean, some are very complicated, and some are fairly straightforward. Some of them can be done by one person, you know, working on ten different rules. And some of them take a lot of work by a variety of people.

With respect to this particular one, there's a paper that I have been informed of that draws attention to the authorized medical physicist and a requirement for compatibility by agreement states. If I recall, it was like April the 28th of 2008.

And so there is a tempo associated with that, too. And I think there is also a tempo from

those who are, we'll say, agreed who might be disenfranchised in some way because they can't practice their arts and crafts anymore because they weren't listed on a license, actually, in the public comments.

And so that's something that at least I have been apprised of. But I am only one member. And I think that the Committee could -- you know, there is reference in some of these comments about never the intent of the Commission to deny recognition to any medical physicist currently practicing and so forth and so on, that there could be a shortfall of authorized medical physicists to serve as preceptors and alternative pathways, very complex, and so forth and so on. But these are some of the words from either the petitioner or petitioners.

I have heard -- I think it is hearsay -- that there could be people who are in this category, that in large urban areas that -- maybe it's not a problem if they're in some remote sites in West Texas and other places and they weren't listed on the license, one of the commenters said that -- what was it? -- something that whoever would certify him were now dead or scattered in the winds or something because he had been practicing for 27 years and begins

to relate to some of this.

There are issues. And we try and be sensitive to them. You know, it's not something that has an easy answer.

CHAIRMAN MALMUD: Thank you.

MR. RATHBUN: Yes, sir.

CHAIRMAN MALMUD: Dr. Fisher?

MEMBER FISHER: Now, take the example where the issue is simple, the issue is urgent, the issue is important to both the patient community and the medical community.

What is the most rapid time frame under which a very practical needed rulemaking could be accomplished? What is the minimum amount of time required to implement a very necessary, important, and practical change?

MR. RATHBUN: It can be very short, but my personal opinion is this wouldn't fall in that category. But if there were an urgent security-related matter or reactor meltdown matter or something of that -- do you understand what I mean, imminent threat to public health and safety? And based upon my professional experience around here over some years, this would not meet that test.

I mean, the Commission can go and, in

conjunction with the General Counsel's Office and the technical staff, come up with a remedy to an urgent problem in very short order. But that's not normally what happens.

MS. SCHLUETER: The fastest mechanism that we have is referred to as a direct final rule, where there is no public comment period. And we can go down that path, but as an agency, we have to be confident that there won't be public comments that come in that would hit a certain threshold because it throws us right back into the rulemaking process.

So then when we go into the rulemaking process under the Administrative Procedures Act, both for a petition for rulemaking or if we initiate it, we have to have a minimum of a public comment period of I think it is 75 days. Office of General Counsel is in the back. They can correct me.

So, at minimum, we're talking about rulemaking takes a few months if we do not have the luxury of going direct final rule, which we don't usually do in the medical arena for obvious reasons.

CHAIRMAN MALMUD: Thank you.

Other comments or questions? Mr. Lieto?

MEMBER LIETO: I would make the statement that I would disagree that there is not urgency

associated with this. The example you give, I would think that if there were imminent health and safety issues, you wouldn't be waiting to hear from us. The commissioners would probably be on your -- you know, would have established corrective action and said, "Do this now."

MR. RATHBUN: I agree.

MEMBER LIETO: I mean, this affects patient care. I can tell you from personal experience that there is a tremendous amount of resources being expended by licensees to get individuals named to licensees, going through all of these hoops to be jumped through, records, and so forth.

And we are not doing anything except delaying the inevitable that these people do get on the license and whatever, but it is taking months. And I don't mean like two and three months, much, much longer than that.

And that's why I was asking that, because there is no time line here. I know that normally the Commission has metrics associated with various tasks. And I would think that there would be at least a metric where there would be at least a turnaround of some type of action within a certain period of time before the ball is put back in somebody else's court,

just, in other words, that there is progress being made.

And I just don't get a sense that since analysis began on April 11th, well, that the progress, in other words, has been very, very stagnant. And, now, that may not be the case, but the fact that they have not even made some type of transfer to the petition review group raises concern that this is going to take years.

MR. RATHBUN: I tell you, what the petition review board would very likely say to the circumstance that you describe is, "What tangible evidence can you give us to support that kind of assertion?"

It is stated, not with the urgency that you attach to it, Mr. Lieto, but it is stated in some of the comments, that there is a risk that there will be people -- that there will be some shortfall in the supply of authorized medical physicists, you know, things of that nature.

