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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MEETING

OPEN SESSION

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Tuesday

October 28, 2008

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The meeting came to order at 8:00 a.m. in T2B3 of White Flint 2. Richard J. Vetter, PhD, Vice Chairman, presiding.

ACMUI MEMBERS PRESENT:

RICHARD J. VETTER, PHD, VICE CHAIRMAN

DOUGLAS F. EGGLI, MD, MEMBER

DARRELL R. FISHER, PHD, MEMBER

DEBBIE B. GILLEY, MEMBER

RALPH P. LIETO, MEMBER

STEVEN R. MATTMULLER, MEMBER

SUBIR NAG, MD, MEMBER

ORHAN H. SULEIMAN, PHD, MEMBER

BRUCE R. THOMADSEN, PHD, MEMBER

WILLIAM A. VAN DECKER, MD, MEMBER

JAMES S. WELSH, MD, MEMBER

PRESENT: (cont.)

MICKEY GUIBERTEAU, MD, DIAGNOSTIC RADIOLOGIST

NRC STAFF PRESENT:

KIMYATA MORGAN BUTLER

CHRIS EINBERG, DESIGNATED FEDERAL OFFICER

CINDY FLANNERY, ALT DESIGNATED FEDERAL OFFICIAL

OSSY FONT

VINCENT HOLAHAN

DONNA-BETH HOWE, PHD

HARRIET KARAGIANNIS

DORIS LEWIS

ROBERT LEWIS, DIRECTOR

JIM LUEHMAN, DEPUTY DIRECTOR

ANGELA MCINTOSH

GRETCHEN RIVERA-CAPELLA

TERRY REIS, DEPUTY DIRECTOR

ASHLEY TULL

DUANE WHITE

RONALD ZELAC, PHD

MEMBERS OF THE PUBLIC PRESENT:

ROY BROWN, CORAR

TOM BURNETT, MDS NORDION

WILL DAVIDSON, UPENN

PRESENT (cont.):

RICHARD EATON, MITA

LYNNE FAIROBENT, AAPM

EMILY GARDNER, ASNC

MIKE PETERS, ACR

DOUG PFEIFFER, AAPM

RICHARD MARTIN, ASTRO

REED SELWYN, UNIF SVCS UNIV OF HLTH SCI

HARRY SKENE, GEISINGER

ANN WARBICK-CERONE, MDS NORDION

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

8:07 a.m.

VICE CHAIR VETTER Good morning, everyone. My name is Richard Vetter. I'll be chairing the meeting this morning. Dr. Malmud was called away on a family emergency.

Yesterday was a long day for us, so if the weather is any indication this morning, we're going to breeze right through the agenda, but we do want to, before we begin -- and let me explain, we will be moving things around a little bit in order to pick up those papers -- those presentations that we missed yesterday. We'll deal with that as we go.

First, as you know, yesterday, we had a presentation on the shortage -- the shortage of medical isotopes and it was toward the end of the day and we were all rather tired and we sort of left it on the table after the presentations. So just to go back for just five minutes, we would like to put a motion on the table indicating our support of the issue. Steve Mattmuller has the motion.

MR. MATTMULLER: Steve Mattmuller. "The US moly supply for technetium 99 M generators currently is extremely fragile. The ACMUI strongly encourages the NRC to; one, continue supporting the

exportation of H highly enriched uranium material for Moly-99 targets used by international suppliers."

MS. TULL: Will you read the beginning? Sorry.

VICE CHAIR VETTER Read it a little slower and they'll type it as we go.

MR. MATTMULLER: Okay.

VICE CHAIR VETTER Why don't you just read it and then give her the notebook?

MR. MATTMULLER: All right, and then number two, "Provide all possible help towards the development of US suppliers of Moly-99."

VICE CHAIR VETTER That's a motion. Is there a second?

MS. GILLEY: Second.

VICE CHAIR VETTER Debby Gilley seconds. Discussion? I don't think it's very controversial. It's just basically saying we support continued use of HEU and the -- encourage the agency to provide whatever help it can in moving the issue forward. Dr. Welsh?

DR. WELSH: We're saying that we're encouraging the continued shipment of HEU for the production of the moly which is a critical aspect for us as medical practitioners that the technetium 99 is

available but the HEU remains a concern and there have been petitions put forth to encourage suppliers to switch from HEU to LEU. It may not happen. It may not be as easy as just asking for it, but I think that we should continue to encourage that ultimately these international producers use LEU rather than HEU.

VICE CHAIR VETTER Dr. Fisher?

DR. FISHER: I'd like to comment on that. Earlier this year in May, I attended the Sixth International Conference on Isotopes in Seoul, Korea. There was substantial discussion of the production of Moly-99 using high and low enriched uranium targets and one of the most interesting comments made in the opening plenary session by the representative from South Africa, his laboratory name I can't quite remember. His name is difficult to pronounce. But he made the comment that although it's feasible to produce Moly-99 using low enriched targets, it is not commercially viable without substantial federal subsidies.

You're looking at much larger costs to produce Moly-99 using low enriched uranium for reasons mentioned yesterday. It cannot succeed on a commercial scale without substantial federal subsidies from the host country.

VICE CHAIR VETTER Other discussion? Yes.

DR. GUIBERTEAU: I know the --

VICE CHAIR VETTER Your name again, please?

DR. GUIBERTEAU: I'm sorry, Mickey Guiberteau. I'm a diagnostic radiologist representative. I know there's a subtle difference about this and to provide support for the development of US suppliers of Moly-99. There are a number of suppliers but the producers actually are overseas. So having more suppliers doesn't necessarily help us and I would like to see, perhaps, that word "supplier" changed to "producers."

MS. GILLEY: Do you accept that as a friendly amendment?

MR. MATTMULLER: I accept that, yes.

MS. GILLEY: I accept that as a second.

VICE CHAIR VETTER It's been accepted as a friendly amendment to the motion to change "suppliers" to "producers".

DR. GUIBERTEAU: Actually, I was thinking in the second part, but both would be fine.

VICE CHAIR VETTER Other discussion? All those in favor of the motion, raise one hand. One, two, three -- it is unanimous? It is unanimous.

Thank you very much. Okay, now back to the agenda, we'll be starting on Tuesday, October 28th the agenda beginning at 8:00 o'clock. We welcome Dr. Donald Cool and then the 9:00 o'clock presentation by Cindy Flannery will be cut from the agenda and we will deal with that by teleconference. And then we will go back, pick up Dr. Zelac's presentations from yesterday and he will have those two presentations plus item 14. So we'll have Dr. Zelac for three in a row.

And meantime, back to Agenda Item Number 1. Most of you have met or are -- or know Dr. Donald Cool. If you've been on the committee long enough, he was our boss for awhile and then since then, we've had a couple of generations of changes. But in the meantime now, he's back here to visit with us about Revisions of the NRC Radiation Protection Requirements and Potential Impacts to the Medical Community. Welcome, Dr. Cool.

DR. COOL: Thank you, Dr. Vetter. Good morning. Hopefully my voice will hold up with sufficient volume for this discussion. Standing on a rather cold wind-swept train platform as the MARC commuter train system this morning decided to have a little issue with a freight train which resulted in us standing on the platform for over an hour is never

good for your throat.

So it's been an interesting morning. Things can only go up from there, I assume. So what I'm here to talk about this morning for you is the things that the NR staff is currently looking at and considering and looking at the radiation protection framework that the NRC has. Now, we talk about this mostly when we do this as just Part 20, but there's actually, of course, considerably more than that as there are radiation protection criterion standards sprinkled all through the requirements.

This process got started at the direction of the Commission, this year following the publication by the International Commission on Radiological Protection, that's ICRP who published their revised recommendations, Publication 103. Back in 2001, the staff, the NRC staff, had gone to the Commission with some options for whether to start proceeding to look at Part 20 and other parts at that point. One of the options that we gave the Commission was since we knew ICRP was beginning to work on doing an update of the revisions, we actually suggested to them that it might be a nice idea this time around to wait for ICRP to be done rather than doing like we did last time, get all done with the rulemaking just as ICRP puts out a new

set of recommendations and immediately being behind the eight ball once again.

So the Commission agreed with that. The Commission told us, however, not to work on any technical basis and underpinnings, so we've just been commenting on the ICRP draft as they took seven years to do a document, almost as long as the rulemaking, perhaps not quite. So we are not in the position to start considering what to do next as a result of that publication.

I will note to you that the International Atomic Energy Agency is already in the process of revising the international basic safety standards. The European Union is in the process of revising the Euratom basic safety standards. So internationally, there are already moves to incorporate ICRP Publication 103 into the regulations and requirements that most of the rest of the world deals with.

So, we are taking a look at the regulations. Our task is to provide the Commission with options for consideration. That paper is due to the Commission in December or due to the Executive Director on December 15th and it goes to the Commission shortly thereafter. We've been working this with a senior technical group and a steering

committee involving all of the offices of the agency and we have started by taking a look at all of the portions of the regs. Now, most of you remember when we did the revision of Part 20, it came out in 1991 and you know, there were a whole raft of parts. It was -- the actual CFR citation was 10 CFR Part 1920 et al.

What was interesting about that was all of those parts were cross-references. We, in fact, did not at that point go and change regulations where there were separate explicit criteria in place. They were independent from Part 20. So there are, in fact, portions of the regulations in particular some of the things that the reactors have to deal with and the reactor effluence in Part 50, Appendix I, some of the things in Part 30, the low level waste criteria which go all the way back to ICRP publications 1 and 2, the maximum organ burden, maximum commercial concentration values from 1959.

Though the might be just considered a wee bit out of date, and in fact, the 800 pound gorilla, the reactor power industry, has gotten just a little bit frustrated with having to take all the bright young HP's and physicists that come out of universities and go back and teach them how to do the

old calculations so they can actually continue to demonstrate compliance.

As a result, there is a fair bit of pressure around to do something, at least for those portions of the regulations which are really, really old and they would prefer to do everything in one sweep and have everything come up to speed. So there's a certain logic to that. And of course, the reactors also have to deal with this little rule called the backfit rule which means you have to do a demonstration of whether or not there is an adequate basis for change, whether the cost benefit is appropriate. There's a lot of criteria that go into that.

Some of that may come into play in terms of adequate protection, which is the obvious way that you could step forward with that, but there's also issues about updating scientific information. A lot has happened in the last 25 years. There are a number of transboundary implications, some of which I'm sure you are very familiar with. You're in fact, probably the only folks that actually deal with SI units because that's the only way you can export your materials.

Achieving consistency in approach, workers

are moving back and forth across borders, materials are moving back and forth across borders. So there are a lot of reasons that are floating around out there to consider changes and updates. We are in the process of developing this options paper. This slide, because we needed to provide it to Ashley a month in advance for you, is just a wee bit out of date in that the regulatory options, the administrative options part of the papers have now sort of been combined together. I'll be talking about the sets of things that we're considering.

So what are we thinking about? Obviously, the first option could be to do nothing. That's always an appropriate option. We're protecting public health and safety. Things haven't changed substantially. The risk coefficients from that which were known in 1990 have not significantly changed. If anything, they've come down a little bit. You might want to put just a bit of a parenthetical in there. The actual risk coefficients which underlie the existing Part 20 come from ICRP Publication 26 in 1977 and those risks were actually predicted lower at that time. So the risk estimates have come up to five times 10-4 per rem fatal cancer risk from 1.25 times 10-4 per rem which is what the current Part 20 is

based on. So again, you can make an argument that there is an underlying basis for change should you wish to do so.

The second option or actually a sub-option of that, would be since the reactors have the really burning platform, let the reactors work on doing some updates and leave everything else alone. That certainly isn't as resource intensive as trying to attack the entire spectrum or we could start the process of moving towards some degree of alignment with the new recommendations and updated factors and of course, you could just look at Part 20. You could look at Part 20 and Part 50 or you could think really globally and you could think about trying to take everybody all at once.

Now, that's sort of an interesting proposition. As you might guess, the amount of resources necessary as you would step through with each of these options, gradually climbs. You start to think about what would be necessary to do all of the different places and all of the regulations and all of the correlated issues that would go along with that, you would see that that is a really daunting challenge.

Now, let's talk for a minute or two about

some of the technical options. I will tell you at this point that these are issues to be placed on the table. That staff at this point has not firmly come to a particular solution for each one of these technical options. That is in part because we have not been developing any technical basis. The Commission was just see what ICRP was going to do before we moved forward. So there is a lot of information that remains to be needed in order to understand the details, my slide went away, for these -- for a number of these options.

Furthermore, some of the information that we would need for this particular last item, the numeric values which we'll talk about in a little bit, is not yet available. ICRP in Publication 103 put out new weighting factors for tissues, new weighting factors for radiation. The next step in their process is to go through and take that material and use the new biological models for distribution of material in the body, et cetera, updated information on the physics of the different isotope decay change because the nuclear data has been changing and go through to calculate a new set of dose coefficients. That's what you use to calculate annual limits of intake drive the concentrations, that's what's in Appendix B.

The first of those calculations, as we understand it to this point, will be available in 2011. So that's like not now, that's not like not even manana as in not today. It's a fair bit aways. So there are some things that we still need to wait on. That, in fact, gives us, we believe, as the staff, the opportunity now to pick back up from where the Commission had told us to wait and watch to consider looking at and developing a technical basis and understanding the issues and implications that would go along in our revision. This discussion with you today is one of the starting points in that steps in terms of what's on the table and what might be appropriate.

So to quickly walk through these, total effective dose, actually, from a Part 20 standpoint, this would be an editorial change. Part 20 today reads "total effective dose equivalent". Okay, so they change the terminology a little bit. With each of the succeeding generations they've updated the tissue weighting factors, radiation weighting factors, so the process of calculating it is a little bit different. You'd get slightly different numbers.

But, in fact, Part 20 today already uses the underlying concept of combining internal/external

exposures into a single value that we'd use for compliance and in fact, with a change that was final in February of this year, effective dose can be calculated from external exposures.

Some people have not actually picked up that that provides a significant change. Instead of it just being the badge on the lapel, the deep dose equivalent, the dose measure that deploys the highest exposure, it cannot be a calculation of effective dose. So if you're an intervention radiology or cardiology or doing a number of other things and you have the lead aprons and other shielding, you can use the two batching approach, some of the algorithms that are out there. A number of those have, in fact, been endorsed by the NRC and are available as regulatory information summaries. All that's already in place. So from a Part 20 standpoint, this could almost be considered as editorial to bring the terminology up so that when we talk the same language, we're all using a consistent standpoint. This is the really big deal with you look at some of the other portions of the regulations such as Part 50 Appendix I because they still talk about organ doses and whole body doses, and of course, they would want to move to an effective dose or effective dose. That's why this one is on the

table because this would be the place where you would finally get a consistency in the approach to radiation protection.

Constraints, the biggest thing which happened in the ICRP recommendations was an increased focus upon the process of optimization, we call it ALARA. They also use the phrase ALARA, and the use of what they refer to as constraints as a boundary in the optimization process. Now, as ICRP lays this out, a constraint is any value that you would use in the planning of your program and your activities to help decide what protection options were viable or not viable. It helps make sure that you don't actually approach the dose limits. It helps make sure that if you have multiple sources of other activities, that the combination of those two would not result in receiving the dose limit but a constraint as envisioned by ICRP is not a dose limit. It's a planning value, the value that we'd use in setting it up.

So in fact, as the process of developing their recommendations went along, it got fairly clear differentiating what they consider to be a constraint from that which we would consider as a limit, where the Office of Enforcement comes down and bangs a

hammer over your head.

Now, in fact, Part 20 today has the word "constraint". It's defined as a value which requires some licensee action. Very nice, okay. There is, in fact, a constraint already in Part 20. Most of you sort of have to live with it at least because it applies to the airborne effluents from a material facility. It was put in place as a result of some rather interesting negotiations with our friendly Environmental Protection Agency on the Clean Air Act. It has a numeric value at 10 milirem.

The requirement is if you set to exceed 10 milirem, you need to figure out what to do. You need to try and bring those effluents back in. It also requires a report to the NRC. But simply because your effluents went over 10 milirem, doesn't mean it's a violation. It's only a violation if you don't do anything about it.

So the staff consideration on this in the occupational exposure area, would be do we consider putting in a requirement that licensees use such a concept in their programs? Now, the reality is most programs of any significant size and complexity probably already have planning values, reference values, action levels, a variety of different things

that you would have in your system which are less than the limit that you're using for planning, that you're using as targets as part of your process. So if the Commission were to put in a requirement like that, that would be exactly what you would use. There would really not necessary need to be any particular change.

On the other hand, we know that there are some folks around for whom this is not a concept of his employ, industrial radiographers form an example, and so there is the possibility that adding this structure to the requirements would help to improve radiation protection, would help to improve ALARA, would help to reduce the top end of the dose distribution, those within the occupational system that are getting very high exposures.

So this is a consideration. It's a consideration, do you put in such a requirement and then do you put in a numeric value for it or not, or do you simply say that they have to pick one and it has to be less than the limit? So there are some possible implications there. Obviously, the impact would depend on how you wrote it. That's one of the issues that we're seeking feedback on.

That correlates to the next issue which is the dose limits. The United States is the only

country in which the occupational dose limit remains at 5 rem per year. Everyone else has gone to either a 10 rem over five years which is an average of two rem per year with a caveat of a maximum of five in any one year. So you could have five, then you'd have to be substantially less in any five-year period, or they've made it simpler and they've gone to a straight two rem per year.

We are an outlier from the standpoint of where our occupational dose limit is at. So a question clearly on the table for consideration is whether the NRC should, in fact, move to change the occupational dose limits. We could do nothing. We could leave it at five and we could sit here and argue probably with a perfectly straight face, no, ICRP has said maximum of five in any year. We have five, what's the problem? In fact, the average dose in most of the occupational categories is down in the few hundred milirems range. So if you change the dose limit would you actually change the average for occupational exposures? Probably not.

Would you change the upper tail of the distribution? Absolutely, because we know that there are people that are getting over two rem per year in each of the categories, reactors, medical,

radiography, you name it, you've got some distribution up there. We are right now looking at a draft NCRP update in Publication 93. There has been some discussions here and there. I will tell you that that says that there's actually more people above that two rem number than you might have suspected and in more job categories. Maybe that doesn't surprise you, maybe it does. But you could leave it at two.

You could move -- leave it at five. You could move to a straight two, very simple, straightforward, record the doses. Of course, that's reducing the dose limit by a little over a factor of two, goes from five to two and the screaming starts ensuing. How can you possibly do that? Look at all of the impact. What are we going to do with all these people? You're impacting patient care. We can't do the procedures and on and on and on. Okay.

The third possibility, of course, is what the actual recommendation is, make it 10 rem over five years, a maximum of five in a year. It has a little more flexibility, has potentially a lot more burden in terms of record keeping and otherwise, because you'd have to go back to collecting dose histories and keeping track of people over five year terms to figure out how much you can have this year, Dr. Vetter,

because you got five last year. So you can't have nearly that much this year, but, you know, Dr. Van Decker, oh, he's good. He only had minimals on his badge, so he's good to go. So it would make for much more complication and impact on the system.

Again, this is an issue which we want to explore with you and the other licensee categories to try and understand the impacts and implications of the proposal. As I said, this needs to be considered with the concept of constraints because constraints from one mechanism to move the top end of the distribution of doses down, moving the dose limits is the second level.

Now, if you really want to do it up right, you can move the dose limit to two and then tell them to set -- tell licensees to set a constraint lower than that because that's sort of the way to maximize the impact on licensees if that's what you wanted to do. On the other hand, you could deliberately set a numeric value of a constraint at two rem per year or something less than that and effectively require licensees to take some actions to get their programs so their people were not exceeding two rem and not necessarily have to move the limit off. This is part of what we want to try and explore.

Public exposure; current recommendations is 100 milirem per year. Part 20 is 100 milirem per year. Actually, not much of an issue here, except where you're talking about the dose of the embryo/fetus or perhaps young children. Occupational dose provisions have a provision for a dose limit of the embryo/fetus upon declaration of pregnancy. Right now that sits at 500 milirem per year for the gestation period, which means that when the individual declares her pregnancy, you have to go back, assess what has been the dose to the embryo/fetus already, figure out how much is left, put it in the control program. It's actually a potentially complicated process. ICRP's recommendations now are actually a bit simpler. They've said 100 milirem per year. They want to have protection equivalent to that of a member of the public, but their recommendation actually is make it 100 milirem per year and make it from the standpoint of which the individual makes known her pregnancy, in our legal parlance, as in the declaration.

Now, as you can immediately deduce, depending on when she decides to declare, a provision for 100 milirem from the point of declaration for the remainder of the gestation period could be more

protective, or less protective. Of course, the woman has the option to not declare at all. It's not a matter that it may be very visible at eight, nine months she has the right not to declare. So this is a protection that's provided at that standpoint, but again, there are a couple of options. They do pose differences in terms of protection.

One of the things that you might even toss out is well, okay, they've said 100, maybe we should pick some slightly less value so that we know that even if the individual declares a little bit later on in the pregnancy that there's less of a chance for the dose to the embryo/fetus over the entire gestation period to have exceeded 100 milirem. So again, there are a variety of options that we want to try and look at and consider what the implications are.

As I already mentioned, there are numeric weighting values, the tissue weighting factors, organ weighting factors are already available. The calculations per dose coefficients, annual limits of intake drive their concentration are not yet available and we will have to await those. So what are the administrative possibilities? We could begin rulemaking activities now. We could pretend that we know enough and start the process and work on

developing the information as we go along in a rulemaking.

Of course, there's a couple of problems with that. We don't like starting a rule without really having a technical basis and it's not all that good to say you've started a rulemaking when you really still need to understand issues and implications on some rather important issues. You can delay the discussions and continue to work on the basis of interactions. That's what the staff believes is an appropriate approach. Do not say, we're going to initiate rulemaking but rather to start by saying we believe that it's appropriate to start moving towards considering some greater degree of alignment and we need to spend the next two to three years at least because some of the technical information is going to be available in that time, understanding and vetting out working with the various constituencies so that when we get to that point, there is a better understanding of the issues and implications so that you can write a statement of considerations, a regulatory analysis, backfit analysis, and all of the pieces that would be necessary to go along with the rule.

Obviously, you can package these still as

Part 20, Part 50, all the parts. I'll tell you frankly at this point, the resource implications of trying to go do everything are really, unless somebody found an enormous quantity of money, too much to really consider. So the staff at this point is looking at ways that this could be packaged since there is not an unlimited amount of resources, since there are a few other things that the Commission would like us to do in rulemaking besides just this over the next few years, security for example.

So some points to ponder. There changes can be very significant. As Debby, I think would certainly agree with me, what we start to do here will, because of the adequacy and compatibility considerations, also need to be looked at by the states. The states, in general, don't like to have different sets of regs for different portions of radiations that they regulate. So the reality is that we need to, from the get-go consider the implications of some of these major issues all across the board, all across the activities, all across the types of radiation because this will be a move to try and realign our framework and in fact, the US Federal framework. The staff is also working with the Environmental Protection Agency, the Department of

Energy, Occupational Safety and Health Administration to try and look at using this as an opportunity over the next few years to move everyone back in the consistent framework. You can probably say I'm crazy and I should get a drug test because I've obviously been smoking something. That might be true, but that's what we would like to try and do, but there are major implications. There's lots of effort that's not part of the rulemaking. There's all sorts of guidance. There's computer code activities and all sorts of other things, particularly in the reactor side of the house because all of those codes are still on ICRP 2 type methodology.

That's going to take a bunch of time to do the development, V&V and everything necessary for a licensee to actually demonstrate compliance. The reality is that being able for licensees to have the materials necessary to comply is probably out 2014, 2015, 2016, even if you start some of this work today. The technical basis is it is still working. When will we have enough to move forward? Is it the ICRP dose coefficient the first set, the most common radionuclides, most of what we use, we expect some time in 2011.

Some of the more esoteric things in the

complete set which corresponds to everything that's in Appendix B right now, probably won't be available until maybe 2014. To do we wait all the way to `14 to start? Is there a mechanism to try and start some of it earlier and catch up some of the other pieces? That's another one of the implications. How do we gauge benefits and impacts? How do we best figure out what is the right combination of things here for protection.

We're providing adequate protection today but we know we want to update scientific information. We want to update calculation about -- how do you go about packaging and understanding what all those implications are around such a diverse set of activities from the things that you have and the whole diversity that you have to the reactors to the new reactors, to gases diffusion plants, all the other facilities?

And with that, that's a quick synopsis of where we're going and I will be glad to entertain questions. Thank you very much, Dr. Vetter.

VICE CHAIR VETTER Richard Vetter, Chair. Thank you very much, Dr. Cool, for that very clear presentation, laying out the issues for us. If I may ask the first question, how do you plan to solicit

stakeholder input in this process very early on in order to stimulate, perhaps, some people in the licensed community to do some research, collect data and so forth that might be useful to you?

DR. COOL: A very good question. Step one is to get the options paper to the Commission and have the Commission and have the Commission actually agree that we can do this. That's actually not a given. Although we would think this is -- it might seem very reasonable, the Commission needs to tell us to do that. Presuming that would happen, we would then start to use special society meetings. I've already been talking with a number of the folks to try and get a least placeholders for various medical communities that otherwise we would be looking to try and perhaps establish some convened facilitated discussions around particular licensee groups.

I would actually hope that we could use your committee and the context that you could generate to start to engage in some of those to come and talk with some of your particular subsets and specialties to do a presentation like this with some of the issues to get them thinking. The process that we're thinking about is actually to use the first six, nine months in a first round to get people really thinking, asking

the questions and asking them what are your questions and issues? What else is out there? I mean, this presentation has been at 50,000 feet. The details are always in the detail. Now, all those issues in there, what are the implications? Get people thinking about it and engaging the second round a little bit later this year and into the early part of next year to bring people set back and say, "Now that you've thought about it," to do some iterative interactions because we have enough time to do that process to be able to build the information.

With Commission agreement, the staff I think also will look to try and update some of the information that is available. There was, for example a NUREG that was done in the mid-`90s which took a first look at the implications of moving from five rem to two rem. We would probably ask our Office of Research to move to contract to do an update on that so there would also be other mechanisms that were being use to develop the materials.

VICE CHAIR VETTER Thank you. Dr. Suleiman?

DR. SULEIMAN: Yeah. First of all, I want to commend the NRC for actually approaching this. I think it's long overdue. I'm always embarrassed --

M. GILLEY: So am I.

DR. SULEIMAN: -- speaking we're so far behind the times. I think, you know, you're still using the 1977 effective dose equivalent, you know, metrics. I don't see it as gloom and doom as you do because I don't think these numbers ultimately are more than one significant figure in terms of accuracy, I mean, when you look at the underlying risks.

DR. COOL: I very much agree with you.

DR. SULEIMAN: Okay, number 2, it's something we've done at FDA on a hit or miss basis but you may want to adopt by reference scientific standards, in other words, some of the dose weighting metrics, you don't necessarily need to codify that as a regulation. Maybe say you use the most current ICRP published tissue weighting factors or whatever in terms of calculating the dose so you adopt some sort of standardization. Recognize that the rest of the world understands the science.

We participate in these meetings, you know, with the ICRP and other organizations as well. Then you don't have to go ahead and publish a whole set of you know, metrics and even if there's newer data, five years from now, it's probably not going to be a whole lot different. You know, science is

science. Physics is physics. Some of these dose constants get revised, but they're not going to change dramatically.

So I wouldn't use that as an excuse to hold up the process. The five-year business, we used to keep track for lifetime, so I don't think that's a -- that's a big challenge. Having been trained originally as a health physicist and being very aware of the doses, I think going to two and this is the more philosophical thing, probably won't impact on most facilities, most users, but it will impact, I think on the occupational group that's pushing the five rem or the 50 miligray, you know, limit.

So I think that's an important concept to go through but I think -- again, I think there's a need to standardize with the rest of the world that it's embarrassing for me, many, many -- I mean, 10, 20 years ago I was told by my colleagues overseas saying that we don't even bother with the old units, and here we are 20 years later still doing that. So I think it's an important move. I think there are some places where you can be much more efficient in how the process goes and clearly, you open it up with the stakeholders, but I think rather than just have this ongoing endless dialogue, if you were to plan it in

such a way, you could probably have done it a whole lot more efficiently and with -- we're not reinventing everything from scratch. I think most of this information is out there.

