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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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MEETING

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TUESDAY, MAY 25, 2010

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ROCKVILLE, MARYLAND

The Advisory Committee convened in Room T2B3 of Two White Flint North, 11545 Rockville Pike, at 8:00 a.m., Bruce Thomadsen, Acting Chair, presiding.

MEMBERS PRESENT:

BRUCE THOMADSEN	Vice Chairman Therapy Physicist
DARRELL FISHER	Patients' Rights Advocate
DEBBIE GILLEY	State Government
MILTON GUIBERTEAU	Diagnostic Radiologist Representative
SUE LANGHORST	Radiation Safety Officer
STEVE MATTMULLER	Nuclear Pharmacist
ORHAN SULEIMAN	US Food & Drug Admin. (FDA)
WILLIAM VAN DECKER	Nuclear Cardiologist

JAMES WELSH Radiation Oncologist

PAT ZANZONICO Nuclear Medicine Physicist

NRC STAFF PRESENT:

ROB LEWIS MSSA Division Director

JIM LUEHMAN MSSA Deputy Division Director

CHRIS EINBERG Designated Federal Officer

MIKE FULLER Alt. Designated Federal Officer

ASHLEY COCKERHAM ACMUI Project Manager

MEG AUDRAIN

CINDI CARPENTER

SAID DAIBES

MARC FERDAS

JAMES FIRTH

SANDY GABRIEL

VINCE HOLOHAN

DONNA-BETH HOWE

SOPHIE LE

GRETCHEN RIVERA-CAPELLA

MARIA SCHWARTZ

RONALD ZELAC

ALSO PRESENT:

ROY BROWN CORAR

JANET BUKOVCAN MDS Nordion

ALSO PRESENT (CONTINUED):

SIMON CHOI	FDA
ROBERT DANSERAU	New York
CAROL FLORIAN	Symetosphere
JIM NANCE	Symetosphere
GARY WILLIAMS	VA NHPP

AGENDA ITEMS	PAGE
Safety Culture	5
Update on Grandfathering Certified Medical Physicists	49
Revisions to the NRC Radiation Protection Requirements: Potential Impacts to the Medical Community	62
Post-Implant Written Directives for Yttrium 90 Microsphere Procedures	186
Subcommittee Report on Byproduct Material Events	109
Administrative Closing	145

P R O C E E D I N G S

(8:15 a.m.)

ACTING CHAIR THOMADSEN: Welcome back to Day 2 of the NRC ACMUI meeting.

We will be beginning with a presentation from Ms. Gilley on the NRC efforts to develop a safety culture policy.

Ms. Gilley?

MEMBER GILLEY: Good morning. The safety culture is something that NRC has been embracing and talking about with the agreements states for the last year or so. I'd like to give an introduction to it but I'm really looking to have the ACMUI members to provide some dialogue and information back to NRC and the agreement states on how best we could forward with the adoption of a safety culture policy.

Policy segments help to guide the activities of the NRC staff and can express the Commissioner's expectations of others. They are not rules with the meaning of Administrative Procedures Act and cannot be accorded the status of a rule.

Agreement states cannot be required to implement elements of the policy statement and policy statements cannot be considered to be bind upon them

or enforceable against them -- against NRC or agreement licenses.

The types of activities that have occurred that have indicated that maybe we needed to focus more on a safety culture include the loss of control of sealed sources of prostrate brachytherapy performed without the evaluation of seed placement and iodine 131 in therapy administered to a lactating mother that resulted in radioactive iodide uptake to infants, and years of undetected boric acid corrosions in the reactor pressure vessels head cavity at the Davis-Besse Nuclear Power Station.

The safety culture policy statement from the Commission should expand the NRC's policy of safety culture to address the unique aspects of security and to ensure the resulting policy is applicable to all licensees and certificate holders.

They published a draft policy statement in the Federal Register in November of 2009 and they held a safety culture workshop February 2nd through the 4th, 2010, where they redefined or enhanced the definition of safety culture and developed some safety culture traits.

The original definition of safety culture is the assembly of characteristics, attitudes, and

behaviors in organizations and individuals which establish that as an overriding priority. Nuclear safety and security issues receive the attention warranted by their significance.

With the completion of the workshop, there was lots of information received in that workshop. They redefined or enhanced that definition to state nuclear safety culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.

So where are we in that? They're still looking at comments and trying to find guidance documents that would be appropriate for medical applications. They have identified eight traits of a safety policy culture. And they are here today -- or Ed and I as an agreement statement member, since we usually have to follow suit with NRC, are looking for your input to identify other activities that might could be used in the medical facilities to enhance safety culture.

What work practices might be in place, work planning and control that we might could look at, continuous learning environment, effective

communications -- I'm not aware -- know if many of you are aware that sometimes communication within an organization has led to medical events, and others that might be out there based on your experiences.

I'd also like to acknowledge that there are two NRC employees here that can assist me in defining this safety culture policy, James Firth, who helps me with the slides, and Maria Schwartz, who are sitting in the first row back there.

The other information in the package that you received includes the eight traits that they've come up with. You may want to refer to that.

And, Dr. Thomadsen, I would like to open the floor for conversation from individuals on their thoughts about safety culture.

ACTING CHAIR THOMADSEN: Very good. Thank you very much.

Let me first ask if there are comments from the Committee? Questions?

Mr. Lewis?

MR. LEWIS: I just, for an additional point of reference, we are very much in the information collecting mode for materials licensees on safety culture issues. And in a lot of ways, we're a lot behind the way that the reactors use the term

safety culture and have a more systematic application to their work.

And our medical licensees, among our material licensees, you know, have a strong reputation for a good safety culture. And hospitals are in business to save lives. So they naturally have good safety cultures.

So hopefully what you can help us with today is just some ideas of how safety culture or things that we already do that aren't called that, can be made more tangible and systematic amongst our material licensees in the future.

ACTING CHAIR THOMADSEN: Let me ask you, do you have some example in mind as to what that might look like?

MR. LEWIS: Maybe I could get some help from the staff but yes, I do, because we do many things in our programs geared towards ALARA or reviewing our work. They are up there, you know, continuous learning environment. And I think in the performance-based regulatory environment that we are trying to work towards in our inspection program or our licensing program, we want to have feedback in how to paint those into a box or share best practices amongst licensees in terms of proceduralizing a

continuous learning environment.

Is there any examples at your licensed facilities where you have, you know, a strong safety-conscious work environment program or something that other licensees that may not have the benefit for.

So we are in the mode this year of collecting all those data points. And the next step would be to try to materialize those into some regulatory guidance or the policy statement. And eventually -- like we have a -- if I could, we have a medical use policy statement. Everybody here knows that. You know our policy is not to interfere with the practice of medicine.

The policy statement is embodied in all of Part 35 in how we define medical events. It is embodied in all of our licensing guidance in NUREG-1556.

So in the same way, we ultimately want the safety culture policy statement to be embodied in our regulations and guidance in a tangible way.

Jim, do you want to add to that?

MR. FIRTH: Okay. Jim Firth, NRC Staff.

A couple of things. I mean one, when we had the workshop in February, we had someone from the Joint Commission who has been involved in terms of

some of their work on safety culture and sentinel events. And also in our previous workshop in 2009, some of the feedback we had was that to get it incorporated into some of the medical licensees is to work through some of the standard-setting organizations that would then be embodied in terms of the professional practices, it would then be then incorporated in terms of what the licensees do.

As we move to implementation, what we are wrestling with is we have a very large diversity of licensees on the materials side. And even in the medical side, you know, the larger facilities versus the smaller facilities. So what is the best way, in terms of working things through implementation?

We're not going to be going out as often as we go out on the reactor side to see what's going on. So we're looking in terms of -- one other thing to add is that we did a pilot looking at trying to look at what we were doing in the reactor oversight process to see how that would translate to materials licensees.

The example we started with were uranium fuel fabrication facilities. And what we noticed is that a lot of the principles of safety culture are either implicit or explicit in the existing NRC

regulations. Not all of them but there's a good -- a large set that are.

There are reporting requirements. There are things in terms of safety-conscious work environment and employee protection that also translate and correspond very well with what we looked at as areas important to safety culture. There are other areas that are not necessarily as explicit.

ACTING CHAIR THOMADSEN: Other comments? Yes, please? Dr. Langhorst.

MEMBER LANGHORST: Sue Langhorst. You talk about getting into this conversation with licensees and so on. And I thought there were two additional workshops scheduled. But did I hear correctly that they were cancelled?

MR. FIRTH: Jim Firth, NRC staff. Yes, the two workshops that were planned, April and October, have been cancelled. And part of that is that we didn't know how long it would take to arrive at a common definition and underlying traits using the workshop.

MEMBER LANGHORST: Okay.

MR. FIRTH: We made a lot of progress. The people that were on the panel were very pleased with the progress. A lot of the comments that we

received afterwards, because we extended the comment period so it would close after that workshop, a lot of the comments that were received afterwards said -- asked the NRC to use what came out of the workshop in terms of the definition and traits. This is a good starting point for the final policy statement.

So based on that and based on the feedback we had of the people that helped us plan the workshop, that it represented stakeholders on materials licensees, the public, reactors, a full range of stakeholders, their feedback to us was that they didn't see the need of having a workshop similar to what we had before.

MEMBER LANGHORST: Okay.

MR. FIRTH: So we're not going to have those two workshops. We are going out on meetings as we get word -- information out on the definition and the traits to try and get feedback on how receptive are groups and organizations to the definition and the traits because one of our objectives is that we would like to have a common language of safety culture that can be used by NRC and others. If it is not endorsed or not embodied by others then things are not going to work as well.

There's also multiple definitions of

safety culture in terms of NRC, OSHA, and others. So if we can come up to some definition that people are going to be widely using and also help communications. So over the summer, we are having -- going out and trying to go out to workshops, conferences, and other meetings to try and get that information.

We have under consideration a possible workshop, possibly like in the October time frame. But that's sort of tentative.

MEMBER LANGHORST: Okay. I would just urge the NRC to let licensees know that those workshops may get cancelled because I couldn't -- it was too quick on the first one and I could not attend or even sit in. And so I thought okay, I'll have other chances. And then they were gone.

And so I understand that you got done what you wanted to get done in that environment of developing at least a new statement that everyone could agree with. And so I am very glad that you are continuing to have that dialogue with licensees.

MS. SCHWARTZ: And that fair. Even if we do not have the second workshop in the September/October time frame, we do plan, when we pull things together from our outreach activities, to have a second Federal Register notice where we will ask for

comments again to make sure we don't have an fatal flaws in what we have arrived it.

MEMBER LANGHORST: I have another question.

ACTING CHAIR THOMADSEN: Please continue.

MEMBER LANGHORST: Debbie, in your slide on safety culture and the definition, it said nuclear safety but then no place else did it say nuclear. It just -- how does NRC propose to marry in an overall safety culture with the nuclear part of things?

And my point is is sometimes there are so many things we have to address from an NRC regulatory perspective that uses up resources from other safety needs and sometimes it is not the greatest of balance but our license is very precious to us. And so we have to make some tough decisions on which safety aspect we have to focus on.

MR. FIRTH: Okay. James Firth, NRC staff.

The definition that came out of the workshop was a result of compromises and other discussions among a panel and also the other people that were participating. Part of the discussions and deliberations was that some organizations feel that it is very important to stress that nuclear is different. And you hear this on some of the nuclear power plants

that whether it is new construction or existing power plants when they have people coming in, it is very important for them to stress that even though you deal with safety culture elsewhere, here it is different. Here it is even more important than elsewhere.

And the way that got reflected was they added nuclear as nuclear safety culture in what is being defined. We haven't come to a final conclusion on that but that's what the discussion was. But the intent is not necessarily to have this be partitioned and separate from elsewhere.

We also heard from other stakeholders that given that they deal with industrial accidents are even more significant and what they worry about more than the nuclear based on their business. So it didn't resonate as much, I think, with them having the nuclear as different. They wanted everything brought together. So that's one of the things we are wrestling with is that some groups really feel that they need to differentiate that it is different for their organization but others want to bring everything together in terms of industrial safety, nuclear safety, and so forth.

MEMBER LANGHORST: I think it is very -- sorry -- I think it is very important that you can't

get a one-size-fits-all in developing a safety culture. It has to be adopted by the organization and it has to be fed continuously to have it be successful.

And sometimes you can have a very good safety culture but it may be focused more for this one part of safety at one given point in time and there may be issues that come up with a license commitment or something. So I just -- it's very hard to regulate it if that is any intent of the NRC.

ACTING CHAIR THOMADSEN: Thank you.

Debbie? Or Ms. Gilley.

MEMBER GILLEY: I just want this group especially to be aware that my personal thing is that patient safety should be primary. And I worry a lot about the competing safety cultures here. And us having to make decisions.

And I would hope that the ACMUI would support that the patient safety is the primary focus and the nuclear safety, if when in conflict, would take a second seat to patient safety. And that bothers me a little bit because I think that there might be opportunities out there where we would be putting those decisions to either violate our regulations demonstrating we have a nuclear safety

culture at the expense of our -- to allow the patient to get what they need.

ACTING CHAIR THOMADSEN: I would -- if I may, I think there's a confusion in this discussion between cultures and practices in that when you have competing demands for the resources, it is the practice that determines what gets the resources.

But a safety culture is an awareness of having to deal with the risk in the organization. I don't think you can have a nuclear safety culture in the absence of an overall safety culture for the organization. And I think that if you have a safety culture for the organization, it will filter down into the nuclear safety and patient safety and all the rest of the safety things.

And the demands for the resources would be determined by the needs. But the overall safety culture would be for the entire organization. That would have to be how I see it.

Dr. Suleiman?

MEMBER SULEIMAN: Yes, I get troubled by it because I think it -- I can't see how you can have partitions and different safety cultures. I mean the way I look at everything, everything -- it is an attitude. It is almost like good practice.

A lot of regulations that we are involved with, their primary objective is safety if you translate back to the intent. So I don't see how you could say this is safety and that's not because there's always this -- you know you were saying one against the other. But I don't see it that way.

You're always making decisions. And sometimes you say well, we can use the item -- exercise just the other day. Right. Right. Are you protecting the public or are you protecting the patient?

Well, at some point, you may be shifting the balance so you are actually causing harm. So you're trying to maintain balance. So the nuclear, the security, I think what I suspect the intent was was that have an attitude where people respect the safety regulations and respect what people are trying to do rather than people just saying look, this is my job. I've got to do these. And I'm not concerned about what's happening there.

So I think a safety culture would inherently -- a good safety culture would inherently have a lot of respect for each other. And I find it interesting that you are trying to segregate -- like that there is a nuclear culture and then there is an

occupational and then there is a -- it's got to be one big -- it's an attitude.

ACTING CHAIR THOMADSEN: We have a member of the public.

MR. NANCE: Jim Nance from Symetosphere. We attended the workshop. And the only thing I wanted to interject was as an observer there that the only reason the word nuclear was put in there was because the NRC felt that they could only regulate or have a policy against nuclear safety culture, not against all safety culture because they cannot go and audit or observe if you're doing OSHA, if you're doing all the other safety cultures.

So from my perspective as an observer, that was the only reason the word nuclear was put in there was because NRC said we have to be able to have this, that if it does go to rulemaking, not that it will, but if it ever did go to rulemaking, that we would have to have that in there.

ACTING CHAIR THOMADSEN: And that's one of my concerns. I don't think you can -- I don't think you can make a rule for attitudes. And that's what the culture is.

You can make rules that define behaviors. And that's what you already do. And if you are

looking to try to control safety of radioactive materials, you can have regulations that do that.

But you can't regulate people's attitudes. You can't even evaluate people's attitudes even on what it looks like. But you can control and regulate behaviors. So I'm not -- I'm skeptical of the whole concept of trying to write rules for cultures.

Yes? Dr. Zanzonico?

MEMBER ZANZONICO: Pat Zanzonico. Apropos of that point, and I think hospitals and other medical centers are not unlike many organizations. There is a hierarchical structure and they are very results driven.