And, of course, that is a concern. Absolutely that is a concern. But that is not quite the same as -- and, you know, I understand the assertion of junction with patient care, but that is still less than I guess supporting tangible evidence

to make that case. And if you have that, I think that the Committee would want to bring that forward, one way or another.

I mean, really, honestly I think if you have something -- I know your resolution. I understand that. But I think that what people will be looking for is supporting data and information to support some of the types of comments that I have seen in the public comment.

MEMBER LIETO: Just a follow-up question. With that data, would that go to yourself, Mr. Rathbun, or should that be sent to Janet, I mean, or should it go to the working group chair, whoever that may be?

MS. SCHLUETER: You can mail it in to either one of us.

MEMBER LIETO: Okay.

MS. SCHLUETER: We would send it to the working group chair.

MR. RATHBUN: We're not going to stand on form with respect to who you address it to.

CHAIRMAN MALMUD: Thank you very much. We appreciate your visiting with us, filling us in on the process.

MR. RATHBUN: Well, thank you.

CHAIRMAN MALMUD: With that, we will move on to the next agendas item, which is going to be the conclusion of this meeting and some paperwork that needs to be done.

MS. TULL: No.

CHAIRMAN MALMUD: No?

MS. TULL: No paperwork this time?

MEMBER NAG: Are you getting money?

PARTICIPANT: No conclusion or no --

MEMBER NAG: No payment.

MS. TULL: What I'm about to --

PARTICIPANT: We forgot to tell you about that change?

17. CLOSING

MS. TULL: What I'm about to pass around is a draft, a very rough draft, of all of the motions and action items that were made. So, as I go through them, you can see them, follow along. If there are changes when the meeting summary comes out or the recommendation memo comes out, it's because I looked at the transcripts. These are not vital.

Those are coming around. And I am also sending -- here is a 2008 calendar for April so we can schedule our next meeting. I crossed off some dates that we can't pick from.

And while those are going around, we are not completing any paperwork right now because we are going to do it all after the meeting. So for your time sheet because a lot of people go home and you have an extra travel day, something comes up, you do subcommittee work on Thursday, and then you have to resubmit your time anyway.

So we're going to try the new process for turning in time. Tami or I will send you an e-mail tomorrow that will have the regular form 148 attached to it that you always receive. And then you will fill it out, quick submit e-mail. Your time will be submitted. And then you will print it off, sign, and mail it to NRC. So that is how we are turning in time from now on.

And then the second thing is your travel vouchers, which is how you claim expenses for this. We're not having you sign them while you are here. Again, things always change. I understand flights get delayed, things happen.

So you will get an e-mail with the .pdf attached. You're going to fill out your own travel voucher this time. And I will send an example of one I have completed because I do them all the time. And I will also highlight any blocks that you need to fill

out. There are a lot of blocks on this form. I understand that.

I did a little test run with Mr. Lieto and Dr. Vetter when they came in July. I sent them the forms, said, "Complete these. Let me know if you have any questions." And it seemed to be a pretty straightforward process.

So if you want to get paid for your travel, you are going to have to do your own expense report this time. We're all growing up.

MEMBER NAG: And everything will be approved.

MEMBER LIETO: Her point is that if Dick and I can do it, anybody can do it.

(Laughter.)

MS. TULL: I will send you examples. And I will try to make it as easy as possible. And we will need the original. So when you fill it out, there's not going to be any e-mailing back and forth. You are going to sign the original, send it in to Tami. And then we will get them to travel to get you your money back.

And right now I don't know if travel is backed up or what, but it is taking me about three weeks to get my money. So don't be surprised. You

know, if you want to call us a month later and you don't have anything, let us know. But if it's two or three weeks, give it a few days. So it is taking time to get money back.

Okay. So now everyone has the handout for the motions. Do you have anything?

CHAIRMAN MALMUD: I have a question for you. Oh, do you want to do the motions first or the calendar first? What did you want to do first?

MS. TULL: Motions.

CHAIRMAN MALMUD: Okay.

MEMBER NAG: Can you send one of the motions back to --

MS. TULL: We have an extra copy.

PARTICIPANT: It's two pages?

MS. TULL: There are two pages. There is a page of motions and a page of action items. Those are two separate things.

PARTICIPANT: I do have an extra page of action items up here.

MEMBER NAG: The action is the motion.

MS. TULL: No, they are separate in the eyes of NRC. Motions are recommendations we have to consider and make a policy decision on. Action items are to-do's or ACMUI items on which to act.