DR. COOL: Two notes, if I could, Dr. Vetter. First, I should probably have you talk with our colleagues in the General Counsel's office. Legally, according to the Federal Register and the Administration Procedures Act, as I understand it, we cannot incorporate by reference that which has not gone through an Administrative Procedure Act process. Because the ICRP recommendations and the dose coefficients are not a public commented process, we in fact, cannot at this point simply do as you suggested, although I would love to do that and simply reference the latest set of values that have been done by the ICRP.

I would not with quite interest, that is exactly the approach the International Atomic Agency is currently talking about for the international basic safety standards but legally, we're not allowed to do so.

VICE CHAIR VETTER Ms. Gilley?

MS. GILLEY: Debby Gilley. I just wanted you all to be aware of the 35 agreement states. To my

knowledge, they do not treat occupational exposure from x-ray sources and material sources any differently. So the impact of this particular change in these occupational dose limits will have impact on all medical users, the individual radiologist and some of the other ones that we typically see have a little higher occupational doses than some other activities. And it's something to be very conscious of as we go forward. We don't treat them differently.

VICE CHAIR VETTER Dr. Fisher.

DR. FISHER: Yeah, Don, you did a really nice job of summarizing the main issues. I think this 50,000 foot perspective is really quite good to have at this time and you've certainly keyed in on the key issues. The NRC has, I think, been wise not to try to change regulations with every new ICRP publication. It's like trying to shoot at a moving target and just as sure as there's an ICRP 103, there will be in a few more years another set of recommendations slightly modified from those that we have today. I mean, and the NRC just can't be jumping each time NRC comes out with a new set of regulations. But I do agree that it's time for an update and it will require an immense amount of work.

One thing to keep in mind as a member of

this committee is that the concept of effective dose does not apply to medical patients and you spoke to this -- the new concept of constraints. Constraints for public exposure would generally be those under the ICRP 103 philosophy, would usually be those that are set by the regulator. However, constraints for occupational exposure would be those that would be established by individual licensees with guidance from the NRC or the states. And I think if you're going to strictly follow the new recommendations, you certainly recognize that there's a difference between dose limits and regulated dose constraints. That would get you in some difficult areas.

I think the scientific evidence for -- the scientific rationale for moving from a five rem to a two rem annual dose limit is pretty well justified and would not greatly impact on most licensees. It could be challenging for some occupations, those that receive the highest dose during nuclear power plant operations upgrades, maintenance, operations, I mean, those are the -- so it will have some impacts on select occupations and -- but for the purposes of planning occupational exposure, even a five rem annual dose limit provides a substantial level of protection. I think we all need to recognize that.

So I won't say anything more than that, but I commend the NRC for its, in one sense, lack of action over the years, as it carefully evaluates these options and also the planning to update regulations to be more consistent with international guidance.

VICE CHAIR VETTER Yes, Dr. Cool.

DR. COOL: For everyone's benefit, Dr. Fisher mentioned quite correctly the constraints in the context of public exposure and you're correct, and ICRP 103 and generally viewed that in the public exposure area constraints are usually due to something that a regulatory organization would more likely set. The staff, in looking at this, has looked at the variety of things that are already out there because there are, in fact, not constraints but other limits and requirements that are in place for most every kind of facility from decommissioning to a variety of things, such that the staff's view at this point is that there would not be a need for the agency to put yet another layer of constraints that the regulatory structure in place today already has the function of constraints with Part 20 and a limit and other limits in other places, the regulations serving as de facto constraints and other restrictions on public dose.

I would also note just for all of your

benefit, the concept of the constraint is not applicable to medical exposure according to ICRP. You have to deliver that which is most appropriate for your patient. So that concept as the limits simply would not apply in the actual treatment of the patients. This would be dealing with the occupational individuals doing the work, et cetera. Thank you.

VICE CHAIR VETTER Ms. Gilley?

MS. GILLEY: I just wanted to ask some of the radiation safety officers in the room, are you seeing some of your individuals approaching five rem per year or is this -- some of you deal with both interventional radiologists and all that and I'm getting mixed emotions from my state as to whether how difficult this will be for some subsections of the medical community to be able to be in compliance with this.

VICE CHAIR VETTER Well, Richard Vetter. As the radiation safety officer representative and a radiation safety officer, I could give you my reaction to the question which is that it's not uncommon at all for a few interventional radiologists to well exceed five rem to the badge. Now, they are covered in lead and so the debate we get involved with, with the state is what protection factors can we apply to the badge

reading.

But I mean, it's clear -- and if you put too much pressure on interventional radiologists about that they simply forget their badge in their desk drawer because to them, the number one priority for the day is the patient. And many of them, they don't care what they're getting. I mean, they certainly are using proper protective equipment but they're not worried about that badge reading, they're worried about their patient.

So it is an issue in interventional radiology and one other issue is, I'm not arguing one way or another on this, I'm just saying that it's important to get stakeholder feedback on this, Dr. Cool, that the average nuclear medicine technologist gets two, 300 milirem a year. If you set a pregnancy limit of dose to the fetus of 100, you know, you can't expect them to be wearing lead aprons all day. That's simply not very effective. So the point I want to make is stakeholder input on this issue is going to be very, very important.

MS. GILLEY: May I ask one more question?

VICE CHAIR VETTER Yeah.

MS. GILLEY: Do you do the weighting factors that described in one of the NCRP publications

for your individual radiologists where you wear a badge under the apron and a badge at the collar?

VICE CHAIR VETTER We would certainly like to utilize the weighting factors in NCRP 122.

MS. GILLEY: 122, okay. But you don't --

VICE CHAIR VETTER But not all states allow that, that's the point.

MS. GILLEY: Thank you.

VICE CHAIR VETTER Mr. Lieto?

MR. LIETO: Yes, Ralph Lieto. To answer Debby's question, most certainly interventional radiology, cardiology areas are going to exceed two rem in a year. It's almost a given, especially in teaching programs as the -- where fellows are learning the trade. It's expected, almost, that they're going to approach that five rem in a year, so in terms of the highest reading to the badge. So I think that definitely needs to be taken into consideration.

MS. GILLEY: I was going to ask you if you used the weighting factors that are described in NCRP 122.

MR. LIETO: I'm from Michigan, no. The -- to just as a follow-up on DR. Vetter's point about pregnant occupational workers, as we see increased use of the PET radiopharmaceuticals, you're not going to

be putting lead aprons on these women. It's absolutely useless. And so we are seeing that in busier departments, especially cardiology with cardiology use be a predominant type of procedure and the large activities that are used there, you can almost expect that a pregnant technologist is going to exceed 100 milirem over the gestation period. So it's -- this is going to be very problematic to go down to 100 milirem for these individuals, whether it's declared or not in the situation.

But the -- I have a question for you, Dr. Cool. Correct me if I'm wrong. In your discussion about the total effective dose, you were mentioning that the NRC has come out with a regulatory issue summary about wearing multiple monitors and taking into account -- or using weighting factors for the two dosimeters for coming up with an effective dose.

My understanding is that those weighting factors are based -- in order to use those, they're based on ICRP weighting factors from ICRP Report, I think, 26 or whatever, but my understanding is that those factors have to be approved by the lead agency for dose limits which is the EPA. So to change the -- to change those factors, it requires a change by the EPA to approve those weighting factors and dose limits

as a national standard or am I -- have I got something that's off base here?

Because my premise on this is we were looking at trying to get our state to adopt this and one of the issues that came up with adopting the more recent weighting factors, is that one of the leading monitoring companies said that the national standard for these weighting factors is based on the values set by the lead agency for setting these limits which is the EPA.

DR. COOL: Okay, it's in one sense more complicated, in one sense more simple. EPA certainly has federal guidance which is available. There is the federal guidance itself for occupational exposure and then there are various federal guidance reports, which have all sorts of dose coefficients specific for the US. Those are guidance to the federal agencies. It is not a legal mandate that the NRC use the EPA values. In fact, you will find that the values that are in Appendix B are not exactly the same as the values that are in EPA Federal Guidance Report 11.

What I suspect and whomever it was, was telling you, was that the current weighting factors in the NRC regulations are ICRP Publication 26. The weighting factors upon which the formulation for this

two-batch calculation are actually ICRP 60. The NRC actually recognized those as valid for use for external exposure. So yes, we have validated something making us inconsistent.

There is already at least one article out in the Health Physics Journal which has updated some of those formulations to use the new ICRP 103 formulations. Part of what we would be looking to do as part of this process would be to try and move and hopefully be able to endorse, adopt a system that would be based on the most recent set of weighting factors. But what you have today based upon the NRC regulation, now, and our regulatory information summaries would allow you to calculate to badge effective dose and it would actually be using weighting factors that come from 1990 ICRP Publication 60.

VICE CHAIR VETTER Okay, try to get the discussion back up to the 50,000 foot level and Dr. Cool's presentation. DR. Thomadsen.

DR. THOMADSEN: Well, I would -- before you go back up, while we're in the nitty gritty, I would like to give a different opinion than the two that have been given. We do use two badges and we have no problem, we would have not problem with

keeping our interventionalist, our cardiologist or anybody below the two level. They don't come close. They don't come close.

DR. COOL: Because you're calculating effective dose.

DR. THOMADSEN: That's exactly correct. That's exactly correct. So that would not be a problem if you guys could come out of the Dark Ages in the states. The -- I agree fully. Well, Michigan has quite aways to go. I'm from Michigan. I agree fully with Ralph. I don't remember if DR. Vetter had also said that, that the pregnancy limit for nuclear medicine technologist would be a problem for that to be lower. There isn't much you can do about that.

VICE CHAIR VETTER Okay, other questions? We have a question from a member of the public. Please identify yourself.

MR. PFEIFFER: Doug Pfeiffer with AAPM. Thank you very much. First I would like to echo what DR. Thomadsen just said. That is also my experience, that our interventionalists using the two-badge system we have no problems keeping them under the two rem limit. Without that capability, though, they would be well exceeding the five nuclear medicine technologists, that pregnancy limit would be an issue

particularly for out PET technologists, so keep that in mind.

One other thing I would like to add in is when you start thinking about dose constraints, the implication of that will also go into the design of facilities when you start using it for public exposure limits and the additional shielding required to meet some constraints beyond what the regulatory limits are, can be very high with potentially very limited positive impact from that. So I would encourage you to be very careful when you start talking about constraints because they will impact shielding designs also, greatly increasing the amount of shielding that could be required. Thank you.

VICE CHAIR VETTER Thank you. Dr. Fisher?

DR. FISHER: If we have time, just a couple of quick comments and one question. In my experience, of course, I work at a Category 2. My office is in a Category 2 nuclear facility at a national laboratory. And we already -- we already function under a system of dose constraints. We're limited institutionally to about 500 milirem per year as workers. But my understanding of the ICRP 103 philosophy is that it -- the focus is moving from intervention and process such as would apply to

nuclear cardiologists, interventional radiologists and perhaps even astronauts, to one of planning and preparing for emergency situations or accidents and instituting dose limits and dose constraints to minimize those situations. I wondered if you'd comment on that, perhaps a system that would allow a higher exposure to interventional radiologists and cardiologists doing critical patient care and to astronauts who are fulfilling a deep space mission for example, where occupational exposure limits do not prohibit certain essential work activities but are designed to limit accidental exposures. And my question is, do these occupational limits apply to astronauts?

DR. COOL: I can answer the question first which is no, they do not apply to astronauts. There is currently working in the international framework of things, a framework document to deal with protection and safety aspects for space missions, et cetera. And the limits do not apply. They have a whole set of different considerations and some very unique circumstances with very heavy ion radiations and things.

So that's one short answer. The second piece of this very quickly, yes, ICRP 103 moved from

a process system of practices and intervention to a situation based approach where you had a planned situation, that is you were planning to do something and you could do all the planning in advance, an emergency situation where something has happened and you have to react to it right now or an existing situation which like radon and other things, it exists and you have to decide what you want to try and do about it. You couldn't really plan for it. It's there. Now, ICRP's philosophy was to -- in 103 is now to attack that always the same way. And that is to establish a boundary, an optimization boundary, either a constraint or what they call a reference level for emergencies in existing situations and then to optimize protection below that. So it's always the same system trying to optimize protection, whatever the situation you're in.

My understanding of ICRP 103 that they would not -- that document would not have endorsed a separate or unique dose limit for a particular occupational category. All of that activity would assume to be a planned exposure situation where you could do that planning and the optimization and that is the only situation in which dose limits apply.

VICE CHAIR VETTER Any other final

questions? Dr. Cool, we very much appreciate your coming here well in advance of any regulatory action, rulemaking, et cetera, explaining what the issues are and I think on behalf of the ACMUI, I'd also like to encourage you to update us on a regular basis as this -- which may be every other year, I'm not sure how long this will take, but we expect it will be more frequently than that, to keep us apprised of these issues as they move forward.

DR. COOL: Thank you very much. As -- presuming for a moment that the Commission agrees that we should start taking these next baby steps towards technical basis, I would actually hope that this committee would be willing to work with the staff to help us establish some of the stakeholder interactions with your particular groups of users so that we can get to the next levels of information over the next few months. Keep those cards and letters coming.

VICE CHAIR VETTER I'm sure each one of us would be happy to work with you on that, either as a co-author at a meeting or as a sponsor for you to present at a meeting or whatever the case, we are very interested in facilitating stakeholder input. Thank you again.

Okay, the next item on our agenda is to go

back to yesterday. We scratched DR. Zelac's presentations from the agenda in order to allow more time to discuss the issues that were on the agenda yesterday. So DR. Zelac.

(Discussion off the record.)

MS. TULL: I have the -- this is the same draft risk that was sent to the committee but it's a hard copy of the comments that Ralph provided. It's a redline strike-out version. So keep what's in your binder because that's the original one and this one contains ACMUI comments.

VICE CHAIR VETTER Okay, so we're going back to agenda item number 9 from yesterday, Potential Rulemaking and Associated Regulatory Information Summary Regarding Multiple RSO on a Medical Use License. DR. Zelac, the floor is yours.

DR. ZELAC: Thank you. Before I begin, I think this is an opportunity, I think it really depends on all of you, to one, stay on schedule and two, possibly even pick up a little time on the schedule because what I'm trying to do with this is simply to bring you up to date as to where we are with three ongoing processes. There are three things that we're doing that are not completed at this point but are moving along and this is simply to let you know

where we are in the process, what's being done and what will be done.

The first of these has to do with the issue of multiple RSOs on medical use licenses. As you all know, that issue went to our Office of General Counsel and the decision that we received was, no, it cannot be done. It's against regulations. So on that basis, we will be moving ahead with consideration in the next round of modifications to Part 35 to include that as an issue.

First, of course, it's going to be considered and part of that consideration will depend on the responses that we get to this regulatory issue summary, if any, that's being sent out. This RIS, of course, has gone to all of you. You've all had an opportunity to comment and your comments have been received and will be considered when this document is reworked. It is still a draft.

It has also gone out to our regional offices and we have received comments from the regional offices. Again, those comments as well will be considered when this draft is reworked before the document becomes final. And lastly, on your recommendation and with good practice as well, because this would impact all of the agreement state programs,

it is being sent out with an all agreement states letter to all of the agreement states for their input and comment. Depending on when Mr. Lewis has the opportunity to take a look at the covering letter, the all agreement states letter, it will be going out relatively soon I suspect and there will be a 30-day opportunity for feedback from the -- all of the agreement states.

So in summary, for this particular draft RIS, one we have comments from you, two we have comments from the regions, and three, we anticipate receiving comments from the agreement states. When all of those are received, we'll take them all into consideration at the same time and come up with a revised document that would be the final.

If you are so inclined and so recommend, this document, once it is revised, can come back to you for a second look.

VICE CHAIR VETTER Questions for DR. Zelac regarding this draft RIS? I have a question. Richard Vetter, I have a question. Regarding the interpretation by the OGC, they have concluded that although there may be policy reasons for allowing a medical use license to include multiple RSOs, the current regulations do how allow, could you please

cite the regulation that says we -- it says the regulations do not allow. In other words, there must be somewhere in the regulations where it specifies only one RSO.

DR. ZELAC: The opinion we get, the interpretation we get covers the whole gambit of information relating to the issue which means all of the Federal Register notices relating to publications of the rule, it relates to the rule itself. I can't speak for Office of General Counsel except to say that there are multiple places in Part 35 where it speaks of an RSO or the RSO in contrast to all of the other authorized individuals where it speaks of them in plural. That could well be the basis and I suspect it is.

MR. LEWIS: There is also 3524(b) but it's not so much the regulation itself, it's the statement of considerations that form the regulation which made it very clear that the intent of that regulation was to name one and we provided all of that info to the committee as an action item from our last meeting.

VICE CHAIR VETTER Okay, thank you. Mr. Lieto?

MR. LIETO: Yes. On the issue with the statement that came from the Office of General

Counsel, and the comments that were incorporated into the draft RIS that DR. Zelac had sent out earlier to the committee, the citation is a -- was from the Federal Register was sent to the committee. It's an answer to a question in the Statements of Consideration. There is absolutely nothing in there that references any previous regulation, NRC directive, headquarter policy, OGC directive from before 2002. This has been an ongoing process at least from the 1980s maybe even precedes that time period. And so again, to cite something in 2002 as for the ongoing policy and -- of naming one RSO for the past 25, 30 years, you know, just doesn't seem to get to the gist of the -- or to the answer to the question.

So I really -- you know, to me it's still does not get to why there is a single RSO. Your comment about in the rules that it references a RSO or the RSO well, it does the same thing for authorized users for AMPs and so forth. So you know, it doesn't -- and there's nothing in -- if you look in the definition for RSO, it does not say that it's singular to the license. So again, I mean, I'm willing to accept something that states that there's -- that it's prohibited but it's -- there's -- again, there's

nothing that's been provided from OGC in their reference document or in the regulations that say it's prohibited. The fact that there's a reference to the RSO you know, again, maybe stems from historical language or whatever but again, I'd like to see something and I would hope that the committee would like to see something that says it's prohibited from being done and there was nothing that was provided.

The introduction and the background to the RIS gives the implication that the training and experience criteria is what's at question and we're not questioning that. I mean, we're not asking for changes to that. What we're asking for is those individuals that do meet the current RSO training and experience okay, why can't they -- you know, what prohibits them from being named on a license?

And I think there's a very real and serious practical reason and concern for this. With broad scope licenses, there's, you know, a practicality of transition and so forth, and it's probably a little more straightforward and less problematic. But what we're finding out there in the real work with community hospitals and so forth with multi-modalities of therapy, nuclear medicine, diagnostic radiology, an extreme reluctance for a

singular individual who is usually a physician, to assume responsibility for all modalities, either because of time commitments just you know, from the standpoint of their concern about not being involved in those other modalities, yet having a licensee responsibility for those radiation safety duties. I think the RIS also ignores the transition of the regulations over time to management responsibility for the license. It's true back in the `70s and `80 that pretty much that the RSO -- early `80s that the RSO was the end all and be all responsible person for a license. But during that time at least for medical use licenses, there was the NRC focus on the person who controls the purse strings and personnel control making management overall responsibility for the license.

And over time, I think these two things have been continued on a parallel separate track and I think we're seeing this come to a head a little bit because of the fact that why not let management decide if they want to have RSOs who meet the training and experience in that modality as the designate on their license and the management decide who has overall responsibility.

I use that analogy and it may not be

accurate, I mean, we have a Commander in Chief who's called the President but yet doesn't necessarily mean that he has to have all the military training and experience that's equal to the best individual that makes those decisions. And that management is the one that's ultimately held responsible for the license. If the management wants to have RSOs designated for individual areas, if that would serve the best purpose, and have a -- and wants someone with overall responsibility, I don't see why that's prohibited in the license. I'll leave it right there.

VICE CHAIR VETTER Mr. Lewis?

MR. LEWIS: Mr. Lieto, I think the NRC staff, we're sympathetic to the point you're making and that times have changed and what should be done and allowed and the RIS reflects that and suggests a path forward through the rulemaking. But I think that our Office of General Counsel has the sole responsibility for interpretations of the regulations and as the regulations are currently written, they are very convinced that the regulatory history that is the Commission record, even if it's in response to a comment that was on the proposed rule, that the Commission endorsed that entire rulemaking package as our policy.

And the last thing on record, in many cases in regulatory interpretations is 30, 40 years old, but it's the last thing on record and until it's changed, that's the policy. So we have a case where the lawyers are convinced and I don't think we have a success path arguing with them that the regulations do in fact, allow more than one because they've made their decision. We do have, though, a success path that I think will satisfy the issues. Maybe we need to discuss if that's in a timely way or not but we are sympathetic to the need that you're demonstrating.

VICE CHAIR VETTER DR. Zelac, is there still time for members of the committee to comment on this and if so, what would be the deadline?

DR. ZELAC: I thought that what had been received already was the combined input from the committee. However, if you wish to add additional comments, the letter to the agreement states has not yet been sent, which means there is at least 30 days from when it is sent for us to be receiving comments. So if there are more comments to be provided from members, I would prefer, if possible, to get the overall opinion from the committee as opposed to that from individual members and I hope that's what the document that had been received represented. However,

if you wish to modify that, add to it, augment it whatever, just so indicate and --

MR. LEWIS: If I could ask, actually, did we -- we did provide the OGC's e-mail and their second e-mail where they found additional arguments in the Statement of Considerations to the committee? If you want us to resend that, we will be happy to do that.

VICE CHAIR VETTER Yeah, Richard, if I may make excuses for the committee, this fall has been an extremely busy professional fall with many, many meetings and I'm afraid Mr. Lieto got very little feedback from members of the committee on this issue when he sent out his e-mail. And I'm just making excuses. It's been extremely busy, most -- not most of us, several of us on this committee just got back from the IRPA meeting in Argentina and there were earlier meetings of other society matters earlier in the month. It's been an extremely busy fall.

So if you'd indulge us and give us a little more time to provide feedback and if Mr. Lieto would be willing to solicit one more round of comments, we may be able to provide some additional input.

MR. LIETO: I'm always open to solicitations.

VICE CHAIR VETTER Okay.

DR. ZELAC: And we are always open to receiving the comments.

VICE CHAIR VETTER Thank you very much. Ms. Gilley.

MS. GILLEY: Debby Gilley, agreement states, there are agreement states that list more than one Radiation Safety Officer on a license. We do have corporate Radiation Safety Officers for certain activities. And we have not experienced any problems. But we are very specific in those licensing activities to make sure there is responsibilities and accountability and my concern with listing multiple Radiation Safety Officers on a license is that we get into the finger-pointing when an incident happens. And so we need to be very clear that there is direct chain of command as to who ultimately is responsible for the radiation safety activities at a facility or licensee.

VICE CHAIR VETTER Any other comments or questions?

DR. SULEIMAN: She just answered my question.

VICE CHAIR VETTER Thank you. Mr. Lieto?

MR. LIETO: Just I think Debby, you know,

answered one of the points that I had made or tried to make in this document. Regarding the OGC comments, the only thing that was provided or that I had was distributed to the committee was a single statement referencing a Federal Register citation which I then pulled and sent to the committee as attachments to the comments incorporated into here. So if there are other OGC comments and specific citations, those were not available when I formed this --

MR. LEWIS: Well, we'll make sure you have whatever we have. I remember there was about a paragraph long e-mail. There was a subsequent e-mail where they dug further into the statement.

MR. LIETO: Okay, so Part 2 we don't have.

VICE CHAIR VETTER DR. Zelac?

DR. ZELAC: Just to conclude, if my memory serves me properly, although the principal issue that originated had to do with multiple RSOs, there was also the sub or side issue of the ability of individuals to be named as RSOs, impediments that existed in that process. And part of that had to do with the availability of preceptors. That's why this particular document is trying to lay out exactly where we are in the whole process at the moment of being able to have individuals named as RSOs.

It speaks to some things that have occurred recently in terms of regulatory interpretations. It's speaks to things that we intend to do and it lays out hopefully, a path forward for all of us to reach the achieved goal.

VICE CHAIR VETTER Thank you. Okay, so where we're leading this is Mr. Lieto is going to send us an e-mail reminding us of this draft RIS. If you are not a Radiation Safety Officer, please feel free to solicit comments from your Radiation Safety Officer or equivalent at your institution and try to provide some feedback. And if you have no feedback, simply indicate that to Mr. Lieto, so that he can proceed with his proposed revisions to the RIS. Thank you, DR. Zelac.

We now move to Item Number 10 which will be Status of Technical Basis for Follow-up to the Ritenour Petition.

DR. ZELAC: Just as a reminder, the Ritenour Petition sought to have specifically medical physicists who are certified and individuals that were certified as health physicists are able, based on those certifications alone, to be named as authorized medical physicists and Radiation Safety Officers as long as they met the ancillary additional training

requirements that exist in the regulations.

That petition was settled out. It was completed in terms of its consideration and the outcome was that the Commission decided that there was possibly a group if individuals who were adversely effected by the modifications in the training and experience requirements that came into play in 2005. On that basis, they suggested that we, staff, should consider further modifications of the training and experience requirements, not only limiting it to those persons seeking authorized status as medical physicists or Radiation Safety Officers, but opening it up to all individuals who might be seeking authorized status, meaning authorized users, authorized nuclear pharmacists, in addition.

The one caveat towards doing that was to receive adequate information from the user community to form what we need to form in order to move ahead and that's the technical basis. If we get information from the user community, which suggests that there -- in fact, there have been individuals adversely effected by the current requirements, in sufficient numbers to justify moving ahead with rulemaking, then that's exactly what will happen.

Now, the question, of course, is well, how

does this information get to us and to form this technical basis document which is required? And what we had decided to do with your input was to contact the boards, the certification boards and to give them specific requests for information. That is what you see in your notebooks under Item 10. This is the letter that in fact, was sent to the eight certification boards that are listed as having recognized certification processes on the NRC public website plus one additional board that was listed previously in Sub-part J but has not yet received recognized status for their certification process.

Now, you had also recommended that this same request for information be sent out to the various professional societies. And that we were not able to do because in order to do that, in order to seek information for more than it turns our fortuitously nine organizations or nine individuals, you need clearance for that process from the Office of Management and Budget. That process of requiring this approval, takes multiple months.

On that basis, in order to move ahead adequately in a time frame with what we intended to do, we have elected to send this to the certification boards themselves. That is indirect contact, of

course, with all the professional societies and I don't think we're going to frankly be losing any information or any input by this process. This letter that you see which says addressed to certification board, as I said, was sent out to the eight boards that have recognized processes listed on the website, plus one additional board, the American Board of Medical Physics, which was in Subpart J and up until this point it time has not yet achieved recognized status.

These letters were sent out on October 15th. Our intent, our hope, was that we could get input back by mid-January. The first intent is that when the current rulemaking process involving Part 35 is concluded, that we can then move forward with additional changes to Part 35 and this would be one of them.

VICE CHAIR VETTER Ms. Gilley? I'm sorry, are you done, DR. Zelac?

DR. ZELAC: I am finished.

MS. GILLEY: I was just wondering if it might be possible for the organization of agreement states or the conference of radiation control program directors to contact the professional associations to provide information, since we would not have the

constraints of the Federal Government for impacting us.

DR. ZELAC: The best that I can tell you is that the feedback that we have received on this very issue because clearly we would like to have as much input as possible, was that if the letter that's sent out is essentially soliciting in some way the collection of information from further individuals, you automatically have exceeded your limit of nine. If you want to as a person, take this letter and do what you wish with it, that's --

MS. GILLEY: So you would receive one letter from the organization of agreement states or the CRCPD with the comments from nine professional associations attached to it. It would not be in non-compliance with the federal requirements?

DR. ZELAC: My only problem is that you are a special employee of the NRC and as such, if a letter requesting the same information that we have sent out and it is sought by you, even if it isn't in your official capacity, but it's a result of your official activities, that may raise an issue.

MS. GILLEY: Okay, thank you.

DR. ZELAC: I can't --

MS. GILLEY: But this is a public meeting,

correct?

DR. ZELAC: This is a public meeting and everyone knows that we seek information can respond accordingly.

VICE CHAIR VETTER Mr. Lieto?