And at the top of the hierarchical structure in hospitals, of course, are physicians. And the results that drive the operation are patient procedures. And obviously the physicians and administrators and so forth want to push though as many patients as possible and maximize income and so forth and so on. And hopefully in the process deliver optimum patient care as well.

Often times, however, the individuals who are most aware of lapses in safety are no where near the top of that hierarchy. People like technologists, nurses, even housekeeping staff, you know, who may see

unshielded sources, et cetera, et cetera, because all of that helps optimize the results component of the operation.

And to get to another point and then I'll get back to my first point, is that I agree it is very difficult, if not impossible, to regulate a culture unless there is an enforceable component. I mean that's just human nature. And that's just the reality. I mean people will certainly pay lip service to a safety culture much like they pay lip service to ALARA.

But unless there is a stick connected with the carrot, the fact is that the day-to-day business of an operation are so overwhelming that it is very easy not to pursue, in a tangible sense, a safety culture, a lab, or et cetera, et cetera. Again, people will pay lip service to it, especially when they are inspected or audited or some such thing as that.

And so, you know, as much as we may not like it and as much as I, as a user, don't need more paperwork and more regulations and more reports, et cetera, et cetera, unless there is an enforceable component to this, it is going to have very little tangible impact for the reasons you cited.

One -- and I don't want to get overly proscriptive or overly detailed at this point but one possibility would be to include a suggestion, if not an requirement, in a safety culture statement that a non-management individual be identified as a safety culture officer.

And I'm thinking of that, again, not a physician, not an administrator, not a physicist, not a radiopharmacist, but perhaps a technician, perhaps a nurse be prescribed as someone who is responsible for that. Perhaps there could be a professional level person as well. But definitely including a non-management person.

And also requiring a periodic safety culture report. Again, none of us need more regulations or more paperwork. But I just don't see this having any practical impact unless number one, there is a tangible product such as a report connected with it, and even more importantly, some enforceable action.

I think the NRC and other regulators should not underestimate the impact they have on the operation of hospitals certainly. The quickest way to free up budget money is to say well, it is a regulatory requirement. No matter how much else --

there may be a compelling need for something, once it becomes a regulatory issue and it potentially exposes the hospital to monetary and other sanctions, suddenly money that wasn't available becomes available.

And likewise, unless there is some sort of tangible sanction associated with violation or neglecting a safety culture, I just don't see it having a practical income -- a practical impact. And even at that I'm skeptical because it is one of these amorphous concepts.

But I think there has to be some proscriptive component, not just a philosophical component to this notion. And there has to be some enforceable sanction connected with it as well. Otherwise, as I say, I see it having little practical impact.

MR. LEWIS: Dr. Thomadsen?

ACTING CHAIR THOMADSEN: Mr. Lewis?

MR. LEWIS: On your comment and Dr. Zanzonico's comment, let me offer a thought for discussion purposes. But first let me say that both of your talked about new requirements. And we're not talking about new requirements.

We're talking about a policy statement, which is not an enforceable vehicle. But think of it

more of like a lighthouse that guides our activities and prioritizes our NRC activities to look in the right places in the future.

But that said, let me -- where do I see safety culture? Where do I see it show up? And it shows up in events, after-the-fact events.

We have our thorough analysis of some medical event or license event that is reported to us. We go out, do our inspection, issue our violations, resolve the enforcement, agree to the corrective actions.

A lot of times I see the root cause or a contributing cause is a poor licensee safety culture. And everybody that reads the report say oh yes, that's right. Yes, they had a bad safety culture. But the question I'm asking now is why do I always see that after the fact? What can I do about safety culture before an event happens as a regulator?

And that's a different way to look at the question. And we should be doing proactive things. And what are those things? That's kind of what is before us.

ACTING CHAIR THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: Actually you can have -- you can encourage a safety culture with very strategic

regulations. I mean, for example, this is a personal experience. I won't go into a lot of detail but we've debated within FDA the necessity of certain regulations, you know, there are a lot of professional activities and so on.

But then you'll say but these professional, top-layer activities, only penetrate 20 percent, 30 percent of the practicing community. And so you say well how do you invoke, how do you get people to practice better, do better, and sometime you realize that a strategic regulation may just, you know, requiring some people to do something simply but on a regular basis, after a period of time can actually teach people to do things properly.

Let's say have a five-minute meeting every morning to discuss any potential safety issues, you know. I was once lectured by a senior -- when we were advocating that -- to draft a -- whether we should or shouldn't even consider a regulation. And he said if it is a safety-related issue that is going to have impact on public health, don't shy away from it.

The flip side of that, I was at a major academic research institution and this was on fluoroscopy. And there had been a lot of voluntary technological advances for the fluoroscopy systems.

And one was a concept called speedometer odometer dose dose rate. You cannot blame the physicians for the amount of radiation they were delivering if they didn't know how much radiation they were delivering.

So this concept had been thrown around. And it was a pediatric interventionalist who said we approached administration and they said no. If it is important, it will be required as a regulation.

So that was a cathartic moment for me where I said, you know, maybe we need to cross the line and mandate that because it is a safety feature. If you continue to want people to adopt it voluntarily and let the marketplace decide, you are going to have some people who are not doing that properly.

So I think careful thought, some critical regulations could, in fact, reinforce a safety culture. If you turn it loose completely, you're going to have the good players, and they're the ones always here at this table talking about how great things are, and you're going to have the people who aren't here who are out there doing all the things that cause us the problems.

So it is an attitude. But I think without being overly proscriptive, that's always the critical thing, you want balance. It doesn't mean you have no

regulation. But you don't want to get so proscriptive that people are obsessed with the regulation and lose sight of why they are there.

ACTING CHAIR THOMADSEN: Thank you very much.

We have a member of the public. Please identify yourself.

MS. FLORIAN: Hi, Carol Florian, Symetosphere. I'm a cultural engineer. And I participated in the cultural -- or the safety culture workshop for the NRC.

ACTING CHAIR THOMADSEN: Can you stand a little closer to the microphone please.

MS. FLORIAN: Closer? Is that better?

ACTING CHAIR THOMADSEN: Much better.

MS. FLORIAN: Okay. I would just make a few comments. It is very difficult to regulate safety culture because it is an after-the-fact thing. What you need to work to is it is actually possible to create and design the culture you are looking for in the organization. And what that ties back to is changing how people function in their daily role as opposed to them being functions by controls, change the beliefs that the people have so that they are doing things because they truly believe they are the

right thing to do.

And I know it probably sounds a little cliche but we have a specific way that you can take the traits, for example, that the workshop came up with, problem resolution and metrics, personal responsibilities and attitudes, those are the things that you want to see change in your organization so that people do those things because they believe it is right action to take.

And you can take the traits, it is possible, tie them to concepts. And concepts are something that you can implement in the organization and measure. And it speaks to Mr. Lewis's question what are some specific things that you can do?

And you can take those traits and tie them to different things like root cause analysis or reducing medical errors, those kinds of things, putting continuous improvement in place and making sure that you feed back all that information. And you keep changing it and giving the people who actually have to do these things each day a stake in what it is. And then they begin to take ownership for what it is that they do.

And you'll start to see the culture change in the organization. And then you have a tangible way

to take it and be able to measure it.

ACTING CHAIR THOMADSEN: Thank you.

Mr. Mattmuller?

MEMBER MATTMULLER: Yes, just for the record, I attended a three-day safety culture NRC program. And I'm not sure where these other people went on the third day but I was there on the third day.

ACTING CHAIR THOMADSEN: Can you move your microphone closer?

MEMBER MATTMULLER: Sure. And primarily -- I participated and the one point I tried to make there and to remind people here is that we are completely different than most applications that the NRC regulates. And that we give radioactive material to patients on purpose because of the benefits that it provides as opposed to using the power of the atom to generate electricity.

And so from our perspective, it is totally different. It's 180 degrees different. But also we have within a medical center or within the medical profession, we have the Joint Commission who is a much larger force in a medical center than the NRC is.

And they have been after safety culture or I can think of some of their earlier started over 20

years ago, the quality assurance program. And, in fact, not that we shared notes but they do have a document right now called root cause analysis in healthcare. And so it is something they actively promote, and manage, and look for when they come and do their inspection visits.

And as far as -- to touch on what Pat mentioned -- there is a stick now in healthcare and that is reimbursement is now tied to quality results in that I know our facilities participates with a couple of insurance companies that do surveys. And if our quality level is at a certain level, we get a higher reimbursement rate, which obviously gets the attention of the leadership for our medical center.

So -- which also touches on another important point that for all safety culture, it has to be driven from top down. That if the leaders of the organization aren't embracing it, it really -- it's very, very difficult for the organization to have a good safety culture. So it really have to be emphasized that it needs to start at the very top.

And also to touch on what Orhan mentioned that to help get leadership's attention, the policy or it's not a regulation, it's a policy for the Radiation Safety Committee that senior administrator from the

hospital attends so that's one way to help require that they at least -- you know, that they are there to see from a radiation safety perspective how their culture is operating at their medical center.

ACTING CHAIR THOMADSEN: Thank you.

One thing, I get the distinct impression that we're not giving you exactly what you were looking for in this discussion. One thing that --

MR. LEWIS: I disagree.

ACTING CHAIR THOMADSEN: Oh, well, I'm delighted.

MR. LEWIS: I think it's been a very helpful --

ACTING CHAIR THOMADSEN: Oh, good.

MR. LEWIS: -- discussion.

ACTING CHAIR THOMADSEN: I'm glad.

MR. LEWIS: That's what we look to our experts for.

ACTING CHAIR THOMADSEN: I'm glad. One thing that might be also helpful as far as guidance for what this Committee could offer back to you as guidance would be some examples from what you were saying where the investigations have identified that a cause of events were poor safety cultures.

If you could provide us with some examples

of what that looked like to the investigators, that we could then look at how we might make recommendations for how those practices might be turned into something that was more concrete.

MR. LEWIS: I think we could do that. I'm looking to our Region III people who have been our lead on safety culture. And Patty, I was wondering, I think we have some examples we could provide the Committee. It may be like a series of documents. We'll try to point to what parts to look at or something.

ACTING CHAIR THOMADSEN: That would be very good.

MS. PELKE: Hi, good morning, Patty Pelke from Region III NRC.

First of all, I think this has been a very productive discussion. From a regional perspective, what we have observed is that safety culture is embraced throughout the entire organization. It has to start at the top and it has to maintain a very strong focus from the top. And it integrates throughout the rest of the program.

As far as inspection activities that we have had where safety culture has come out as maybe -- it might not be identified as a root cause but

certainly is a contributing cause and certainly is a contributing cause in a lot of events that we've identified. It's a process where a treatment is started and there are some questions. There are some precursors that really start to formulate at a very fundamental level. And those precursors don't seem to be addressed.

And individuals, they may not be familiar with the types of equipment that they are using, they may have used something similar in the past but not exactly the same. And they continue the process even though they have had questions along the way. They don't take a let's take five, they don't have a take five process where they step back.

For those of us that were here yesterday, Dr. Potter talked about what he does in the OR when he does his run through before they had a brachy treatment on the issues that they identify or what they want to verify with the right patient, the isotope they are going to use going forward, and then they proceed.

So it is those kinds of what you might want to think of as soft issues that really come to light as events are identified. And the fact that they do formulate at a very, very fundamental level.

And that folks continue to have the questioning attitude but seem to proceed and then mistakes occur as opposed to having a process where they step back, take five, and start asking those questions and addressing those at a much more fundamental level.

That's more in the medical arena. But we've also seen it, you know, production over safety happens for a number of our licensees as well as opposed to possibly stepping back and looking at a safety marriage where you are not compromising safety over production.

And, again, that, I believe, comes from a very strong culture at a high level within an organization.

ACTING CHAIR THOMADSEN: Thank you.

Yes, Dr. Van Decker?

MEMBER VAN DECKER: I feel compelled to make some comment after being put on the top of a heap of a hospital. I can promise you I'm nowhere near the top of a heap of any hospital anywhere.

(Laughter.)

MEMBER VAN DECKER: But I did run a performance improvement committee at a hospital for like 15 years. So, you know, I have some sense for,

you know, some of the stuff that goes on in big organizations and even in small practices.

And I think that it is important for the people at the table to recognize that safety culture in healthcare is a prime issue. Now whether it works well all the time or whether an individual institution works well or not, you know, this is a prime focus.

And maybe some of the communication of how that happens in the realm of nuclear, which obviously has another bigger piece to it, needs to be talked out a little bit more. You what the lady from Region III was just talking about is a JCHO standard, right, time outs before any operative procedures. It's not just radiation procedure. It's any surgical procedure you are going to do with conscious sedation has to have an identification of the patient part, the patient, dah, dah, dah, dah. So, you know, there are pieces of that in what we do.

You know from my perspective, I think that, you know, most, you know, physicians, technologists, the physicists I work with would look at this and say yes, you know, this is kind of what we know we should be doing all along. I mean we have continuous learning improvement and we have radiation safety committees. We try to talk to each other.

So I don't think there is anything new in these touchy-feely concepts. The question is when the rubber hits the road, what's the exact specifics of what these things mean? And perhaps some, you know, better identification from your perspective of what you've seen as bad safety cultures, specific examples, and then finding the correct vehicle to spread it out to the penetration level to the community is an important piece of this puzzle.

You know my last comment on this is from my perspective the thing that makes the best safety culture is some backup feedback mechanism of what is going on with results, some kind of peer review in the process, and some kind of incident reporting mechanism that is not tied to the fear of retribution if somebody reports something obviously.

And so there needs to be, you know, that little stamp on the bottom of peer review that this is for improvement characteristics and dah, dah, dah, and, you know, we have people like radiation safety officers, you know, whether they run their own safety committee or whether it is another person of the safety culture that they kind of go through, you know those committees have to feel comfortable and active in bringing up points.

Fighting for resources is a reality of any organization, whether it be medical or otherwise. And we have to find ways to do this in manners that create good outcomes and the right thing for both the workers and for the patients obviously.

But, you know, the concept you have up here, mom and apple pie, right, I don't think anybody around this table is going to argue with. So the question is how do we get the feedback going at the local level? How do we get a feedback going at a national level that we can create better education? That we can feel that we are discharging the duties of what we'd like to do?

ACTING CHAIR THOMADSEN: Dr. Suleiman and then Dr. Zelac?

MEMBER SULEIMAN: I think one thing that is critical and it cuts across a lot of things is just communication. It always -- it doesn't surprise me, it used to, that most accidents, whatever you find out that people associated with it were aware that things weren't right.

But there is always this issue of feedback, communication to a level where something will be done regarding that? Sometimes people are afraid because they will be ostracized or they will be

-- if safety isn't predominant, you know, they may be afraid to open their mouth.

Sometimes you'll see things that are obvious and you are afraid to say something because you think you are the only one. And then you talk privately and you find out other people are thinking the same thing. But people are just afraid to raise the issue.

I think this recent oil leak, I hear that there were disagreements, you know, over what to do. So that wasn't a surprise.

You hear about airplane crashes where one of the people in the cockpit was aware, was raising some concerns. And the other person wasn't listening.

So it's not like we're not sensing -- what I've always found in a -- and when you walk into any kind of a group or do an inspection, you can almost sense if they've got a good attitude. I think you're right, Bruce. I think attitude is a key component of that. And the ability not to be afraid to speak up.

Now the flip side of that is if you open up the gates and you allow everybody to say everything, then you've got so much background noise where you are saying well, what's critical and what's just somebody who is whining and complaining.

So I think communication and the culture that people shouldn't be afraid to raise certain issues would help cement that safety attitude. But I think there are things you can do tangibly that would reinforce that.

ACTING CHAIR THOMADSEN: Thank you.

Dr. Zelac?

DR. ZELAC: This is a drilling down observation and question simply for clarity. And so first to the slides that you saw during the presentation, if you look at them, you'll notice that the draft safety culture policy statement includes safety and security. And that followed the November Federal Register notice putting that statement out for public comment, which indicated that these two could be combined into one policy statement.

Look next at the workshop results slide and the word security is gone. So my question really, just for clarity and so we all understand where we are, is is there now going to be a separate policy statement for security? Or is that somehow embedded in the word safety?