Okay. So the first page is motions. The first motion is that "AU should sign all orders for byproducts material requiring a written directive." This motion did not pass.

The second motion, "Elekta Perfexion should be regulated under 35.1000 until 35.600 is modified to be performance-based, which allows the Perfexion to be included in 35.600." That I believe did pass.

The next motion, "Accept NRC's staff proposed change to 35.57(a) for experienced RSOs, AMPs, and ANPs to require the experienced individual to receive additional training if the individual is seeking authorization or responsibility for new uses." This motion passed.

The fourth motion, "Accept NRC's staff proposed change to 35.57(a) for experienced RSOs, AMPs, or ANPs with modification. There would be no requirement for experienced RSOs, AMPs, or ANPs to obtain written attestation to become authorized or have responsibility for new uses." And then the modification is to use words from 35.50(d), instead of only referring to it. And that motion passed.

The next one is to "Accept NRC's staff proposed change to 35.75 to release patients if the

total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed five millisievert per year."

The first vote that we took was five-five. The second vote that was taken after we received the subcommittee report was two to nine. So this motion did not pass.

The next motion, "Accept NRC's staff proposed change to 35.491(b)(2) to specify superficial ophthalmic treatments." And that passed unanimously.

The next one, "Reject NRC staff proposed change to 35.491(b)(3). NRC staff should put regulations for intraocular devices into 35.490." That motion passed.

"Accept NRC staff proposed changes to 35.400, 500, and 600 to not require medical licensees to only use the sealed sourcing devices as approved in the SS&D registry." That motion passed.

Next, "Accept NRC staff proposed change to 35.290 to allow physicians to receive training and experience in the elution of generators and preparation of kits under the supervision of an ANP. That motion passed," back of that page.

"Vote to form a subcommittee to annually review byproduct material events, perform analysis,

and report to full Committee at spring meetings." Lieto will be the chair of the subcommittee. And the subcommittee also includes Dr. Nag; Dr. Thomadsen; Dr. Suleiman; and agreement state rep, which will be Ms. Gilley, any staff designated; and also NRC designated staff. That motion passed.

The next one, "ACMUI will publish subcommittee reports on byproduct material events as necessary to ensure the end user receives the message." That motion passed.

"The written directive for yttrium-90 microspheres use may include dose at targeted organ, which means dose in rad or Gray, or activity administered, which would be dosage in millicuries." That motion passed.

MEMBER NAG: That should be millicurie/gigabequerels.

MS. TULL: Okay. The next one, "Accept NRC change to include a paragraph for medical event reporting for yttrium-90 microspheres use." So this would be similar to 35.3045, "Medical Event Reporting." The motion passed.

Next one, "Accept NRC change with modification for paragraph inadvertently deleted from yttrium-90 microspheres guidance." The new paragraph

will read, "Procedures for administrations requiring a written directive should for yttrium-90 microspheres use be performed in accordance with the written directive." That is one that I will have to go straight to the transcript for as well. That one passed.

Next, "Accept NRC change for notification of experienced AUs becoming an AU on a new license similar to notification under 35.14." The motion passed.

Next, "Accept NRC change." The new paragraph will read -- oh, this is the proposed change, "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." This one did pass.

Next, "Reject the NRC staff proposed change." And it looks like the ACMUI proposed a modification. "The written directive should include after implantation but before release of the patient from licensee control, the radionuclide, including the chemical physical form yttrium-90 microspheres, the manufacturer, treatment site, and the total dose or dosage." That motion passed.

This last one I'm going to have to go straight to the transcript for. It deals with T&E. Your three main points are to accept the board standards for training for each program, to accept the board certification without attestation, and to replace "competence" with "has met the training and experience requirements," which struck the word "minimum."

Is everyone okay with those? Dr. Suleiman?

MEMBER SULEIMAN: I was going to let it go, but, just for accuracy, yesterday when we had the other vote where it was a tie and then Dr. Malmud voted and there was a question about whether he could break a tie or not --

MS. TULL: Yes.

MEMBER SULEIMAN: I mean, I went home and I brought Robert's Rules of Order. All right?

MS. WASTLER: I was going to address that particular question, but since we went back on that one --

MEMBER SULEIMAN: Voted.

MS. WASTLER: -- and re-voted, it is a moot point. But I did go back and read through the bylaws and was going to address that.

MS. TULL: The Chair can vote according to ACMUI bylaws.