MR. LIETO: I have a question for DR. Guiberteau in terms of his activities with the ABR. Does the ABR have the type of information where if they were contacted that they would know whether their diplomates were RSOs or AU's on licenses or AMPs on a license or is it pretty much once they get their certificate as a diplomate, it's God's speed and best wishes?

DR. GUIBERTEAU: The short answer is, no, they would not have that information and if they do have it, it would be exceptional.

VICE CHAIR VETTER Yes, DR. Eggli?

DR. EGGLI I think though, one of the things that ABR and the other certifying boards could provide is the number of people potentially disadvantaged between the time that the regulation went into effect which would be October 2005 and the time at which the Board was recognized, because during that gap, none of the diplomats of the Board could become AU's by the Board's certification process.

So although it doesn't get to quite what you're looking for, it does give you some concept of the potential order of magnitude and I think that's one of the things that the certifying boards could all provide is the numbers of potentially disadvantaged individuals and that might in part, serve as your technical basis. So ABR certifies nearly 1500 people every year in that ball park, so if you look at 2006, diplomates and 2007 or I guess it's primarily the 2006 diplomates, there are potentially 1500 diagnostic radiologists out there who are disadvantaged who may not be able to get an alternate pathway preceptor statement. Would that kind of information be helpful, Ron, if you had that kind of numbers?

DR. ZELAC: Certainly, anything of that kind would be helpful and, in fact, that was part of, you know, what we anticipated receiving from the Board based on this letter that went out. It speaks to that in terms of it asking about those diplomates that were certified prior to the time when their process was recognized by NRC.

DR. EGGLI: So that's certainly something that all of the certified boards can provide because those are hard numbers and hard dates. It doesn't say that they were disadvantaged but they were potentially

disadvantaged.

DR. ZELAC: That's correct.

VICE CHAIR VETTER That's -- Richard Vetter, that's a very, very significant point and I personally think it would be helpful to the process if each of us contacted the principal board in our areas simply to relate that information. I will do that in my case for the American Board of Health Physics. Any other questions or comments on this issue?

If something occurs to you in the meantime, DR. Zelac is looking for information between -- looking to receive information before mid-January, so please don't hesitate to contact him of there's any questions or additional information that you might have. Thank you, DR. Zelac for updating us on the status of the Ritenour petition and actions that are being taken to solicit data for the technical

14. STATUS OF COMMISSION PAPER FOR MODIFYING TRAINING AND EXPERIENCE ATTESTATION REQUIREMENTS

DR. ZELAC: Last but not least, --

VICE CHAIR VETTER: Item 10? Let's see. Where are you?

DR. ZELAC: -- if you haven't tired of hearing about things from me yet is the number 14, --

VICE CHAIR VETTER: Number 14.

DR. ZELAC: -- which is the one that is actually scheduled for now. That has to do with the status of the Commission paper, which is seeking Commission's input on modifications of the training and experience attestation requirements.

This, of course, results from the recommendations that we received from the Advisory Committee through the presentation that was made by Dr. Eggli at the last meeting of the Committee with the Commission in April.

What you see in your handout is an all agreement states letter that was sent out, as you can see, in mid September and requesting input from the agreement states as to their support or lack of support for the three recommendations that you have made.

The first page of that is the actual letter itself. And you can see -- in fact, I think that was the only page that was in your handout and the questions that were asked of the agreement states on page 2.

And I think probably the best way to tell you where we are is to indicate that we did receive responses from nine agreement states plus Conference of Radiation Control Program Directors. And I will

summarize what those responses were.

We also sent the same letter to our regional offices for input from regional staff. So we have at this point in time input from agreement states, including from the Conference of Radiation Control Program Directors and from the regions.

This information is being incorporated in a draft Commission paper, which will use this as part of the basis for making recommendations to the Commission as to what modifications appear to staff to be appropriate to address this issue.

So let me first I think read the question and then tell you what, first, the agreement states and, secondly, the region's positions are. And let me also tell you before I even start where these responses came from. It might be useful for you to keep in mind.

We did receive responses from California; from Florida; from Illinois; from Iowa; from Kansas; from Louisiana; from Minnesota; from North Carolina; and from Wisconsin; plus, as I said, the Conference of Radiation Control Program Directors.

So the first question, do you support the recommended, meaning from you, the recommended, elimination of the attestation requirement for

individuals seeking authorized status via the board certification pathways; i.e., eliminate attestations for anyone that wants to become an authorized individual via a board certification pathway?

The answers, from the agreement states, the respondents strongly supported, meaning 80 percent were for elimination of the attestation requirement. We had an unconditional yes from seven of the ten respondents plus a conditional yes from one of them, making the eight.

The one that was conditional suggested that that elimination of attestations was only appropriate for 10 CFR 100 and 200 users. But in other situations, it would be appropriate to retain it.

Any time that you have a question, you know, about any of these things that I am saying, please feel free to just jump right in.

From the regions, regional staff unanimously supported elimination of the attestation requirement. You can see the agreement states, 80 percent for, regional staff, 100 percent for. I think you get the flavor of where our recommendation might be going to the Commission.

Second question --

DR. NAG: What about CRCPD? You said that agreement states --

DR. ZELAC: CRCPD, again there were ten responses totally. And they were included in this summary, speaking of the agreement states.

DR. THOMADSEN: Was there any comments with the negative ones other than where you had the conditional as to why they were against that?

DR. ZELAC: No. The nos were unconditional and unexplained, simply no.

Now, the second question, do you support the recommended modification? Again, the recommendation is coming from you, the Committee. The recommended modification of the attestation requirement for individuals seeking authorized status via the alternate pathways and that modification being to delete text associated with preceptors attesting to individuals' competency being sufficient to function independently as authorized persons for those medical uses for which they sought, again the key word being the one that you have always objected to: competency.

Responses from the agreement state. The respondents that we got marginally opposed, I mean 60 percent were against, modification of the attestation requirement in this way.

Let me give you a breakdown of where these went. We had an unconditional yes, no comments, simply unconditional yes, for four of the ten. Forty percent favored such a change.

We had an unconditional no for five of the ten. And for one of the nos, there was a suggestion that, again, because of the relatively common interpretation of competency having to do with medical practice, as opposed to what was meant and intended by the Commission, as stated multiple times, that this did not relate to medical competency but to the ability to fulfill the responsibilities relating to radiation safety of the position which was sought, one organization suggested replacing has achieved, which has a future -- excuse me?

DR. EGGLI: Yes. When you finish your comment, I would like to add something in addition.

DR. ZELAC: Certainly. One organization suggested replacing the word "achieved," which is kind of an open-ended suggesting future and, therefore, possible liability, with "demonstrated," means this person has in the past shown that they can do this without making any presumptions as to their ability to continue doing this in the future, you know, making that essentially a prior time-limited endorsement of

that person's qualifications in order to reduce liability concerns.

So the response from the agreement states, again, 60 percent against doing it, 40 percent doing what you had suggested.

VICE CHAIR VETTER: Dr. Eggli?

DR. EGGLI: I think that in the alternate pathway that we had offered substitute language that it's not clear went out to the agreement states for their consideration, which that substitute language was "have demonstrated mastery of a body of knowledge" or, actually, it was "completed the requirements for licensure."

There were words to that effect that we recommended as substitute terminology in the alternate pathway. And I don't see that as having gone out to the agreement states. And would that have impacted the decision the agreement states made if they had been offered simply to remove the part of the attestation if they weren't offered the substitute language?

DR. ZELAC: The current regulation -- I don't have it right in front of me, but basically asks for the person, the preceptor, who is providing an attestation statement to attest to the individual

having completed the training and experience requirements and then the competency statement.

The recommendation was to get rid of the competency statement. So what would remain, then, would be training and experience, which I think is exactly what you are referring to.

DR. EGGLI: Now, can I ask again, maybe toward Debbie, would the agreement states have seen that as the context that we weren't asking for a complete removal of attestation but that we are willing to see an attestation of completion of requirements of all the training and experience requirements? If that were not emphasized, would that have been missed?

MS. GILLEY: It's possible. It's hard to read the mind of 35 states, but this was as short turnaround time document also for us. So some states weren't probably able to mobilize to give it full consideration.

VICE CHAIR VETTER: Dr. Nag had a question?

DR. NAG: Yes. Dr. Zelac, when you said demonstrate what that state said is the best thing about achieving, you said there was a case, demonstrate. Demonstrate what? Demonstrate

competency or --

DR. ZELAC: Well, that wasn't really. I don't have the letter right in front of me, but the sense was that use of the word "demonstrated" would suggest that this is something that the person has in the past shown.

Now, what words followed "demonstrated," that's really left open to us. There is no suggestion that the words that followed had to be inclusive of the word "competency" because we all have made some different suggestions for different words to achieve the same objective.

DR. ZELAC: Dr. Welsh?

DR. WELSH: I'm not clear on whether the question that went out emphasized that the concern of the Committee was the use of the specific word "competency." Was it underlined? Was it italicized? Was there a comment saying that this is the specific concern? Because if the question is --

DR. ZELAC: The question again was, do you support the recommended modification of the attestation requirement for individuals seeking authorized status via the alternate pathways to delete text associated with preceptors attesting to individuals' competency being sufficient to function

independently as authorized persons for the medical uses associated with the authorization sought?

DR. WELSH: If the question was as written here, then I would not be convinced that the casual reader without the background of all the discussion, that the place here understands that the word "competency" to a medical practitioner is a very key word. And unless it was italicized, underlined, put in quotes, they might have missed the specifics for the general concept.

DR. ZELAC: If I can respond, the discussion, which was part of the letter, said, "ACMUI also recommended that the attestation requirements associated with more prescriptive alternate pathways to authorized status be modified to delete text associate with preceptors attesting to individuals' radiation safety-related competency being sufficient to function independently," et cetera.

VICE CHAIR VETTER: Dr. Eggli?

DR. EGGLI: Again I would wonder if they went back and looked, if everybody went back and looked, to see what was left. There is a subliminal message in the request that suggests that we want to remove all attestation.

And unless you go back to the original

regulation and see that there is a nice piece left that says we are still attesting to the completion of the training and education requirements and experience requirements, I think there's a subliminal message that suggests that we drop that, too.

And I think our concern as a Committee is to create a viable alternate pathway that preceptors will actually use. And if the language doesn't get adjusted, then effectively the alternate pathway withers and dies because preceptors won't take that legal risk of writing that statement that looks like an attestation of competency because there's just too much risk.

So my concern is that the alternate pathway be salvaged as a viable pathway for people who are not able or because of their training not part of organizations that have a board certification pathway available to them.

DR. ZELAC: I think there are two things to be said here. First is you haven't heard what our original staff has said.

DR. EGGLI: Okay.

DR. ZELAC: And, secondly, both of those, what the agreement states have said and what the regional staff have said, and, plus, we who are

involved with the formulation of recommendations to the Commission fully understanding exactly what you are saying and the objective to be achieved. And being sympathetic to that, you don't know what the recommendations will be to go to the Commission.

So you are hearing something that doesn't agree with what you have recommended. That doesn't mean that that is the end of it.

DR. EGGLI: No. And I apologize for jumping the gun and not waiting for the regional recommendations.

DR. ZELAC: That is perfectly all right.

VICE CHAIR VETTER: If we could hear the regional recommendation, please?

DR. ZELAC: I would be more than happy to. The regional staff unanimously supported modification of the attestation requirement, et cetera.

DR. EGGLI: I am much happier.

DR. WELSH: Okay. We are all happy. You obviously hit a hot button there. Okay.

VICE CHAIR VETTER: Please proceed, Dr. Zelac.

DR. ZELAC: Yes. There was a comment from regional staff that is probably worth noting, but this is more of an administrative thing than anything else.

Staff noted that if the attestation text "uncompetency" was deleted, the attestation itself should probably be renamed to "recommendation for authorized status" or something similar to that.

Last question, at least the last of these three that were sent out, do you support additional methods for attestations, such as the attestation being provided by consensus of an authorization group; for example, a residency program faculty represented by a residency program director?

Response from the agreement states plus CRCPD very strongly supported this recommendation. In fact, 90 percent of the responses favored this recommendation.

We had an unconditional yes for five of the ten respondents. We had conditional yeses for four of the ten. And let me just give you a rundown of what those conditions were.

From one state, the recommendation was that the signer, the attester, or a cosigner be an authorized individual.

In other words, there should be somebody that is contributing to this attestation who, in fact, has knowledge of the responsibilities that this person is seeking to achieve. In fact, there were two of the

states that said the same thing.

Another comment from the yes group was that the signer must have actual knowledge of the candidates' work experience. That makes sense.

And another comment was that, for sure, the wording of the regulation needed to make it very clear that this attestation represented a group consensus, the person who is representing the group. And there should be a consensus among the group that this recommendation is appropriate. In addition, we had one probable no. So 90 percent, 9 of 10, were for, one probable no.

The regional staff strongly supported but not unanimously allowing additional methods for attestations. The staff noted that since residency program directors are typically not authorized users, to accept attestations from them, multiple training and experience sections of Part 35 would require a modification. Again, that is kind of an administrative matter, and it really is not of much concern.

So strongly supported but not unanimously. There are several comments that came in from the regions which said, "This is not the way to go. We should not permit this."

So we have got the input. And that's really what I wanted to bring to your attention, where we stood in terms of what we asked and what we got in the way of input from these two separate groups on the same questions.

And the next step, of course, is the Commission paper with the recommendations to the Commission for modifications to these attestation requirements in Part 35 dealing specifically with these three recommendations that you had made to them and that they obviously for anyone who was there or read the transcript was favorably impressed with for good reason.

DR. EGGLI: I can say personally I am pleased with the outcome.

(Laughter.)

VICE CHAIR VETTER: That was Dr. Eggli.

DR. ZELAC: Any additional questions?

VICE CHAIR VETTER: Yes, Mr. Lieto?

MR. LIETO: I guess it's more semantics. I have a question for Dr. Zelac. And then I would like to ask Debbie Gilley also. In question number 3, when you wrote "additional," was your intent alternate or supplement?

DR. ZELAC: No. Additional, exactly the

way we got the directive from the Commission, additional, not to replace but as a supplement to what is there already, multiple ways to acquire the same information.

VICE CHAIR VETTER: So those would be alternate ways to have acceptable attestation, not additional to what is already there or supplemental to what is there? Supplemental means what is there plus what you recommended. Alternate means what is there or these other ones.

PARTICIPANT: I think the agreement states -- I've not seen their comments or just specifically knowing who made what attestation. We're looking at it as multiple alternative ways to get to the same finish. But I can't speak on behalf of all the --

MR. LIETO: This is Ralph Lieto. I am sure Dr. Eggli's intent and the Committee's intent was alternate acceptable methods of attestation. Additional, again, it may be semantics, but I am just wondering looking at this now and seeing it for the first time if others were hopefully taking it as the alternate pathway, as opposed to being --

VICE CHAIR VETTER: This is Richard Vetter.

I think that is the way they took it or we wouldn't have seen 90 percent yes from the states and strong support from the regions.

MR. LIETO: As long as that is the way we are all taking it, that is fine.

VICE CHAIR VETTER: Yes.

MR. LIETO: Okay.

DR. ZELAC: I can't speak for the Commission, by interpretation, I thought, was that that was what they were thinking. And that is what was reflected in the staff requirements memorandum, which was the basis for this letter. We tried to use what they had specifically asked us to consider.

VICE CHAIR VETTER: Dr. Guiberteau?

DR. GUIBERTEAU: Just in terms of clarification since this is my first meeting, this in no way would impact the attestation that the boards get from program directors in terms of the potential candidates have completed all of their required training.

DR. ZELAC: That is correct.

DR. GUIBERTEAU: And, two, if I may, to bring up since we're on the board pathway and I believe this has been discussed before, but I would like to suggest that it is a matter that needs some

determination from this Committee.

And that is the extensive reworking of the training pathways and the certification process by the American Board of Radiology and the diagnostic radiology RRC changing from a pattern where at the time our candidates take their examination, they have completed the training, they have been attested to to the board, and they have received an examination and, therefore, get a certificate if they pass that portion of the examination that says that they are AU-eligible.

In the future, they will complete their training. They will receive the attestation. And they will take an examination on the curriculum set by the Nuclear Regulatory Commission at the end of their four-year residency. But they will not be eligible to take their exam until 15 months after that. So that there will be a considerable gap of 1,250 to 1,300 people who cannot be AUs if they do not have their certificate.

I mean, my point here is that there needs to be some consideration of solutions to allow those people perhaps to become AUs since they have completed all of the requirements. They have taken the test. The only thing they don't have is their final

certificate for everything else.

VICE CHAIR VETTER: Dr. Zelac?

DR. ZELAC: I think the response to that concern is the fact that all of the authorized individual training and experience requirements include an alternate pathway that has requirements which are more spelled out but not necessarily more rigorous by any means than those in the board certification pathway.

And the expectation is that if an individual has not fully completed their certification process because they have not yet taken the examination but have completed all of the training and experience requirements that have led up to their being in that position, that they could and would be expected to be applying for authorized status via the alternate pathway.

DR. FISHER: So in order to be truthful to those who are actually applying to the board to take their examination, we would have to insist that all of our programs train to the alternate pathway.

DR. ZELAC: This is something that Dr. Eggli has brought up numerous times, the fact that programs need to do this.

DR. EGGLI: That was one of the

impetuses in my commenting on having a viable alternate pathway available, but the effect of this is that essentially no diagnostic radiologist will ever again achieve authorized user status by board certification. That essentially forces all diagnostic radiologists down the alternate pathway and eliminates functionally board certification as a mechanism to achieve authorized user status for these individuals, which I see as actually problematic.

I understand there is a remedy in the alternate pathway. The alternate pathway is more prescriptive than the board certification pathway. Preceptors I think, at least having been in that position for many years, are more comfortable with the board certification pathway than the alternate pathway and not because we don't think we're training people adequately. But when you have a more prescriptive regulation, if you miss it by a little bit, you have missed it by a mile, even if you have covered all of the necessary material.

I would hate to see American Board of Radiology because of this alteration in training, which actually brings them into closer alignment with all the rest of the medical boards in the United States, which is not certifying people immediately on

completion of training. I would hate to see the board certification pathway disappear for diplomats of the American Board of Radiology, which functionally would occur unless this training gap of 15 months between completion of the requirements and final achievement of the certificate can be dealt with.

And, actually, there is more there than just the American Board of Radiology. If I could speak to the cardiology boards because right now the people who are beating up on me are actually cardiologists, rather than radiologists.

Once they complete their training and take their certification exam, they can't immediately get their authorized user status until they actually get their cardiology board certificate from the American Board of Internal Medicine.

And there is a time gap between when they complete their training and they can get their actual board certification. In core cardiology, the certifying Board of Nuclear Cardiology will not release that board certificate until they get their core certifying board in underlying cardiology. So they have a gap between when they complete training and when they can become authorized users.

I don't know if Dr. Van Decker experiences

it, but I have cardiology fellows who are struggling in the employment market by not being authorized users. And I am personally one of the people reluctant to write an alternate pathway preceptor statement.

So it's not just the American Board of Radiology. It's others as well.

DR. ZELAC: The best that I can say is that the requirements in the board certification pathway go through, as you all well know, including examination. You're not certified until you're certified. You don't get certified until you have taken the exam. So that --

DR. EGGLI: I understand that point, but the --

DR. ZELAC: That's part of it. The other side of it is that while the recommendation that was made in terms of additional persons that might provide attestation requirements is pointed towards residency program directors, I don't see why it couldn't just as well apply to fellowship program directors. You know, that would kind of get these people off the hook.

DR. EGGLI: Right. But it does functionally eliminate board certification as a pathway for the individuals who have a gap between

completion of training and when they actually get their board certificate.

In some cases, they have already taken and passed their exam. They just don't have that certificate in hand yet because of other requirements of the board that aren't necessarily related to passing an examination.

DR. ZELAC: Couldn't such an individual seek a letter from the board that said, "You have passed the examination. You have completed all the requirements"; i.e., effectively a certificate?

DR. EGGLI: Well, recently I was told that I had to submit a copy of the certificate, as opposed to the letter. I actually did try. And I don't know which regional office it went to. It was someone who is now working out of state. I did ask them to.

I attached the letter that said that they had passed the examination, but, unfortunately, the letter also says, "You're not considered board-certified until you get your underlying cardiology board." And that individual was unable to get authorized user status based on that letter.

VICE CHAIR VETTER: A comment from Dr. Howe?

DR. HOWE: Dr. Eggli, I have a basic question. You're training radiologists and cardiologists. And you're giving them the training and experience that is required in the regulations. Why is it you don't feel your program is such that you can sign off that these individuals have completed their training and experience and can function independently without having a board certification?

It seems like it's your decision not to allow them to be authorized users until they get the certification process. What is it about the certification process that your program doesn't meet?

DR. EGGLI: Our program does meet the board certification process. Again, for the boards, the --

DR. HOWE: I mean the alternate pathway. What is it about your program?

DR. EGGLI: The alternate pathway is more prescriptive than the board examination. The concern is that I will be challenged to document every component of the training, where in the board certification pathway, as long as I comply with the training program, as outlined by the American Board of Radiology and the RRC as far as the training requirements go, I don't have to keep records that

document these experiences.

The only records that I think we're required to keep is documentation of therapy experiences, but as long as the training program meets the board's and the RRC's requirements, I don't have to keep records that detail individual experiences.

If I go down the alternate pathway, it is conceivable that I will be required to produce documentation that I didn't keep that these people have actually sort of dotted all the i's and crossed all the t's in that training and experience. Even though I am personally comfortable with it, I don't have documentation that proves it.

VICE CHAIR VETTER: Dr. Guiberteau?

DR. GUIBERTEAU: I think that Don has done a very good job of framing this correctly. I can't tell you how many calls I get from AUs who are reluctant to sign attestations. And it's becoming rampant. It's almost a panic. I get at least two calls a week through the American Board of Radiology.

I have a personal interest in this because I am responsible from the ABR perspective in terms of providing the examination that the candidates will take, which at the moment is spread out through multiple examinations because we have both a written

and an oral exam and a physics exam, et cetera, et cetera.

I guess what I am getting at is that our consideration is taking all of these components into one radiation safety, radioisotope safety, NRC curriculum examination that would be given before the end of residency but not before the end of certification for two reasons. Now, we haven't done this yet, but it would be simple for us to do.

One is that perhaps it might provide a justification, a technical basis for some change in allowing program directors or, for instance, the ABR to write a letter saying they passed the exam, they have been attested to, and they have completed the training and basically they're applying to you. They haven't gotten their complete clinical certificate yet, but they have completed the entire curriculum and demonstrated a mastery of the basis of knowledge that the NRC wishes them to have.

The other perspective on that is that it might also provide an external measure by which preceptors might be more willing to write their letters. I don't know that.

But we're trying to find some way. I mean, if we are going to go to this model if there is

any way that that could in terms of the board certification process, if that could provide an additional way to do this?

VICE CHAIR VETTER: Any final comments, Dr. Zelac?

DR. ZELAC: Just a question. Could you indicate the principal reason that these individuals have for their reluctance to sign attestation statements?

DR. GUIBERTEAU: I think primarily it's medical/legal and it's a matter of their -- it's also the competency issue. Now, if that changes, that might change things.

I might also add here when our residents get their certificate, as Dr. Howe pointed out, they get a certificate in diagnostic radiology. And if they pass the AU portion, they get AU-eligible. All right?

Some don't pass and don't get it. Some programs don't attest. So they're not eligible to get it on those certificates. So, in truth, the certificate contains two pieces of information.

The question is, if we could give you that piece of information that's pertinent to you before this clinical certificate, could that be acceptable?

And, to be honest, I don't expect this to be resolved today, but I think this deserves considerable consideration. It's not going to happen tomorrow, but these examinations take years to develop. And we would really like to have some further consideration of this at some point.

VICE CHAIR VETTER: Dr. Eggli?

DR. EGGLI: I guess Dr. Guiberteau can speak to it probably better than I can, but I believe this new process starts for in-bound residents in the year 2010. Is that correct?

DR. GUIBERTEAU: That is correct.

DR. EGGLI: And so by 2013, I would personally like to see a solution that maintains board certification process as a viable process for diagnostic radiologists becoming authorized users.

But at the same time, maybe we can address some of the issues that are associated with the cardiology board exam, which creates a similar gap, during which time individuals cannot become authorized users by the board certification process because in a sense, these gaps in here end up throwing the baby out with the bathwater because the intent was that board certification should prepare people to be authorized users.

But, yet, now we have a situation where we can't do that because of this lag between when the individual completes all of these requirements and when the board certification goes.

I guess to again further address Dr. Howe's question, we live in a very litigious world. And there is sort of safety in numbers. The board certification process gives me great comfort that not just me personally feels this person has crossed the threshold but that a certifying body agrees with that impression.

And there is a real comfort for individual preceptors that although I am still accepting an individual liability by writing that preceptor statement because NRC could if they choose hold me personally responsible for that statement if the individual turns out not to perform up to standard.

I am more comfortable when the board also says that this individual has crossed the threshold. And maybe it's just that they come down to "It's just not me," but there are more people out there who agree with the assessment. And, again, that addresses the third part of the training and experience attestation is it's not just me.

Other people who are professionals and who

have observed the performance and tested the performance of these individuals agree that they have crossed the threshold.

So maybe you can say it's the safety in numbers, but I am far more comfortable when I have that other level of backing before I put my signature on that preceptor statement.

DR. ZELAC: Of course, the follow-up to that position is the fact that what we have heard so far from the agreement states; from regional staff; and, of course, from you is that those attestations should be eliminated entirely for board-certified individuals.

DR. EGGLI: Right. But, see, now what happens, then again, Dr. Zelac, is we take that board certification pathway away from diagnostic radiologists and cardiologists because of this time gap.

So what I would like to do is somehow find a way to make board certification a relevant process for the authorized user status again.

DR. HOWE: Dr. Eggli, it sounds as though in your program you have taken away the alternate pathway because you're not going to sign a preceptor attestation until the person is board-certified.

So you haven't negated the board certification pathway. You have said at your program, that is the only pathway.

DR. EGGLI: Our program has made that decision, yes, that the board certification pathway is the only pathway.

VICE CHAIR VETTER: Dr. Thomadsen?

DR. THOMADSEN: We also have had problems, and it's interesting that it's with new nuclear cardiologists coming into our program. We have not been able to get attestations for them.

VICE CHAIR VETTER: Okay. Any final questions or comments. Dr. Zelac?

DR. ZELAC: No.

VICE CHAIR VETTER: Okay. I am hearing Dr. Guiberteau and Dr. Eggli. Is there a recommendation or is there something that the Committee needs to do at this point? Dr. Eggli?

DR. EGGLI: I want to do two things. First of all, I want to say that this in no way diminishes the work that has already been done. A very good thing has happened, I think. But then, secondly, we need to develop a way of looking at this question and coming up with a solution.

I hate the concept of another

subcommittee, but maybe the Committee as a whole should think about the process. We should engage the affected stakeholders in the form of American Board of Radiology, in the form of the certifying Board of Nuclear Cardiology.

American Board of Nuclear Medicine is a little bit less effective because they only have a three-month gap between the completion of training and when the person can get a board certification.

But I think we should engage the stakeholders into the process of trying to develop a solution that both satisfies the training needs of the program and may help satisfy the NRC requirements of achieving authorized user status through the board certification process and keeping that process relevant.

VICE CHAIR VETTER: Dr. Guiberteau?

DR. GUIBERTEAU: I agree wholeheartedly. And I also think the time is right for some sort of decision on this, whether to stick with what we have or to make it a bit different.

I do think the American Board of Radiology because of this large number of diplomates every year would be flexible in terms of perhaps considering providing a certificate for AU eligibility at the end

of residency if that would make a difference. Now, it wouldn't make them board-certified, but it would complete the process with a piece of paper from the board.

I think the Committee knows best how to approach this, but it really is an important question. And we are doing all of our budgeting and all of our planning for this examination process. It is set, really, in terms of radiologic education and turmoil because it is going to change the training pathways considerably.

And I think once it gets on track, we won't have another opportunity to change this in a timely manner.

VICE CHAIR VETTER: Well, if I may suggest, I don't think this is something the Committee as a whole should be discussing here. It is way too complicated.

But perhaps Drs. Eggli and Guiberteau could think about this, possibly even proposing an agenda item for the next meeting that would be a little bit more thought out.