ACTING CHAIR THOMADSEN: We have an answer.

MR. FIRTH: James Firth, NRC staff.

In the workshop, I mean the workshop definition --

ACTING CHAIR THOMADSEN: Yes, keep going.

MR. FIRTH: -- yes, the workshop definition was the outcome of the collaborative process. And it was -- basically the way the workshop went was we had groups for materials industrial, materials medical, and then more of a reactor focus. They work separately then come back together.

What some groups -- with a lot of groups, security was not resonating in some cases because they felt that they want to keep things simple with -- it would conflict a little bit with some of the other safety culture definitions that they're using.

A lot of it -- they didn't feel that security was necessarily unimportant. They just felt that security could be similar to emergency preparedness, environmental protection. That there are attributes that are under safety culture and they felt that there was no need to elevate security as the only one getting that special treatment.

So the workshop participants were proposing not include security. They felt that it was important to NRC so they deliberated a little bit in terms of whether to include it or not. But it did not

resonate with them. So they did not include security in either the definition or the traits.

We're still wrestling with how to incorporate security as we move forward towards a final policy statement. At this point, we haven't necessarily be focusing on a second policy statement but we have not made any decision in terms of whether security would end up in the definition or in the traits or if this is going to be discussed elsewhere in the policy statement.

So we're still working on that. And we're hoping to get some more feedback as we go forward towards a final policy statement. But at this point, we're not necessarily playing against the second policy statement specific to safety culture.

ACTING CHAIR THOMADSEN: That answers the question?

PARTICIPANT: Yes.

ACTING CHAIR THOMADSEN: Fine.

Dr. Howe?

DR. HOWE: I know all of these new members bring their own experience into reviewing these questions. And the discussion that I am hearing is you are discussing it from the point of view of large medical facilities or medical facilities with JCAHO

oversight or with radiation safety committees. And when you are thinking about these issues, you need to also think about the majority of our licensees, which are not the broad scope licensees but the individual physicians because the safety culture will apply to them also.

So if you could bring that to the table as you are doing your deliberations and discussions, it would be very helpful for us.

ACTING CHAIR THOMADSEN: Thank you.

Yes?

MR. FERDA: My name is Mark Ferdss. I'm from Region I and have another regional perspective for you.

Just a little bit about my background. Before I got into the medical area, I spent most of my career with the NRC on the reactor sites. So I do have a nuclear power plant experience for multiple years. And that is where safety culture has really shown itself and it has developed to now infiltrate down into the other areas that we regulate.

And what I would say that there is not as great a difference as what you might think between a nuclear power plant and the medical community, especially in the bigger hospitals, the bigger

facilities. It all comes down to the balance of safety versus production I'll call it. Production meaning more hospitals, they're in for-profits. They're also in for treating patients. So it's a balance. You have an input and you have a throughput.

And the saying in the nuclear industry, especially on the reactor side, is if you have a strong safety culture, you'll have a strong production. You'll do things well. You won't be shut down. You're not going to be continuously shutting down to investigate why things are happening. And you can continue to your economic goals.

What I would offer is that the key here is, I think, the safety culture statement is to drive down into the characteristics that are mentioned here. You have an overarching statement but if you go down into the characteristics, it gives eight characteristics. So those are the keys.

And as was stated, what we're seeing in our inspections is when things happen, event occur and you look at the issues, the contributing causes to it are usually one of these eight characteristics that broke down.

For example, if you look here, one of the first ones is proceeding in the face of uncertainty.

That's very similar to the timeout process. Some facilities use them, some don't.

The others are that I would offer up is procedures or work instructions are not up to date, the current practices. So what -- I guess the point I'm trying to make here is that the policy statement here tries to put those types of things in plan language for the industry in all aspects to consider when they are looking at how their process and programs are run to see that they have these types of mechanisms, the checks and balances in place as they go through.

They identify things. People raise questions. They fix them. They have bigger events. They do continuous learning. They do root causes.

So I wouldn't -- I guess what I would offer up is not just the big policy statement. Look at the characteristics of what they're trying -- of what the policy statement is trying to show. And to, I would say, advise our licensees that these are factors that they want to consider in their decision making because it will balance safety versus the production or whatever their output is and do it in a safe manner that protects everyone, not just the organization but the people around it.

So if you have any questions, I'd be very happy to answer them in more detail.

ACTING CHAIR THOMADSEN: Thank you very much.

Dr. Guibersteau?

MEMBER GUIBERSTEAU: I think an element here that I haven't heard exactly but I think underlies all of this is that when you get a regulatory agency in an effort to encourage a culture of safety, which I think is very laudable, that underlying that are the regulations because the NRC, for instance, is a regulatory agency.

And in any culture, as opposed to civilization, the laws are, you know, are the regulations should be both reflective of the culture and encourage our, if you will, enforce the culture. So I think part of this effort, we need to be certain that the regulations are perceived as being understandable by those in the culture.

And that they also be perceived as having be founded in demonstrable advantages in safety as, for instance, as often quoted, the seatbelt culture. That was very successful. I mean they needed to wear them. They didn't. Well, you need to wear them or you'll get a ticket. They didn't wear them.

But buckle up for safety and we demonstrated to people what could happen to them if they didn't, and to their children, people get in cars now and it is the first thing they do.

So I do think as part of an effort of any regulatory agency with duties to oversee health and safety, that we need to make certain that the regulations are perceived as understandable and that they demonstrate some safety advantages. And we communicate this, as Orhan has said.

ACTING CHAIR THOMADSEN: Thank you.

One of the things I don't see in the characteristics, unless it is straight number five, leadership safety behaviors, is adequate resources, five.

As I've done analyses on events, and I've probably looked at about 300 now having done root causes analysis, and this is for other institutions, I'll say right away, not for Wisconsin, but the most common problem I find is that there were not adequate resources for what the institution was trying to do. I would certainly add that to one of the traits.

Oh, yes?

MR. FIRTH: All right to illuminate that a little bit, the NRC characteristics and the draft

policy statement did get to resources more explicitly.

And what came out of the workshop, you are right. That's not necessarily out front in terms of being explicit in the language.

In the discussion in the workshop, leadership safety behaviors would encompass resources in terms of leaders of the organization would make sure that the resources are available for doing things necessary to maintain safety. So that was one of the pieces of leadership safety behavior.

What we would also need to be doing as we proceed forward is we're not necessarily going to be stopping at those traits in terms of that high-level description, that as we get into guidance or doing other information, we get more explicit examples in terms of what are the leadership safety behaviors, what would be the examples in terms of work planning and control that would then be used to a more concrete environment that is tailored to a few more types of licensees.

ACTING CHAIR THOMADSEN: Thank you. Although if you are subsuming resources under that, as has been pointed out before, you could subsume all of those points under the leadership item.

I think it is about time to tie up this

discussion. Any last comments? Yes? Mr. Mattmuller?

MEMBER MATTMULLER: I will just also add that through the Joint Commission at large medical centers or even smaller safety management committees. And that has representatives from throughout the organization a hazardous materials safety officer, security, facility management, emergency, infection control, radiation safety, nutrition services, vice president of administration, nursing representative, surgery, behavioral health, so all areas of the medical center are involved in this safety committee.

Now that said, it's -- in some regards to touch on what Dr. Howe mentioned, it's almost easier at a larger facility to have leadership focused on a good safety culture and to drive it down. And to support it and nurture it and keep it going.

At a small facility, where it could just be a single physician, that's a much greater challenge because then you are dependent upon their commitment. And how you could regulate that, I'm not sure. That would be a challenge for you.

ACTING CHAIR THOMADSEN: Thank you.

Thank you very much, Ms. Gilley.

Dr. Zelac will now give us an update on grandfathering certified medical physicists. And as a

fairly recent grandfather and a medical physicist, I'm very interested.

(Laughter.)

DR. ZELAC: First of all, I think to allay some key concerns perhaps, I think we will be able to get back on schedule. This is simply a progress report. And I think it is somewhat anticlimactic based on what we all heard from Ed Lohr yesterday concerning the Part 35 rulemaking.

On one of his slides indicated what was coming up in the next one. And one of the things mentioned was a specific "plan to include consideration of Ritenour petition for rulemaking," PRM-35-20).

This is a progress report on where we are as a follow up to the resolution of the Ritenour petition, which was filed, as some of you may recall, by the American Association of Physicists in Medicine. And in my first slide, I'll give you a little history of how we got to where we are.

October of 2002 was the general revision of Part 35, which covered and followed a considerable amount of effort over multiple years to move from a very prescriptive regulation to one that was more performance-based whenever possible.

New training and experience requirements were established. But the prior requirements, which were under Subpart J of the prior rule were retained due to concerns expressed by this body as to the appropriateness of the new training and experience requirements.

Individuals who had been authorized to the inception date, October of 2002, were grandfathered. In other words, they did not have to meet any new training and experience requirements to continue that for which they had already been authorized.

April 2005 was a revision of the portions of Part 35 dealing with training and experience. The Subpart J pathways, which had to do with recognition of Board-certified individuals automatically to become authorized, was eliminated. Also associated with April 2005 was additional grandfathering for those individuals who had been authorized between October of 2002 and April 2005.

In September of 2006, the AAPM, American Association of Physicists in Medicine petition was filed. It sought grandfathered status under the portion of the regulations dealing with grandfathering, 10 CFR 3557, to permit continued practice of medical physics and for serving as

radiation safety officers for individuals who had been certified by the American Board of Radiology and the American Board of Medical Physics, boards listed in the former Subpart J but not listed on NRC agreement state licenses. In other words, certified individuals who were practicing but whose names did not appear on licenses. The petition sought to have these individuals grandfathered.

Resolution of the petition occurred in May of 2008. NRC concluded that the petitioner had raised a valid concern regarding the impact of these revisions to the training and experience requirements in Part 35.

NRC would attempt to develop a technical basis, now in today's parlance called a regulatory basis, to support a rulemaking to address for all authorized individual categories the issues raised in the petition. In other words, the scope of the potential consideration would be expanded from medical physicists only to other certified individuals who may not have now, at this point, have certifications which would permit them to achieve authorized status via the certification pathway, their certifications having been received prior to the recognition date for the particular certification process.

I should probably move on and skip to something else. Here is a summary of what went on in the resolution of this follow up. First, information was gathered through a letter of inquiry. This letter was sent to the recognized medical certifying boards, both past, i.e., whose names appeared in the Subpart J, i.e., those boards whose certification processes had been reviewed and whose certification processes were now recognized by NRC.

Nine boards were contacted in October of 2008, specifically the American Board of Health Physics, the American Board of Medical Physics, the American Board of Nuclear Medicine, the American Board of Radiology, the American Board of Science and Nuclear Medicine, the American Osteopathic Board of Nuclear Medicine, the American Osteopathic Board of Radiology, the Board of Pharmaceutical Specialties, and the Certification Board of Nuclear Cardiology.

The boards were asked for the number and percentage of their currently-active diplomates, those certified prior to the posted recognition dates for their certification processes who were not grandfathered and who were or might in the future be seeking authorized status.

Five of the boards responded, the American

Board of Health Physics, the American Board of Medical Physics, the American Board of Radiology, the American Osteopathic Board of Radiology, and the Certification Board of Nuclear Cardiology. Four of them conducted these surveys among their memberships. The CBNC, Certification Board of Nuclear Cardiology did not need a survey in order to respond to the questions since their certification process was based on the regulatory requirements for the certification pathway, therefore all of their diplomates automatically met the requirements.

For those four boards that did respond, the survey return rates from their surveys averaged 52 percent, quite high. The range also very acceptable from 36 percent to 90 percent.

The response, there were, in effect, negatively affected diplomates. The average percentage of negatively affected diplomates was 33 and the range was from 14 to 66 percent. And in terms of absolute numbers of negatively affected diplomates, over 10,000. And the range from 77 for one board to nearly 8,000 for another board.

The conclusion that was reached from looking at the information that was gathered was that pursuing corrective rulemaking was warranted and

justified. And on that basis, we in MSSA prepared a technical basis or a regulatory basis document. That document has been reviewed by staff in our rulemaking group. And the conclusion from them was it appeared to be sound and sufficiently robust for us to proceed.

The technical basis document, the regulatory basis document, is in review now. And we expect that once received by the management of the rulemaking group to be accepted. And to get to the position where it will be included in the next rulemaking, which will, as you heard earlier, proceed later this year.

The option, of course, is that as it continues through the review process, there will be some fatal flaw in what we have put together. And on that basis, if, in fact, it is found to not be an acceptable technical basis, that will conclude NRC's action and activities in this matter.

That is not anticipated. But it is still a possibility since we do not have yet a formal acceptance of the regulatory basis document.

So in summary, there has been response by NRC, based on the direction from the Commission to this question, and the response has concluded that there is appropriate reason to spend resources and

time to create a regulatory change that would essentially grandfather certified individuals who were practicing and whose certifications don't match preceded the recognized certifications existing today.

I'm open for questions if you have any.

ACTING CHAIR THOMADSEN: Yes, Dr. Zanzonico?

MEMBER ZANZONICO: The question I have is regarding licensed medical physicists. Certain states, including New York where I'm from, have licensed physicists.

Now the eligibility for licensure now includes -- one of the eligibility requirements -- one of the eligibility criteria includes board certification. So that would be subsumed, I think, under what you discussed.

But I think a cohort of practicing medical physicists certainly in New York State and I gather in the other licensing states where non-certified, non-board-certified physicists were licensed. So it strikes me that they kind of fall through the cracks because I gather the appropriate board certification would allow individuals to be grandfathered in. But now you have, I think, a small cohort but a finite number of people, non-board-certified but for licensed

-- were grandfathered in when the licensing programs were implemented.

Where do they stand in this situation?

DR. ZELAC: With respect to licensure, which is obviously separate and distinct from these regulations, individuals who were practicing and were considered as appropriately qualified to continued practice and, therefore, received licensure, clearly were practicing be it in an agreement state or NRC, meaning that those same individuals have met the qualifications of training and experience that are necessary for them to start that activity.

So I think the answer to your question is that these individuals are already or should already be grandfathered. Now if, in fact, they were practicing and licensed and yet they were not listed on the license, this would not apply to them. But they would always have a pathway, if they were to go to another institution, for example, to achieve authorized status by applying via the alternate pathway.

If they are not certified anyway, that would be the appropriate way for them to achieve authorized status.

MEMBER ZANZONICO: Understood. But my

recommendation is that that be included -- that sort of language be included in the regulation because the problem I see in that, for example in New York City, we're regulated by the Bureau of Radiological Health, and frankly we recently had a meeting, the RAMPS, the Radiological and Medical Physics Society of New York, had a representative from the Bureau of Radiological Health, and frankly they were not clear at all where this stood.

And they were citing NRC language. And it sounded like they were not only confusing themselves, they were confusing the audience, you know, the practicing medical physicists that comprised the audience.

So I think there needs to be some clarification of where the status as authorized users of licensed medical physicists in those states where there is licensing -- and I understand exactly what you are saying, that they should automatically be subsumed -- that was not clear frankly on the part of the representatives from the New York City BRH.

And I think that needs to be clarified for their benefit as well as generally.

DR. ZELAC: It's probably appropriate to note that this would be -- what we're discussing now

would be a component of the broader, the big picture rulemaking that is going to be started. And clearly that entire rulemaking and all aspects of it would be put out for public comment.

And there will be ample opportunity for people either to raise questions or to raise issues relative to any one of the parts of that rule. So that, I think, would, you know, get it out for public consideration.

Anything else?

ACTING CHAIR THOMADSEN: Dr. Howe?

DR. HOWE: I think in the discussion we just had there probably needs to be some clarification. You may be thinking of licensing as in medical physicists being licensed by a state to practice medical physics.

We're talking about whether a medical physicist is on a license or, in a broad scope facility, is recognized as an authorized medical physicists.

So we don't recognize medical physicists that are working in diagnostic or manual brachytherapy because they don't come under our authorized medical physics definition. But we do recognize medical physicists that are capable of handling radiation

safety programs if they come in through the diagnostic medical physics thing.

But we're not talking about the licensure of individual medical physicists standalone license but a license of a facility or a practice.