MEMBER SULEIMAN: And Robert's Rules also say the Chair not only can vote to break a tie, a Chair can vote to make a tie and, therefore, would prevent something from --

MS. WASTLER: But just to respond to that while the question is out, and if you go through the bylaws, in the preamble, it specifically states that for parliamentary matters not explicitly addressed in the bylaws, Robert's Rules of Order will govern.

In this particular case, though, it specifically states that: one, with regards to the votes, a majority of the current membership is required to constitute a quorum. So, in other words, it is majority rule for the votes.

And the chair may take part in the discussions of any subject before the ACMUI and may vote. Therefore, because it has to be a majority rule, when there is a five to five vote, there is no majority. And it does not pass.

MEMBER NAG: Thank you. I think that was when the chair did not vote, right? How was that in --

MS. WASTLER: No. In this particular

case, the bylaws say that the chair will take part in the decision and may vote. It also says the decision shall be made by a majority vote of those members present and voting. So if there are ten members here and voting and you have five for and five against, that is not a majority.

MEMBER NAG: My question was, when it was at five-five, was it with or without the chairman?

MS. TULL: Without.

MEMBER NAG: It was without. So if the chairman was allowed to vote, it would have been six to five.

MS. WASTLER: Right, but subsequent to that, you went back and re-voted on that and opposed it. That was the one that we had the second vote on.

MEMBER SULEIMAN: Dr. Malmud and I want to be difficult and --

MS. WASTLER: Right. You decided to go with the subcommittee.

MS. TULL: Sally?

MEMBER SCHWARZ: The T&E will copy words from the transcript? I think nuclear pharmacy is supposed to be included in that. It was not.

MS. TULL: Okay. I will go straight to the transcript on this one.

MEMBER SCHWARZ: That's fine.

MS. TULL: Okay. So I will --

MS. WASTLER: But yes, it was.

MEMBER SCHWARZ: Okay.

MS. TULL: Okay. And so for the action items, this is the second page. There are four action items. The first one, "Dr. Malmud forms a subcommittee for Perfexion as it relates to 35.600."

The subcommittee chair is Dr. Nag. The subcommittee also includes Mr. Lieto, Dr. Thomadsen, and Dr. Welsh. The subcommittee will consult with representatives from the agreement state, which will be Ms. Debbie Gilley; vendors; ASTRO; and AAPM. Okay?

CHAIRMAN MALMUD: Yes.

MS. TULL: The next action item, "Form a subcommittee to further discuss proposed change to 35.75 to release patients if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisievert per year."

The subcommittee includes Dr. Vetter, who is the chair; Dr. Eggli; and Dr. Fisher. And I believe this is closed.

MS. WASTLER: That's closed now.

MS. TULL: The subcommittee met and has

already reported back to the full Committee.

MS. WASTLER: And the full committee voted.

MS. TULL: And the full committee voted. Correct. The vote on that was --

PARTICIPANT: Nine to two.

MS. TULL: Yes. Nine opposed, two in favor.

The next two action items are for NRC staff. So I will initiate the process for NMED access for Drs. Thomadsen, Welsh, and Fisher. Is there anyone else that does not have access to NMED?

PARTICIPANT: I have forgotten my user name and password.

MS. TULL: E-mail INL on that one.

PARTICIPANT: I don't have it.

MS. TULL: You don't? Who else raised their hand? Sally? Dr. Nag?

MEMBER NAG: I'll send you an e-mail. I'm sure I had access, but I never used it. So I don't know what my name is.

MS. TULL: Okay. Who else?

MEMBER SULEIMAN: I have it, but I can't remember. I'll e-mail it if I need it again.

MS. TULL: Dr. Eggli, you need your

information? I'll ask them to reset passwords and send you your user names on that kind of stuff.

Okay. Anyone else? Dr. Vetter?

VICE CHAIRMAN VETTER: I'm sorry?

MS. TULL: You're good?

VICE CHAIRMAN VETTER: Yes.

MS. TULL: Okay. Okay. And the next one is NRC staff will add an agenda item to the Spring 2008 meeting for Dr. Thomadsen's presentation on causes and medical events. Dr. Thomadsen will provide NRC with suggestions for questions NRC can ask to receive more accurate information on the causes of events. Is that accurate? Okay. That will be on the Spring '08 agenda.

MEMBER NAG: I would like to make one comment.

MS. TULL: Yes?

MEMBER NAG: I like this very much. This is something we had been asking a long, long time, I think slowly has been implemented in regular fashion.