I also want to point out that the time gap exists for all of these specialized individuals, for AMPs, for RSOs. No physicist can graduate from a

program and become an authorized medical physicist until they practice for whatever the board requirement is, two or three, five years before they can even take the board.

In the meantime, they need to work under the direction of an authorized medical physicist. The same thing can happen with physicians, although I understand that it is much more problematic for physicians. But those things I think need to be taken into consideration in trying to come up with a proposed solution.

So if you could think about that, Dr. --

DR. EGGLI: Is this a subcommittee, then, or --

VICE CHAIR VETTER: No, I am not proposing a subcommittee at this point unless you want a subcommittee. I think because we have some time, it's a few years before this becomes effective, it would be good to be very thoughtful about it. And perhaps, Dr. Eggli, you could more or less take the lead in terms of discussing this with boards and possibly coming up with a solution.

DR. EGGLI: For Dr. Van Decker, is this something that would be of interest to the cardiology community as well?

DR. VAN DECKER: Yes. I think that we share some of the same pragmatic issues involved in all of this. Obviously alternate pathway was something that was a big piece of cardiology in the past. And so we have had more experience that way as well.

But certainly for our certification pathway right now, which is our preferred pathway as well in a lot of different ways, you know, we do have interest in this.

VICE CHAIR VETTER: Dr. Zelac?

DR. ZELAC: This is more of an administrative comment, but I think everyone recognizes that Part 35 was modified in 2002, training and experience were modified in 2005. And, of course, each time that we do that, besides the effort that goes into doing that, it is the agreement states which have to make modifications to their requirements as well.

Now, with that in mind, I know that the position of previous Commissions and perhaps carried over to this one is that Part 35 should be something that is relatively stable when at all possible so people know what to expect and move ahead with their plan and their programs and with their expectation

that reasonably there will not be significant changes at the time that they want to use some part of that regulation.

Since we are now talking through the attestation to additional modifications to the training and experience requirements in Part 35, I think it would be very beneficial, personal opinion, if there were going to be further changes to those T&E requirements, that they be lumped and packaged together so that we don't have to go back again and then again later.

As I noted earlier, the intention at the moment is to make changes to Part 35 dealing with a variety of subjects, including the attestation for T&E, in the next rulemaking that will begin when the current one completes, which is expected to be sometime in the spring, I believe. We'll find out in a few minutes.

So on that basis, it would be very nice if whatever input we were getting from the Committee could get to us in time to incorporate into, personal opinion again, the next rulemaking.

VICE CHAIR VETTER: Mr. Lieto?

MR. LIETO: Just a final question. Dr. Zelac, just to be explicit, do you feel, then, waiting

until the next spring meeting of ACMUI might be a little bit too long of a wait for getting the input of Dr. Eggli, Dr. Guiberteau, and Dr. Van Decker?

DR. ZELAC: If it were possible to get input sooner, I think that would be beneficial.

MR. LIETO: Thank you.

VICE CHAIR VETTER: Dr. Nag?

DR. NAG: With these in mind, I would make a motion that we do have a subcommittee and the subcommittee comes up with a recommendation that can be passed by the entire Committee by phone before the next meeting. That's the motion I'm putting forth.

VICE CHAIR VETTER: Is there a second to that motion? Dr. Thomadsen. Discussion of the motion to appoint a subcommittee to address the training and experience issues for physicians with --

DR. NAG: Not just physicians, physicians and --

MS. GILLEY: Authorized users.

DR. NAG: For all the --

VICE CHAIR VETTER: For authorized users?

MS. GILLEY: Authorized individuals.

VICE CHAIR VETTER: Authorized individuals?

DR. NAG: And through that, that it be

an ACMUI -- that the conference sets up before the next meeting.

VICE CHAIR VETTER: With a teleconference sometime this winter. Is there a second to that motion? Oh, there was. Sorry. Yes. Discussion of the motion?

(No response.)

VICE CHAIR VETTER: All in favor of the motion raise one hand.

(Whereupon, there was a show of hands.)

VICE CHAIR VETTER: All those opposed?

(Whereupon, there was a show of a hand.)

VICE CHAIR VETTER: Seven for, one opposed, and --

PARTICIPANT: I abstain.

VICE CHAIR VETTER: And more than one abstention? One abstention. Sorry. I was voting for. So that's --

MS. TULL: There are nine.

MR. LEWIS: I think you miscounted.

VICE CHAIR VETTER: Okay. For again, please?

(Whereupon, there was a show of hands.)

VICE CHAIR VETTER: Nine for. Opposed?

(Whereupon, there was a show of a hand.)

VICE CHAIR VETTER: Abstaining?

(Whereupon, there was a show of a hand.)

MS. TULL: That adds up.

VICE CHAIR VETTER: Thank you.

And, Dr. Eggli, would you be willing to chair that subcommittee?

DR. EGGLI: Sure.

VICE CHAIR VETTER: Who else would like to volunteer to be on that subcommittee with Dr. Eggli?

DR. EGGLI: Well, I would like to volunteer Dr. Guiberteau and William Van Decker.

MR. LEWIS: Dr. Guiberteau is not a member of the Committee.

DR. EGGLI: Okay. Can we use him for technical assistance?

MR. LEWIS: Yes.

DR. EGGLI: Okay.

DR. NAG: I would like to help on the --

VICE CHAIR VETTER: Dr. Nag? Okay.

DR. NAG: The next time I will still be here.

VICE CHAIR VETTER: Okay. And so the subcommittee can coordinate its activities through Ashley. And Ashley will schedule a conference call

for the Committee sometime this winter to discuss this issue.

Okay. Thank you, Dr. Zelac, for getting us almost back on schedule. So we are scheduled for a break now at this time. If we could please be back at 10:45? We're still a little behind schedule.

(Whereupon, the foregoing matter went off the record at 10:34 a.m. and went back on the record at 10:48 a.m.)

VICE CHAIR VETTER: Okay. First an administrative announcement by Ashley.

MS. TULL: During one of Ron's presentations we were talking about the one RSO issue and there's a question of what documentation had been sent from OGC and I have a copy of the email that I sent to you guys back in May as well as the second document is what was provided during the April meeting that was also justification from OGC. So those are these copies that are coming around.

(Off the record comments.)

15. STATUS OF CURRENT AND FUTURE 10 CFR PART 35 RULEMAKING

VICE CHAIR VETTER: Okay. We are back on the agenda item number 15, Status of Current and Future 10 CFR Part 35 Rulemaking. Ms. Bhalla and Mr.

Lohr will be presenting that.

MR. LOHR: Thank you. We are from the actual Rulemaking division within the NRC and Neelam and I do most all of the medical petitions and rulemakings. And currently we want to discuss what is out in the public right now as you know the proposed rule and we want to also talk about future Part 35 rulemaking from the Rulemaking perspective. This will be a short presentation we hope.

As I said, we have two Part 35 rules that we want to talk about or two pieces if you will, what's currently out in the public as you know right now for public comment on the medical event definitiions and then we want later in this presentation to talk about future Part 35 rulemakings as we project them which, of course, as you know are subject to change.

The other day I believe this committee and this group has gone over very well in-depth of what the Part 35 medical event proposed rule encompasses. This is just a short brief piece if you will. You have discussed this in great depth and we do not intend to do so, just to point out to those who may not be familiar with this as to what the rulemaking entailed.

To give you a status, the proposed rule actually published in the Federal Register on August 6th. Our public comment period was originally supposed to expire on the 20th of October. Based on this committee's request, we moved it forward to November 7th so that all the public comments and such could be vetted here in a public forum and this group could then send the recommendations to the NRC.

Do understand that everything that we receive in the public comment period will be reviewed by the working group and we will resolve what we call public comments and those resolutions will appear in the final rulemaking.

To give you a little bit of a time frame involved, it's approximately a year to develop and publish this final rule. It's very dependent on what these public comments have to say and what this group will put in writing and send to the NRC. Sometimes when we receive information that we didn't have when we started the proposed rule, we will have to go back and do additional analysis, additional research.

But we anticipate that this will publish in 2009 pending Commission approval and that's a point I want to bring out is that all rulemakings are approved by the Commission or their representative

before they're ever published. So this is not done in a vacuum. This is done with upper management's approval.

There's always a question of why the process is so lengthy and my supervisor, Mark Delligatti, came before this group I believe last year and laid out the process and I wanted to reiterate that it is a delivered process and it's a collaborative process. Everybody gets to bring their viewpoint to the table and all viewpoints are considered whether they come from a group such as ACMUI or from individual practicing or just a citizen. Each one carries the same weight of consideration within the working group at the NRC.

And again, we must resolve these comments. And the Commission does take its role very seriously in reviewing and approving of these regulations. So there is, of course, as you know, multiple rulemakings going on at the agency not only on the material side which is what we represent but also on the reactor side the funnel through the Commission's office. So this is part of what takes so long in the process. But it's a deliberate process so that things do not -- nobody gets run over shall we say in the process. Everybody has their say in it.

MS. BHALLA: I just want to add on that that comments are also received from the agreement states. So when we send our proposed rule, we also include the agreement states for their comments.

MR. LOHR: I want to talk a little bit about our next Part 35 rulemaking. As I said, we anticipate the current 35 rulemaking to finish up late in the summer in August. There will be numerous amendments that have already been identified by the NRC medical team and all these proposed changes to the 35 either have been reviewed by ACMUI or will be before they come to us in rulemaking.

I want to reiterate that things do not come to rulemaking unless the medical team brings them to us. And so the medical team is our client, if you will, and us in Rulemaking our role is then to take what they bring to us and get it through the rulemaking process, make sure it stays legal, make sure all the inputs are handled properly and all the viewpoints are brought to the table and resolved.

I do want to emphasize that and this was brought up by Dr. Zelac that the Ritenour petition should be included in the next rulemaking. But as you have read in the Federal Register from the petition resolution it is very clear that there is not a

technical basis at this point that data would have to come in from the community for the medical group to form that technical basis to bring to the rulemaking group. But the plan is and we have it in our schedules and rulemaking is to have the Ritenour petition as part of the next Part 35.

So I just wanted to reemphasize that if it is not a technical basis formed by the medical group, it will not come to rulemaking. There will not be a rule. And the petition said that and we want to make sure that's very clear that it's not misinterpreted as automatically goes into rulemaking space. That technical basis must be developed and brought to us.

Again, I want to talk about our time lines. We anticipate beginning next summer at the finish of this current Part 35. But these are schedules. Many things affect our schedules, anything from empower to budget to whatever. We then anticipate taking approximately a year to do the proposed rule and put it up for public comment just as we've done this one and then another year then to resolve the comments and go through the concurrence process to do a final rule in 2011.

In summary, if we have any questions on the actual process, we can answer that. If there are

any questions as to what will appear in those rules, that's really the medical team. They will bring us those. We can address what's, of course, in the current rulemaking because we have that. But anything into the future I believe Dr. Howe is going to talk about some of that at the next presentation. But understand we already have some items that they have brought to us in a user need memo and I believe all those have been before the ACMUI already. Is that correct, Dr. Howe?

DR. HOWE: I believe so, yes.

MR. LOHR: So at this point, I'll just open up if you have any questions on the process.

VICE CHAIR VETTER: Any questions on the process? Dr. Eggli.

DR. EGGLI: Technical basis, I guess that's one of the concepts that I'm a little bit confused about. I guess that means the justification for making the rule essentially.

MR. LOHR: Essentially.

DR. EGGLI: Are there standard components of that or is it just you simply lay out the justification and you lay out how many people are affected? I mean, what does it take to make a satisfactory technical basis for a rule?

MR. LOHR: We actually have guidance from the Rulemaking group that goes to all our customers, if you will, within NRC including the medical team that spells out what must be in a technical basis and I don't think there's anything unclear to the medical group as to what they need and I think that they have asked for from the community what they need for that data piece. I think the other pieces they have that are administrative in nature, how does it fit the NRC goals and those sort of things, that all appears in the technical basis.

MS. BHALLA: Could I just add to it? Basically, as Ed said, technical basis is really our customers are going to bring to us the basis and one of the main things is what is it in the rule that's not working right now. That is the foremost thing. And then because rulemaking is a very expensive process, rulemaking is also a lengthy process. So then we also ask in this technical basis is are there other avenues. Is rulemaking the only avenue that's left to you or could you do it in terms of some other ways that you could? Then, of course, comes the question of how many people will be affected by this. Is there a burden on the licensees? What are we going to achieve and that's the first thing why the rule is

needed.

So even for within NRC, I think there used to be a little bit of I won't say a misunderstanding, but people didn't have -- like they didn't quite know exactly what our technical basis is. So recently in our Rulemaking division we have come up with a paper so to speak where we are defining or we are explaining what our technical basis is and that came from the Commission and now when we give our rulemaking courses, little seminars and so on, we also include this paper technical basis and it is available if ACMUI would like to have that. We would be very happy to send a copy of that.

MR. LUEHMAN: Dr. Vetter.

VICE CHAIR VETTER: Yes.

MR. LUEHMAN: Just to add on to what Neelam and Ed have said, I think one of the key, to answer Dr. Eggli's question, statements has to be in the technical basis and Neelam touched on it is what's the problem. But I think we want a very definitive statement of the problem. A lot of times having worked in rulemaking you know the effected branches or divisions will come and say, "This rule is no good." "Well, we have to have to have a little bit more than that." "Okay. This part of the rule is no good."

"Well, you're getting warmer." And you really have to get it defined. Because as you have in earlier discussions, one of the things that you find out in rulemaking is you only want to change what you absolutely have to change what is exactly the problem. Because if you make changes too broadly, then you have the potential for unintended consequences when you start going and changing words or sections that are outside what you immediately have to change. Then you create one of the big dangers in rulemaking which is to create unintended consequences to fix one thing but then through inaccurate wording create problems in other areas.

So one of the major goals of the documents that Ed and Neelam are talking about is to get a precise, as precise as we can, problem statement from the users that want the rule changed and then some precise to the extent that it's available data that supports why that it's a problem and what could fix it. And in the past, I think that rulemakings have gotten hung up when the Rulemaking group then gets a less than precise statement of the problem, embarks on the rule, goes to the first stage of the rule.

And, for instance, if we started with an advanced notice for rulemaking or a proposed rule and

it's very unfocused and you get a lot of comments back "Well, you guys are changing way too much. You're creating all these problems," I think that we've learned that lesson the hard way. So what we're trying to do in the rulemaking area is really force the groups that are asking for the change to be very focused in their comments. It results in a better rulemaking and, as Neelam said, it's a very resource intensive process.

VICE CHAIR VETTER: Okay. Dr. Thomadsen.

DR. THOMADSEN: Could we get a copy of that document please?

MR. LOHR: Sure.

VICE CHAIR VETTER: That would be helpful. Thank you. Dr. Nag.

DR. NAG: Yes. I would like to mention again that you have from the ACMUI some information that it gives to medical group I believe.

MR. LOHR: That's correct.

DR. NAG: Right. And then there's always some loss of communication when it goes from one group to the other to the other to the other. So it goes from ACMUI to the medical group and then from the medical group, they make the technical basis and then it goes to the rulemaking group and then from the

rulemaking group it goes out for the public comment. In between there can be some losses of details. There can be perhaps even miscommunication or there can be because of the time sequence that can be dangerous in overall situations or overall techniques that by the time that the rulemaking is done some of the things are not appropriate.

So I would like once this tentative rulemaking has been done to then instead of going for the public comments first to then come back to the ACMUI to say, "Yes, this is what we are tentatively doing. Do you have any comments before it goes out for public comment?" You may be able to shut down some of the problems. Could you comment on that? Is that plausible or is that something that's even doable?

MR. LOHR: That is not a process, Dr. Nag. We in Rulemaking have a process that we have to follow. The APA spells out the -- I can't remember what the APA stands for. Administrative Procedures Act.

MS. BHALLA: Administrative Procedures Act.

MR. LOHR: Thank you. It spells out the process. We have to follow this process or our

regulations are not legal. Part of the process is, of course, to get input as we start down the road for the technical basis. This is where your committee fits in. As I understand, you're an advisory committee to the medical group. Okay. So you would make advice to the medical group. They in turn take that advice and then they put that in their technical basis such as they bring to us.

Once it's in our hands we then are following process. Our process then for your feedback is the public comment period. So it's not closed, but there is -- In process if we were then to bring you back in, we would have to bring the whole public back into it in fairness and if we don't follow a process, then our regulations are not legal and subject to challenge.

DR. NAG: In that case can the feedback be at the earlier stage, that is, when the medical group gives its recommendations to you to make the rules, can we be seeing a copy to make sure that that is what we really intended?

MR. LOHR: That's between you and the medical group, sir. Once it comes to us --

DR. NAG: Well, a member of the medical group, is that possible?

MR. EINBERG: I believe that's possible.

MR. LEWIS: I hate to walk in the room and jump in the conversation. But the process by which we get back to the committee is something that I admit we need to work on and Dr. Malmud and I have taken an action to talk about that. We haven't gotten to it yet. That's actually one of the action items on our list.

Your point is right. We need to do a better job of telling you how we took or did not take your comments and whether the process is what we have to define. We know what we have to do. We just have to get it in the right process.

VICE CHAIR VETTER: Dr. Suleiman.

DR. SULEIMAN: Yes, I raised this question earlier, but I'm going to raise it again. Basically, I think it would help streamline or it would be one little tiny step in the right direction. When you write some regulations, why can't you adopt scientific constants for example? I'm not saying you adopt the ICRP standards or guidelines on dose limits, but let's say you've defined pi, 3.14, whatever, and all of a sudden somebody comes up with a slightly different -- you don't have to codify that every time the number changes. Why can't you say using the most

scientifically available equilibrium constants or whatever and not have to take those constants and republish them in the CFR? Wouldn't that make some of the part of your rulemaking easier?

MR. LOHR: I think part of that answer lies in the answer that you received earlier on the legalities of doing that and part of the answer lies in what's brought to the working group or to the rulemaking group from the customer or in this case the medical team. We would not add. We may suggest to them that they want to add some things, but we would not add to their want or desire to change a particular piece.

And if they brought to the rulemaking group a reference if you will, we're just going to incorporate this as reference I believe is what you're referring to, that would be considered under -- Of course, we would then go to our Office of Legal Counsel and say, "Can we do this" and they may say yes or no. So it's really up to the customer who brings that to rulemaking to whether or not they would want that.

DR. SULEIMAN: I mean, I'm trying to make the differentiation between something that has been politically or administratively decided versus a

scientific value, you know, a scientific methodology. Let's see how you calculate dose for example.

(Off the record comments.)

DR. ZELAC: In response to what you're saying, I should note that our attempt is to do exactly what you are asking for whenever possible and I give as examples several places in the current Part 35 where rather than refer to some particular standard we tried to put language in which is general enough so that when that standard is revised individuals using that particular section of the regulations can use the revised version immediately.

DR. SULEIMAN: Without having to --

DR. ZELAC: As an example, 35.432, Calibration Measurements of Brachytherapy Sources says "Before the first medical use of a brachytherapy source on or after this date a licensee shall have..." and then number three down the step is "... used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs one and two above."

DR. SULEIMAN: So you actually do that.

DR. ZELAC: It's an example. We try to do it whenever we possibly can. We also certainly try not to develop any standards of our own. If there is

something in the regular user community which is recognized and accepted by that community, we will adopt it.

VICE CHAIR VETTER: Okay. Dr. Howe.

DR. HOWE: My comment was very similar to Ron's response and I think another important part of this picture is in some cases we have specific regulations that you have to meet. In other cases for Part 35, you don't have to provide your procedures. You have to provide a commitment that you will do something. So generally for those sections where you provide a commitment that will do something, we allow you to adopt, to use, a nationally recognized standard.

So it depends on whether the regulation is very prescriptive or we can take that section and make that more performance based. There is a mixture in there depending on where we are. Part 20, I don't think we have that flexibility on doses, things that Dr. Cool was talking about.

DR. SULEIMAN: I think there are so many other societies and organizations in play that maybe you need to make more of an effort to incorporate that style because maybe there's some benefit to be gained by adopting work that some other organization or

society has already done.

VICE CHAIR VETTER: Dr. Nag.

DR. NAG: I think in that respect we, the members of ACMUI, can be of help because we are working with these organizations and publications all the time. So if we are aware of certain standards, certain obligations, we should forward that to the medical team to be of assistance to you.

VICE CHAIR VETTER: Is there any other -- Yes.

MR. LUEHMAN: I just want to comment on that, Dr. Vetter. I think that as Ron said that we attempt to do that. But then in response to the question when does a standard become a standard, I mean, there are lots of different standards out there. There are lots of different standard setting type organizations and we not only have to look at not only the medical community. But as Donna-Beth said when you have some of the regulations which not only affect the medical community but go over into the other effected communities that we have, the reactor community, the materials community, the type of standard setting bodies and the processes that different standard setting bodies use, can be different.

And so we have to be careful that as I said in the beginning what is a standard and it may be very defined and clear in a medical context how those standards and whether they're adopted in other communities may not be exactly the same. So we have to be careful when we write our regulations because again getting back we may have unintended consequences because the standards that are set in other areas aren't using, you know, they have draft standards. There's a lot of different ramifications and so we have to do that very carefully. We try to do it, but it's not going to be universal. It's never going to be universal.

VICE CHAIR VETTER: Mr. Lewis.

MR. LEWIS: I would also add that we do try to consider standards wherever possible as part of a rulemaking. There is a trick to that though. Rulemakings are defining the minimum regulatory acceptable practice and standards often are written towards best practices especially standards by consensus organizations. And we often find this in a situation where we don't necessarily want to put the best practice in the regulation because it's one way of doing things. But in terms of our mission and safety, defining the level of safety, it is not

necessarily appropriate from a regulatory perspective to have such language in a regulatory requirement.

DR. SULEIMAN: I understand. I mean, one size doesn't fit all and there are some organizations that are recognized as being able to generate standards. FDA recognizes some voluntary standards, but recognizing them doesn't mean the same thing as saying, "If you meet it, you comply with our regulations." I understand that.

And sometimes I would argue a voluntary standard in terms of a public health standard is not a very good standard because it's not mandatory. I mean, if you're trying assure safety, then it has to be mandatory. What I'm getting at is don't duplicate work that may have already been done elsewhere.

VICE CHAIR VETTER: Any final questions or comments for Ms. Bhalla or Mr. Lohr.

(No verbal response.)

If not, thank you very much. We appreciate your updating us on the status of current and future 10 CFR rulemaking.

16. POTENTIAL CHANGES TO 10 CFR PART 35

VICE CHAIR VETTER: Dr. Donna-Beth Howe will now update us on potential changes to 10 CFR Part 35 and seek our advice. We don't have much advice of

course.

DR. HOWE: You always have. Okay. Ed was talking to you about the fact that the medical group brings things to the ACMUI and then eventually takes them off into rulemaking and over the years I've been presenting to you potential changes because we're getting you involved very, very early on. For one reason or another, the NRC has realized that we have a problem with the regulation or we need an additional regulation to clarify something.

And so I bring these to the ACMUI. What we pass on in the user need memo which is our document that goes over to rulemaking is generally an exact duplicate of what you're seeing or if you make a motion that changes some wording, then we put the revised wording in.

In some cases, we don't know what the rule would look like. So we propose a generic type of change, where we want to go. We don't know how to get there, but this is where we want to be. So in those cases you're not going to see rule language going to the Rulemaking group and it will be the group that's working on the rule that works out the specific language.

Now I just have a few items for us today.

You probably have to follow along on the printouts because these are kind of small to see.

(Simultaneous speakers.)

Okay. In this particular issue, we're looking at certificates of financial assurance. Most medical licensees don't trigger certificates of financial assurance for sealed sources. But we've had a few cases where we've got people that are getting new Perfexion Gamma Knife units. They still have the existing Gamma Knife unit that has a fairly high activity. So it's not a case that it's about ready to source exchange, but they're going to the new technology and we can see this happening more frequently with the Gamma Knife and maybe other cases in the future.

So for a very short period of time the activity for the sealed source and the cobalt may exceed the level of which you need a financial assurance statement that may be higher than what you have. And so what we're recommending is that the financial assurance requirements in 30.35(b) be revised so that we have an addition that says if you have byproduct material for half-life greater than 120 days of quantities specified in paragraph D of the section except we're going to allow licensees to

exceed those limits for a short period of time, 60days we think is more than adequate, due to source exchange for very large sources.

VICE CHAIR VETTER: Is there a motion to support that?

DR. EGGLI: So moved.

DR. NAG: Second.

VICE CHAIR VETTER: Dr. Eggli and Dr. Nag seconds. Discussion?

(No verbal response.)

All in favor? Yes, I'm sorry.

DR. EGGLI: One discussion question and I have no knowledge of it, but if you're installing a new Gamma Knife and have the old one side-by-side is 60 days a resonable time to get the new one calibrated and online?

VICE CHAIR VETTER: Yes.

DR. EGGLI: Okay. Good. All in favor?

DR. NAG: One comment on that. On the -- we have to ensure that having the two sources together would not exceed the radiation exposure of -- That's something.

MS. GILLEY: That's different. Release them from any other regulatory requirement.

DR. EGGLI: That's a different matter.

This is just financial.

VICE CHAIR VETTER: Okay. One more time. All those in favor?

I believe it's unanimous. Thank you very much, Dr. Howe. Next item.

DR. HOWE: Part 35.40, in this case it says the part of the regulations that deals with the written directive and in the current proposed rulemaking they've dealt with the fact that for permanent brachytherapy there are two components to the written directive. There is the before administration and then there is before completion of the procedure and, in the propose rule, they made it clear that the authorized user needs to sign. If there are changes, the authorized user needs to sign both documents if there are changes.

So what we're doing is we're extending that concept to all other brachytherapy and HDR procedures that also have a before administration and before completion of the procedure components to the written directive. And so where in this case we don't have specific rule language, but we're recommending that 35.40 be revised to clarify that the AU needs to sign and date both before administration and after implementation parts of any written directive for all

modalities that have the two parts.

VICE CHAIR VETTER: Is there a motion to support that recommendation? Dr. Eggli.

DR. EGGLI: So moved.

VICE CHAIR VETTER: Dr. Thomadsen second. Discussion? Yes, Mr. Lieto.

MR. LIETO: What is the impetus for this, Dr. Howe? Had there been medical events or I should say potential medical events that have created this? In other words, what's the health and safety issue that we're also trying to address if it's not a medical event issue?

DR. HOWE: I can't give you a specific medical event. But the issue is to make sure that the authorized user is aware of any changes made to the written directive especially when you have two part written directives to make sure that things were in accordance with the authorized user's wishes.

VICE CHAIR VETTER: Dr. Nag.

DR. NAG: It would be permanent brachytherapy that would fall under these two parts because if it does then it's really easily solved when you think about the things we were discussing yesterday. Is that a two part issue?

DR. HOWE: This particular clarification

is already in the proposed rule for permanent brachytherapy. So we're just extending to those other parts with the two part directive.

DR. NAG: Okay. So it includes now the HDR and --

MS. GILLEY: No, it only includes manual brachytherapy. That's 400.

DR. NAG: Also HDR. No?

MS. GILLEY: 35.40. Excuse me.

DR. HOWE: HDR does not have a two part written directive. So this would be all other parts of manual brachytherapy.

VICE CHAIR VETTER: Mr. Lieto.

MR. LIETO: So we're talking that this is to address low, medium and pulse dose rate remote after loaders in permanent brachytherapy. Is that correct?

DR. HOWE: I don't think so. I'm looking right now to make sure. High dose rate, remote afterloading, radionuclide therapy, dose fractions, all other brachytherapy, yes, including low, medium and pulse rate afterloaders. Yes, you're right.

MR. LIETO: So it includes all because I agree with Dr. Nag. This would resolve that very lengthy discussion we had yesterday on permanent

brachytherapy. But this would also then apply to Part 1000 or would this also apply to the Part 1000 Y-90 microspheres because that's considered a brachytherapy device?

DR. HOWE: It's considered a brachytherapy. When you -- it's kind of difficult to answer across the board for Part 1000 because 1000 is 1000 because it doesn't necessarily fit. If your particular 1000 device fit everything in the written directive requirements, we would in the guidance say, "You should meet the written directive requirements for the basic device."