MEMBER ZANZONICO: Again, I understand. And I understand your explanation.

It's not clear that all local regulators understood that. And we're under their jurisdiction. And so, you know, we would be subject to their misunderstanding of the applicable rules.

So either they need to be reeducated, the local regulators. Or the language needs to be clarified so that it is not subject to that kind of misinterpretation. That's the reality.

DR. ZELAC: The real issue had come up because clearly, as I mentioned in the presentation, for those individuals who are practicing and named on licenses were grandfathered when the regulations dealing with training and experience were modified.

The issue had to do with really those individuals who are certified, practicing, but whose names did not appear on licenses and, therefore, were not grandfathered. And what could be done to, you know, alleviate the difficulties that those

individuals might experience when trying to get authorized status at another institution in the future.

ACTING CHAIR THOMADSEN: Dr. Langhorst?

MEMBER LANGHORST: Sue Langhorst. I was just wanting to ask will you be asking this group to help you review this technical basis document?

DR. ZELAC: There had not been an intent to do that. What we have done was to put together what we thought was appropriate, meeting all of the regulatory, all of the procedural qualifications for acceptance by our rulemaking group.

And there response that we got back from the staff there who had received it was that it was adequate and there shouldn't be any issues. In order to give it to them formally for the formal review and acceptance, we have to put it through various levels of review, including going back to our Office of General Counsel one more time, since we added a bit of explanatory language that they have not yet seen.

But, in fact, if there are difficulties, we will bring it back. If it is smooth sailing from this point on, which we anticipate, no need to burden you with it.

ACTING CHAIR THOMADSEN: Other questions?

(No response.)

ACTING CHAIR THOMADSEN: Thank you very much.

I am going to report on a meeting that I attended here for this body on the International Atomic Energy Agency's Safety Standard for Protection against Ionizing Radiation, a proposed document that was sent to the NRC, as a member state of the IAEA, for their comment. This is a document which outlines their recommendations on radiation safety for their member states.

The document itself was in fairly good shape. There was a lively discussion for most of the day. I would just pay attention to those features which might effect medical applications since that is what the ACMUI would be interested in.

The only problems that I saw with the document, and through the discussion heard that might be appropriate here, first was the concept of potential exposure, which was not discussed much at the meeting. If you are unaware, this is a concept that came up a few years ago, I believe through the ICRP, that users of radioactive materials should include in the exposures to people, the idea of potential exposure.

That is that something might happen. And given the probabilities that something might happen, that they should expect that exposure to eventually hit the personnel. That seems very poorly based and I would not suggest that it be perpetuated in standards.

The second is simply the use of the term optimized regarding the use of exposure received performing some function. Through much of the document, this is a very common terminology that the exposure to radiation should be optimized.

The term is used quite differently from how it is used both in industry in industrial engineering and safety and in the general population. In fact, it seems to be used quite uniquely in that document. And it probably should be replaced with a more conventional term.

Third, they do include medical reference levels, which are not explained how these would be applied. These would be diagnostic exposure levels for various studies. They come from what is an average exposure that a patient would receive for these studies.

If those averages are then set as maximums, this can be a problem. As I say, the document is very sparse on discussion on how these

reference levels should be used other than just discussing those.

And the final point that does not effect medicine so much is the requirement to measure radon in public places, that is that the government should do that. I personally think that that is a bit of overkill on this document.

I will note that the American Association of Physicists in Medicine saw an earlier draft of this document and submitted a number of comments. And to the credit of the writers, all the comments had been addressed very effectively. The documents were pretty innocuous as far as I could tell.

With that, I will ask if there are any questions. Mr. Lewis was very instrumental at that meeting. If he has any comments he would like make, they would be welcomed.

MR. LEWIS: Sure. And Don Cool is in the audience who helped me with the meeting as well.

ACTING CHAIR THOMADSEN: Oh, I didn't seem him there.

MR. LEWIS: And, you know, I think that this new document is one input into our next revision of Part 20, which the Committee has been briefed on in the last two meetings, I believe. And it is not

necessarily saying that we would adopt any of these requirements in our regulations.

I will say that the comment on optimization, I appreciate the point you are making. But I do believe it is probably not realistic to expect the international community to use a different term on that because they have two terms that are kind of embedded in their approach. And one is practices should be justified. And the second is those practices that are justified should be optimized. And that's just their terminology.

It would be like trying to get NRC to take compliance out of our regulations or something. So I think that there is an English aspect that often comes up at IAEA. They try to look at a term that means the same thing in many different countries that use English. And then other countries that will translate it, that it is easily translated. And optimize is the term they have. And it is not just IAEA but that's in the ICRP recommendations as well.

So Don, you want to add some thoughts?

MR. COOL: Good morning. Don Cool, NRC staff.

You've touched on one of the things that has been perhaps most hotly debated as the basic

safety standards draft has been developed over the past five or six years. And it has been cooking quite a long time.

And I agree with Rob. The word optimization, as in referring to the process of looking at trying to -- how to best provide protection is very well embedded. Having said that, there has been an enormous debate about whether you say something is to be optimized or whether you say something should be subject to the process of optimization or should be reduced as low as reasonably achievable, social and economic factors taken into account.

Each one of those gets to be progressively longer. And as you might imagine, there is always this tendency to not want long phrases in there that keep getting repeated both because it adds a lot of text and introduces potential difficulties.

This isn't the first time and you are certainly not the only one who has suggested can't you say something besides optimized, the principal argument being there that you can never know for sure that something is the optimum at any given moment because circumstances might change.

The counter argument in the discussion has

always been well if you simply say it is subject to the process, nothing ever actually requires you to implement whatever you decided was the best approach to ensuring protection.

And so if the Committee or otherwise had some thoughts on a better way to express that phrase, we will have some additional bites at the apple as this continues through the process.

And just so the Committee can be aware, the member state comment process is concluding in just a couple of days. The U.S. government comments representing a lot of different agencies, FDA, DoD, HHS, you know lots of people have contributed. Those will be submitted in the next couple of days.

The IAEA will be assembling those comments. Rob, as our representative to the Radiation Safety Standards Committee will get some discussion during their upcoming meeting in just three weeks. They will have almost their entirety of their meeting, if I understand it now, devoted to it in the November time frame when the IAEA hopes that they would have a draft that would resolve of these comments from the different member states.

So we will have some additional opportunities to try and provide small suggestions

although certainly things are beginning to gel. And I'll be glad to answer any other questions about that if the Committee has any more suggestions. Thank you.

MR. LEWIS: And before you leave the mic, Don, is that -- on the diagnostic reference levels, I do believe within the U.S., the FDA, I think, has made use of the diagnostic reference levels but not in the way that they are required, just in a way of helpful information in selecting an image.

MR. COOL: Don, Don Cool, NRC staff again.

Yes, you are correct. That is one of the items, amongst many items, that have been placed into the draft basic safety standards by the IAEA. The medical area was the area that was the most significantly changed in this draft from the existing document which dates back to 1996 in their effort to try and strengthen the requirements because of so many different medical events and situations and the fact that these standards are what, in fact, gets used in many of the smaller countries of the world who will simply adopt these standards.

And the other thing I would note, and another opportunity that we will have, the basic safety standards, as a requirements document, a shell document, is supported by a number of guidance

documents, the safety standards guides, which are, in some respects, similar to the 1556 series of guidance that the NRC staff has, regulatory guides and otherwise.

And I fully expect that there will be updates or additional documents in that series where they will provide some elaboration. And we may well hopefully would have opportunities to provide input on those as the IAEA works on drafting them as well.

ACTING CHAIR THOMADSEN: Thank you.

Any other comments? Yes?

MEMBER ZANZONICO: Yes, Pat Zanzonico.

I share your concerns about the possible use or misuse of these medical reference levels, especially if they were to find their way into NRC documentation because, again, I think a number of members of the user community, regardless of how they may be qualified, would interpret those as maximum permissible doses.

And one instance where we are finding a problem, this is just, you know, a story from home, is the development of new radiopharmaceuticals for evaluating drug pharmacodynamics. That is radiolabeled drugs and their being applied in the initial stages to patient-customized or patient-

specific dosing of non-radioactive drugs, the various radiopharmaceuticals.

Many of these have very poor tumor-targeting properties because they are not intended for tumor imaging per se. They are intended to measure a response to a drug, measure the tumor-specific uptake of a drug, and plan a dose of the non-radioactive drug accordingly so that in order to get usable images, one might have to administer activities of these non-tumor-targeting radiopharmaceuticals. And, therefore, deliver doses that are in the tens of rads, which are well above what people are used to in diagnostic imaging in any modality.

And I know Orhan and a number of people have quoted the RDRC limit of five rad as saying well, we can't do that even though it has no applicability. And it is clearly a misinterpretation, a misunderstanding of the rules and regulations.

But, again, if these sorts of values were to find their way into NRC documentation, whether they were regulations, whether they were just for informational purposes, et cetera, et cetera, I worry that that same misinterpretation may apply, that a reference level is interpreted as a regulation and precipitates this kind of misunderstanding and misuse

among the user community.

ACTING CHAIR THOMADSEN: Thank you.

Dr. Suleiman?

MEMBER SULEIMAN: Yes. Let me give a brief review of reference level. It actually dates back to the states. I think the State of Illinois back in the `70s actually had what they called exposure limits.

The concept was picked up by the Conference of Radiation Control Program Directors, an FDA Program NEXT, Nationwide Evaluation of X-ray Trends, would periodically sample. And you would get a distribution sort of like when you take your child and they say he or she is in the 80th percentile.

So the concept here was find out what is going on out there. And if facilities are at one extreme or whatever, 75th, 80th percentile, at that point the concept evolved that something is not right or why are you in that higher percentage. So investigate it.

And so from the very beginning, I think the concept was very well accepted that this was intended to be like an investigation level. Why are you doses so high?

And over and over again from day one,

people have been concerned that these creep in and become absolute limits. FDA now is involved with a major radiation initiative, some of it dealing with some of these incidents regarding radiation products.

But the reference level issue has come back. Now I say in the `80s and `90s we were in a period of the dark ages, I feel, in the United States. A lot of these concepts were picked up by Europe. And they've come back, the American College of Radiology has been advocating very strongly reference levels. And so the concept has come back in a newer, more improved version.

The fundamental premise still is, you know, at this point you investigate and follow up. And why are your doses higher?

There have been cases where you can justify a higher dose for a certain procedure if it is warranted. And so the question has come to me recently are we going to do this in nuclear medicine.

For some reason people think nuclear medicine is much more optimized. And I said absolutely not, I said, because I hear stories all the time where higher amount of activity are administered strictly to get the exam done quickly, you know.

So I share Pat's concerns. I think as long as you have the ACMUI staffed with people of high integrity and professionalism, I think it won't creep into the NRC, you know, at least the wrong approach.

How you guard against people taking guidance or taking concepts that are defined for one thing and then turn them into something inappropriate, I think the group that adopts that, it is their responsibility. I think we can -- I think it is a good concept. I think it is an important concept in that it is flexible.

So I see this as a way of keeping radiation doses as low as reasonably achievable if you have got a benchmark. You know one of my soapboxes over and over and over again is how do you know you are practicing ALARA if you don't know what the dose is? And if you know the dose, what does it mean?

So I think the concept of reference levels helps reinforce the value of knowing what your dose is. And would be a step in the right direction.

But I agree with Pat in terms of be careful how these concepts are used.

And the term optimization, I don't know what you do about that because different exams may require a different amount of radiation based on the

different types of image quality.

ACTING CHAIR THOMADSEN: Yes?

MR. COOL: Don Cool of the NRC staff again.

I would note that even when you go to the glossary of the document, you will find two components to the definition of optimization, one dealing with the non-medical, if you will, where you are trying to minimize exposure as low as reasonably achievable, and the second piece dealing with medical where it is modified to be the right exposure or the right amount of material to achieve the medical purpose.

I'm not able to quote the words exactly but in the drafting process, there was a lot of discussion about the difference, particularly related to patients, and optimization between simply trying to minimize versus making sure that you've got the right amount to do the job.

ACTING CHAIR THOMADSEN: Thank you.

Yes, Dr. Van Decker?

MEMBER VAN DECKER: Two questions if I might. Number one, can you give me some sense for where the raw data came from for the medical reference list that we're talking about? How did we come to this -- or how did this group come to this as the

medical reference list? Where was the raw data acquired from?

And question number two is can you comment a little bit about occupational worker limits that might be in this that I didn't see on the slide?

MR. COOL: Sure. Don Cool, NRC Staff.

The first question, and I assume are referring to the medical diagnostic reference.

MEMBER VAN DECKER: That's correct.

MR. COOL: The basic safety standards requirement is that a member state should establish diagnostic reference levels based on a series of things. There are not actually any numerical values for any medical modality or test in the document. During the drafting, there was a clear recognition that it was going to vary, depending on the country, varying depending upon the available technologies and other materials.

And so the requirement, at least in my remember what is in the draft, was simply that having such a thing in there to be able to benchmark yourself within your particular circumstance, was an appropriate concept for the requirements.

MEMBER VAN DECKER: So my follow-up question to that before you get to part two is if you

were to see that concept propagated forward, how would you see foresee acquiring a benchmark for medical reference standards?

MR. COOL: Well, I'll start and Rob may want to add as well. This is Don Cool of the NRC staff again.

Quite frankly I don't envision that that piece of the basic safety standards would, in fact, ever enter into the NRC's regulatory structure, that, in fact, the U.S. through things that the FDA may do, to the Joint Commission and other activities which provide a mechanism for looking at, and benchmarking, and understanding where best practices accomplishes that requirement.

I would suggest to all of you that one of the important factors is that because it may be a requirement in the International Basic Safety Standards doesn't mean it necessarily needs to be a requirement in the U.S. regulations because some of the things clearly are not any particular agency's activities. And more specifically, there are lots of things in this standard which are not NRC's and which, therefore, wouldn't be EPA, in the case of the radon program, and otherwise.

Rob, did you want to add?

MR. LEWIS: No, you said it. I think -- well, first of all, you know, we're not obligated to follow the basic safety standard. We have our own rulemaking process.

But I was going to say the same thing. Putting these diagnostic reference levels into the NRC regulations is something that we haven't even talked about on the staff. I think we would have some serious questions about getting into medical practice.

And I think the second thing Don said I totally agree with, I think we are closer to meeting this standard in the U.S. than we are for not meeting it. I think that we could make a legitimate case that our government has a system through the FDA program and through the states that we make available these reference levels already. And that's what kind of IAEA would be looking for.

MR. COOL: And then if you will permit me to come back to Dr. Van Decker's second question, the occupational dose limits, one of the places where the international standards do differ from the U.S. requirements, one of the things that we have already talked about with this Committee that currently is under discussion with regards to whether or not there should be changes in the United States, the

occupational dose limits are an average of two rem -- I'll use the U.S. units -- two rem per year, maximum of five in any one year. That is sometimes referred to as ten rem over five years, maximum of five in any year.

The U.S. regulations, of course, are still a single five-year number. Some countries, in fact, have moved to a single two rem number, not wishing to go through all of the averaging process. That is one of the places that is different.

That does not mean that the NRC will or will not move towards changing the requirements. That's one of the things that we have been engaging all of the stakeholders in. And there is a wide variety of views on it. So that is open to discussion.

But I will note that the U.S. is, I believe, the only country in the world that still has a single five rem occupational dose limit. Everyone else has lowered it.

ACTING CHAIR THOMADSEN: Thank you.

Dr. Zelac?

DR. ZELAC: Since we have about one minute to stay on schedule, I will be very brief. But I had reason to review the draft document. And I found a

couple of the sections in there, while not objectionable, not necessarily requiring any recommendation for changing them, that were of interest to medical practice.

And if you can indulge me for a minute, I'd just like to point those out.

There is a section, my number, that says prior to the granting of an authorization for medical radiation use, the person or organization, i.e., the applicant, shall be required to submit a very detailed safety assessment, which they then go on in the document to describe, which shall be reviewed and assessed by the regulatory body.

Now it sounded to me like that is more detailed, from what I saw, than what is currently required. So that is something to keep in mind.