I mean, we never had it. Then we had it after the fact, sometimes a few months after. And now we are having it when we leave. And I think this is the way it should be done. I would like to publicly congratulate you.

MEMBER SULEIMAN: Well, for the record, let me thank you that I got in my NRC badge.

(Laughter.)

MEMBER SULEIMAN: I'm going on for how many years now?

MS. TULL: Ten years?

CHAIRMAN MALMUD: Dr. Fisher?

MEMBER FISHER: In the spirit of consensus motions and congratulating Ashley for this, I would recommend two minor typographical changes to this. One would be the written directive for Y-90 at microspheres use may include dose to target tissue, rather than target organ, minor correction.

And then reject NRC proposed blah blah blah and the total dose or, instead of "dosage from a device," the correct term would be "administered activity" since it's a device, not a drug.

MS. McINTOSH: This is Angela.

If it's a recommendation that the Committee has voted on, whatever the language is that was actually used is what we have to go by. You would have to re-vote to change the language.

MS. TULL: Correct. On most of those, whatever you recommend, we will consider. So if I took this to the medical team and we know that it's

administered activity and not the terminology that NRC uses, many times that's what happens. We do accept your recommendation, but we will make it fit NRC when it's minor like that. So those changes would be reflected in the final guidance.

MEMBER SULEIMAN: Okay. Can I ask a clarification on that, too? Because I was looking at notes from last time. And I thought we used the term "administered activity" last time. And "dosage" crept into the language this time. So is dosage actually defined in NRC language as administered activity?

MS. TULL: Yes. It's prescribed dosage, yes, is administered activity. It's in 35.2, yes.

DR. HOWE: Orhan, also prescribed dosage is for radioactive drugs. But we wanted to make sure that people when they talked about dose, they distinguished between activity when they were talking about dose and what we consider dose.

MEMBER THOMADSEN: Then that could be cleared by using the term "activity," as opposed to "dosage."

MS. WASTLER: And just one more thing. I know Ashley was talking to you about reporting your time and sending information to her and to Tami. Tami, I think she's hiding. I asked her to come down

for you to meet members of the committee so you can put a name to a face. This is Tami Holliday.

MS. HOLLIDAY: Hello.

(Whereupon, there was a chorus of "Hi.")

CHAIRMAN MALMUD: When is our next report due, this Friday or next Friday?

MS. HOLLIDAY: Actually, I was getting ready to send an e-mail out tomorrow morning. It's due this Friday.

CHAIRMAN MALMUD: This Friday. Thank you.

MS. TULL: Tami, you've got to use a microphone.

MS. WASTLER: Tami, you can sit right there at one of those chairs.

MS. HOLLIDAY: Good afternoon. I was going to send an e-mail out on Wednesday, tomorrow, morning to say that they're due. I need to have them this Friday by 3:00 o'clock.

MS. TULL: So what I'll do is I'll e-mail the new form that I have. Tami doesn't even know about this yet. I have a new form. And it has the F.Y. '08 contract rates and has the little "Submit e-mail" and "Print form" buttons on it. So I will get that to Tami. And she will send that to you via e-mail tomorrow. But time is due on Friday.

Also, I don't know if members claim time normally, but you can claim time, for example, Sunday when you traveled. Say you traveled for four hours. You would claim four hours of service time, like getting paid, not just travel time, but pay for travel. Does that make sense?

CHAIRMAN MALMUD: Yes.

MS. TULL: If you travel more than six hours, you count eight. The same thing for tomorrow, anyone traveling tomorrow, if it takes you more than six hours to get home, claim eight hours on Sunday, eight hours Monday-Tuesday, and four hours to get home Wednesday or eight hours to get home Wednesday. You can claim all of that time.

MEMBER NAG: Ashley, I think it's correct you put eight hours, but you get paid for one day because anything six hours or more is one day payment.

MS. TULL: Correct.

MEMBER NAG: But you should put in six hours for accuracy.

MS. TULL: Yes.

MS. WASTLER: I guess the last piece of business is --

MS. TULL: The last item is schedule --

MS. WASTLER: -- to schedule the next

meeting.

MS. TULL: -- the next meeting. So if you look at your calendar, I have crossed out the first week of April because this room is not available. I don't think anyone wants to go anywhere else.

CHAIRMAN MALMUD: When is Good Friday? And when is Easter Sunday?

MS. TULL: Good Friday is in March.

CHAIRMAN MALMUD: March?

MS. TULL: And Easter is in March as well. So we're clear for April. The 14th and 15th --

CHAIRMAN MALMUD: When is Passover? Do you know?