DR. NAG: But the Part 1000 Yttrium-90, that is already -- It is No. 1 in the guidance. No. 2 in the guidance is already written that if there were stasis, then you would face it and you sign it. It's already there.

DR. HOWE: So for the Yttrium-90 we took the -- we recognize that you might have stasis as a different method and an endpoint. So we added that and that's a case where the written directive is modified for the particular device. But if we had even the written directive for the Perfexion was modified for the Perfexion because the written directive for the Perfexion you need to specify which

sectors you're going to have on each treatment because you don't have just one collimation. Right now, I can't think of one that we haven't modified the written directive for but it could be.

MR. LIETO: Is the intent of this proposal that the authorized user that does the first part is the same authorized user who does the second part? Because I could see an authorized user writing it, writing a written directive, which may be a day or two in advance or maybe even that morning and then another AU would be the one that is actually there during the procedure and could sign off and I guess I would ask my colleagues at the table is that acceptable.

DR. HOWE: I think I would want to defer to Ron and Ed as to what the proposed rule says. I don't think it got to this level of thought, but it doesn't mean it doesn't address it.

DR. ZELAC: This is Dr. Zelac. I believe the general expectation is that the physician that gives the directive, makes the directive available. is in fact the person that would sign the concluding directive, that what he or she wanted initially in the initial directive was in fact carried out or modified and acknowledged what those modifications were.

DR. NAG: From a technical standpoint

although most of the time the one who started was the one who ended is the same. Many times it is not. For example, I may implant a patient and I have to be out of town. So the implantation for the dose length can be three days or five days and I may not be the one available to take it out. But I assign it to an authorized user and it's perfectly legal and right now we are doing it that way. So you are going to change an established procedure if you say that same person has to be signing it before and after. So I don't think that should be acceptable.

DR. HOWE: Dr. Zelac.

DR. ZELAC: If I can interject, I don't think there's anything that's being proposed here which is going in that direction. No one said anything in particular in this writing that says it had to be the same person. That's wasn't an issue.

VICE CHAIR VETTER: Mr. Lieto was simply requesting a clarification.

Dr. Thomadsen.

DR. THOMADSEN: I was going to make the same point that Dr. Nag just made.

VICE CHAIR VETTER: Okay. Any other comments on this recommendation or on the motion to support this recommendation?

Dr. Eggli.

DR. EGGLI: I have a run going here. Yes, but I move to support.

VICE CHAIR VETTER: You've already done that. We're discussing the motion to support. All in favor, raise one hand.

Unanimous.

MS. GILLEY: I'm much more agreeable today.

(Laughter.)

VICE CHAIR VETTER: We appreciate that. All right. Thank you, Dr. Howe. Next recommendation.

(Off the record comments.)

DR. HOWE: Okay. In this case, we're looking at 35.65 and 35.590. 35.65 has traditionally been those sources that are used in medical use for calibration, for various purposes, that are associated with medical use but not with patient irradiation.

In 2002, we added transmission sources to it not totally appreciating that we may have been adding a transmission source that involved patient irradiation into a section that has no authorized user associated with it and isn't normally set up for patient irradiation. And so the recommendation here is that the transmission sources would stay in 35.65

if there's no patient irradiation. We'd move them to 35.500 authorization which is very minor authorization, diagnostic sources because you would be irradiating the patient in the scan and we'd make the training and experience very minimal as it goes with the 35.590.

Most of these transmission sources are used by 35.200 authorized users and so we were also proposing that if you're a 35.200 user you're automatically authorized to use these transmission sources. So that was the problem.

The recommendation is to revise 35.65 so that it does not apply to byproduct material that used intentionally to administer radiation for byproduct material to patients or human research subjects and that 590 would be revised to say that an authorized user under 35.280 requesting use of a transmission source in administering radiation to a patient or human subject would be covered under the training and experience of 35.590.

VICE CHAIR VETTER: Is there a motion to support that recommendation? Dr. Eggli. Is there a second? Mr. Lieto. Discussion?

DR. HOWE: Ralph, do you have discussion?

VICE CHAIR VETTER: Ms. Gilley.

MS. GILLEY: What is the purpose of a transmission source if it's not to image the patient for the purposes of nuclear medicine to do some type of anatomical --

DR. EGGLI: It may be a semantic thing, but we use the same source often for quality control. We put it across the collimator and flood a camera with this same source that we use for transmission purposes. So there is no difference between a cobalt sheet source and a transmission source. It's the same thing. It's just how you're using it.

MS. GILLEY: But for SPEC capabilities and all I think it's SPEC that they use a transmission source to an anatomical location and then they do the nuclear medicine component and lay it over in a computerized fashion.

DR. EGGLI: There are some cameras that do attenuation correction that use transmission sources.

MS. GILLEY: I think of the cobalt-57 not as a transmission source but a quality assurance for your camera source. So I guess I have --

DR. EGGLI: That's not what this is referring to.

MR. FISHER: Are they talking about x-ray here?

DR. EGGLI: No.

MR. FISHER: Germanium sources and PET scanners.

DR. EGGLI: Right. It's primarily PET scanner.

MR. FISHER: But would this not also include an iodine-131 transmission flood source used for patient dosimetry?

DR. HOWE: If you were using the flood source to calibrate your device that would be under 35.65. If you put a patient between a flood source.

MR. FISHER: For the patient to determine attenuation factors, that would be the 590.

DR. HOWE: That would be the 590 for this proposal because you are deliberating irradiating a person.

VICE CHAIR VETTER: Dr. Van Decker.

DR. VAN DECKER: I think I need a clarification I guess. When we talk about transmission sources, I assume that one of the ones that we're talking about here is gadolinium line sources that are used for attenuation maps and SPEC and obviously these are common and used in the 200 uses all the time for improving image quality and making better diagnoses. So I guess my question is

how does this affect that current use right now.

DR. HOWE: It should not affect it. It just moves the source into the parts of the regulation 35 that deal with patient delivered administration of radiation to patients. It's diagnostic because it's diagnostic. We have very limited requirements on training and experience and because it is normally used in 200, the concept was to in here recognize that a physician authorized user that's authorized for 290 would automatically be recognized as a user for these sources. So there is a connection.

VICE CHAIR VETTER: If I may ask Part D is an authorized user under 35.290 requesting use. Requesting could simply be built into the procedure. Correct? So when a procedure is ordered the procedure describes the use of the transmission that is in essence the request. You're not looking for a specific written request each time a patient is scanned.

DR. HOWE: No, that's more intended to be it would be added to the license. In other words, we would add transmission sources to the license and say any time you had a 200 authorized user you'd say for 35.200 uses and 35.500 and many times our regions will automatically add 500 because it's eight hours of

training and experience on a device and they'll automatically put it in.

Yes, Ralph.

MR. LIETO: If I'm understanding this right regarding the Item D, you're adding this to training and experience requirements. Is that correct?

DR. HOWE: I've made it --

MR. LIETO: As opposed to an authorized use.

DR. HOWE: It's added to the authorized use because it's not included in -- If you're exposing patients or human research subjects, it won't be in 35.65. 35.500 does not prescriptively list things that are in it. So that automatically moves it to 35.500 and then you look at the training and experience requirements to use a device under 35.500 and you have all of these requirements. You're either (a) and I would have to look to see what (a) is or you've completed training and use in the device for uses requested or another alternative is that you are an authorized user under 290. So if you're already an authorized user you are automatically authorized to use this 500 device.

VICE CHAIR VETTER: Dr. Eggli and then Ms.

Gilley.

DR. EGGLI: I think to try to restate that is if you are already authorized for Part 200 uses having met the training requirements of 35.290, then these sources are automatically included and you are deemed appropriately trained for their use if you are authorized for Part 200 uses. Is that correct?

DR. HOWE: That's correct.

DR. EGGLI: Okay.

MS. GILLEY: I'm going to get into implementation of this. Is the intent of this change to have transmission line item on licenses because right now if they're less than 30 millicuries, we're not having to have line item them.

The second issue is for those authorized users that have 290 capability. Are we now looking at also including the line item for these transmission sources to be added to their authorization?

DR. HOWE: Our regional experience is that if we have sources under 35.65 under the 30 millicuries that they will include it in the automatic authorizations in the regulation.

MS. GILLEY: That's correct.

DR. HOWE: If they exceed 30 millicuries, then they take them out.

MS. GILLEY: It's line item.

DR. HOWE: The intent here would be if you use any source that's being used to irradiate a person, it will come under 500. Now we also have a revision in that you haven't seen because you weren't on the ACMUI earlier and that was using a notification process to identify when you have sources that might have been line itemmed before for sealed sources.

MS. GILLEY: Okay.

VICE CHAIR VETTER: Just to clarify, we're not -- Again, even under 500, we're not talking about line itemming these sources, are we? Because they come automatically with a camera basically. So then we'd have to demand a license every time we buy a new camera or change out the sources.

DR. HOWE: We can make that clearer.

MS. GILLEY: I hate to be the idiot here but I do need to ask one more question of the professional group here. Is there any time you would do a transmission source that you weren't also doing a nuclear medicine procedure because I think it's already covered by the fact that it is included in the nuclear medicine procedure? Fill me in. I don't know all the new technology out here.

DR. EGGLI: Moving the transmission images

always accompany a clinical study.

MS. GILLEY: So we already have authority to image the patient with a transmission source.

VICE CHAIR VETTER: Steve.

MR. MATTMULLER: This is Steve Mattmuller. To build on what Debbie is saying, technically I can understand where you're -- what's driving this. But you can blame your co-workers on educating us on technical analysis. Practically, I don't see any advantage to going through this whole rulemaking process because as Debbie suggested anyone who would use one of these sources is already authorized under 200 and there would be no advantage in my mind to going through all these steps.

So I guess the real question I have for you is is there a situation that I'm not thinking of where an authorized user for a transmission source isn't an authorized user under 200.

DR. HOWE: Part of our problem is the transmission sources are not over in a category that all the other sources in that category are quality control, quality assurance. There is no patient radiation. There are no authorized users. This is an attempt to recognize that these transmission sources are really used in medical use because they are used

to administer radiation to patients for a purpose. The purpose is generally to get better images, etc. and to put this under the authorized user that normal uses it and that would be the 200 authorized user.

VICE CHAIR VETTER: Mr. Lieto.

MR. LIETO: To answer Steve's question, there is no circumstance where this would not be done as a part of the imaging procedure. I understand in terms of revising 35.65 to clarify the use and the existence of these sources.

I would object to adding a line item under 590 requiring this additional training and experience in order for 590 use. Because what you're saying is that to be authorized under 590, although there are no sources listed under that, generally speaking it would be another requirement for radiation biology, radiation protection, mathematics. You're saying that if there is something that comes down the pike that would not be a transmission source this would be an additional line item under the training and experience that they would have to have. I think it's just unnecessary.

DR. HOWE: What I gave was an or. You're either (a) or you're coming down the pathway in (b) or you are already authorized for 200. So I'm just

giving three different ways you can use this. There is no additional training.

MR. LIETO: But it's unnecessary. There is no procedure where all you do is a transmission of a patient.

MS. GILLEY: Dr. Vetter, behind you.

VICE CHAIR VETTER: Dr. Zelac.

DR. ZELAC: Thank you. I think it's important to point out that the authorizations given under 200 which is what we're talking about are for unsealed material. If there are sealed sources that are used in conjunction with that unsealed material for nuclear medicine and other studies, then there has to be something that says it's okay to do this. Right now, it's 35.65 and the point being made is that these sources are simply in the wrong place because 35.65 doesn't involve -- was not initially intended to involve human application and this clearly is human application. So it's being put into a place 500 which is meant for diagnostic use of sealed sources.

VICE CHAIR VETTER: Mr. Mattmuller.

MR. MATTMULLER: Steve Mattmuller. Again I would agree. Technically you're absolutely right about how you're describing these sources and how they're actually used. But practically I would argue

and I think the Committee agrees that anyone who is going to use this is already licensed under 200. So you would put this through the whole expense as we've been reminded rulemaking process. But in the end there would be no benefit to the community.

DR. HOWE: Dr. Eggli.

VICE CHAIR VETTER: Dr. Eggli.

DR. EGGLI: I actually don't have a problem with this as a 200 user. What this says is basically you have to be a 200 user or better to use these on a human subject and the regulation doesn't say that currently. So I don't have a problem with this being added. It's not going to cost me an ounce more training. These are the little administrative rulemaking things that I don't believe are horribly expensive to accomplish and it kind of cleans up the regulation.

And as a Part 200 user I don't have a problem with that being there because it imposes no additional burden on me whatsoever and I don't know that it's a bad thing to say that any source that's used for human imaging, in this case a sealed source, has to be done under the authority of someone licensed for human imaging as opposed to calibration.

And if you look at Part 65, the title says

"Authorization For Calibration, Transmission and Reference Sources" and the implication is that's not for human use. It's for purely calibration and I think reclassifying these sources as intended for human use is not a bad thing and imposes no additonal burden.

DR. HOWE: So when you look at the types of medical use in the definitions you see that it's 100, 200, 300, 400, 500, 600 and 1000. There is no 65. So it is cleaning up the regulations.

VICE CHAIR VETTER: Dr. Van Decker.

DR. VAN DECKER: I'm sorry. And so there would be a listing of these transmission sources in this category. So Americium would be in there as well as Gadolinium. How would -- Other ones showed up.

DR. HOWE: We also have as part of our rulemaking package looking at how we list sealed sources on the license and when you need an amendment to do it, etc. And so I think we can cover some of these issues that you're concerned about under that part of the user need memorandum what we talked about making some revisions.

VICE CHAIR VETTER: Dr. Eggli.

DR. EGGLI: Aren't those covered under the possession requirements? For instance, we brought in

a camera that had a barium source. We didn't have barium on our license. We had to add it to our license. Doesn't that cover the issue that Dr. Van Decker is talking about? I mean, as long as the source is listed, as long as you're allowed to possess that amount of radioactivity, that you can use it for calibration purposes. I'm not sure what the issue is here.

DR. HOWE: We have some general ways of writing authorizations and it really is up in the authorization section and in the authorization section we can either write specific isotopes in maximum amount or in some medical use, especially the unsealed materials, we'll say for any isotope authorized under 35.200. So we don't list the isotopes. We know what those isotopes are. They don't just change that much and it also allowed us when we went into the NARM rule not to have to revise everybody's license because if it was previously NARM material used under 200 it was automatically authorized.

We have other sections where you did list them singly. Now we have an OGC interpretation that for sealed sources we have to list them singly. We have a lot of medical community uprising on that that doesn't want to list some of these sources

independently because it's a burden. So we're looking at revising that section in the regulation in one of the previous things that I brought before the ACMUI that's currently in the user need memo. So I think we can address if you have real concerns about having to list them on a license.

VICE CHAIR VETTER: Richard Vetter. Yes, we do not -- it's very important that this not be line itemmed. An example is Dr. Fisher's example where he's using I-131. Tomorrow it could be any source that would be used as a transmission source. It has to be written in a general fashion.

Other comments or questions?

(No verbal response.)

So the motion is support this recommendation. It's been moved and seconded. Discussed. All in favor, raise one hand.

(Show of hands.)

Eight in favor. Opposed?

(Show of hands.)

Three opposed. Thank you.

Dr. Howe, if we could move to the next item.

DR. HOWE: Okay. This one is generator elution. In January - February time frame of this

year, we discovered that one of the major generator manufacturers had generators that were exceeding the moly-breakthrough values but not on the first elution, on subsequent elutions.

This is not the situation that prior to 2002 the rule said you have to elute the -- on each elution you had to check for moly-breakthrough. In 2002, based on prior history, there was a determination that the only real problems that they were seeing for decades literally were transportation issues and if the generator was made incorrectly, that would show itself on the first elution and patients would be protected because the material would not be used on patients.

What we discovered in January and February was that Mallincrodt was having a tremendous increase in moly-breakthrough that was not picked up on the first elution, may not be picked on the second elution, but would be picked up later on. They're still trying to determine the root cause for this. They believe that maybe some of the materials that went into the generator production were different than they were before and they're trying to figure out how to stabilize this.

So it became very obvious to us that our

current rules that say you cannot administer material that exceeds the moly-breakthrough value to patients and that we considered measuring moly-breakthrough on the first elution, meeting that criteria was not sufficient. There are other with molybdenum generators that are not being caught on the first elution. So what we're recommending is that we go back to what we had prior to 2002 because we now have a technical basis and knowledge that this can be an issue and we're recommending that the moly-breakthrough be performed on each elution.

VICE CHAIR VETTER: Is there a motion in support of this recommedation? Dr. Eggli? Is there a second?

MR. MATTMULLER: I'll second it.

VICE CHAIR VETTER: Mr. Mattmuller seconds. Discussion? Dr. Eggli.

DR. EGGLI: I have old dose calibrator software. It won't let me administer a dose unless I do moly-breakthrough on every elution anyway. I don't see requiring. All you simply do is you put the elution vial in a shield and put that in your dose calibrator. I don't see how that poses much of a burden to any enduser and I do it on every elution we elute in our own pharmacy and if I'm going to buy bulk

tech from a commercial supplier, I would like to know that that was done there, too. So I think this is a very reasonable move.

VICE CHAIR VETTER: Mr. Lieto.

MR. LIETO: I would like to ask Steve. Is this something where patients were administered moly in excess of the limits?

MR. MATTMULLER: Steve Mattmuller. It's my understanding they were not. The higher moly levels were caught in the moly assay before the product was released and the other comment I would like to make is that I see this more as an FDA/practice of pharmacy issue. In the package insert for the generators, it requires you to do a moly assay on very elution. In fact, this problem was brought to light because people were doing the moly assay on every elution.

To me, this somewhat goes back to the previous discussion that it's already being done. So what is the value to the NRC to go through the expense of rulemaking process to change this regulation so it's in compliance or so it's stated the same as current practice and its current FDA requirements and FDA labeling?

DR. HOWE: I can answer that. Originally,

NRC had regulatory authority over all radioactive drugs and then FDA came in and put radioactive drugs under the MDA and when FDA entered into the picture, NRC wrote in its regulations that you could not use a kit. You would not do anything unless you followed the FDA-approved labeling. We required it. And if you didn't follow the FDA-approved labeling, it was a violation of NRC.

In the Radiopharmacy Act rulemaking in 1994, there was a petition for rulemaking that came in that said, "NRC, you are inhibiting the practice of pharmacy. We don't necessarily follow the FDA package inserts. We have all kinds of reasons for not doing it. You are enforcing FDA regulations and FDA is not enforcing them." So at that point, we took out the requirement that you follow the package inserts.

We did say nothing in our rule relieves you from FDA, other state and federal requirements for drug elution or drug management, drug preparation. The requirement to measure moly-breakthrough has been an NRC requirement from almost day one of technetium.

The problem was identified at those facilities that do measure the elution each time. But our licensees are not required to measure it each time. So at a commercial pharmacy I might expect them

to measure it each time. But at a smaller facility, they're meeting regulatory requirements. They don't necessarily have to.

Do we know that every patient that received moly did not receive a moly-breakthrough value that exceeded what they were supposed to see? I don't think we can say that. I think we can say that a number of them were identified across the country. The problem was identified to the manufacturer. We had increased inspection.

But was every patient given moly under the breakthrough? I don't think we can go there because we don't know if everybody followed the FDA and the FDA labeling may or may not be followed. There are many reasons not to follow it. There are many reasons to follow it. It's not an absolute requirement on the enduser. It's part of the approved labeling.

VICE CHAIR VETTER: Dr. Suleiman.

DR. SULEIMAN: The label for this specific product says after every elution you do a breakthrough test. I also understand it's good practice for pharmacists to do it on a regular basis and so that's how it got caught. So it gets back to it's being covered by two specific requirements. Do you want to codify it? I mean, it's just a question.

VICE CHAIR VETTER: Dr. Eggli.

DR. EGGLI: I understand that a commercial pharmacy is going to follow all of the FDA regulations. Outside of a commercial pharmacy, offlabel is considered a practice of medicine. Many drugs, not just radioactive drugs, but drugs of all kinds are routinely used offlabel as part of the practice of medicine.

So I do not think that the FDA regulation covers those users who conceptually have no problem with offlabel use. So I think it's reasonable for NRC to put it back into the regulation.

VICE CHAIR VETTER: Mr. Lieto.

MR. LIETO: I don't know if I share Dr. Eggli's comment that there's no added exposure. There are some types of devices for doing moly checks that does require the transfer of the elution vial into another container to do that. So there are --

DR. EGGLI: I think I said no added exposure.

MR. LIETO: There are some added extremity exposure that's going to occur with doing this for every elution as opposed to doing it for the first elution which is the current requirement.

I guess I do have an issue with putting

this back into the regulation. Since it's been out., there has been no reports either in N Med or any place else of any patients being dosed as a result of moly-breakthrough and I guess I'd again have to ask Steve for his expertise. If there was moly-breakthrough and they go to make a kit or something of that nature, wouldn't that immediately show up on it being a very compromised quality exam?

MR. MATTMULLER: No. Absolutely not.

DR. HOWE: If it's not required, you would never catch it.

VICE CHAIR VETTER: Dr. Eggli.

DR. EGGLI: Yes, the point on the no N Med is you don't know what you don't know. If you're not determining that moly-breakthrough either did or didn't occur and you're not looking for it, there's nothing to report and I can make a kit that's going to QC at 99 percent with moly-breakthrough or aluminum breakthrough in excess of the regulatory limit. How am I going to know if I don't measure it? So again, you don't know what you don't know.

DR. HOWE: And, Ralph, you're supporting the concept that not everybody measures the elution, every elution. So those that aren't don't know and because where we're ending up with the new technical

problems with generators that were not foreseen before, you are having failures and they're not -- Some of them are not just marginal failures.

They're really significant breakthrough on subsequent elutions and those that were caught were caught. They were brought to NRC's attention because the person didn't receive the right answer from the manufacturer and they wanted a new generator and there wasn't another one available. So they came to the NRC and said, "What's going on here" and we started looking into it and we found that they were having significant quality control problems that they couldn't identify before they sent them out and users couldn't identify on the first elution.

VICE CHAIR VETTER: Dr. Guiberteau.

DR. GUIBERTEAU: I think consistency is a good thing. I do think that the teaching standard for radiologists are the Nuclear Regulatory Commission documents. We don't really teach to FDA standards and whatever in the labs. The radiopharmacists do teach this. But out in the communities and people who aren't able to get radiopharmaceuticals from a central pharmacy have generators and I do believe, although, Ralph, I think you made a good point, that if the requirement basically is to elute after every -- to

measure moly-breakthrough after every elution, I think to keep this consistent and not confusing for those people who do some nuclear medicine but also general radiology that this would be a good thing.

DR. SULEIMAN: I want to clarify. These aren't FDA standards. What these are when the drug gets approved by FDA the manufacturer agrees to put this in this label. So it's part of their labeling instructions. It's not a separate FDA standard per se. But it's one of the conditions of approval for the drug and they probably included because of the pharmacopeia, the pharmacy standards.

DR. VAN DECKER: Which the user then promptly ignores.

DR. SULEIMAN: Yes.

VICE CHAIR VETTER: Okay. Other questions or comments? The motion is to support this recommendation to require a moly-breakthrough test on every elution. All those in favor of the motion?

(Show of hands.)

Nine in favor. Opposed?

(Show of hands.)

One. Is there an abstention?

(Show of hands.)

One abstention. Okay.

Dr. Howe, next.

(Off the record comments.)

DR. HOWE: This was just our proposal.

VICE CHAIR VETTER: That was part of it.

DR. HOWE: This was just to say we want to say on each elution.

VICE CHAIR VETTER: Yes. Okay.

DR. HOWE: Okay. You're not going to believe this one. Okay.

MS. GILLEY: Is this one in here?

DR. HOWE: There's a new page. Ashley should have passed out a new page.

MS. GILLEY: Okay.

MS. FLANNERY: Dr. Vetter, I just want to add something else on the same topic of the moly generators. I don't think it made it into the slides, but there's been a lot of discussion with NRC staff to also include in the rulemaking to make measurements of moly-breakthrough that failed to be reportable because right now it is not reportable.

We happened to find out about these cases before by chance. But in this whole process we learned that it is not a requirement for people to report moly-breakthroughs. So I am interested in getting ACMUI input on this issue as well.

DR. HOWE: And it was my oversight in not making an additional slide. So we wanted to make a report in Part 30. Well, we would probably make a report in Part 30 and also in 35 because Part 30 would cover the commercial compliances and Part 35 would cover the medical users that are using generators.

So we would make an addition to Section Subpart M Reports and we would add a reporting requirement that if the generator elution exceeded the moly-breakthrough values specified in the earlier part of the section that it would be reported to the NRC.

VICE CHAIR VETTER: NRC or agreement states?

DR. HOWE: We can only write the rules for NRC.

VICE CHAIR VETTER: So it wouldn't be written in such a way that agreement states would have to report to NRC. They would report to the agreement state.

DR. HOWE: Yes. It would be written that NRC would report to NRC and then depending on the level of compatibility it might be the agreement states reporting to the agreement states.

VICE CHAIR VETTER: Okay. So just to clarify, the proposal is to require moly-breakthroughs

that exceed the specs specified in the regulations reportable.

DR. HOWE: Yes.

VICE CHAIR VETTER: Discussion? Well, first of all, is there a motion to support that recommendation? Yes, Dr. Eggli. Thank you. Is there a second? Yes, Dr. Welsh seconds.

Discussion? Dr. Eggli?

DR. EGGLI: I would have thought this was unnecessary. But hearing what Dr. Howe said about the experience of an enduser who couldn't get a vendor to make it right is one level. It's a financial level and if the vendor -- Do I take it then that the vendor did not report this to NRC?

DR. HOWE: No, they did not report it to NRC.

DR. EGGLI: I wouldn't have thought that this would be necessary. But it looks like it probably is. And if the vendor isn't going to remediate it under good faith, then maybe the regulators have to make sure that the problem is remediated.

DR. HOWE: I don't believe the vendor reported it to the FDA either because I believe we were the first ones to find out and then we passed the

information on.

DR. SULEIMAN: This was another thing. It's still in place. So I don't want to comment too much, but I argued internally saying that the system works. I mean the elution picked up the problem. It got reported. But the reporting mechanism isn't very clear. I mean, it was unfortunate. We had to learn it from the NRC. We should have heard it first from the company.

DR. HOWE: And we heard just in passing from our licensee because there was no reporting requirement.

VICE CHAIR VETTER: Mr. Lieto.

MR. LIETO: I was just going to ask. This is a device failure, is it not?

DR. SULEIMAN: That's not a device.

DR. HOWE: It's an interesting issue. It's not a device.

DR. SULEIMAN: That is a drug manufacturing kit. It's regulated by the Center for Drugs.

DR. HOWE: And we have gone through OGC to determine if it's reportable under -- Cindy can talk more to that.

MS. FLANNERY: We actually looked at two

regulations, 30.50 as well as Part 21, and it was determined to not be reportable under either one. So that's why NRC staff is really interested in putting it under Part 35.

DR. HOWE: And put it under Part 30 also to capture coming from the pharmacies.

VICE CHAIR VETTER: Based on our own collective experience, I might be safe in saying that it would be very rare that this would have any impact on a licensee because it's simply really rare to happen. Is that correct?

DR. HOWE: There's been an increased frequency.

VICE CHAIR VETTER: Sorry.

DR. HOWE: There's been quite an increased frequency for one manufacturer of this happening.

VICE CHAIR VETTER: Okay. So it would catch if it's in the best interest of patient safety. It would catch when there's a manufacturing problem with generators.

DR. HOWE: Yes.

VICE CHAIR VETTER: Okay. Any other discussion or questions regarding this issue?

(Off the record comment.)

The motion is to support the

recommendation that when there's moly-breakthrough exceeds the threshold as included in the regulations that this would be reportable. All those in favor of the motion, raise one hand.

(Show of hands.)

Ten. Opposed?

(Show of hands.)

One. Thank you all very much.

The next one which you -- let's see.

DR. HOWE: Yes. This one you're really going to like. It has to do with training and experience, one of your favorite topics.

(Off the record comments.)

And it essentially goes across almost all the training and experience requirements. For those sections that require supervised work experience under the supervision of an individual who meets the requirements in that particular section, we more recently looked at the way it was written and our general counsel pointed out to us that that meant the supervising individual had to meet the requirements in that particular section, not that they were authorized for that use which would have grandfathered all of the authorized users, authorized medical physicists, authorized nuclear pharmacists and RSOs but that they

had to meet the requirements in this particular section.