Another section, prior to clinical use, calibrations of radiotherapy units are to be independently verified. They then went on to describe multiple methods of fulfilling this requirement.

And lastly, periodic radiological reviews are to be performed by the radiological medical practitioners at the medical facility, in cooperation with the medical radiation technologists and the medical physicists. The radiological review has to

examine and critically review the current practical implementation of the radiation protection principles of justification and optimization for the radiological procedures that are being performed in the medical facility.

So this is getting down to if it were to be enacted, a requirement for the kind of reviews on procedures relating to safety, patient and otherwise, that we were discussing earlier.

ACTING CHAIR THOMADSEN: Thank you, Dr. Zelac.

Any other comments? Dr. Welsh?

MEMBER WELSH: I apologize for this as it is getting quite a bit off subject but whenever I listen to presentations like this and hear discussion about occupational annual dose limits, et cetera, I can't help but wonder about the artificial categorization that we have set up here at the Nuclear Regulatory Commission.

We started out with a discussion about international safety standards. And it is impractical to have some kind of policy for all types of safety. So it makes sense to have radiation separated. So you have radiation safety issues.

But ionizing radiation safety standards do

seem like it forms a natural subgrouping. And what is not natural is the distinction between nuclear and non-nuclear. And from a regulatory perspective, I suppose -- well, it's still ionizing radiation. And things like electronic brachytherapy and radiation oncology, things like PET CT studies in diagnostic radiology, topics such as annual exposure limits don't make a real distinction between whether the radiation is from a natural source or nuclear source or a manmade source.

And I know that in recent years NARM has fallen under the purview of the Nuclear Regulatory Commission. But there is this grey zone that continues to expand because of things like PET CT, because of things like electronic brachytherapy.

And I wonder how the IAEA, how other countries, and how the states effectively regulate ionizing radiation as a category rather than what I think we perceived here as an impracticality or impossibility of regulating all ionizing radiation, which would seem natural. But is it so impractical that it is impossible?

MR. LEWIS: I think that you raised a very good point. And most other countries would regulate radiation within an authority, a regulatory authority,

whether it is machine-produced radiation or a byproduct material.

Most other countries don't have the scale of the U.S. or the lawyers.

(Laughter.)

MR. LEWIS: But we have the system we have. And I think our future is bright in that regard, that as we move forward to consider whether to adopt domestically the current international standards for radiation, which apply to machine or sources, we are going to work closely with the CRCPD, the Conference of Radiation Control Program Directors, who, at the state level, does set standards for machine produced.

We are going to work closely with the other federal agencies, the EPA, the FDA, and others through the ISCORS, the Interagency Steering Committee on Radiation Standards, which Don Cool chairs.

And moving forward with all of the agencies together is something we, as a nation, have never done before. So we think we got passed this time.

That said, we are a long ways away. And different agencies are at various states of their thinking on the regulatory requirements for radiation.

So it is a long road ahead but we realize the issue that you raised.

And I think it is more compartmentalized and easier to deal with in most of the rest of the world than in the U.S.

Do you want to add to that, Don or Debbie?

MR. COOL: Don Cool with the NRC staff.

You raised a very good point, Dr. Welsh. The IAEA, not wanting to speak for them but just observing their behavior over the last few years, has been moving very much in the direction of trying to look at all of the different radiation hazards. So they have been moving more aggressively into the naturally-occurring materials area.

They have been working very hard to strengthen things in medical where they have been seeing a lot of issues in some of their member states. And they don't have the legal little divisions that we have here that breaks up jurisdiction into bits and pieces. That is, in fact, why you see the basic safety standards covering all of the attributes.

They, like the rest of us, still struggle greatly with how you regulate that which is manmade and which we can exert a lot of control over versus some of the naturally-occurring materials which exist

in fairly significant concentrations at times plus fairly significant doses but for which you can't apply the same sort of controls or achieve the same sort of dose reductions. And that tension will continue.

ACTING CHAIR THOMADSEN: Dr. Suleiman, did you have a comment?

MEMBER SULEIMAN: Yes. I've wrestled -- we have a tendency of wanting one size fits all. And it would be nice to have everything under one radiation agency.

But even then, even FDA has multiple statutes and the drugs, the medical devices, generic versus new drugs, different types of products, you're dealing with occupational, the general public you are dealing wit patients who are clearly getting a benefit along with the associated risk.

I was telling somebody -- the other day the issue came up about one of the imaging procedures. I said well, the non-radiation effects, if they do an alternative procedure, is puncturing the GI tract. I mean like colonoscopy virtual versus -- there are other risks that are not radiation.

So FDA, in terms of medical applications, has to deal with all sorts of risks. And the good news is on the radiation side, I had a big argument

with some of the ethicists and I said just tell me the risk, I'll tell you the dose.

And they said no. We don't want any radiation associated with this procedure.

I said tell me the risk, I'll tell you the dose.

And so here we're dealing with extremely smart, educated, credentialed people. And because they don't understand radiation, it a binomial reaction. They don't want to deal with it all yet we are dealing with all sorts of toxic, dangerous products that -- who is it said that any poison at a low enough dose, you know, can be tolerated?

So I'm not sure whether just breaking it -- we work -- I think the states sort of give you the umbrella coverage in terms of regulation but you still have other risks associated with these products.

So you can have some safety expert here -- we talked about safety this morning -- safety isn't a unique thing for radiation. It covers other aspects as well.

So that's why we're here. I don't think you are ever going to have one agency, one profession, one speciality that is going to be able to cover everything. So I think it is just going to have to --

there is a lot of work for us to continue to do.

So we're not going to get everything resolved in the next ten years and everything will be happily ever after. You know I don't see a clear differentiation.

ACTING CHAIR THOMADSEN: Thank you.

If there are no other comments, I'd like to thank the NRC contribution to this discussion and the clarification of the issues involved.

We'll take a break. Please return at 10:30.

(Whereupon, the foregoing matter went off the record at 10:09 a.m. and went back on the record at 10:34 a.m.)

13. POST-IMPLANT WRITTEN DIRECTIVES FOR YTTRIUM 90 MICROSPHERES PROCEDURES

ACTING CHAIR THOMADSEN: I am coming back again to discuss microsphere postscripts and unintended consequences of some stuff we have done.

For permanent implants, the user is supposed to complete the prescription. And what I am referring to as a postscript. And there is the regulation. It says, "For all other brachytherapy, including low, medium, and pulsed," et cetera, you have "before the implantation, treatment site"

included in the "radionuclide, and dose; and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure times, or the total dose."

For the microspheres written directive, as revised in September 2008, the pre-administration, all the typical information that we would write in the directive, including the statement "or dose or activity delivered at stasis" assuming that that happens a significant part of the time.

And after the procedure, the written directive has a postscript where "After the administration but before the patient leaves the post-procedural recovery area," you include "the date, the signature of the authorized user, and the total dose or activity delivered to the treatment site."

And we'll point out that if the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or activity administered when stasis occurred and the administration was terminated.

And we'll note the post-administration entries into the written directive are not an

amendment to the written directive but, rather, the entries complete the written directive. And that is the language from the regulations.

The issue that I would like to discuss right now is, at least as we do this procedure in our facility, all procedures go to completion, almost. We have a handful of procedures that terminate through stasis.

We have had one problem with a stopcock very early on. We have had -- well, here I say three because of stasis. We now have had two more. Interestingly, four of these, the two on the slide and the two since were when we had proctors from the vendor working with new interventional radiologists, teaching them the technique as part of their proctor cases, and tend to tell the doctor to stop, rather than at stasis but when you have slowing of the anti-grade flow.

We continue discussing the issue. When the postscript -- oh, if. The idea is that the postscript is to complete the written directive. It really makes little sense if the treatment actually completes the written directive any more than it does to write the written directive at the end of a series of treatments using a cobalt teletherapy machine.

If the written directive is a directive, what good is there to have a directive after everything is done? It's not directing anything.

Why am I even discussing it? Well, it does cause problems for facilities where the authorized user is not present at the procedure, which is perfectly allowable. And it may be a very lengthy procedure involved, which it often is. The timing is never clear with these because of the catheterization of the arteries.

This places an onerous burden on usually the medical physicist, speaking from experience in this case, or somebody else, who then after the procedure has to hunt down the authorized user -- and this may be late in the day or it also may be trying to find an authorized user who themselves may be in a procedure where they can't be interrupted and get the at this point unnecessary completion filled out before the patient leaves because if the procedure has been done according to the written directive, it's not clear that you need to complete that any more than you need to complete the written directive for that cobalt treatment.

If we compare this with the prostate implants, where the concept seems to make more sense

and in a prostate implant, the total strength of the sources to be implanted is not always known until after you are done with the procedure.

Particularly in live-time implants as you're doing the implant, you may be doing correction to the implant to make up for where seeds actually ended up, rather than where you intended for them to go.

In a microsphere case, the desired activity is known at the time the source material was ordered. You know what you are going to do with that patient. You may have compromises in the delivery that may prevent the total use because of stasis, but it is not because you have changed the desired activity.

The postscript and what I would propose is that the postscript should only be necessary for microspheres if there is a clinical need for premature termination of the delivery. If you are just completing the prescribed delivery, you probably don't need to have a second go at the written directive. That is my proposal here.

Discussions? Dr. Zanzonico?

MEMBER ZANZONICO: Pat Zanzonico.

We are performing these procedures as well

as Dr. Mattmuller. I think our experience is very similar that almost all of the procedures to date have gone to completion, although obviously the interventional radiologist is aware that there was a possibility of stasis and that may cause a premature termination of the procedure.

I would agree. I mean, it seems to me the point of the postscript is for sort of conservation of activity purposes, to make sure that all of the activity that was prescribed and delivered is accounted for and that which was not administered likely is accounted for, so forth.

So I would agree there doesn't seem to be any clinical or radiation safety need to redocument the administered activity if the procedure went as planned and all of the prescribed activity was delivered.

I mean, as you point out, there are some clinical exigencies which would require terminating the procedure prematurely like I guess most likely stasis. But otherwise I think that is a reasonable, very reasonable, proposal given the clinical realities of this procedure.

ACTING CHAIR THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: I really agree. I think

using external beam therapy is a gold standard. There your precision and accuracy is very good. You know, 10 to 20 percent you can quibble a little bit about those numbers. If you get into the seed implants, you get softer, but you still have some idea of the dose you are delivering.

To say that you are calculating an absorbed dose and delivering it is probably not true. You are really delivering activity. And the dose distribution is, I mean, the way the particles are going to be distributed.

So it would be almost a moot exercise to try to retrospectively -- in fact, I would challenge you as to what is the dose anyway. I mean, it is probably a very difficult task to challenge, to address.

So I agree as long as people don't take this and apply it to other procedures, where dosimetry is much more critical and can be done.

ACTING CHAIR THOMADSEN: Dr. Gilley?

MEMBER GILLEY: Isn't the microsphere a part 1000 procedure?

ACTING CHAIR THOMADSEN: Right.

MEMBER GILLEY: And aren't we regulating it by guidance document, as we do with part 1000? So

I guess the guidance document has been revised how many times and --

ACTING CHAIR THOMADSEN: The last revision was that --

MEMBER GILLEY: You put this in in the last revision?

ACTING CHAIR THOMADSEN: Yes.

MEMBER GILLEY: So we may be looking at revising the guidance document again as long as it stays in part 1000. Okay. Because I am not sure that this quota 35.40 for permanent input postscript is an accurate reference for a part 1000 procedure.

ACTING CHAIR THOMADSEN: I think we had used that as a guidance for the --

MEMBER GILLEY: Guidance document?

ACTING CHAIR THOMADSEN: -- the guidance document.

MS. COCKERHAM: Yes, 35.40 is mimicked throughout the guidance document.

ACTING CHAIR THOMADSEN: That's why I referred to the rule, as opposed to the --

MEMBER GILLEY: Right. But we could establish in the guidance document a variation to the written directive because it is a part 1000 procedure.

MS. COCKERHAM: Exactly.

ACTING CHAIR THOMADSEN: Correct. Yes. Any comments from -- I see that. They aren't raising their hands, though. Ron? Dr. Zelac, would you care to --

DR. ZELAC: I will make a statement, but it's not backed up with fact because I don't have the current version in front of me. I believe that one of the things that is called for in this pre-implantation portion of the written directive was the anticipated shunting of other sites, the liver, the lung, et cetera, in terms of some estimates based on studies that have been done as to what fraction of the total activity to be administered is expected to go there.

ACTING CHAIR THOMADSEN: Yes, that is correct.

DR. ZELAC: Okay. What I think is anticipated in completion of the written directive is simply the verification, in fact, that that has occurred --

ACTING CHAIR THOMADSEN: I don't think that --

DR. ZELAC: -- and haven't had additional something to one of these other sites. In other words, what I am saying is in terms of the administration, a total activity administered could,

in fact, match what was stated in the original portion of the written directive, the pre-implantation portion. But the distribution with respect to target versus other sites could differ markedly depending on the circumstances and the outcome from the procedure itself.

And I think that is of value in terms of the follow-up or potential follow-up for the particular case in terms of it, in fact, being or not being a medical event.

ACTING CHAIR THOMADSEN: We at our institution never do imaging afterwards based on the Bremsstrahlung. The quantification of such images is very poor at best, in which case all of the documentation afterwards says is that the amount of material that we instilled into the patient was the amount of material that was written for in the written directive.

MEMBER ZANZONICO: Pat Zanzonico.

Yes. The shunting would not cause a change in clinical procedure. And the physician would not be aware of how much shunting would occur if it was different than that predicted during the administration of the microsphere certainly.

So I think the only clinical scenario

where the procedure would be terminated prematurely is, as you say, there was unexpected pressure on the injection needle or the plunger, which would make them think something is clogged somewhere that they weren't anticipating. But there is no real time indication of shunting above and beyond what was predicted pre-procedure. So I don't think that's a realistic component of the guidance or the regulation.

ACTING CHAIR THOMADSEN: Right. Yes, Dr. Zelac?

DR. ZELAC: I can add one other thing. And this doesn't relate to the necessity for the completion relative to what actually occurred. But what I think is reflected in the current version -- and, again, I can't read it. So I'll just -- I know it's up there. I can't read it.

What I'm driving at is I believe that the wording had been changed with respect to what has to be done post, that it can be "an authorized user," as opposed to "the authorized user." So another physician who was authorized for this procedure could, in fact, be found and be the one to complete the procedure.

ACTING CHAIR THOMADSEN: Right. But in addressing that in many facilities, there may only be

one authorized user. So that doesn't really change the issue.

DR. ZELAC: No. In some, it will help.

ACTING CHAIR THOMADSEN: In some, it may. In some, it may not. And you might also say that this may be alleviated in those facilities in which an interventional radiologist who is doing the procedure becomes the authorized user, but in not every institution will that be the case.

Can you read that yet? I can read it up there. All right. Can you scroll down just a bit to get the rest of that last sentence on the "After administration"?

DR. ZELAC: Well, it looks like it still on this version says, "the AU." I thought it --

ACTING CHAIR THOMADSEN: I believe that has been changed.

MS. COCKERHAM: To clarify, that revision, it's changing "the," "an AU" to "the AU" or "the AU" to "an AU." It is also included with the IR revisions that we're trying to make. That is the guidance that is currently in concurrence. So that's why you're not seeing it.

This is what is posted from the public website right now. So this will be replaced within a

few months.

ACTING CHAIR THOMADSEN: Any comments? Yes, Dr. Welsh?

MEMBER WELSH: So if a procedure goes exactly as planned in accordance with the pre-procedural, pre-administration written directive, would it be possible to obviate the need for the post-procedural written directive? Would it be acceptable to have perhaps a checkbox to say "procedure exactly as in accordance to the pre-procedure written directive"?

ACTING CHAIR THOMADSEN: My proposal is that you should be able to obviate.

MEMBER WELSH: And if there is a difference; for example, stasis, only under those circumstances, which may be a minority of situations, would there be a true need for additional documentation?

ACTING CHAIR THOMADSEN: Correct. That any type of note after the procedure, if the procedure goes as planned, would just be a typical completion note, as with teletherapy, rather than part of the written directive.