MEMBER THOMADSEN: Yes. Passover is the --

MEMBER NAG: 19th?

MEMBER THOMADSEN: Yes. The 19th is the "erev" of Passover, the night before. Most people would not be traveling on the 17th or 18th because they would be getting ready.

MS. TULL: Okay.

PARTICIPANT: Of April you mean?

MEMBER THOMADSEN: Of April.

PARTICIPANT: Yes.

MS. TULL: Okay. So we can mark off the

17th and 18th. The reason the 14th and 15th are marked off is for the NCRP meeting is the 14th and 15th. So if we wanted to tack ours on, if anyone was in town for that and wanted to tack our meeting onto the end of that, it doesn't sound like that is a possibility with Passover. So we're looking at the 21st through the 24th.

So your choice is do you want a Monday-Tuesday meeting again? Do you want a Tuesday-Wednesday or do you want a Wednesday-Thursday?

VICE CHAIRMAN VETTER: Monday-Tuesday works good for me.

MS. TULL: Monday-Tuesday?

VICE CHAIRMAN VETTER: I'm unavailable all that week.

MS. TULL: You are?

PARTICIPANT: The 21st or the 7th?

PARTICIPANT: There is the week of the 7th to 12th.

MS. TULL: What about the 7th or the 8th?

CHAIRMAN MALMUD: How about the 28th-29th? Is that too late?

MEMBER NAG: Yes. I mean, 7-8 is a possibility as well as if you are doing it at the end of the week, then 24th-25th.

MS. TULL: Anyone not available on the 7th or 8th?

MEMBER FISHER: I'm tentative.

MS. TULL: If we schedule this, would you be not tentative?

MEMBER FISHER: I'll make it.

MS. TULL: Okay.

MEMBER FISHER: I'll cancel whatever I've got.

CHAIRMAN MALMUD: Seventh and 8th?

MS. TULL: So we've got Monday, April 7th, and Tuesday, April 8th will be the next ACMUI full meeting.

CHAIRMAN MALMUD: Monday, Tuesday, 7th and 8th, terrific.

MS. TULL: If something comes up in the meantime, we'll have a teleconference.

MEMBER NAG: I thought we'll have to schedule a teleconference anyway.

MS. TULL: Do we have to? Only if we have something.

MS. WASTLER: Only if we have a specific topic that needs discussion before the next meeting.

MEMBER NAG: Okay. I thought that, for example, it would mean we can send something back for

discussion to the group because the thing is if we have a target date, that forces you to work on it. If you don't have a target date, then we get all --

MS. WASTLER: If the subcommittee is at a point that they want to present back to the full Committee on that topic before the next meeting, we can set up a teleconference.

MS. TULL: So, Dr. Nag, you can send me an e-mail. Let me know.

MS. WASTLER: It's very easy to do. And then we can try to initiate that.

MS. TULL: Then I can poll ACMUI.

CHAIRMAN MALMUD: Thank you.

Dr. Vetter?

VICE CHAIRMAN VETTER: Yes? You tried to get a block of rooms for us for this meeting?

MS. TULL: Yes.

VICE CHAIRMAN VETTER: Are you going to do that for the 7th and 8th or should we be making our own hotel reservations?

MS. TULL: I got a contract from Marriott last time. I had no authority to sign it. And neither did anyone else sitting at this table. We didn't know what to do with the contract.

I talked to contracts. I'm also finding

out who does this for ACRS and ACNW because they do get blocks of rooms at the Marriott for the government rates.

MS. WASTLER: We're trying to achieve that for the next meeting.

MS. TULL: If you want to give me the next month to get that contract, find out who can sign it, what piece of paper we can get? If not, if you made your reservations, say, by the end of November, that is still well in advance. It's the people who made their reservations a month before, two months before that didn't get the rates.

VICE CHAIRMAN VETTER: You can always cancel your reservation.

MS. TULL: Yes. The other option, you can always make the reservation, call and cancel.

CHAIRMAN MALMUD: I call for a motion to adjourn the meeting.

PARTICIPANT: So moved.

MEMBER NAG: Wow. We finished a half an hour before time.

CHAIRMAN MALMUD: Any opposed? Ralph?

(Laughter.)

MEMBER LIETO: I abstain.

CHAIRMAN MALMUD: Thank you, all. Thank

you, all. And, for the record, would you please thank the members of the public who participated as well? Thank you.

(Whereupon, the foregoing matter was concluded at 4:35 p.m.)