I will tell you that none of the regions have interpreted it this way. So we haven't had a outcry, but we believe that we need to clean the regulation up and make it state what we intended it to state and that is that if you're getting supervision you're getting supervised by someone who has experience and is authorized for that particular use.

So that was the problem. And we've stated the recommendation in very general terms because it would be worded differently for each section and that would -- Right now, we're think we have maybe two ways of going at it. One is that we could include 35.57 for individuals without authorization, state it and put 35.57 in because that's experienced authorized users, medical physicists, RSOs, etc. or we could just clearly say that someone that meets the training experience in this section or is identified on a license for this particular use. We don't know what the wording will look like, but we do believe we need to clean it up.

VICE CHAIR VETTER: Dr. Thomadsen.

DR. THOMADSEN: I'm a little bit confused about this. Would this be, for example, if an

authorized user was being trained? Would an RSO be able to provide the training in things such as safety handling of radioactive materials?

DR. HOWE: The supervising individual in most of the medical uses is an authorized user that is authorized for that particular use. In, say, 35.200, you have to have training and experience with generator elution. We had the issue before of the authorized nuclear pharmacist doesn't meet the criteria there. How are they doing this? Well, they're doing it because they're under the supervision for this particular part of 200 AU. So if the physicist is training someone and the requirement in the regulation is the supervising work experience comes under the physician, then the physicist training is being provided because the physicist is actually operating under the AU in providing that training because we recognize the AU doesn't have to provide every single minute of the training. They are the supervising individual.

Does that help, Dr. Thomadsen?

DR. THOMADSEN: That clarifies exactly what my question was. I don't particularly like the answer, but that answered the question.

VICE CHAIR VETTER: Dr. Nag.

DR. NAG: Dr. Howe, I understand your part two and I think that's quite clear. Maybe I don't understand what 35.57 is because I don't understand the meaning of the part one and is that part one needed in fact?

DR. HOWE: No, this is an either or. We don't know exactly how we wanted to word it. One thought was if we brought in the grandfathering provisions of 35.57 in each one of these sections, then that would make it clear that if the rules change the person was grandfathered for this section would be able to provide the training. So this was kind of an or type of thing.

Another easy way would be to have someone identified on a license or a broad scope permit or an MML permit or an agreement state license, the whole.

DR. NAG: I think it would be -- If 35.57 is the grandfather clause, I think we should just add in that who are grandfathered under 35.57. It makes it a little more clear.

DR. HOWE: That gets down into the exact wording which is what the Rulemaking group in connection with the medical group will determine. The basic thing I'm bringing to you is the concept.

VICE CHAIR VETTER: Right. Mr. Lieto.

MR. LIETO: I would like to table this specific item until we get the -- I would like more information on what is the issue that's being addressed and you said that there was an OGC determination.

DR. HOWE: Yes.

MR. LIETO: And I'm assuming in response to maybe a region or somebody asking for -- In other words, what was the motivation for the OGC to make this determination and so forth because I think this has the potential things extremely convoluted and difficult for preceptors and even more so than what we already have in terms of a problem for documenting and attesting to training and experience?

DR. HOWE: Mr. Lieto, I would be reluctant on tabling this because it really is an issue we have to address as soon as we can address it and, Cindy, can you give us more background?

MR. LIETO: This is a proposed rulemaking, right?

DR. HOWE: Yes, but --

MS. FLANNERY: The reason why this is coming up today and it wasn't in your binders, this literally is an issue that came up in the last couple days. And the history behind this is we were

developing some procedures on recognizing foreign trained physicians and physicists and what we found is that the supervising AUs and the preceptor AUs it would not be acceptable for grandfathered individuals to be supervisors and preceptors which is not the intent of the regulations.

So essentially if you have somebody who got listed on the license say ten years ago the way the regulations are currently written, that individual could not be a supervising AU for somebody proposed to get their work experience under. That same individual also cannot be a preceptor AU. Somebody who is going to be a preceptor AU or a supervising AU has to meet NRC's current training and experience criteria.

DR. HOWE: Now it's clear that --

MS. FLANNERY: And that was not the intent of the regulations.

DR. HOWE: -- was not the intent of the regulation, but that is how the regulations are written.

MR. LIETO: I have to be sure I understand. So let's say Dr. Guiberteau is named on a license as an AU, has been and continues to be named. He is training residents and physicians to be AUs. All right. I'm assuming that he was on a

license more than ten years ago. You're saying that he cannot sign as an AU for training and experience of those individuals under whom he's trained?

DR. HOWE: That's the way the regulation--

MS. FLANNERY: You are correct.

DR. HOWE: That's not how we have been taking licensing actions.

MR. LIETO: This is just to clean it up.

MS. FLANNERY: We just learned this the other day and as Donna-Beth just explained, we have not interpreted it that way and that's not been the practice in how the regions have been allowing supervisors and preceptors to be AUs.

DR. HOWE: And I think to make clear how I've interpreted it, I have essentially translated what was said in the regulations. So let's look at 35.290, Section (e)(ii). It says, "Work experience under the supervision of an authorized user who meets the requirements and 35.290(c)(1)(ii)(G) and 35.390 or equivalent agreement state requirements involving..." I have translated that in my mind as has everybody in the NRC to say that's one way of saying you're an authorized user for 200 or 300 uses. But OGC says, "That's not what we said."

MR. LIETO: That seems to negate the whole

grandfathering clause, doesn't it? I mean --

DR. ZELAC: For training purposes.

DR. HOWE: For training purposes and that's what we're trying to tell you is this is a major problem.

MR. LUEHMAN: For training purposes, you're right but not for being an authorized user or something.

VICE CHAIR VETTER: Dr. Nag.

DR. NAG: Yes. I would not be in favor of tabling this. I think this is something that needs to be fixed now. It is more of a legalistic issue and I would like to make a motion that the ACMUI approves this in spirit. The final wording of that may be tweaked a little bit to meet legal standards, but in spirit we should --

VICE CHAIR VETTER: There's a motion on the table that says exactly that. I mean, we're --

DR. NAG: Who made that motion?

VICE CHAIR VETTER: Dr. Eggli.

DR. NAG: Oh, you did.

VICE CHAIR VETTER: I forget who seconded it. Didn't we have a motion?

MS. TULL: I don't have a motion.

VICE CHAIR VETTER: Then I accept your

motion, Dr. Nag.

DR. EGGLI: I'll give him a second.

VICE CHAIR VETTER: Dr. Eggli will second. Okay.

MS. GILLEY: This appears to be an extremely critical issue. Is there any other way besides rulemaking that we could implement this pronto at least through a guidance? I mean, what recourse do we have because this has some --

DR. HOWE: Major implications.

MS. GILLEY: Major implications. That's a good term.

DR. HOWE: I think once we have your vote on the issue and we recognize we will also try to see if we can come up with something that can handle it before we go through a rulemaking process.

MS. GILLEY: This is a compatibility B issue. This affects all 35 agreement states as well as NRC. So this is not something that we have any flexibility or regulatory relief from the agreement states.

VICE CHAIR VETTER: Okay. So this is something that absolutely must be fixed.

DR. HOWE: We believe so.

VICE CHAIR VETTER: If OGC is saying that

their interpretation is different, yes, we need to fix it. Other questions or discussion on the motion? We're approving this but not specific wording. Mr. Lieto.

MR. LIETO: I would ask what other landmines are there out there that you have OGC coming up with these shall I say extremely unusual interpretations of the rules when -- I guess I would say I would go back to the Statements of Consideration which were stated before to be the policies and so forth and I'm sure it's quite -- it's in those Statements of Consideration that the grandfathering applied to all.

DR. HOWE: Ralph, in this case, in some cases, we have OGC taking maybe a different read on what is written. But none of us are able to say what is written is not what is written and that's why we have this issue.

VICE CHAIR VETTER: Dr. Nag.

MR. LEWIS: There probably is other landmines in all honesty, but we wrote what we wrote trying to be as generic as possible and as specific situations arise, we find out that some course corrections need to happen. That's just the regulator.

VICE CHAIR VETTER: Dr. Nag.

DR. NAG: That's confirmation that there are lawyers and there are lawyers and one lawyer may interpret it one way. Another lawyer may interpret it another way. Is it possible to go back to OGC and say, "This is what we meant" and can you interpret it in that light? Sometimes it depends how you ask the question.

DR. HOWE: Dr. Nag, I understand what you're saying and I will tell you that the senior experience medical staff once we were aware of it we read it and we went "Oh, my gosh, she's right."

DR. NAG: Okay.

DR. HOWE: This is not one of those equivocal "can I maybe read it this way or maybe read it that way." It says flat out you meet the training and experience requirements in 290.

VICE CHAIR VETTER: Okay. So let's make it legal. So Drs. Eggli and Guiberteau can, in fact, train their residents.

DR. HOWE: It's not only those. It's you.

VICE CHAIR VETTER: I know.

DR. HOWE: And me. Dr. Nag.

VICE CHAIR VETTER: I know it's everyone.

Any final discussion? Final comments?

MR. LIETO: I have a question. Does this effect I mean past or ongoing --

VICE CHAIR VETTER: We don't even want to ask that question.

DR. NAG: Don't ask. Don't tell.

VICE CHAIR VETTER: Don't ask this.

Okay. All those in favor of the motion to support this change.

(Show of hands.)

Unanimously supports. Thank you.

MS. GILLEY: Can we say strongly unanimously supports this thing?

VICE CHAIR VETTER: One hundred percent unanimous.

DR. HOWE: And that is my last.

VICE CHAIR VETTER: That concludes your report.

Dr. Welsh.

DR. WELSH: If we're finished with this section, then in the spirit of what we just discussed, I would like to quickly revisit 35.40, the proposed change there, where the question was raised by Ralph about can you have two different authorized users. Dr. Nag pointed out the answer is yes. We've heard

others saying the answer is yes. So the problem would go away. The question will be asked again. The problem would not be asked again if we change the word "the authorized user" to "an authorized user." Just a suggestion.

DR. HOWE: I would include it in your comments on the proposed rulemaking.

DR. WELSH: Okay. You will include that?

DR. THOMADSEN: Yes.

DR. HOWE: I believe someone here should make that.

VICE CHAIR VETTER: Why don't you make that as a motion?

DR. WELSH: I would like to make it aa a motion that the word --

DR. NAG: Put it as a motion.

DR. WELSH: So you can replace the word "the" --

VICE CHAIR VETTER: And that's in the discussion on 10 CFR 35.40.

DR. WELSH: Correct.

DR. THOMADSEN: Yes, at the bottom of the slide.

VICE CHAIR VETTER: Is there a second to that motion?

DR. THOMADSEN: Yes.

VICE CHAIR VETTER: Dr. Thomadsen. All in favor?

(Show of hands.)

It's unanimous. Good catch.

Does that complete your report, Dr. Howe?

DR. HOWE: That completes my report. Let me just ask a quick question to Mr. Lohr back there. Do you accept this as a public comment?

MR. LOHR: Please clarify what you mean by accept by public comment.

DR. HOWE: The ACMUI has voted unanimously that they believe that the "the" -- that "the authorized user" needs to be changed to "a authorized user."

DR. NAG: "An."

MR. LOHR: Are you talking about the current proposed rule?

DR. HOWE: The current proposed rule.

MR. LOHR: Then I would suggest that they put it in their letter during the public comment period which is ongoing right now and we will receive it and we will take it into consideration. Anything that comes in through public comment will be considered during the rulemaking.

VICE CHAIR VETTER: Mr. Lieto.

MR. LIETO: I am a little confused. The things that we just addressed right now are not --

DR. HOWE: Potential.

MR. LIETO: Right. These are potential. These are not out there for public comment right now. Is that correct?

DR. HOWE: One of them was to bring the rest of the regulation into conformance with the proposed rule and that's the issue that Dr. Welsh is addressing now. He's addressing the one that will bring it into conformance. So he's saying that he has essentially a comment on the proposed rule to ensure that it is "an authorized user," the same authorized user.

MR. LUEHMAN: Because the language that we were considering there was when you were considering, the language that you were considering was an addition to some proposed language and what's being proposed by Dr. Welsh to change is something that was already proposed language, not the additional language that you were adding. You're not changing the additional language. You're changing the existing language of the proposal.

DR. HOWE: It goes to both.

MR. LOHR: If I may, I believe what they are referring to is -- This is from the Federal Register. It says, "... require the AU to sign the written directive after administration." You want to change that to "... require an AU to sign..." Is that correct?

MR. LUEHMAN: Yes.

MR. LOHR: So that would be appropriate then to put it in your comments in this public period back to us on this proposal.

MR. LEWIS: For the permanent implant brachytherapy.

DR. NAG: Yes. Anyway, I would be including that in my comment anyway.

VICE CHAIR VETTER: So how can we make sure -- Cynthia or Ashley, how can we make sure that that comment gets from ACMUI into public comment?

DR. HOWE: Dr. Nag.

VICE CHAIR VETTER: Dr. Nag will do that.

DR. NAG: Yes.

VICE CHAIR VETTER: Thank you.

MS. TULL: Dr. Nag is revising the Committee's comments as a whole based on discussions yesterday.

VICE CHAIR VETTER: All right.

MS. TULL: So he would include that in his report.

VICE CHAIR VETTER: Terrific. Thank you.

Now are we --

MR. LIETO: I'm sorry.

VICE CHAIR VETTER: Mr. Lieto.

MR. LIETO: In a more general nature, the next Part 35 rulemaking that Ed discussed in his previous presentation, he said we'll include numerous amendments identified by the NRC medical team which now those numerous amendments obviously will include not only these but my recollection is that we started doing this, I remember the meeting being back in 2006 at the NIH meeting.

DR. HOWE: I think probably 2002 - 2003. We've been running a long time.

MR. LIETO: Okay. So I know there's probably dozens. Is the intent that these dozens of things that we've discussed are all going to be part of this --

DR. HOWE: Yes. We have a --

MR. LIETO: -- major Part 35 rulemaking ed talk?

DR. HOWE: We have a very long list and some items on that list have already been handled

through administrative rule changes and are already part of Part 35. We've had one direct final rule that put changes in Part 35. So some of the items that we could handle more quickly have come off of that list. Those that were a little more controversial and will take more time to develop remain on the list and those are the items that they will be considering for the next rulemaking.

MR. LIETO: Thank you.

VICE CHAIR VETTER: Okay. Are we done now with Dr. Howe for now?

(Laughter.)

She will be back right after lunch. Okay. Now recognizing that we're a half hour behind schedule, how much time would you like for lunch?

DR. NAG: Forty-five minutes.

VICE CHAIR VETTER: Is 45 minutes adequate? 1:15 p.m. Can you please be back promptly at 1:15 p.m. so that we get through the agenda this afternoon and remember if we can we want to back and capture Cindy Flannery's presentation. If we can't we'll address that on teleconference. If we can work her in this afternoon, that would be good. So 1:15 p.m. Thank you very much. Off the record.

(Whereupon, at 12:29 p.m., the above-

entitled matter recessed to reconvene at 1:15 p.m. the same day.)

VICE CHAIR VETTER: It's 1:15. If we could call the meeting to order, please? The next item on our agenda is number 17, "Medical Nuclear Materials Events." And this will be presented to us by Dr. Howe and Ralph Lieto. Dr. Howe?

17. MEDICAL NUCLEAR MATERIALS EVENTS

DR. HOWE: I am the first parts of the team tag. Okay. I am going to be going through the medical events for F.Y. 2008. Just as a refresher, we had 40 medical events in 2007, 1 in 200, 6 in 300, 10 in 400, 15 in 600. And then we had eight microspheres. So that is where we are last year.

In 2008, we have dropped down nine medical events. This -8 here is because I can't subtract. That's really a -4.

DR. NAG: I was wondering.

DR. HOWE: So we went from 40 medical events last year to 31 medical events this year.

You will also see that I have numbers in parentheses. In most cases when we have a medical event, we have one patient. When you see a number in parentheses, that's an indication we had multiple patients for one or more events.

So in 200, we had three medical events. And I'll get into the causes for those. So we had two more than we had last year. In 300, the therapy on unsealed material, we had four. We were down two. But we had ten patients involved. So that gives you an indication we had one medical event with multiple people.

In the manual brachytherapy, we had the same number of medical events that we had last year. You will see that there are 109 patients involved. And I think you can guess which medical event has a significant number of patients involved.

In 35.600, which I have broken it down into HDR and a subset of HDR because I am just kind of following what our experience is with the MammoSite and other breast balloon cases because they are not our typical HDR uses, although they're becoming more and more prevalent, and then gamma knife. And you won't believe it, but we actually had a teletherapy missed medical event. There can't be more than a handful of these units in the United States, but we still managed to have a medical event with one.

And then for 35.1000 use, we have got four yttrium microsphere events. We had eight last year. There should be a difference. And we're down four

this year.

So now let's look at detail on the 200. It's not a surprise to you that our 200 medical events are those events in which a diagnostic procedure was requested or intended. And I-131 greater than 30 microcuries was given.

We had two cases that involved I-123. In the first case, the physician didn't specify the isotope. He asked in general for a whole body scan. So someone checked off on the I-131 whole body scan.

In the second one, there was a verbal order for I-123. I-123 was written down. But when they scheduled it, they scheduled I-131.

The third case was the typical case that you have where there are multiple capsules to give a therapy dose. In this case --- oh, no. That's not this one. That is another one. Okay.

In this one, what we had was we had an authorized user or referring physician that intended to have a ten-millicurie dose. He didn't write ten millicuries. He wrote ten microcuries.

Then when it was ordered, it ended up being ordered. Even though everything in writing was in microcuries, it was ordered in millicuries. The written directive was in microcuries. They gave ten

millicuries.

It's a medical event because it wasn't what was in the written documentation, but it ended up in this particular case it's what the patient was supposed to get. But a medical event is when you depart from whatever the written documentation was. And they did not have a written directive in this case for the ten millicuries.

So that was kind of two errors make a right. So that gave us our third medical event for 35.200. And then we get into -- Dr. Nag?

DR. NAG: That last one is basically a technical medical event because --

DR. HOWE: It is technical.

DR. NAG: -- it's really not a medical event because, you know, most people would be giving ten millicuries. And that was ordered, and that was given.

DR. HOWE: It's a technical medical event.

DR. NAG: It's just like saying, "You did not have a prescription, but you gave the right quantity. But you are cited for a medical event because you didn't have the prescription." Basically it's similar.

DR. HOWE: Yes. This was one of those

cases where two errors brought it back around to where it was intended, but it met our requirements for being a medical event.

And then in the unsealed materials requiring a written directive, we have the typical one where the therapy procedure is given in multiple capsules. It comes from the pharmacy in multiple capsules in one vial. One capsule is given to the patient. They don't see that there are two more capsules inside. So they send it back to the pharmacy. And then they got it back again and finally treated the patient. So we had a medical event.

Another one was -- let me go back.

DR. WELSH: Can I ask a question going back to the previous slide?

DR. HOWE: Which one?

DR. WELSH: The previous event Dr. Nag was just talking about.

DR. HOWE: Yes.

DR. WELSH: That didn't require a written directive or did it?

DR. HOWE: Well, this was one of our problems with 200.

DR. WELSH: Yes.

DR. HOWE: Once you administer something

with 30 microcuries of I-131, you should be looking for that written directive to say, "This is what you are supposed to be giving."

And we have routinely had cases where people are giving I-131 greater than 30 microcuries. And they're not looking for that written directive to do that final check to say, "Is this what I should be doing? I need a written directive for it."

DR. WELSH: I wasn't even thinking whether it did or it didn't, but you switched to 300 and said, "Now things requiring a written directive." The last one did require a written directive?

DR. HOWE: We wrote ten microcuries.

DR. WELSH: That required a written directive?

DR. HOWE: Ten microcuries did not require a written directive.

DR. WELSH: No, no, no. But the ten millicuries?

DR. HOWE: The fact that they administered ten millicuries --

DR. WELSH: Right.

DR. HOWE: -- did require a written directive.

DR. WELSH: Okay.

DR. HOWE: But they did not go back and check and ask to see if there was one, which would have prevented the medical event.

Okay. For the Bexxar, that was kind of a complicated one. The patient was supposed to be getting Bexxar. Bexxar wasn't sent from the pharmacy.

There was a therapy I-131 dose that came in, I think maybe the day before. It wasn't given. And so when this patient showed up for the Bexxar, they had a syringe with I-131. It wasn't Bexxar, but it was a syringe there. So they picked up the syringe, and they gave the dose.

And in this case, they realized it almost immediately. So they did a thyroid block. They mitigated some of the effect, but they did not mitigate it to the point where it wasn't a medical -- well, it was a wrong radiopharmaceutical anyway.

DR. WELSH: Was that a therapeutic dose of the --

DR. HOWE: They received an uptake, I believe, of -- let me get the right one here. I provided you with the NMED reports. So it's page 6. So in this case, they received 100 millicuries. No, that's not the right one. It's the next one over.

They had an uptake of two millicuries. So

we have about 2,000 rads to the thyroid. And then they had a whole body exposure with ten millicuries.

DR. SULEIMAN: And they were supposed to give the five millicuries?

DR. HOWE: Of Bexxar, --

DR. SULEIMAN: Of the Bexxar.

DR. HOWE: -- which would not have gone to the thyroid.

DR. SULEIMAN: To the thyroid.

DR. HOWE: And then if you looked at my summary slide, you would see that we had a total of 10 patients with the 300 medical events. And the reason we did was because we had a Samarium-153, where the dose calibrator was set up for vials. They measured it with a syringe. It was off by 30 percent.

They had at least eight patients that were potentially affected by this. Some of the patients had died, some patients are still alive. They couldn't go back and absolutely confirm which ones they measured a syringe in and, therefore, gave the wrong dose. So they decided that they would call all of them medical events because they could not confirm one way or the other that they weren't medical events.

This is an issue that we have seen before with licensees that measure P-32, Samarium, Strontium.

They calibrate for a vial. They measure in a syringe. They calibrate for a syringe. They measure in a vial. They believe that they can measure things more accurately than the manufacturer. So they put it in the dose calibrator and adjust the dose. And they cannot do that with a dose calibrator. So we end up with a lot of medical events for a particular licensee when we have these kinds of situations.

Okay. Now, moving on to 35.400, which are the manual brachytherapy, we had one case -- and Ashley should be passing out a new page because we had this review. And the region pointed out some inaccuracies of the write-up. This is the 300-400. So just pass out both pages together, I think.

We still have a couple of more errors in here. There is a right point A. And then it says a left point B. Well, that should be a right point A and a right point B.

We had two patients involved. It appears as if they were implementing a new method of including geometric data. And in the process, they put in the wrong magnification factor. And the magnification factor that they used ended up delivering significantly less dosage than the patient was prescribed. So we had two medical events.

We always have a large group of prostate medical events. And in this case, we had 109 patients. The first, we had two cases of leaking sources. This was pretty interesting because one case of leaking sources involved two patients.

But the manufacturer was called. And they actually had three sets of seeds that they were running to give to three different patients. In the first patient, they recognized contamination on the needles. And they did a careful review of the next set of seeds that were supposed to be given.

There didn't appear to be any contamination. They gave the material. And then they looked at the needles when they were through, and they had contamination again.

So they went back. And they decided that they were not going to give it to the third patient. So they went back to the manufacturer. And the manufacturer actually found a problem in the wells. The wells weren't totally sealed. So that was a manufacturing problem.

The other leaking source medical event was our typical Mick applicator where possibly a source gets jammed, they put too much pressure, the source gets sheered. In this case, part of the source goes

into the patient.

Dr. Nag?

DR. NAG: On that first case, where the manufacturer welding or something was a problem, if that happened, then the entire batch should be looked at because it's not only that center but that whole batch of seeds that may have a problem.

DR. HOWE: Yes. And what we have in the NMED report was it was determined that the problem was isolated. So this could have been the entire batch because there were three patients being treated at this one facility.

Then we get to treatment-planning failure. In this case the treatment computer planning didn't function correctly. And so it defaulted to the default values, which did not give the right dose to the patient.

We had three different licensees that had less than 80 percent of a dose given to the treatment site or we had wrong treatment site. These are three Department of Veterans' Administration facilities.

We had 57 patients with less than 80 percent to the prostate and 35 patients with excess dose to the non-treatment site. And those are independent cases. So that's not 35 of the 57.

That's a total of 92. And then we had another VA facility with seven and three.

Some of these may end up not being medical events because they may have been called potential medical events because of the issue of drawing to the dose, iso-dose curves. One physician draws them one way, another physician draws them another. But that will all work out in the inspection process. You will be getting more information on that in another meeting.

And then we had three wrong treatment sites, where they were aiming for the prostate and they didn't get them in the prostate. One claims that the prostate was --

MS. GILLEY: Did you misplace a prostate?

(Laughter.)

DR. NAG: The prostate was misplaced?

DR. HOWE: Yes. That was a misplacement of the prostate. I suspect most of these had to do with ultrasound and not being able to accurately visualize where they wanted to with the seeds.

Dr. Nag?

DR. NAG: I know I had investigated two of them. And the two of them that I knew about were

that when they did the ultrasound, one was when they did the ultrasound, they thought that the bulb of the penis was the prostrate until they implanted that.

And the other one I think was in the middle, the patient moved. And then they went on with the implantation without reverifying that the needle had moved to that point. They implanted part of the prostate at the wrong site.

DR. HOWE: Right. And there was one that said the seed had moved.

Okay. Now moving into 35.600, I will start with the HDR units. We had eight HDR cases. These are five. The three that we will talk about on the next slide are all MammoSite or new devices that function similarly to MammoSite.

You had an equipment malfunction halfway through the procedure. An error message came on. The device just would not send the source back out again. So we had a medical event there.

There were some problems with putting in dwell times. They wouldn't go across properly in the computer system. And so the physicist put them in manually, and he put the wrong dwell times in, wrong spacing.

And in one case, in the wrong dose

reference point, the authorized user wanted to deliver the dost at the surface. This was a gynecological one. They wanted it delivered at the surface of the ovoid. And when they manually put it into the treatment planning center, they put it at five millimeters away.

Everybody followed the treatment-planning system. Nobody went back to the original written directive. And so the dose was resulted in a medical event.

The wrong source length and wire applicator, in this case they had multiple catheters. And they were using the simulation tool. The simulation tool had a kink in it. So it only went out to a certain distance. So that meant they inputted the distance that the simulation tool went out to, which was much shorter than the source should have gone. So they ended up delivering the source outside the patient.

And the final one is the problem. You end up with fractionalization. You write a written directive for ten fractions, a certain dose per fraction. The next person that reads it thinks it is ten fractions, that dose total, divides by ten, gives one-tenth of what is required. We have seen those

over the years.

DR. NAG: Question. I would like to know more about the equipment malfunction on 12 of 29 fractions. Two things. Number one is 29 fractions, I mean, I have done HDR. I haven't had a situation of doing 29 fractions. So I would question that.

And equipment malfunction on 12 times, you know, up to the first time that should become --

DR. HOWE: No. It didn't malfunction 12 times. It got up to the 12th catheter. And at the 12th catheter, it didn't work.

VICE CHAIR VETTER: So it's not the fraction. It's the catheters.

DR. NAG: It's 12 --

DR. HOWE: And they didn't treat from 12 to 29.

DR. NAG: So it's not fraction. It's 29 catheters.

DR. HOWE: Yes.

DR. NAG: Okay. Because 12 fraction to me means that you are treating the patient 29 times. Twenty-nine catheter I can understand. Okay.

DR. HOWE: We end up -- I would have to look at it carefully, but we end up with, you know, kind of descriptions that might not be right on the

market. You can get the flavor of what they are talking about. And I believe this one was they had 12 catheters and they --

DR. NAG: Can you send me the report of that?

DR. HOWE: We have the NMED in here.

DR. NAG: Oh, yes, yes, yes. Okay.

DR. HOWE: Okay. And then the next three are the balloon, the breast balloon procedures. It used to be they were all MammoSites, but now we have got a new manufacturer out there, SenoRx.

In one of them the simulator was checked. The catheter was kinked. The wrong length was used. We may have described that one for an earlier case. But the other case they used the wrong length catheters.