If that is the sense of the Committee, would anybody wish to make a motion supporting that?

MEMBER SULEIMAN: Just a clarification. So there would be validation documentation that it was finished, checkbox or other?

ACTING CHAIR THOMADSEN: Then the question is, do you need to do that before the patient is released if it's completed --- that is the problem that we're trying to get around -- any more than you need with a cobalt treatment? Do you need to do that before the patient is released? The answer is no.

DR. HOWE: Dr. Thomadsen?

ACTING CHAIR THOMADSEN: Dr. Howe?

DR. HOWE: I think the clarifying while that is there --

ACTING CHAIR THOMADSEN: Can you speak a little bit louder? I can't hear you.

DR. HOWE: I am speaking into the microphone. Okay. A little better now.

One of the reasons that it is in there is because the microspheres are manual brachytherapy. And the manual brachytherapy has the ability to complete the written directive before the patient leaves the treatment facility. So that is one reason.

I guess one of the things that we hadn't thought about -- and it is something that you need to keep in mind -- is the 35.41 does require you to

verify that the administration was in accordance with a written directive. So this would not negate your having to have procedures that would provide high confidence that the administration was in accordance with the written directive. So there would be an additional verification at some point.

ACTING CHAIR THOMADSEN: Fully concur with that.

DR. HOWE: And that may take the place --

ACTING CHAIR THOMADSEN: That would have to be part of the procedure.

DR. HOWE: A part of it was to really make sure in those cases where you didn't go all the way to completion because you had TheraSpheres that, at least initially, they had at least 30 percent of the cases which didn't go to completion because they went to stasis.

Now, maybe there is an improvement on estimating how many microspheres go in now and you do better at not going to stasis, but that was one of the original reasons that we put that provision into the medical written directive.

ACTING CHAIR THOMADSEN: Right. Then the proposal would say if that's the case, then you still would need to revise the directive, although it

doesn't seem like that should be part of revising the directive because it's too late to direct anything at that point.

MEMBER ZANZONICO: Pat Zanzonico.

I think the practical issue is the timing --

ACTING CHAIR THOMADSEN: Yes.

MEMBER ZANZONICO: -- correct, that you don't want to have the patient wait in a recovery area or post-procedure area simply for the purpose of getting the documentation by the authorized user, especially in those cases where the procedure went as planned, so even if you just deleted from that passage but before the patient or human subject leaves the procedural recovery area so that it could be done that evening or even the following day, just to document the procedure went as planned.

It's the issue of the timing and the availability of the interventional radiologist with respect to the procedure.

ACTING CHAIR THOMADSEN: Yes. Dr. Guibersteau, were you raising your hand? No.

MEMBER GUIBERSTEAU: No, no.

ACTING CHAIR THOMADSEN: Any other comments? Yes, Ms. Belke?

MS. PELKE: Patty Pelke, NRC Region III.

I just wanted to remind the group that we have had some medical events that have been reported as a result of use of microspheres wherein the material that is delivered had not been prepared appropriately, they're delivered in somewhat of a slurry, and I think the manufacturer indicates to the end user that the vial should be -- I don't want to say shaken or stirred, but you want to make sure that the microspheres themselves remain in suspension. And if those procedures were not followed, then the microspheres had a tendency to clog the delivery system and the material was not delivered as intended.

And then we have also seen, not frequently but on occasion, the catheters that are used to deliver the material are very, very small and in some cases the catheter during the preparation process has developed a very, very small kink. But that has also impacted the ability of the microspheres to be delivered as prescribed.

So I wanted to make sure that we would not be moving forward, that those events would still have the ability to verify those occurrences if we revise our guidance for 35.1000 units.

ACTING CHAIR THOMADSEN: Right. That

would not be changed at all because those would not, those written directives would not, have been completed as written.

Dr. Welsh?

MEMBER WELSH: Is there a motion?

ACTING CHAIR THOMADSEN: Not unless somebody makes one. As Chair, I can't.

MEMBER WELSH: I think that Dr. Zanzonico worded things in a fashion that if he stated that again and put it in the form of a motion, I would second it.

MEMBER ZANZONICO: Right. I move that in item 2, the phrase "but before the patient or human research subject leaves the post-procedural recovery area" be deleted from this document.

ACTING CHAIR THOMADSEN: All right. Fine. Is there a second?

MEMBER WELSH: Second.

ACTING CHAIR THOMADSEN: Second. Comments? Discussion?

(No response.)

ACTING CHAIR THOMADSEN: All in favor, say "Aye"?

(Whereupon, there was a chorus of "Ayes.")

ACTING CHAIR THOMADSEN: Opposed?

(No response.)

ACTING CHAIR THOMADSEN: Okay. That passed. Thank you very much.

Dr. Zelac?

DR. ZELAC: Would there be any objection on the part of the Committee to there being, as Dr. Zanzonico has suggested, a time factor than simply one that is more relieving of the pressures than --

ACTING CHAIR THOMADSEN: I can't see that there would be an objection. Would there be an objection if a time factor that was not so pressing, such as --

DR. ZELAC: Yes.

ACTING CHAIR THOMADSEN: -- that day, be added? I think the sense of the Committee is that that is fine.

DR. ZELAC: That is fine because, as it would be, if this recommendation were followed, there would be no time at all, meaning that it could be two years after the procedure, which really is not acceptable.

ACTING CHAIR THOMADSEN: I think it is a difference between verification that the procedure has been completed from completion of the written directive. And as long as you're considering it

completion of the written directive, I think the written directive was completed at the time of the procedure.

And the whole concept of having to redo it to complete it is strange to bizarre, as opposed to which is not entirely stated here, that the verification has to be within a certain time. I think that verification of completion realistically should be done in a timely manner, which that is not spelled out in the current guides.

Dr. Welsh?

MEMBER WELSH: So I would just like clarification that this will continue to say "the nature of an AU," rather than "the AU."

And I would suggest as a practical number if a number is sought, maybe 48 hours. That would give two days for the medical physicist to track down an authorized user. And I don't think that it would be as burdensome as the current situation is.

And perhaps amend it to also read "unless the procedure went in exact accordance to the pre-administration written directive," in which case there would be no need for this.

ACTING CHAIR THOMADSEN: Dr. Howe?

DR. HOWE: As Pat Pelke from Region III

pointed out, we have had medical events. And in some cases, the authorized user and the facility don't realize they have a medical event until they measure the delivery system.

And so if you're going to have a time factor in there, at least the determination of measuring the delivery system has to be fairly soon after the administration so that the material is not sent to waste or disposed of until you can't go back and make those measurements. So we have to be a little bit careful about the time period.

We do have some that have not recognized they have had a medical event until they made those measurements. They believed they had all of the microspheres into the person. In some cases, they got stuck on the top of the cap and a significant amount got stuck up there.

ACTING CHAIR THOMADSEN: Right. But I do think that that is a different issue.

MEMBER ZANZONICO: Pat Zanzonico.

I mean, the measurements will be done immediately. No one is going to hold on to the tubing or any other -- the contaminated items for any reason. That will be done immediately. It is just associating the documentation by the AU from the patient leaving

the recovery area.

But, agreed, all of these measurements have and in practice will be done as expeditiously as possible following the procedure or as part of the procedure is just the natural course of doing things.

ACTING CHAIR THOMADSEN: Dr. Welsh, did you want to make a motion associated with your comments?

MEMBER WELSH: Yes. So if there is agreement that a post-procedural written directive is not truly necessary if things went in exact accordance with the pre-administration written directive, I would suggest the amendment to read in part one, "And if the procedure did not go in exact accordance to the pre-administration written directive, then, two, after administration and within 48 hours, signature of an AU," et cetera.

ACTING CHAIR THOMADSEN: Do we have a second to that motion?

MEMBER LANGHORST: I second.

MEMBER ZANZONICO: Second.

ACTING CHAIR THOMADSEN: I have a second. Discussion, please?

MS. PELKE: Could you repeat, please?

MEMBER WELSH: Try.

MS. COCKERHAM: Do you want me to try from what I typed?

ACTING CHAIR THOMADSEN: There we go. Please?

MS. COCKERHAM: Okay. This is messy, but I have "NRC should revise the yttrium 90 microspheres guidance to read, 'If the procedure was not performed in accordance with the written directive, then after administration and within 48 hours, the signature of an AU.'" That's rough, but is it getting close?

ACTING CHAIR THOMADSEN: Did that capture your --

MEMBER WELSH: It does. And in reference to what is up there on the screen, in section 1, at the end of section 1, it would be "And if the procedure did not go in exact accordance to the pre-administration written directive, then, two," what was just stated.

ACTING CHAIR THOMADSEN: Okay. Is that what the seconders thought they were seconding?

MEMBER LANGHORST: Yes.

ACTING CHAIR THOMADSEN: Very good. Further discussion?

MS. COCKERHAM: Who seconded? I'm sorry.

ACTING CHAIR THOMADSEN: Well, there was a

tie.

MEMBER LANGHORST: You can go ahead, Pat. Give it to Pat.

MS. COCKERHAM: Thank you.

ACTING CHAIR THOMADSEN: Okay. Let's see. Dr. Langhorst?

MEMBER LANGHORST: Sue Langhorst.

I would say the 48-hour time frame is consistent with other parts of part 35, where you have verbal changes and then you have to document that within 48 hours. I think that is a consistency that is a good thing.

ACTING CHAIR THOMADSEN: Seeing no other hands, all in favor, please say "Aye"?

(Whereupon, there was a chorus of "Ayes.")

ACTING CHAIR THOMADSEN: Opposed?

(No response.)

ACTING CHAIR THOMADSEN: Okay. We're fine. I think we're done with this topic. I think Dr. Welsh is the next presenter here.

MEMBER WELSH: Thank you, Dr. Thomadsen.

14. SUBCOMMITTEE REPORT ON BYPRODUCT MATERIAL EVENTS

MEMBER WELSH: I will present the results of the Byproduct Material Events Subcommittee. This is our annual springtime report. Just in the way of

background, the Subcommittee has again reviewed the Nuclear Materials Events Database, the NMED, and, as usual, tabulated the medical events.

The Subcommittee understands the desired goals and aims, which are to identify trends and possible causes and come up with possible solutions and ultimately get the information back to the users so that this information can be implemented in a corrected fashion.

The Subcommittee found that, as with previous exercises, the admirable goals are not truly possible with just the raw data that is available in the NMED database. As an example, one of the obvious limitations is the absence of denominators.

I don't have to go through the specifics, but I provide an extreme example. If we say that there are 10 events from procedure x and 5 from procedure y, we might think that x is twice as problematic as y. But if the denominator turns out to be a million x procedures and only 100 y procedures, obviously you could draw erroneous conclusions. So unless denominators are available, trends can't be accurately identified.

Now, we can make and we have made educated guesses by the clinicians and physicists based on data

from 2006, but these are simply educated guesses and, therefore, could be quite far along.

Accurate figures are available, can be obtained through a number of agencies. And Dr. Thomadsen had such figures available for a previous report. But I believe that this was because of a coincidental project that he was working on for another reason and the data was obtained maybe through IMV. And unless that kind of coincidence occurs again, the data is not available and it was not available to us during this exercise. So the data can be obtained but at a price.

An obvious question that I have and others on the Subcommittee have is, how do these agencies get this data? Can the NRC and the states obtain the data in a similar fashion?

So initially and perhaps naively, I thought that maybe it would be very easy to just request that the licensees provide the numbers of procedures done each year. This led to some internal discussion, debate, and people laughing at the suggestion. And it was pointed out that licensees will likely not provide these numbers unless they are required to do so. Does that become the best use of resources for such regulation?

So the debate ensued about how and at what cost it might be to obtain the denominators that would allow us to calculate true incidence rates. And what would we truly gain from this? And is it worth a thousand dollars? A thousand-dollar figure I think is an estimate based on one of the data bases that I think was perhaps willing to sell the data for $1,000.

MS. COCKERHAM: Dr. Welsh, it is 550 because I looked, just to clarify. I think when Dr. Thomadsen mentioned that site, we were thinking it was between 500 or 750 and $1,000. And so I went to the website because I needed to ask our management about the options for this. So I believe it's 550.

MEMBER WELSH: If it's 550, that changes everything.

(Laughter.)

MS. COCKERHAM: Not everything, but it helps.

MEMBER WELSH: Well, it does. It does make a little bit of a difference. But then the broader questioning is, if we have the data and it's cheaply available, will this really help us achieve the goals?

So in the option of one Subcommittee member at least, if we learn anything and reduce the

number of medical events by even one, depending on the severity of the medical event, it might very well be worth it.

True identification of incidence rates can help in allocation of resources and training dollars. And, as an example that was provided, if we learn that the incidence of medical events from procedure x is far higher than that of procedure y, the states would be able to direct the training and resources from procedure y to procedure x with justification based on that data.

But if the cost in manpower and dollars is more, the resources might be better spent differently. For example, it was suggested that simply assuring that written directives are followed through by some validated tool, which, of course, in itself becomes a cost in terms of manpower and cash.

A question raised was, will things become easier in the hopefully near future, when everyone moves to full electronic records? And since that day is most likely coming and coming soon, should we start to position ourselves now for when that day comes? It may not be as hard as we initially thought it was going to be.

One of our Subcommittee members identified

a possible trend in radiopharmaceuticals of failure to carefully and systematically verify that the amount of radiation to be administered was indeed administered just prior to the administration.

A suggestion made was that the written directive include a checkbox to verify that the amount of radioactivity to be administered is indeed correct.

And then there were other simple ideas to reduce medical events such as checklists. And the question becomes, should such advice become regulation? That might be a bigger question we are prepared to answer here, but I think it provides an example of what kind of information can be gleaned from this type of exercise and how it could be helpful if it's provided to the end users and incorporated in some form or fashion to improve the overall safety of their program and reduce medical events.

So, getting on with some of the specifics, nuclear medicine byproduct events reported between October 1st, 2008 and September 30th, 2009, diagnostic nuclear medicine, two events were reported.

The 35.300 section, there were 5 events, which was down from 15 the year before and 7 in 2007. Four of them were I-131, no samarium 153, no yttrium 90, strontium-90, and one iodine-125 monoclonal

antibody.

Thirteen shipment reports were tabulated. In part 600, HDR brachytherapy, it was a total of 13. And this compares with 17 in '07 and 10 in '08. Seven of these were HDR brachytherapy, three wrong location, three wrong sites, and one low-dose.

It was commented that, in fact, all of these medical events were probably truly wrong location. And two of them involved cylinders, which underscores the fact that this procedure, while deemed simple, is, in fact, a challenging procedure that needs to be taken quite seriously and is subject to medical event if not.

Six gamma knife medical events were recorded versus one in the previous period. Two were involving the wrong side. Two were wrong location. One was secondary to mechanical failure, but the team decided to proceed anyway. One was a locator box slippage. And another was wrong collimator size.

Overall comments included the observation that these gamma knife medical events were largely due to lack of proper oversight. No teletherapy events or intravascular events were recorded.

As far as 400 -- actually, I guess this includes the 1,000 since we're talking about

microspheres, yttrium 90 microspheres here, too.

Twenty-six events involving 27 patients. And this contrasts with 10 events involving 114 patients in the prior year.

Nine of these were y-90 microspheres, 17 permanent prostate brachytherapy, one event from 2005 at DVA in L.A. reported in this period and involved two patients with seeds located outside the target.

Some of these recorded medical events were based on dose; the D90, for example, and the number of seeds outside of the prostate.

And an obvious question that comes up and has been discussed in greater depth yesterday is whether these medical events would still be so labeled if we had the more modern proposed definition involving activity or source strength, rather than relying on something like the D90. But we don't have the answer to that and couldn't get the answer to that from the NMED Database.

The majority of the y-90 microsphere medical events were underdosings, and they were caused by things like technical failures, such as the stopcock leakage, catheter occlusion due to a blood clot in one situation, leakage at the puncture site of the vial septum.

And several were due to microspheres not getting into the patient because they adhered to the vial septum after inversion. And we heard about that earlier today.

One of them was attributed to the vial being inverted during transport. And it's possible that the microspheres become adherent to the septum of the vial, the rubber stopper at the top, and are difficult to disengage from that.

So, rather than invert the vial, as one might instinctively do, the manufacturer suggested shaking and tapping the vial, especially if it was previously inverted, to make sure that the microspheres are no longer adherent to the septum.

So the conclusions are that the Subcommittee again suggests improvements to the NMED searching to make it more efficient. And this has been brought up in the past.

But to achieve the real goals of drawing conclusions about trends and identifying truly high-risk procedures and ultimately providing feedback to the NRC and to the end users, dominators are really necessary. And without these denominators, the value of this exercise is questionable.

It is a fair amount of work. It is

interesting work. But does it duplicate what Dr. Donna Beth Howe does in the form meeting? Is it really adding anything if we don't have these denominators and can't put things into perspective? That is a question that comes up.

In terms of but if we could get those denominators and improve the effectiveness and efficiency of the NMED Database, this in my opinion is still a very valuable exercise.

In context of some of the discussions we have had during this ACMUI meeting, we have talked about ways to improve safety. We have talked about safety culture. And if we could get feedback to the end users, it will indeed become a very valuable source of information for these end users to improve their own safety and the safety of their patients and reduce medical events.

So at this point I will just stop and give it back to Dr. Thomadsen.

ACTING CHAIR THOMADSEN: Thank you very much.

Comments from the Committee?

MEMBER ZANZONICO: Pat Zanzonico.

I agree that probably the optimum amount, the maximum amount of data could be divided if the

denominator were available, needless to say, as you illustrated. I still think there is considerable value in the data as is.

For example, this issue with the underdosing of the microspheres due to sticking of the spheres to the septum, I personally had not heard of that phenomenon in the past. And just by cataloguing it, hopefully there is some mechanism that the NRC has for publicizing that kind of finding to the user community because unless you have encountered that issue at your particular site, you might be unaware of it. And it seems like a very simple measure that could avoid at least that and just by being aware of it and, in turn, promptly making the user community aware of it.

So I agree it is useful or would be better to have a denominator, but it sounds like just cataloguing it in terms of raw numbers if that information is publicized and not simply filed somewhere within the NRC, it makes it a very useful exercise.

ACTING CHAIR THOMADSEN: Ms. Gilley?

MEMBER GILLEY: I have to ask NRC, do you have a mechanism for doing outreach for reporting that information? Because NMED is not allowed. The

licensees don't have that.

MR. LEWIS: Information notice or generic letter or things like that. We issue many per year based on NMED data, yes.

MEMBER GILLEY: In the event of an urgent situation, is there a mechanism for hot bring-down, for lack of a better term for it?

MR. LEWIS: If there is an urgent situation, we can issue a bulletin or an order if it's a safety-significant issue, which will require licensee action. We could issue those very quickly, yes.

MEMBER GILLEY: Is that passive, requiring the licensee to reach out and touch NRC or is that active, where you would distribute that information directly to the end user?

MR. LEWIS: We would in the bulletin specify what we're asking the licensee to do. So it's directly to the licensee. And, of course, the states would have to do something parallel.

Donna Beth had wanted to add a thought to that.

DR. HOWE: Yes. I just wanted to expand on that. We also through our -- if it happens to be a device issue and also if it's an FDA issue, we have

the ability to go back to manufacturers. And in many cases, like for the microspheres sticking up in the septum, the manufacturer supposedly put out directions to its users that this was an issue. And we can follow up on those things. We can also pass over information to FDA for them to look at if we think there's a drug issue.

So we have a number of different avenues of looking at things.

MR. LEWIS: And one more that we didn't mention, which is very important, is our medical list server. We can send out information.

MEMBER GILLEY: Just a suggestion that we would look at trying to capture e-mail addresses to at least our high-level activities in order to be able to vastly disseminate information on equipment malfunction.

Having had an incident in Florida with a device and working with FDA, we found that they are required to notify FDA. They are required to notify the end user, but there is no urgency in that requirement.

And we didn't feel that that happened to be adequate at the time that this particular event went on, that we felt the need to have another

mechanism to adequately distribute information in an active environment, instead of waiting for somebody to come to a website or look at an information notice.

MR. LEWIS: See, for safety-significant issues, the NRC has part 21, which applies to vendors. And it's not an issue for compatibility for states. So some states don't have a comparable modification regulation.

ACTING CHAIR THOMADSEN: Dr. Fisher?

MEMBER FISHER: Yes. I am looking at your last slide on final conclusion. As a member of this Committee, I think one of the most valuable experiences that II have had is the annual review of the NMED Database of experience. I think it tells us a lot of information about the success of procedures and the causes of some of the procedure failures.

The real impact of these difficulties in delivering radio isotope therapy to patients is that each of these events represents a patient not adequately treated for whatever disease the patient is being treated for. And those are real impacts that have life-saving implications.

As we look at these events, we see a number of events in common. They are human factors. They may have to do with a lack of skill by the

persons performing the procedure. They may be due to the lack of experience in the person performing the experience [sic.] or setting up the apparatus. They may be due to lack of pre-procedural quality assurance.

Examples of these are wrong site gamma knife. It's like the problem of wrong site surgery, taking out the wrong kidney, which is really a terrible event.

Many of these are wrong location treatments or use of wrong collimators that could have been prevented by improved pre-procedural quality assurance.

With the limited experience I have supporting two local hospitals in brachytherapy quality assurance, I have observed that as the level of quality assurance goes up, the number of these events goes down. And I think -- so improvements if there are to be improvements would be in efforts to improve the skill of the people involved, making sure that mistakes are prevented in advance, by ensuring a greater degree of experience if that is possible, and improved quality assurance.

So my feeling is that this exercise is extremely important and the database is one of the

most illuminating things that we see as we meet here.

ACTING CHAIR THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: FDA does have a program called Med Watch. It's all encompassing. It involves medical devices. It involves drugs. It involves -- first off, manufacturers are required to report to us if there is a problem, but patients not necessarily. But they can use this system to report.

The lack of denominator has always been troublesome to me because some of the biggest columns are picked up because of a difference in rate. And I think the inherent safety of a lot of these procedures will become even more evident if we had a better idea of how often they are used. Also, it would be an internal check.

This information is available. I mean, you may just go to the manufacturer. They may be willing to tell you how much of those products were sold during the course of a year.

I also find trends analysis important. I mean, basically this looks like to me it's down to background level. The one thing that I picked up across the different products -- and I'm really glad you picked up on it, Dr. Fisher, because we discussed it on the Subcommittee -- was the absence of a

mandatory checklist or pre-operational quality assurance.

I think not only do you possibly have people that are not completely qualified. You may have very qualified people that are too busy that are not at the site. They're in a hurry and just don't take the necessary time.

I mean, we have seen this with airline pilots. We have seen this with anesthesiology. I understand it is somehow in a lot of other applications and a lot of industry, a checklist. It's so simple. It's so obvious that it's beneath people to actually require it. But how else could you verify that what you are about to do, everything is in place?

And I think some of the mistakes that we have seen could very well have been eliminated by requiring that. And you don't want to be overly prescriptive, but I think the whole concept of quality assurance wouldn't be of any value if the fact that you're testing certain things regularly catches problems ahead of time.

So in terms of your safety culture, I think if you were to do one thing that would sort of cover all things, it would be to require some sort of validation right before something was done. I mean,

we are thinking about that at FDA right now in terms of some of the equipment. Before somebody pushes a button, has somebody made sure that everything is proper before we hit the button?

So I do find it useful, but I think we are missing some critical information. I think the denominator issue, we should make an effort to fill it up.

ACTING CHAIR THOMADSEN: Dr. Welsh?

MEMBER WELSH: So, then, I would say I do agree with Dr. Fisher, although my last sentence here says that this exercise may be of questionable value. After we completed our exercise and looked back and I looked back objectively at what we had learned from this particular specific exercise, I questioned my own slide, my final slide, because of exactly what Dr. Zanzonico pointed out.

I was not aware of the frequency with which microspheres adhere to the septum of the vial and how this occurs when people might be inverting the vial and shaking it or if it's upside down during transport. That was valuable information to me.

To find a suggested solution from the manufacturer I think is an example of how this information can be disseminated, gotten back to the

provider, the manufacturer. And a solution is thereby generated to prevent this from happening more frequently next year. So hopefully we'll see fewer of these types of events in 2010-2011, thanks to this.

But I do agree with Dr. Suleiman that the denominator is an important component of this particular goal. And if you don't have true incidence rates, you are missing something.

If we were to compile this data and try to get it back to the end users, say, radiation oncology and publish something in the International Journal of Radiation Oncology Biology and Physics, it would be promptly rejected because without denominators, the peer reviewers would say, "This is not truly scientific. This is not perhaps as valuable as it should be for publication in a scientific journal."

But if we did have the denominators and we had true incidence rates and we could publish genuine trends that could be published in a peer review journal, it could become very valuable and widely disseminated to the end users.

So I would like to raise the question about whether or not we think that the denominator is -- as a group, do we think that the denominator is as important as I and maybe a couple of the Subcommittee

members think? And if the answer is yes, how can we get it?

ACTING CHAIR THOMADSEN: Dr. Mattmuller? And then a member of the public.

MEMBER MATTMULLER: I have to admit I have always been a proponent of giving the denominator because I have thought --

ACTING CHAIR THOMADSEN: Can you speak more into the microphone?

MEMBER MATTMULLER: I'm sorry. I have to admit I have always been a proponent of giving the denominator, but through our discussions in previous meetings, I got to thinking that, well, if we did have an actual denominator, would we then argue over what action rate or action level are we going to start looking at incidents?

You know, if 7 gamma knife incidents represents only .001 percent incident rate, are we then going to say, "Well, that is so low we don't have to worry about it" or the same for the microsphere incident. I would suggest we would still look at them, regardless of what the incident rate is.

So in a way, I guess I am reversing my previous thoughts that it would be nice, but I am not sure it would change what we still actually do and

consider during this discussion, which I agree is valuable.

ACTING CHAIR THOMADSEN: Thank you.

Please identify yourself.

MS. BUKOVCAN: I'm Janet Bukovcan. And I'm with MDS Nordion, manufacturer of TheraSpheres. I just thought that it would be relevant for me to talk to you about what we do when we hear about incidents like spheres getting trapped onto the rubber septum of our TheraSphere dose files.

So every time that we get a complaint, it gets logged and we do a thorough investigation. We notify FDA if necessary. And we trend the complaints that come in; so, for instance, all of the complaints that we had, spheres potentially getting trapped onto the septum.

So we trended those. And then after we had several of them, we decided that we needed to improve our instructions for use. So we did an update to our package insert, notified the FDA. And then once that got approved through the FDA, we actually sent out a bulletin to all of our users to notify them of the changes to the package insert.

At that time, we also made some other improvements to our package insert that we notified

our customers of. And one was that we actually converted the format of our instructions for use into a checklist.

So I know that you were talking about a checklist earlier. And so we did put our instructions for use into a checklist format to make it easier for the users to follow.

ACTING CHAIR THOMADSEN: Thank you.

Yes, Dr. Van Decker?

MEMBER VAN DECKER: Just a couple of general comments, I guess, from an overall performance improvement basis. denominators are great in life because they give us exact scientific data. And I would agree with you there, Jim.

I would also say in this perspective, denominators may not be as helpful to us as we would like to believe. I mean, these numbers tend to be very small compared to the amount of activities that are going out in there procedure-wise.

If all of us took a pencil and paper and put guesses as to what realm of order we thought these procedures were being done in, we would probably be relatively close for what's millions, what's hundreds of thousands, and what's a few thousands.

I think that the real goal here is that

those people where an event occurs, probably the most worrisome one is the one where it is a sporadic event in a less used item because then communication and education become how do you get out into that community?

And those are the ones where you can probably make the biggest difference of all, rather than one where there's a lot of people doing it and there's a lot of communication going on.

And the last comment I would obviously make as far as your last question goes is if there is are porting database around, someone is going to look at it and make comments about it. Clinicians involved obviously should be in the first and foremost of looking at this stuff and trying to control where the data is coming from and where we think things are going. So just a few thoughts.

ACTING CHAIR THOMADSEN: Dr. Welsh?

MEMBER WELSH: I would reply by saying I agree, that maybe the biggest impact is getting information on those lesser used procedures. But what are they? That's where the denominator is essential.

I can guess about how many Y-90 microsphere procedures are done, similarly for prostate implant brachytherapy. But without really

knowing, knowing that there were nine Y-90 microsphere events last year doesn't tell me whether or not this is a higher rate than I would have thought.

Eight in the whole year, well, it's eight too many. But is it 8 out of a million, 8 out of 100? I'd like to specifically and scientifically.

MEMBER VAN DECKER: You don't think it's a million, right?

MEMBER WELSH: I don't, but I am not going to share my exact guess.

(Laughter.)

MEMBER VAN DECKER: Okay.

ACTING CHAIR THOMADSEN: Other comments from the Committee?

MEMBER WELSH: Well, I would like to propose that if some of us do agree that the denominator is valuable, unless there are objections, I would like to raise the question about whether or not $500-$550 would make this exercise even more valuable than it currently is.

ACTING CHAIR THOMADSEN: Would anybody from the NRC care to comment on that?

MR. LEWIS: I would be open to looking into that issue. I mean, the denominator of the event equation is something that comes up a lot at NRC. And

we have to ask, if we really need the information, first of all, why wouldn't we require it?

Second of all, if it's available through some other means that we can, that is very efficient. It is something that we would want to do.

We don't want to have an unnecessary regulatory burden to collect the denominator if it's truly unnecessary for the trending analysis. So there are a lot of issues in there to explore.

In terms of this particular database that may be $550, I don't know much about it. Literally the first I heard about it was sitting here. So I think that I'm willing to look at what it is and what it could do.

To be honest, I have my doubts for that cost that we're going to get actual statistics on all of the diagnostic and therapeutic procedures that are performed around the country, but if it's a data point and it's $500, it's not too much in the grand scheme of things. So I'm willing to look at it. I don't think we need a Committee motion or anything to do that, but if I can get that --

ACTING CHAIR THOMADSEN: That cost would be for therapeutic. It would not be diagnostic. Those would be separate. That would be a separate

report.

MR. LEWIS: Okay.

ACTING CHAIR THOMADSEN: I would just call attention to the cost. If you were to gather that data yourself and pay for somebody's time, it would probably very quickly exceed $550.

MR. LEWIS: Yes.

ACTING CHAIR THOMADSEN: Ms. Gilley?

MEMBER GILLEY: I would encourage not to go that route with the agreement states with unnecessary regulatory burden to assist with trying to collect the denominator in this case. Sorry.

ACTING CHAIR THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: I know we have a lot of that information, but a lot of it is proprietary. I remember an exercise once a bunch of years ago where I was about to show some information and somebody says, "That's proprietary."

I said, "I got it off their public website."

So a lot of this information may very well be simply there for the asking. We're not dealing with hundreds of companies. I mean, you could probably just make an effort with somebody who knows what they are doing, even the contractor who pulls the

NMED annual report together.

Some of the information may be just there for the asking. And other information may not be so readily available. And then you could decide if it's worth pursuing.

ACTING CHAIR THOMADSEN: Last year I will point out that I contacted a number of companies, including those making microspheres and brachytherapy sources, and found that while I did get some numbers eventually from some people, most companies were not happy about giving them out. And my success rate was quite low.

MEMBER SULEIMAN: Yes.

ACTING CHAIR THOMADSEN: I'm sorry. Ms. Gilley?

MEMBER GILLEY: I would also caution the reliability of manufacturer data on both medical events or issues and their number of their procedures they have done. I just don't know that that is a valid place to get data that you want to base any scientific experience with.

ACTING CHAIR THOMADSEN: Dr. Welsh?

MEMBER WELSH: The follow-up question is, Dr. Thomadsen, a couple of years ago, you did the similar exercise when you were the Chair of the

Subcommittee. The data that you presented that year I thought was very illuminating because it did include denominators.

We're talking about this subject now. And I guess the question is, how accurate and how reliable are those figures that you obtained in the past? And how accurate will they be if we cough up the $550? The data is going to be useless.