And then we had an error message that showed up on the second one. And the physicist mistakenly read that the error message indicated that the source was off by two millimeters. So he decided to override the error message and give the treatment. But the error message really said it was off by two centimeters. And so the dose was given two centimeters away from where it was supposed to be.

And in the third one, we have the HDR unit

was attached. And the technologist accidentally put the source into the saline balloon part of the catheter. And then when they took it out, all the saline leaked out. And then when they connected it correctly, there was no volume there. The balloon was now deflated. And so the sources were too close to the tissue. And we ended up with a medical event.

So we have seen other cases where people have ended up removing fluid and pricking the balloon and having deflated. In this case, they did not go back and check to make sure the balloon was inflated properly before they gave the procedure.

We had one gamma knife incident. In this particular case, it ended up it was an MRI issue. The MRI tech inputted that the image was taken, I believe, feet first when, in fact, it was taken head first. And because he inputted that it was feet first, the lefts and rights were reversed.

And you wouldn't know this unless you went way down deep into the MRI electronic report to see how it was entered. And so most folks are now looking at little more carefully at the images and the information that comes through with the additional images.

DR. FISHER: How was it discovered?

DR. HOWE: I'm not sure we get a good description of how it was discovered. A lot of times these things are, well, gee, it was really on the left. Why are you slightly over on the right? Here is my gamma knife.

And it was close to the center margin, but I think when they went back, they had discovered that they had put it in the wrong place. And then they went back to see why they had put it in the wrong place. And they realized that the MRI image was mistakenly left right. And we actually had a teletherapy medical event.

In this particular case, the authorized user wanted two shots or the AP view. And he wanted two shots for the PA view. And they were both similar times. And so the person that provided the dose believed that it was one shot for AP, one shot for PA. So they gave 50 percent of what was --

DR. THOMADSEN: What do you mean by "shot"?

DR. HOWE: Orientation.

DR. THOMADSEN: Treatment?

DR. HOWE: Treatment, yes.

DR. THOMADSEN: A beam?

DR. HOWE: Yes, a beam.

DR. THOMADSEN: Okay. A shot would be for a gamma knife. Here it sounds like you are talking about films when you talk about shots.

DR. HOWE: No. I am not talking about films. They were supposed to give a 17-minute exposure. And then they were supposed to give another 17-minute exposure. And then they were supposed to flip over to the PA view and give another similar time exposure. And they only gave one each.

DR. NAG: It's a field within a field. So you have a smaller field, like we do what's something like -- this same thing has happened with the linear X generator, where you are using multiple fields. And it would not be a medical event. I mean, it would be like forces but not be a medical event, right?

MS. GILLEY: Only in California. That's not true through all states. Some states treat medical events with linear accelerators the same as they would radioactive materials.

DR. HOWE: It would not be an NRC medical event because we do not regulate the accelerators providing therapy treatment.

And in 35.1000, we had 4 medical events involving the yttrium microspheres. And in all cases,

we had the dose didn't go into the patient. It went into the wrong vial. It generally went into the waste vial. So we had that they put the stopcock in backwards. It caused a kink. They set up the stopcock wrong. So the dose went into the vent dial.

They didn't turn the stop cock on the delivery device. And so everything went into the waste vial.

And the fourth one we didn't get enough description to know exactly what they did, but there is a good assumption that it had to do with stopcocks and vials and the dose did not go to the patient. Okay?

Debbie?

MS. GILLEY: Are we not seeing a trend with these stopcocks and microspheres? And should we not be looking at some alternatives, technology, or a different -- I mean, I realize there's a lot of them being done, but this seems to be very preventative. Is it not?

DR. HOWE: We are seeing some manufacturers actively working on the device delivery systems. And we have seen it evolving with time to try to eliminate some of these problems.

DR. THOMADSEN: The waste vial

indicates it was a theradose --

DR. HOWE: TheraSpheres.

DR. THOMADSEN: -- a TheraSpheres patient. And they have just come out with their Mark III delivery system, which is we are getting trained on that next week. But the point is to address all of these stopcock issues.

So they have taken it seriously, and they have redesigned it. That's what they said.

MS. GILLEY: Excellent.

DR. HOWE: Two of these we know are TheraSpheres. We don't know the other two. We have had a more recent medical event with stopcock and errors. And that has been a SIR-Sphere. So it's not exclusively TheraSpheres.

And we have from day one, one of the major problems with the microspheres has been the delivery system, making sure that things get --

VICE CHAIR VETTER: Dr. Nag has a question.

DR. HOWE: Dr. Nag?

DR. NAG: There is more of a comment. I think the increased number you are saying, that's two things. Number one, when initially this was done, it was done by a small group who was doing so many of

them. And, therefore, they were the one who started the program and they had the training and they were doing it.

And now you are seeing this going to a larger number of centers, many of whom are doing it for the first time, perhaps with inadequate training. Well, I have seen most of the time inadequate training that leads to error, not so much faulty equipment. You know, you blame faulty equipment, like more of the training that I have seen.

DR. HOWE: Well, the faulty equipment is part of the training. In other words, if you aren't properly trained to set it up correctly and if you don't turn the dials in the right places -- and I'm not sure I would go so far as it's a difference in where the devices are now because from day one, we had medical events in some of the big facilities because you do have delivery problems with these devices. And we have a higher percent. I mean, it's not a lot of them, but we have quite a few medical events with them.

Yes?

DR. SULEIMAN: Who reports these, the manufacturer or --

DR. HOWE: No. The licensee has to report

them to NRC. They're medical events.

DR. SULEIMAN: Because if the user reports it, it's a device problem. If the manufacturer reports it, it's a user problem.

(Laughter.)

DR. THOMADSEN: By definition.

VICE CHAIR VETTER: Dr. Thomadsen had his hand up.

DR. THOMADSEN: I was just going to say three of the four events were at large places, who probably have done -- I know two of them at least have done lots of these.

DR. HOWE: Yes.

DR. THOMADSEN: The fourth one I just don't know about. So it may not be --

DR. HOWE: I think I had a few more slides.

MS. GILLEY: I just would encourage if we are seeing these trends that we have some recommendation, either additional training is needed or we need to at least go back to the manufacturer and encourage them to find a better delivery system or improvements to the delivery system to prevent such events which I felt like could be corrected and we should --

DR. HOWE: Well, one of the things we did in the beginning was we changed the sealed source and device registry because in the initial sealed source and device registry, it was just the microspheres. And we when back and we said, "No. This device is the delivery system, too."

So we have tied the delivery system into the sealed source and device so that we have a handle for improvements. And because of the medical events, we are seeing engineering improvements.

MS. GILLEY: Good.

DR. HOWE: And the companies are taking a look at what is happening and they are trying to figure out a root cause and trying to address it. We had some pressure issues. So they put a pressure syringe on we had.

And now the new TheraSphere device doesn't have any stopcocks. So as long as they connect the tubes up in the right places, it should be okay.

Okay. And then I have a few cases that were reported to us, but they really weren't medical events. And I thought they might be of interest to the ACMUI.

The first one was we had an I-131 patient that came in for a 150-microcurie I-131 thyroid

ablation. And this particular facility has them come back about a week later and does a whole body scan without giving any additional I-131.

The patient came back. They were given five millicuries of I-131 because somebody didn't realize that wasn't on the written directive. It ends up this is not a medical event because at this point the thyroid was ablated and the dose was not high enough to bring it up to a medical event.

And even once in a while we had a patient intervention. And we had a patient that pulled the needles out and put them at her feet. And the nurse comes in and finds them. So that's not a medical event.

The strontium eye applicator, this one came in from the agreement state. We believe it's not a medical event. We're still tracking down specific information.

What happened in this case is the device was calibrated in '92, I believe '91-'92. They changed ownership. The device was being used in accordance with good decay correction.

And then because the agreement state now has to implement them at 35, they had to get the device recalibrated. They got the device recalibrated

with the new calibration system that NIS is proposing. And so the value of the activity in the strontium eye applicator changed.

So when then the inspector went out, they said, "You've got three medical events because you don't have the right activity for the eye applicator."

And so we went back out with our information notice and sent that to the agreement state. And we said, "If you think it is a medical event just because the activity changed" --

(Whereupon, the foregoing matter went off the record briefly.)

DR. HOWE: So this is an issue that the ACMUI addressed a number of years ago. When they change the calibration, the authorized user, if they are getting good results should keep the time the same, change the dose, and continue on.

And so we think that the activity changed because of the calibration, but the physician was getting good results. And the previous events that were called medical events we believe were not really medical events.

Yes, Dr. Welsh?

DR. WELSH: Regarding that first one on your list there, five millicuries were administered.

Maybe I'm still confused about which ones require and which ones do not require written directive.

As Bruce asked earlier when you talked about the diagnostic medical event where ten millicuries were intended, ten microcuries were written, ten millicuries were actually given, that was a medical event. Here it's five millicuries. Didn't that require a written directive? It doesn't sound like there was a written directive.

DR. HOWE: It did require a written directive, but to get it to a medical event, you have to also go over some dose limits. And in this case because it was athyroid person, the dose limits weren't exceeded. So there are a number of factors that you have to meet.

MS. GILLEY: The second organ of interest of iodine-131 is the stomach. So if you don't have a thyroid to get the organ dose of a thyroid because it's ablated, the next choice is the lining of the stomach. And it has to meet the threshold for a medical event.

DR. THOMADSEN: I thought something such as treating the wrong patient didn't require a threshold. I mean, that was by definition a medical event. I thought not having a written directive when

you're supposed to is automatically a medical event, regardless of thresholds.

DR. HOWE: Dr. Thomadsen, that was the discussion yesterday --

DR. THOMADSEN: Exactly.

DR. HOWE: -- on making a change to the rules.

DR. THOMADSEN: Right. What is the current rule, though?

DR. HOWE: The current rule is if you don't have a written directive -- well, generally there is something in writing. In this case they wrote. There was a written directive for a whole body scan. Okay? The technologist interpreted that to be "Okay. I need five millicuries" and gave the five millicuries. But in this particular case, the physician didn't ask for five millicuries.

Then you have to go to dose because what we go back to in this case is what was the intended dose. Intended dose was zero. He had a written directive. The intended dose was zero. He gave material that wasn't supposed to be given.

Then you have to go and see if that material resulted in a dose to the patient that exceeds our limits. It's the same as if you expected

technetium and you gave the wrong technetium.

Yes, there was something that said, "You were going to get a bone scan. You got a kidney scan. Do you exceed the dose threshold?" And the answer is no. It's not a medical event. So you have to do multiple things.

MR. LUEHMAN: That doesn't mean there wasn't a violation. There may have been violation. It's just not a medical event.

DR. HOWE: Yes.

MR. LUEHMAN: That was the discussion yesterday where you had the medical --

DR. THOMADSEN: Actually, I thought the discussion yesterday because yesterday's discussion was about changing things -- the discussion today is about what exists currently.

DR. HOWE: Right.

DR. THOMADSEN: Okay.

DR. HOWE: So what we are looking at is we are looking at a diagnostic procedure because this person was athyroid and did not raise up to the dose levels that would be required for a medical event. So it's immaterial.

We had to be careful because there was a presumed -- the procedure was a zero dose, a zero

activity for the second part of the procedure. They gave the material. Okay? But once you give the material, you then go over the dose issues.

VICE CHAIR VETTER: Mr. Lieto, you have a question?

MR. LIETO: Yes. I am a little confused because you are saying that there was a written directive, which to me means there was a script saying that they are to give the patient five millicuries from the authorized user. That's a written directive.

DR. HOWE: There was a written directive for the 150 millicuries.

MR. LIETO: Right.

DR. HOWE: And then we went back and asked what the licensee's procedures were for people coming back. Was it understood from their procedures that the whole body scan after the therapeutic required an administration? And they said they had procedures. It said no administration.

MR. LIETO: Okay.

DR. HOWE: Now, once they gave the five millicuries, should they have asked for a written directive? Yes.

MR. LIETO: Okay.

DR. HOWE: And they didn't have one. So should they have given it? No. Did it become a medical event? No because it didn't reach the dose threshold.

MR. LIETO: Okay.

DR. HOWE: And then the last case was a fluorine-18 infiltration. And Cindy was going to talk more about that. But we have essentially some questions that we asked, but we had been on record earlier, and I mean much earlier, before the 2000 rule, probably before the '80 rule, that said essentially infiltration was something that happens and it would not be called a misadministration. And, therefore, it still wouldn't be called a medical event.

So those are the four cases that I thought you might be interested in.

VICE CHAIR VETTER: Thank you. Thank you, Dr. Howe.

DR. HOWE: Very well.

VICE CHAIR VETTER: Mr. Lieto?

MR. LIETO: My portion addresses the other material events that are reported involving medical radioactive material use. These are based on events from the NMED database.

I have on here through October of this year, but, in actuality, because of the timing of providing the reports, there may be events during the month of October that we did not capture at the time making these reports and so forth.

As Donna-Beth reported, there were 31 medical events involving patients. There were 32 other reportable medical use-related material events.

There are a couple of changes on the slides because we found that after submitting the slides, that there was an event in the database that, in actuality, did not exceed the reportable threshold involving a lost source. And I will describe that as we go along.

First of all, I want to express my appreciation to Duane White from NRC staff for his assistance because he was very helpful in explaining some of the nuances in doing searches on the NMED database to capture these other events.

In terms of categories of events, there were for lost sources, both sealed and unsealed, 11 events. For leaking sealed sources, there were seven events. And fetal embryo dose, there were two events.

For landfill alarms, which is something that we reported in the past, which were either due to

decay in storage waste being disposed of improperly, unknown origin, as well as patients who had been released under 10 CFR 35 whose waste gets into the general waste stream and sets off landfill alarms. There were four events that were reported into NMED on this situation.

And, therefore, the final category was what I will call "miscellaneous," which is to capture everything else, which included in this report equipment malfunctions, which were three events; packaging problems and contamination, which were four events; and an overexposure of the extremities.

One of the things that I do want to kind of as a preliminary is that the reports that both Donna-Beth has presented and what I am going to be presenting actually provide the input to a more detailed report of the Materials Event Subcommittee, which makes a report in the spring, which addresses all the events that we described here plus any that might have been reported in this last month and a slightly more detailed analysis as well as specific recommendations will be made from that subcommittee. It is an ongoing I guess action item or Committee program. So, actually, next spring will be our second subcommittee report.

First of all, I will start off with some of the specifics. Regarding the lost sources, this is somewhat in a chronological order. The first event was an iodine capsule that was used as a calibration quality control check in a neck phantom.

The source was there. Some counting was done. But sometime between doing the calibration and quality control and getting back to the hot lab for storage, the capsule was lost.

A second event was an iridium-192 seed, a ribbon that was removed after treatment to a patient. I think there were a number of ribbons, I think about eight or nine ribbons, involved in the treatment.

Sometime between removal and inventory back in radiation oncology, one of the ribbons was found to be missing. A search of the patient's room and area was negative and subsequent search of the off-site laundry three days later found the ribbon, and it was returned into storage.

The next event was an iodine-125 seed use for breast tumor localization sometime. During the tumor removal process during suction of the breast site, the seed was thought to have gotten sucked into the canister of the suction device and later disposed of via that route before a survey was completed.

And next was again another iodine-125 seed. There was a batch of seeds obviously being autoclaved prior to for implantation in a patient. The pig in the autoclave overturned, spilled the seeds out. And during the recovery process, only 19 of the 20 seeds were recovered.

In another case, 18 seeds, which were unused after an implant, were transferred to the nuclear medicine technologist for storage and disposal, which was really the standard procedure for this licensee.

The nuclear medicine technologist was not very well-trained in their procedure and process, took the seeds, dumped them into a NucMed decay and storage bin.

And ultimately this made its way out as general nuclear medicine decay and storage waste. So apparently it was not surveyed properly before disposal, but this was the route of, shall we say, transfer to the local landfill.

Two seeds in another application, iodine-125 seeds, were unused after implant, were left in an applicator, which was not their standard process. And during cleaning, it is presumed that the seeds were ejected during the cleaning process of the

applicator and subsequently flushed down the drain.

Again, another I-125 seed situation became lost after implant during the post-implant inventory. One of these seeds was determined to be missing and was not able to be found. And it was suspected that somehow it got disposed of via the general trash route and was not recovered.

The next incident here -- I should probably point out that one of the incidents that may still be on your handout is an I-123 capsule that was supposedly not returned to inventory after use in an uptake phantom for calibration and quality control for an uptake procedure.

It was reported as being 200 millicuries. When we were reading the narrative on this, we asked that NRC staff follow up on this event. And subsequently it turned out that it was a 200-microcurie capsule, which put it over the threshold. And I believe subsequently that report has been removed from the reportable criteria for the NMED database as lost sources.

The next event was two gadolinium-153 transmission sources. Basically a gamma camera was being disposed. It had had two gadolinium-153 transmission sources, the type that was described

earlier in our proposed rulemaking changes. And subsequently when the camera was disposed by simply transferred to a scrap recycler, these two transmission sources went with it and were not recovered.

The next event was five iridium seeds in a ribbon that were lost, became lost. The inventory -- this was done, I believe, after inventory of the implant and upon removal became lost, it's suspected that they went out in the trash/laundry prior to proper survey and were not recovered.

The next incident was a large batch of palladium-103 seeds, which were unused for an implant. I believe this was an implant that was intended to be done.

And there was an area undergoing renovation where these seeds were being stored. It was presumed that they were put into a lockbox at the time for storage prior to their disposal and/or use.

When they went to go back and get this, the so-called lockbox area was not locked up. The pig containing the seeds was gone. And it is again presumed that this went out into the general trash during the renovation process of the area.

The next and last incident or event

regarding lost sources was again another 125 seed that was unused after implant, during inventory was discovered that was one of -- the inventory, the six unused seeds at the time became lost, presumably -- again, I think this one was -- was this flushed down the drain also? -- but, anyhow, became lost during the process of the post-inventory evaluation of the unused seeds and was not recovered.

There were seven events involving leaking sealed sources. Now, these are not leaking sources that were reported under the medical event process that Donna-Beth discussed earlier.

One event involved five seeds that were unused after implant. The licensee did white testing of the storage pig cartridge and one of the seeds and found removable contamination significantly above an action level.

They returned the cartridge and seed to the vendor, who did analysis. The vendor said based on the analysis of the damage to the seed, that it likely occurred during the seed being used in the applicator and the leakage occurred during that time. There was no patient contamination in this event.

In the second event, a seed became jammed in the applicator. The technician, who did not use

any gloves, unloaded the seed from the cartridge. And after the technician unloaded the seed, did a survey immediately afterwards, found both the cartridge and her hands contaminated. And so it was obviously a leakage caused by the process of using the seeds in the applicator.

The decontaminated the technician. And calculations were done in terms of dose due to the contamination and was below any reportable level.

In another incident, the vendor during seed assembly of iodine-125 seed strands damaged the seed during this process, severely contaminating the working and crimping tool used to make these seed assemblies.

I think this is noteworthy because, as I will report in a subsequent one, this has a very high potential for the contamination if not caught to contaminate other seed assemblies and these being distributed to licensees.

The next event was five seeds from two different lots that were unused after implant. In other words, there were two different implants involving a total of five unused seeds that the licensee did white testing of and were found to be leaking and in one of the situations visibly damaged.

There was no patient or work area contamination that was found by survey and also I think a survey of the patient's thyroid.

thyroid. It was thought that the cause was that as these seeds were being shipped, they were stacked in the shipping container. And it was thought that some excessive force caused damage to the seeds and that during the cartridge loading, the leakage resulted.

The next event, a patient was brought back after proper seed implantation. And during the process of trying to open up the ureter with a cauterization tool, a seed became damaged and resulted in contamination of both the patient and the equipment. A thyroid bioassay was done of the patient. And the dose to the thyroid was estimated at less than a rem.

The last two events, a vendor reported a leaking I-125 seed, which was estimated to cross-contaminate potentially over 1,500 seeds that were shipped to multiple customers, both in the United States and internationally.

The vendor did follow up with all of these customers. And so one thing that wasn't clear is whether this event is related to any of the previous events that were reported earlier.

We suspect not because that there were no follow-up. At least there was not any indicated in the narrative on this, any reports from customers on these potentially contaminated seeds.

In the last incident, a licensee reported one seed being leaking. It was found to be leaking after survey of a group of seeds that were found after autoclaving and cartridge loading but prior to patient implantation.

They were returned to the vendor for analysis. And the vendor found surface contamination also but no defects in either of the welds or encapsulation. So it's not clear where this contamination originated from.

There were two events reported on fetal embryo dose. I think that is kind of noteworthy in that obviously the licensee was following standard and very good measures to assess the pregnancy status of the patient.

In both incidents, these were patients that were receiving I-131 sodium iodine for thyroid ablation. In the first case, the patient had a serum pregnancy test done two days prior to administration, and in the second incident, the patient had a negative test that was done within five days prior to

administration.

So obviously the licensee was following good standard procedures to try to assess that the patient was not pregnant. And obviously the patient didn't think she was pregnant at the time.

In the first incident, the event was discovered. And the estimate to the embryo dose was 32 rads. I believe it was the medical consultant that was called in on this case who stated that there were no adverse effects expected to the embryo fetus because of the stage of pregnancy during the exposure.

In the second incident, the patient informed the licensee three weeks after administration that she was pregnant. The dose was estimated to be 35 rads or Centigray to the embryo. And I don't remember what the medical consultant's report on this was other than that they were going to, I believe, follow the pregnancy and monitor the patient and the child. Obviously the patient failed to follow written instructions to avoid becoming pregnant.

Very briefly, there were four landfill alarms, all involving agreement state reports. They all involved I-131 waste. In two of the events, the waste origin was unknown. And in the other two events, it involved one improper disposal of hospital

waste that got into the general waste stream.

MS. GILLEY: May I interrupt? I want everyone to know that agreement states do not have to report landfill alarms. That's no longer a reporting requirement for us. And in the State of Florida, we have about 100, 130 of these landfill alarms every year. This is voluntarily reporting that you're not really reflecting what's happening out there in the profession.

MR. LIETO: Regarding miscellaneous, there were three machine malfunctions, one involved a gamma knife, doors that failed to close after treatment. At the end of the treatment fraction, the patient couch moved out withdrawing the patient from the treatment helmet, but the source door -- the shielding doors failed to close on the sources. The medical physicist entered the room and manually closed the doors, receiving negligible dose, and patient dose did not deviate above a level requiring -- being outside the written directive guidelines.

The next two events involve HDR sources. Both of these occurred during source servicing, source exchange, and occurred with the manufacturer's field engineers. The first, during an emergency retraction test, the source failed to retract properly. Part of

the source became disconnected, and the top of the source capsule was clipped off within the vault door. The vendor sent out a team to assess the situation, and the recovery of the source, and its evaluation was done all under the vendor's, what I'll say - I don't know if I should -- emergency response team, but their response team trained to assess this.

The source was clipped off. Part of it was found I think in the inner vault, because the surveys were found to be extremely high as they were assessing the situation, so it did require some specialized recovery efforts. During the other, the next event, the field engineer was trying to get the old source to exit into the source exchange container and failed to do so. The cause was determined to be that both the dummy and the active, or the old source exited at the same time, and because stuck. The vendor -- the manufacturer told the field engineer to clip -- to cut the source wire, and put the source into the emergency storage container, and await further action. The engineer cut the dummy source instead, and placed that into the emergency shielded container, so subsequently the vendor had to send out a specialized team for the source recovery and exchange.

In terms of the packaging events, there were four events. The first event involved a licensee returning an unused block of seeds that were not used for an implant. It was not packaged properly, such that the pig became open during transit. The seeds spilled out of the pig container within the inner packaging. The exposure levels significantly exceeded the limits for the package labeling. The manufacturer received the sources, determined there was no contamination or loss, and they did estimates on expected exposures, and these were found to be -- that none had occurred.

The next incident were three packages of cobalt sources, flood sources being received by a licensee, found the surface contamination to significantly exceed the acceptable guidelines. The contamination was determined to be Technetium, so it was not determined where the origin of the Technetium was.

DR. VETTER: Ralph, we just have a couple of more minutes for you.

MR. LIETO: Okay. All right. There were two others, both involving Technetium packages with significant contamination on the surface. Again, there were -- in one case there was significant cross-

contamination by a courier picking up several contaminated packages going to the next stop, and then contaminating -- it was discovered that the packages there were contaminated upon receipt. And also, his hand and vehicle were significantly contaminated. And the last event was a significant over-exposure to the extremities of two manufacturers, radio pharmacy technicians who were making I-131 capsules for human use.

In summary, they're comparing the events over the last three years that I've been making these. The landfill alarms have significantly gone down, for the reasons I think Debbie has alluded to. We're seeing a significant increase, I feel, in the number of leaking sources being reported. Lost sources over the last year, I won't say that they've increased, but there is, I think, an increasing trend there, also. But I think we need to look at this a little bit farther in the Subcommittee report. And that's it.

DR. VETTER: Thank you. I am going to just take one or two questions, comments, now. And if it appears we need more time, we'll do that later, because the next presentation has some problems with flights. We need to get moving. Dr. Thomadsen.

DR. THOMADSEN: Well, it's not a question

on this. It's a question as to how does hearing these now differ from what we do in the spring when we go over these events? And why is it we're doing the events twice a year, as opposed to just doing them once?

MS. GILLEY: We don't have all of them.

DR. VETTER: Dr. Howe could perhaps add something to that.

DR. HOWE: I think the original intent was that in October, we would give you an overview of all the events that happened in the past year. And that if you discovered something that was a trend of interest, then your spring group would have delved more into that particular area, and develop a more detailed report on whatever was of interest to the ACMUI. So, originally, it wasn't intended that you got the same information in October and in the spring. It was that you got a more detailed look at some aspect of what was going on that you thought was of particular interest.

DR. THOMADSEN: Actually, I think in the spring we are going through the details of each of these events.

DR. HOWE: But you don't have to.

DR. THOMADSEN: Right. Or we wouldn't

have to do it now, if we're going to be doing that as part of the analysis in the spring.

DR. VETTER: Dr. Welsh.

DR. WELSH: Was there any difference in the way you acquired the information this time through the database, or is it identical to what -

MR. LIETO: It will be the same. There may be some additional events that were not captured between the time that we had to submit our report for the Committee and the end of the fiscal year, so there could be a few added events. Hopefully not, but there could be.

The report that we've done in the fall actually predates the forming of the Subcommittee that was established -- well, actually, the first report was this past spring, so I could see where we could just roll these both into one.

MS. TULL: This is Ashley. Just to add some perspective on this. Medical events have always been reported in the fall. It's been a standard thing that Donna-Beth and Ralph have done. And what came out of it is this is just a brief overview, and I think Dr. Nag may have actually brought this up, and wanted more information, more detailed analysis. And then if there is a bigger issue, or we do see a trend,

then you, as a Committee, could make some sort of recommendation to the NRC so that we could maybe get a message back to the licensees. So it's a more in-depth, if needed, type thing.

DR. HOWE: And this is Dr. Howe. You also have at the bottom of all the NMED reports that you've seen a series of references, and those are documents that may or may not give additional information. And there's time between October and the spring to go back and get more additional information if you thought a case was interesting, but you didn't really have enough information to see what was going on with it. So the information presented in the spring can be different than what's in the fall, and I hope it is.

DR. VETTER: Okay. So I guess, I don't hear any recommendations at this point.

DR. THOMADSEN: Well, I'll make a motion that we do -- we review the events in the spring. We can start looking at them earlier so we can -- if we need more information, we can go to those references and have things ready for the spring meeting.

DR. VETTER: Okay. Is there a second to that? Ms. Gilley?

MS. GILLEY: Second.

DR. VETTER: Discussion? Yes, Dr. Eggli.

DR. EGGLI: Given the large number of medical uses and the very small number of events, I don't see any obvious trends here. To me, it looks like noise in a very small number. I don't know that this needs to be repeated in the spring.

DR. VETTER: This year.

DR. EGGLI: This year.

DR. VETTER: Dr. Thomadsen.

DR. THOMADSEN: The only reason to repeat it in the spring is to have a consistent database that we're looking at over the years. I agree that we probably don't need to go over everything in detail again.

DR. VETTER: Dr. Eggli.