ACTING CHAIR THOMADSEN: The data we used was from the IMV surveys, which have an incredibly high return rate. And it was -- we had those surveys because it was for the writing of an NCRP report.

Where we also correlated the numbers with information from Medicare; from the VA system, a very large national employer; and several other smaller databases that I can't quite recall. And the correlation was done through the American College of Radiology's statistics group and found that there was a surprising consistency between projections from the different databases that we used.

However, only the one, the IMV, covered all patients. And the others, such as Medicare and the VA, only covered a portion of the patients, which had to be accounted for in their comparisons.

I don't know if that answered the

question.

MEMBER WELSH: So it is pretty reliable data?

ACTING CHAIR THOMADSEN: It seemed to be, yes.

Any other comments from the Committee?

(No response.)

ACTING CHAIR THOMADSEN: It sounds like we don't need to make any motions unless, Dr. Welsh, you suggest that a motion of some sort is necessary about something.

MR. LEWIS: We will take an action item. I mean, if you want a motion, it's up to the --

ACTING CHAIR THOMADSEN: It is not necessarily about obtaining the database since you have already told us you will be looking into that if there is something else that you would like to move.

MEMBER WELSH: So perhaps I would like to make a motion that NRC staff consider looking at means of obtaining a denominator to improve the overall value of our annual exercise.

ACTING CHAIR THOMADSEN: Okay. Although I think that they said that they were going to do that --

MEMBER WELSH: Maybe it's not necessary.

ACTING CHAIR THOMADSEN: -- without a motion.

MS. COCKERHAM: Dr. Thomadsen?

ACTING CHAIR THOMADSEN: Yes?

MS. COCKERHAM: Do you want me to read what I wrote just as NRC staff action -- and, Robbie, you can correct me or Dr. Welsh -- that the NRC staff should consider the necessity and evaluate options to collect or obtain data for the denominator for medical events to improve the overall value -- I was writing what you were finishing -- of the Subcommittee's report.

Does that capture accurately what we would like to do?

MEMBER WELSH: Second it.

(Laughter.)

ACTING CHAIR THOMADSEN: So we can pass this. And then you can put it on your list and hopefully just write "Accepted and completed" soon.

Do we have a second for that?

MS. COCKERHAM: It is an action. So I don't need a motion.

ACTING CHAIR THOMADSEN: No motion, no action. Fine. Oh, it's an action. No second.

MS. COCKERHAM: Yes.

ACTING CHAIR THOMADSEN: Fine. Thank you very much, Dr. Welsh.

Dr. Langhorst?

MEMBER LANGHORST: Sue Langhorst.

I would like to say a few words about Dr. Fisher, if I may. Dr. Darrell Fisher is an exceptional radiobiologist and dosimetry expert. He has served the role of patient advocate in other organizations. And his volunteer work in support of cancer patients is laudable.

Dr. Fisher's active involvement in ACMUI deliberations is invaluable in discussing sometimes highly technical issues and helping us all focus on patient impacts.

So I would like to make a motion that ACMUI fully supports Dr. Darrell Fisher as the patient rights advocate and that we express our appreciation and honor to serve with him.

MEMBER MATTMULLER: Second the motion.

ACTING CHAIR THOMADSEN: We have a motion. We have a second. Discussion?

MEMBER MATTMULLER: No need for discussion.

ACTING CHAIR THOMADSEN: I don't think so either.

MEMBER FISHER: I should probably abstain from voting.

(Laughter.)

ACTING CHAIR THOMADSEN: Let's take a vote. All in favor, say "Aye"?

(Whereupon, there was a chorus of "Ayes.")

ACTING CHAIR THOMADSEN: All opposed, "Nay"?

(No response.)

ACTING CHAIR THOMADSEN: Hearing none -- and I cannot vote, but I would personally support the -- as Chair, I'm not supposed to vote on that. And we have the one abstention by Dr. Fisher.

Dr. Fisher?

MEMBER FISHER: I didn't expect this, Sue. I'm sorry. I really appreciate the words and the motion by the Committee.

I have reflected over the last three years over these events and wondered what should be my appropriate response when I knew that I was being accused of something that was sort of far out and untrue.

And so I chose to let the NRC handle it in the most appropriate way. And I think that they have. You can never please all people all the time and

especially in the case of intervenors. You just have to expect that these things come up as part of doing business.

I admire the work of the Committee, and I have always been committed to helping ensure that the work that we do is helpful to the Nuclear Regulatory Commission in its work.

I am a watchdog for patient rights. And I monitor each and every statement made by not only members of the Committee but the staff and the members of the public to make sure that the rights of those persons not present at these meetings is always taken into account because they are the victims of cancer who need these treatments the most.

And so I really do sincerely appreciate the motion that was just passed. Thank you.

ACTING CHAIR THOMADSEN: And thank you.

Ms. Cockerham, it is time for you.

MEMBER MATTMULLER: Excuse me?

ACTING CHAIR THOMADSEN: Oh, I'm sorry. Dr. Mattmuller?

MEMBER MATTMULLER: Yes. In consideration of yesterday's presentation by Ms. Mary Jane Ross Lee in the NRC's efforts for new domestic producers of molybdenum 99 and her efforts and the NRC's efforts

with the interagency group, I would like to make the following motion, "ACMUI strongly recommends the NRC provide maximum staff and support to facilitate the licensing process for new domestic producers of the medical isotope molybdenum 99."

MEMBER GILLEY: Second.

ACTING CHAIR THOMADSEN: We have a motion. We have a second. Do we have discussion? Mr. Lewis?

MR. LEWIS: Well, I question the use of the word "maximum." I mean, we can't -- it's like --

PARTICIPANT: What about "optimize," you want to "optimize"?

MEMBER MATTMULLER: "Optimal." I'll be happy to use "optimal."

ACTING CHAIR THOMADSEN: That means nothing.

(Laughter.)

MEMBER GILLEY: I think maybe the intent is to prioritize when those applications come through, --

MEMBER MATTMULLER: Yes.

MEMBER GILLEY: -- to give them the essential manpowers, resources that are needed in order not to delay the possibility of domestic reduction.

MEMBER MATTMULLER: Yes. And maybe more importantly, before they get here, that NRC staff spends enough time to guide them through the process and to make them aware of their weaknesses in their potential application before it gets here so when it does get here, it is a very strong application that you can legitimately process very quickly and efficiently.

ACTING CHAIR THOMADSEN: Other discussion? No?

(No response.)

ACTING CHAIR THOMADSEN: So the actual wording that you have moved now reads what?

MS. COCKERHAM: Would you like me to read it?

MEMBER MATTMULLER: Yes, please.

ACTING CHAIR THOMADSEN: Has it been altered with --

MEMBER GILLEY: Maximum.

ACTING CHAIR THOMADSEN: Okay. And it reads?

MS. COCKERHAM: "NRC staff should provide optimal staff and support to facilitate the licensing process for new domestic producers of the medical isotope molybdenum 99."

ACTING CHAIR THOMADSEN: Okay. Dr. Suleiman?

MEMBER SULEIMAN: I would like to clarify that this is not to stimulate them because I think the NRC has been doing a good job anyway. So it shouldn't be interpreted as --

MEMBER MATTMULLER: Right.

MEMBER SULEIMAN: -- they're asleep at the wheel and we're trying to prod them.

ACTING CHAIR THOMADSEN: Good point.

MEMBER SULEIMAN: Just a clarification --

ACTING CHAIR THOMADSEN: Thank you.

MEMBER SULEIMAN: -- so somebody doesn't read this later on and say, "Oh," you know.

ACTING CHAIR THOMADSEN: Yes. Good. With no other hands showing, all in favor, say "Aye"?

(Whereupon, there was a chorus of "Ayes.")

ACTING CHAIR THOMADSEN: Opposed?

(No response.)

ACTING CHAIR THOMADSEN: Passes unanimously.

Any other issues before we have Ms. Ms. Cockerham's closing?

(No response.)

ACTING CHAIR THOMADSEN: No.

15. ADMINISTRATIVE CLOSING

MS. COCKERHAM: Okay. While I am getting started, Gretchen, can you go to the G drive and pull up the recommendations folder? There's one file, and it will be a recommendations that they just made during this meeting. Okay.

So while Gretchen is getting that, I was going to discuss the next meeting dates with you, which I know everyone has already received a flurry of e-mails about last week.

So I think right now the input that we have from the Commission is that they are tentatively looking at a briefing date on October 20th, which is a Wednesday. And so what we would try to do is coordinate our regular meeting with that October 20th briefing if that does happen. If that is the case, October 20th and 21st I believe would work with the entire Committee with a few modifications and movings of meetings. Does that still stand?

ACTING CHAIR THOMADSEN: Yes.

MS. COCKERHAM: Yes?

ACTING CHAIR THOMADSEN: Yes, yes. There is another meeting in Washington that two of us are involved in, but I am actually working with the people doing the schedule. And it's Monday, Tuesday, and

Wednesday. And we can make sure that it's --

MS. COCKERHAM: You can support Wednesday-Thursday?

ACTING CHAIR THOMADSEN: Right.

MS. COCKERHAM: Are there any other conflicts or anything that weren't put into the e-mail space?

(No response.)

MS. COCKERHAM: Okay. So I'm going to put in October 20th and 21st as our first preference. I think for this meeting I'm not going to pick any backup dates because we're really just going to wait to hear back from the Commission on confirming this. And that may take some time. So I'll get back to you via e-mail if these dates change as soon as I know something.

Okay. It looks like Gretchen has the recommendations up. So I just want to verify that these are worded correctly. The first one was where you created a subcommittee to evaluate patient release issues, to objectively review and analyze available data, which may include regulations and guidance and international recommendations, to provide a statement on the issue, to provide recommendations for improvements to existing NRC rules and guidance. If

necessary, we should include the issue of patient release to hotels.

So this is a Patient Release Subcommittee, which includes the named individuals.

ACTING CHAIR THOMADSEN: We didn't put into that but sort of inherent should be the subcommittee should report at the next meeting, I would think.

MEMBER LANGHORST: That is what I thought would be the best.

ACTING CHAIR THOMADSEN: Okay.

MS. COCKERHAM: Okay. I will make that revision.

And then for the second one, this is the Permanent Implant Brachytherapy Subcommittee. We will revise the draft subcommittee report, resubmit it to the full ACMUI for a formal vote. And then the ACMUI will submit that final report to the NRC.

MEMBER SULEIMAN: I thought it was an e-mail vote.

ACTING CHAIR THOMADSEN: Yes. I think that was the case.

MS. COCKERHAM: You're going to clarify an e-mail vote?

MEMBER SULEIMAN: Because it's near-term.

MS. COCKERHAM: Okay. Number 3, this is an action item. NRC staff should provide inspection reports that describe safety culture problems as contributing factors to violations. I believe Mark Ferdus from Region I might have answered this question and given the Committee specific examples that they asked for, but is there still an open action for this?

ACTING CHAIR THOMADSEN: Yes. I don't believe that the information given actually addresses what was required here. And I don't know that we need the complete inspection reports. I'll leave that up to Mr. Lewis and how he would like to provide the information.

MR. LEWIS: Just say, "and provide information."

ACTING CHAIR THOMADSEN: Yes.

MS. COCKERHAM: Okay. So remove "inspection reports" and add "information." Okay.

Number 4, "NRC staff should revise the Y-90 microsphere brachytherapy guidance to delete 'but before the patient or human research subject leaves the post-procedural recovery area'" under item 2 of the written directive section. I think that's right.

Okay. Next one, "NRC staff should revise yttrium 90 microsphere brachytherapy guidance to read"

-- and this is under number 1 for written directives -- "And if the procedure was not performed in accordance with the pre-administration written directive, then, two, after administration and within 48 hours, the signature of an AU."

ACTING CHAIR THOMADSEN: Is number 5 superseding number 4? Is that --

MS. COCKERHAM: No. They would both stand. One would be deleting. And then the second one is adding a piece, saying --

ACTING CHAIR THOMADSEN: I see. Okay.

MS. COCKERHAM: I separated them as two separate ones, separate questions.

MEMBER ZANZONICO: I have a question having to do with the actual wording of item 5. It should say, "And within 48 hours of the procedure." Then there's no "Oh, yeah," benchmark event for the 48-hour time frame.

MS. COCKERHAM: I'll add that.

ACTING CHAIR THOMADSEN: "Accordance is spelled wrong."

MS. COCKERHAM: Yes. Excel doesn't do word checks. This is me frantically typing while you guys are talking and trying to listen at the same time. Yes. So I'll fix it up. These will all be

fixed before they go in a Word document memo to you.

So that was number 5, correct? Yes. So number 6, "the NRC staff should consider the necessity and evaluate options to collect or obtain data for the denominator for medical events to improve the overall value of the Medical Event Subcommittee report." We're taking that as an action item.

MEMBER LANGHORST: Sue Langhorst.

Did we want them to collect the data or just obtain data? I don't think we had any intent of having you collect data.

PARTICIPANT: No.

MR. LEWIS: It says, "evaluate options."

MS. COCKERHAM: Okay. I worded it very vaguely.

MEMBER FISHER: Yes. I think it means that we're trying to better understand the relative frequencies of events.

MEMBER LANGHORST: Yes, but I think the point is we weren't asking them to go out and start soliciting.

MEMBER FISHER: Collect raw data, right.

MEMBER LANGHORST: To collect rats.

MS. COCKERHAM: I see Debbie shaking her head frantically.

MEMBER FISHER: I am not sure how we do, but I think the motion is a good one. There might be things we can do. I'm not sure what it is.

MEMBER LANGHORST: Okay.

ACTING CHAIR THOMADSEN: Would that be included under just saying options to obtain the data and just deleting the two options to collect?

MR. LEWIS: Read options to collect the data would pay $500 and collect it from --

ACTING CHAIR THOMADSEN: Oh, I see. Yes. That's fine. That's fine.

MEMBER LANGHORST: The point is we weren't asking you to put rulemaking in to "Now as licensees, you have to report this number."

ACTING CHAIR THOMADSEN: Okay.

MS. COCKERHAM: Okay.

ACTING CHAIR THOMADSEN: I think we're fine.

MS. COCKERHAM: We understand the intent.

MEMBER GILLEY: The states will revolt if you --

(Laughter.)

MS. COCKERHAM: All right. So number 7, "The ACMUI fully supports Dr. Darrell Fisher as the patient rights advocate. The Committee expressed

their appreciation and honor to serve with him."

And, number 8, "NRC staff should provide optimal staff and support to facilitate the licensing process for new domestic producers of the medical isotope molybdenum 99."

Okay? And I think I have one --

ACTING CHAIR THOMADSEN: With the understanding that we think they have been doing a bang-up job up to this point.

MS. COCKERHAM: Thus far. And I think have only one question. It's not on the screen, but, Gretchen, do you see a question mark where it said, "Who made the first? Who made the second?" and there is a question mark by a motion Dr. Zanzonico made?

MR. LEWIS: It's all the way to the right.

MS. COCKERHAM: Yes, far right. And then what number is that? Number 5. Do you know who that is?

PARTICIPANT: I think we agreed it was me.

MS. COCKERHAM: You made the motion, but who seconded that?

PARTICIPANT: Dr. Welsh made the motion.

MEMBER ZANZONICO: Welsh made the motion. I made the second.

MS. COCKERHAM: And you seconded. Okay.

So that was for number 5, Welsh motion and then Zanzonico second. Sometimes these don't come up. Sometimes it doesn't matter, but sometimes I get questions like "Well, who made that motion?" Then we go read the transcript. So I keep track of them here.

All right. So that covers it. The next meeting is tentatively set for the 20th and 21st. These are all the recommendations from the meeting. Please take off your name tags, put them on the table.

And Shayla will e-mail you regarding your time and travel. She will give you the example forms. And you will submit it like we always do. And then time will be due next week since we just had our pay period end last week.

ACTING CHAIR THOMADSEN: As long as you are up there, can we see who needs to go to the airport when?

PARTICIPANT: Oh, sure.

(Whereupon, the foregoing matter was concluded at 12:05 p.m.)