DR. EGGLI: Again, when the numbers are so small compared to the total number of events that they begin to look like noise in the system, I'm not sure that the fact that we may not have captured 100 percent of what occurred in October of this year is going to have any dramatic change, unless there's a huge surprise in there. The one event that may be of note is the VA system event, but that's being looked at intensively. And the question is, does this Committee have anything to add to that?

DR. VETTER: Ralph.

MR. LIETO: Well, I guess I would -- we do try to put a little more statistical, shall we say numerical validity to the conclusions maybe that you're stating. In other words, are these very small number events that are occurring? We don't make recommendations at this time period. I was going to say that if we do -- are only going to do it once, I guess I would tend to agree with Bruce, that we would do it in the spring when we have all the data in for the fiscal year, and any final -- hopefully, current reports, and make either recommendations that there's no recommendations, or we may have some recommendations to be made, especially in light of the event that's coming out regarding the I-125 seeds, because that should be the Subcommittee that makes any recommendations.

DR. VETTER: Dr. Suleiman.

DR. SULEIMAN: First off, these are always going to be soft data. I mean, it's trying to put a whole lot of effort to get more statistical certainty is a wasted effort, but it's interesting to follow on a routine regular basis, so from that point of view, I think it's good to monitor it more regularly so we get more experience in doing it. Which brings me to my second point; why are we doing this? I mean,

doesn't the NRC staff do this, and just give us this information? I mean, why are we doing this? I think it's interesting information, but -

DR. VETTER: Dr. Nag.

DR. NAG: I had made the original suggestion last year. My suggestion would be that in the fall, it be a standing report in the fall, so every year automatically we would get this report in the fall. And then if we see some significant need, for example, for this year if we find that by February or something we have more data on the VA event, that would be a single time, we asked for that time, not a standing event.

DR. VETTER: Mr. Lewis.

MR. LEWIS: To answer the direct question, yes, the NRC does analyze all of these events in many ways, but one of the more visible ways is our annual NMED report, which we issue in the spring, and our annual Agency Action Review Meeting, which is specifically for the Commission -- it's a Commission meeting where they look at trends across the industry.

All of that being said, the Committee's work in this area is invaluable to us, because you bring a medical perspective on the trends, especially on the trends issue, and how things are practiced that

the NRC staff can't bring to the issue.

DR. VETTER: Dr. Welsh.

DR. WELSH: One other point that I think might have been brought up at previous meetings was that by having this data on material events and medical events, we could, perhaps, publish a paper that would be disseminated to the end-users so that they could get feedback about what has been going on. And regardless of whether there is a trend or not a trend, at least they would have an idea, if there was a trend, how do we correct it?

MR. LEWIS: And the difference between this industry and some of the other industries that we regulate, particularly reactors, is the amount of communication between the licensees. In the materials world, and in the medical world, there's very little in terms of user groups and cross-communication on event response compared to what's done in the reactor world, so the work that the Committee does serves a critical function in that cross-cutting look.

DR. VETTER: So the motion was to have another report in the spring.

DR. THOMADSEN: Each year have one report, that being in the spring, and including any analysis that's going on.

DR. VETTER: Okay. This motion was to have one report in the spring. So the next report would be next spring.

DR. NAG: The following year there will not be a report in the fall.

DR. VETTER: Unless someone makes a motion that there's some particular issue we want to look at in more detail. We need to move along here. I'd like to halt discussion of this, unless it's really critical. All those in favor of the motion for one report in the spring. One, two, three, four, five, six. Opposed? Abstentions? One, two, three, four abstentions. Okay. The motion passes. 6-4, 4 abstentions. Six in favor, four abstentions. Is that correct?

MS. TULL: Somebody didn't vote.

DR. VETTER: Somebody didn't vote, or I miscounted. All right. Those four, one, two, three, four -

DR. THOMADSEN: I'm sorry. What?

DR. VETTER: Those for the motion, those in favor of the motion. Two, four, six. Those against the motion, those abstaining. One, two, three, four, five. Thank you. Thank you, Ralph.

The next item on the agenda is a

presentation by Dr. Jeff Heier of NeoVista on interocular Strontium-90 eye applicator. Please, Dr. Heier. Am I pronouncing it correctly?

DR. HEIER: You have it exactly right.

DR. VETTER: All right. So if you would introduce your team.

DR. HEIER: Absolutely. My name is Jeff Heier. I'm a vitreal retina specialist from Ophthalmic Consultants of Boston in Boston, Massachusetts. This is John. I'll actually let you introduce yourself.

MR. HENDRICK: I'm John Hendrick. I am the President and CEO of NeoVista, and this is Bill Vermeere. He is our Radiation Safety Officer for NeoVista.

DR. HEIER: I'd like to thank you for the opportunity to speak with you this afternoon. I'd also like to acknowledge right off that I have received research support from Neo Vista, and served as a consultant, but I have absolutely no financial equity in NeoVista or any other company involved in ophthalmology. My interest here is purely scientific and clinical.

I'm going to take just a moment to -- okay, great. I'm going to take just a moment to

explain the disease state that we're talking about. Many of you know of, or have family members or friends who have macular degeneration, and exudative macular degeneration is the devastating form of it. In exudative macular degeneration, you get a growth of new blood vessels coming up from layers underneath the retina. They grow into the layer just underneath the retina, and into the retina, and they leak and they bleed, and they often cause devastating loss of visual acuity.

The U.S. has roughly almost 2 million people with advanced age-related macular degeneration, of which about 200,000 develop wet macular degeneration annually. As our aging population is increasing, this number is expected to increase exponentially. The World Health Organization estimates that will be in epidemic proportions in about 20 to 25 years.

That's the bad news. The good news is we've had dramatic advances in the treatment of macular degeneration over the past couple of years. In particular, intravitreal injections of agents called anti-VEGF agents have led to us being able to stabilize this disease. And in many patients, result in significant improvements in their vision. And we've

seen visual recovery in many of these patients. That visual recovery occurs in upwards of 30 to 40 percent, but there is a cost to that recovery.

First of all, it requires multiple intravitreal injections. If you have family members or friends involved in this, you've seen that they may get injections every month for a period of a couple of years. This, obviously, results in a tremendous burden on the patients, on their families, and on clinicians. That's the physical burden.

There's also a very significant financial burden in this. The drug that is most effective, and that has been approved by the FDA is a drug called Lucentis. It costs $2,000 an injection. Patients may get 12 in a year, and so they could get upwards of $24,000 worth of injections in a year. That's just the drug itself. So there is a need for additional therapies, although we've made tremendous headway.

Why do we look at radio therapy? Well, there's been a great deal of radio therapy exploration with macular degeneration in the past with variable results. We know it has efficacy. We know it can work in this disease, but we've been harmed by the collateral damage to surrounding tissues in the application of the radio therapy. We know ionizing

radiation is significantly anti-angiogenic, anti-fibrotic, and anti-inflammatory, all effects that are important in the treatment of this disease.

We also have seen synergism demonstrated with radio therapy, and the exact anti-VEGF agents that have shown such promise in AMD. And, in fact, Avastin in radiation therapy are used in colon cancer, and now many other cancers, as well.

The diagnosis and treatment of this disease is done when a patient comes in. They're referred to a retina specialist. They're examined, various types of diagnostic evaluation are ordered. This called the fluorescein angiogram, and this is critical to our diagnosis and management of these patients. And it's also critical to the delivery of radiation therapy to these patients. We look for various signs in these patients, such as leakage that's seen here right off of the center, that enables us to determine what treatment is best for these patients, and how to apply that treatment.

Once we've decided on a treatment approach, we then have to analyze the different components of that grouping of neovascular blood vessels. We look right, this is an area of leakage, but there is an area here that is also involved in the

neovascular process, and so truly, the complicated part of treating these patients is in the diagnosis, the evaluation, and the determination of management of these patients.

Once we've made that decision, if, in fact, we determine that the brachytherapy approach might be ideal for these patients, then our orientation is guided by these fluorescein angiograms. And they're determined by other factors, things like lesion size, lesion safe, proximity to the optic nerve, surrounding structures to there all play a role, and there are other diagnostic evaluations that may help us in guiding that therapy.

And here you see actually the device is put into the eye, and it goes directly over the lesion. And that's what's unique about this device, it's placed directly over the lesion minimizing collateral damage to the surrounding tissues. And that's been the very difficult part in the past.

This is an animation of the NeoVista procedure, and so what happens when we decide to do this is, first of all, the patient is consented about the risk of the procedures. And the biggest risk in these patients is the risk of the surgical approach to the delivery of the brachytherapy. It's not the

brachytherapy itself, it's the surgical approach, which has a complication rate of about 3-5 percent.

This is -- an angiogram is brought in with us, and we use that to, again, reconfirm how we're going to deliver the therapy. We administer it through a surgical approach, which is the most common surgery we all perform in retina surgery today, this initial approach. The NeoVista device is then introduced into the eye in the mid-vitreous position. At that point, one of our assistants would come in and transfer, or actually move the edge of the device, and Bill has an example of it here, that would engage the radiation while we're in the mid-viterous cavity, so we're holding the device, our assistant engages the device, and then we place the device right down on the eye. We then time the delivery of the device, which is roughly in the four minute range, so the retina specialist holds this actually touching a small part of the retina for four minutes, keeping it stable during the delivery of the device.

At the conclusion of the delivery, the device is again lifted back into the mid-vitreous cavity, and the system then retracts the device, or retracts actually the radiation back up into the handle, and the radiation source is then pulled back

after the lever has been placed, and it's pulled out of the eye. And then the eye is closed with sutures.

Here you see again the delivery of the device positioned over the lesion. And one of the true benefits of Strontium-90 in this case is the rapid fall-off. So here we see the device being delivered to an area of corneal vascularization, and the fall-off is roughly 10 percent for every .1 millimeters when delivered from the point source. So if we look at various regions, we're delivering 24 gray to the center of the lesion, the edge of the lesion, again, that will be dependent upon the size of the lesion, which can vary anywhere from less than a millimeter to 7, 8, 10 millimeters in size.

We see delivery to the lens is far less than 1 gray. Delivery to the optic nerve, again dependent upon positioning, is roughly about 2.4 gray. And here we see a threshold for clinically observable damage. And, again, this is one of the beauties of the delivery of this device. We see for corneal edema it's 30 to 50 gray, and the dose delivered to the cornea is extremely low. The conjunctiva shown here, cataract, which was a significant complication of previous deliveries were getting far less than the dose that would cause a cataract, far less than the 2

gray.

Radiation retinopathy is a significant finding in previous cases. The threshold is somewhere between 35-55 gray, and delivery of 24 gray, again, is only to the point source, only to the source where there's the neovascular membrane. And then one of the most important complications in the past has been optic neuropathy. And, again, we're delivering far less than would be toxic to the optic nerve.

As a retina surgeon, I'm trained to handle the radiation device in the eye. NeoVista procedure has basic treatment planning requirements as it pertains to the radiation dose, and to the delivery of the dose. The placement and orientation of the device is the only changing component of the procedure, and it's very dependent upon the retina surgeon's evaluation of the angiogram, the other testing, and then his evaluation for the patient of how this should be delivered. And considerations there in terms of size and orientation also have to do with where you want the tip of the device that's actually going to touch the retina to go into position in the retina. You'll do things to avoid the optic nerve, vasculature, or other areas of the retina.

In the case of a device malfunction, we

would withdraw the delivery dice from the eye, we would move it immediately away from the eye. We would place the cover back on the device. We would return the device to the shielded box which it comes in, and then have notification of the appropriate personnel.

It's my understanding that there were concerns of the procedure from a meeting last year, and as best as I can, from my appreciation of them, I'd like to address those concerns. Here were the concerns, used by ophthalmologists with little or no radiation treatment, little or no radiation oncology input, primitive dosimetry, and questions about technology that may fade with inadequate multi-disciplinary approaches.

With regards to the training, this training is the training that was recommended for Strontium-90 for the surface applicator, and I underwent this same training with regards to delivery of the NeoVista device. I had training both at Harvard, in terms of radiation training, and then I've actually -- this is a -- I've been involved in previous radiation studies for macular degeneration, and I had proctorship in those, and delivery of the radiation training for that delivery. I feel that that training was more than adequate for the delivery

of what we're doing here. There are complications and risks associated with this that all have been -- have fallen under the concern of a retina specialist, and all of the complications that we perceive with this would fall under things that I would need to diagnose as a retina specialist, and I would need to treat as a retina specialist.

If we look at the input of radiation oncology, Strontium-90 utilization in the NeoVista device, the dosimetry, the determination of the radiation is absolutely fixed here. The only component that has any degree of change is the delivery or the positioning of the device. This is very unique from the other types of radiation applications into the eye. The application of radiation for tumors, for the oncologic applications with the eye are extremely different. There's dosing that has to be determined, there's placement that requires very significant coordination.

In the previous radiation study I was in, there was significant coordination that needed to go on between the radiation oncologist and the retina specialist. This is very unique, that all of the components here need to be determined by the retina specialist.

With regards to dosimetry, again, the dosimetry is fixed. That's determined. We actually receive the dwell time periodically from NeoVista, but that is fixed. It is the application of the device that's critical here in the positioning.

Finally, with regards to technology that may fade, the Strontium-90 has had very significant success in the Phase II studies. It's now undergoing enrollment in their Phase III studies, and that enrollment is proceeding nicely. If the results of the Phase III studies replicate the results of the Phase II studies, there is no question that this would have application to many patients with exudative macular degeneration, and it's awaiting the results of those Phase III studies that are critical. Right now, there are patients being enrolled in 45 sites across the country.

There are a couple of points that I feel are important. The repetity of this disease onset, as many of you know, this is not a disease that progresses in a very slow manner. Usually, patients will present overnight with loss of vision. They'll come into the clinic having lost vision the previous day. The need to deliver treatment to these patients in a timely manner, that treatment often has to be

delivered within days to certainly within a week to allow the best outcomes. Across the board, it is felt that the sooner treatment can be delivered, the more likely you are to achieve good outcomes in these patients.

In addition, the urgency with which we try to schedule these, this is delivered in an operating room. When we try to schedule these in the hospital outpatient departments, you have far more rigid requirements to get these scheduled. In our ambulatory surgery center, we have far greater flexibility to schedule these. And they're often scheduled, for instance, if I have a patient today that I see and determine they need this, I can often get them on the schedule for the next day, or the day after, with the caveat that there may be a block. They may say you're probably going to go between 12 and 2. From the previous studies I was in, I recognized that the ability to coordinate a retina specialist, an OR, and a radiation oncologist in that time frame was virtually impossible. And it was actually the reason that I initially didn't do this study, because I felt it wasn't doable. The ability to do that in a timely manner is critical to the success of these patients.

If we look at why else these are best suited for ASC as opposed to a hospital outpatient department, again, the frequency of the cases, the potential to see these regularly. I have a fairly typical busy retina practice. I see 45-50 patients a day, as is very typical for retina specialists, and of these patients, 1 to 3 of them have newly diagnosed wet macular degeneration. That means you are going to be routinely trying to schedule these patients if, in fact, you determine that this is the best treatment for those patients.

The need for efficient operation is critical. There is a significant push, trend, however you want to look at it, of retina surgery moving to the ASC because of advances in our technology, advances in our ability to deliver treatment in the ASCs, this enables more efficient treatment for these patients. And in a treatment like this, that would be absolutely critical.

Finally, I'd like to point out that prior utilization of Strontium-90 applicators for the treatment of -- post-treatment pterygium is something that is not new. There have been a number of reviews of large retrospective series of Strontium-90 delivered to post-pterygium treated patients, and all

of the complications in these large reviews, all of the complications have fallen into the purview of the ophthalmologist. They've all been complications that have been diagnosed, and then managed by the ophthalmologist.

Here we see the extra vitreal Strontium-90 eye applicator, that which was used in the past for the treatment of pterygia. And here is actually a pterygia device that NeoVista is looking at that is actually before the FDA right now.

Here you see the Strontium-90 applicators. And, again, you'll notice that the dosimetry, the delivery is very similar between the superficial device and the intravitreal device. Again, the main difference is, one is delivered externally, and is always -- it's unshielded, essentially, and one is delivered intraocularly where it's shielded until it's opened. And, to me, that's actually a much safer approach to it. It's shielded until I'm right where I want to be. In the worst case scenario, it has the same exposure as the surface delivery.

Finally, I'd like to point out that this therapy is unique with regards to the interaction between specialists in both ophthalmology and radiation oncology. This application is very

different than the application we've seen in other diseases. Again, 100 percent of the planning in this case is done by the retina specialist, and the complications are those that are going to have to be seen, diagnosed, and dealt with by the retina specialist.

The safety of this device in terms of surface delivery has been supported by 30 years of work in thousands of patients. The only complications have been ophthalmic, and they've been managed by the ophthalmologist. The level of recommended training is fully adequate to justify the use of this applicator inside the eye, again, which by all accounts should be safer than that delivery outside of the eye.

Finally, to end with this slide, which just compares the characteristics of the surface applicator and the intravitreal applicator, and they are extremely similar. Dosimetry, delivery is the same, positioning is the same other than one is on the cornea, one is in the retina. The radiation management component is the same, the recognition of delivery and treatment by the eye care specialist is the same.

I would like to respectfully request that the Commission consider the training that is

appropriate for the surface applicator be considered appropriate for the delivery of the retinal therapy, as well. Thank you for your time.

DR. VETTER: Thank you for a very succinct and clear presentation. Are there questions from members of the Committee? Yes, Dr. Nag.

DR. NAG: Thank you for an excellent presentation, going into far greater detail than I had done last year on the details of the technique. Have you done the I-125 eye plat? Okay. There, again, most of the things are very similar. You have a radiation -- here is the Strontium leg in I-125 dose. It's placed directly on, in your case, a lesion, in the other case, a tumor. The application is a surface application in both case, so why would you think that in the NeoVista you would want a different set of training requirements than you would for I-125 brachytherapy? Because they all have very, very similar -- and I think you did reference the Finger paper, and I know Paul Finger very well. I have worked with him.

DR. HEIER: Yes, I was actually on the phone with him yesterday about a patient. It's a good question, but I think, in fact, they are different. I think that the training that goes into positioning

of plats, the complications of plats are certainly more widespread than you see with this delivery. The timing and the side -- the delivery of radiation to the surrounding tissues is certainly different. In fact, there is a complete separate fellowship for treatment of tumors and delivery of that type of therapy to those types of patients; whereas, when you look at the delivery of this, say a surface applicator in corneal disease, it's a much more basic delivery. I think that the delivery to a point source, as we are here, in that time frame is much less. You may be delivering it to a certain area, but you're delivering it outside the retina. You're not delivering it over the retina. You're outside the sclera, and the amount that you need to deliver outside the sclera to actually treat retinal tissues and elevated tissues underneath the retina is much greater, with much more surrounding collateral damage, and a much higher complication rate. So I think they are very different.

DR. NAG: The other question, or other comment I had is that, do you feel you have enough knowledge of radiation effects, long-term effects, and dosimetry? Because right now, you are correct that you are having a single dosimetry. However, as we

have seen with any other radiation modality, once you go into more detail, you then have to modify your dose, to be able to tailor your dose to the disease. And do you feel you have enough knowledge of that to be able to do all the fine tuning? So in the short line, it might be easier for you, because you don't have to wait and try to coordinate a multi-disciplinary -- two people can go to the OR. But in the long line, do you not think that you are damaging a very useful treatment, because you won't have the ability to do all the fine tuning and so forth that you could once you have a radiation oncologist who knows the details of what the effects of both the dosimetry and the effects of the radiation are.

DR. HEIER: Well, I can't argue that I'm nowhere near trained to the level of a radiation oncologist for dosimetry. And, in fact, one of the beauties of this technology is right now, it is a fixed dosimetry delivered right over the lesion. And, in fact, I would absolutely not have any role in increasing the dosimetry there, or changing the dosimetry.

It seems to me as if, if you are going to have attempts at changing that dosimetry, that is a site where you'd have interaction. But that's a whole

different study from this approach. This study, and this therapy, as it's being described right here is absolutely fixed, as it was in the surface application. And I think if you're talking about modifying dosimetry, and changing dosimetry based on lesion size, or other issues like that, you're talking about a different therapy. So I wouldn't argue with that, I would say that that's not an intention here. And that certainly doesn't fall under the guidelines of the training that I've had to-date.

DR. VETTER: I have a question, perhaps for the NRC. Under 35.491, "Training for Ophthalmic Use of Strontium-90", the first paragraph, "Except as provided in 35.57, the licensee shall require the authorized user of Strontium-90 for ophthalmic radiotherapy to be a physician who", and then it goes down and gives the training and so forth. So the question I have relating to that first statement, an authorized user of Strontium-90 for ophthalmic radiotherapy, how is this application any different from the surface applicator relative to this requirement for training?

MR. LEWIS: Dr. Zelac.

DR. VETTER: Is there a difference?

DR. HOWE: We believe there is. We

believe that the training that you get for the eye applicator, the external eye applicator is not sufficient to use this device. One of the proposed changes we have in our user need memo is to retitle 35.491 to surface ophthalmic therapy. We think that there are other things he has to know that if he was doing the external he would not have to know.

DR. VETTER: Like what?

DR. HOWE: Well, for the external one, you also are able to visualize, and many cases they use treatment output to determine when to stop the procedure. In other words, you may go back for several fractions, because you're not getting the treatment output. This appears to be a one shot, and it's very high dose rate delivery. We think there are significant differences between this.

DR. VETTER: Dr. Fisher.

DR. FISHER: A comment. However, there are some simplicities involved here in the delivery of radiation by virtue of using a beta emitter rather than an Auger emitter. And, in fact, as Dr. Heier has mentioned, the dosimetry is actually more simple, owing to the constant source, and the distinct energy range cutoff of these beta particles. It's very predictable over a short range. And beyond a certain

distance, the dose is essentially zero from this source.

DR. VETTER: Dr. Welsh is next.

DR. WELSH: Just to start with a quick editorial. There appears to be a disproportionate number of medical events with the Strontium-90 ophthalmic applicator, so rather than lump this with 491, my reflexive answer, if that's what was being proposed would be add it to 491 to make it safer.

But moving on to the other issues. I know you said that only ophthalmic complications are seen, but this is an eye treatment, so you wouldn't expect anything other than ophthalmic complications, for the most part. I think what you're implying is that there are no radiation-related complications. Yet, scleral malacia is seen there. Is the scleral malacia believed to be physical, or is it possibly a radiation-related effect, as an example of some of the possible complications?

DR. HEIER: You're talking about the surface application -

dR. WELSH: No, with this particular treatment.

DR. HEIER: There has not been a case of scleral malacia with this. So, currently, in the

Phase I and II studies, there are I believe now over 100 patients treated. The only instance of any source of retinopathy seen was in a patient with pre-existing diabetic retinopathy, who actually should have been excluded from the study, and it wasn't even felt that was consistent with radiation retinopathy. And there are patients who are out to I believe the three-year time frame now. But even if you see radiation retinopathy, which our belief is we're not going to because of the delivery to the point source; even if you do, you're still talking about a disease state that in the majority of patients without treatment has them legally blind within a year. And radiation retinopathy actually today is best treated with anti-VEGF agents, where the plan is to combine brachytherapy with the anti-VEGF agents.

DR. WELSH: So it sounds like this is an important treatment that needs to be made available for those who need it, but you did say that one complication was in a patient with diabetic retinopathy, and maybe that patient shouldn't have received the treatment. As a radiation specialist, I would argue that when we have patients who need treatment for their cancer, or a patient who needs this treatment to prevent blindness, rather than

withhold the treatment and let them die of the cancer, or go blind, a dose adjustment might be appropriate. And I would think that with clinical experience, this 24 gray to the center, and 6 gray to the periphery may need adjustments; and, therefore, the one dose fits all model may not hold up in the long run. Therefore, radiation specialists might have more of a role than you're initially proposing here.

DR. HEIER: They may not, but right now the Phase III study is ongoing, so I think we -- it's important to see those results. In the Phase II study, the results were excellent. Now, as we've seen, Phase II studies don't always replicate at Phase III. That's certainly been the history of most treatments. In fact, the anti-VEGF treatments are the first Phase III results I've seen that have outdone Phase II results, but I think you have to wait to see that.

If the results in Phase II are replicated in Phase III, this treatment would be delivered just as it is right now. If those results are not replicated, then it may turn out that this treatment does require modification, and it may require more input. But as it's designed right now, and as the studies are going forward, and as the Phase III

studies are going, this is the delivery.

DR. VETTER: Dr. Nag, and then Suleiman. Dr. Suleiman.

DR. SULEIMAN: Medical applications, the medical use are clear, to me. I mean, there are some differences. That's going to be incorporated in the training. It will come out in the trials, and so on. I'm concerned about why does the training have to be so different? Is the training, from a radiation safety point of view, that it would warrant a completely different set of training? In other words, it's a beta emitter. It's slightly different than -- it is different than the other -- than the Strontium-90 applicator, but why would we want -- this is my argument I was making earlier. Do we have a subset of specialized training? I mean, are the risks and the needs to be addressed by the radiation safety sufficient to be handled by the existing training?

DR. HEIER: Actually, I think, in fact, it's very similar to the Strontium-90 surface applicator.

DR. SULEIMAN: What I'm saying is, I don't see why you'd need -- you could probably modify the training so it would address both devices. But, again, I'm trying to segregate the radiation safety

application from the vendor's training that would be applicable to the device itself.

DR. HEIER: And I want to be very clear. These were all concerns that I had as we look forward here. I'm a clinician. I see these patients all the time, and I'm heavily involved in clinical research. I want what's best for these patients. My initial response when asked to look at this, because of my involvement with previous radiation treatments was, I didn't want to be involved. I didn't want to have to deal with the safety issues. As I saw this, as I spoke to other investigators, as I became involved in it, and now as I've performed eight of these on patients, I'm very comfortable with the safety issues as it's delivered under these parameters, as it's delivered this way.

DR. VETTER: Dr. Thomadsen.

DR. THOMADSEN: Are you proposing that you would still have the same types of interactions with the medical physicist?

DR. HEIER: We have had interactions. They're the ones who helped to determine the parameters going forward, and so I do think those are important.

DR. THOMADSEN: Do they come to the

operating room with you?

DR. HEIER: They do not. And I truly don't mean this disrespectfully, what would their interaction be in the OR?

DR. THOMADSEN: Either in case something happens, as a radiation specialist, dealing with -

DR. HEIER: We have the radiation safety officer there.

DR. THOMADSEN: Okay. You have the radiation safety officer.

DR. HEIER: Absolutely.

DR. THOMADSEN: Well, they could do that, too. Who deals with the checking of the device?

DR. HEIER: The radiation safety officer.

DR. THOMADSEN: So, in this case, the radiation safety officer is acting sort of like a medical physicist.

MR. HENDRICK: If I could make a comment here. The issues that we, as a company, are trying to deal with here, is that trying to keep the cost down. As we all are aware, next year there are going to be significant changes by CMS. The budget process and how they deal with reimbursement of fees for different particular practices we all know it's going to change. And our particular procedure will probably start to

move more towards an outpatient setting, much as ACS, as Dr. Heier has. Currently today, the market is the vast majority of these cases are done inside a hospital, where a physician has his clinic outside. He comes to the hospital. There's already a radiation oncologist employed by the hospital, and that's all worked out.

What we feel is going to happen, and this is why this is extremely important to us to understand, is that that is going to start to move into ASC environment. And if we create a process that is required more than what we're saying has already originally been analyzed, and said this is the amount of training required, that it's going to start to, and it will affect the cost of this treatment being given to patients. So when we looked at that whole process, we're pretty confident, they are almost identical. In fact, our particular procedure is even safer because of a protective device that we have. And so, what has come back recently, the guidance document that came out, that put this into a new technology, basically said you have to be a radiation oncologist now to do the procedure. And I think that that is clearly not warranted in this particular case.

DR. VETTER: Dr. Eggli.

DR. EGGLI: I agree with the statement made about where these procedures will be done. With the exception of tumors, all of our eye surgery now is done in the ambulatory surgery center environment. If we make an assumption of fixed dosimetry, which is to say that the time is not going to be varied, except as adjusted for source strength by the manufacturer, this looks like a very safe procedure from a radiation safety point of view, where, in fact, the complications are primarily related to the surgery, not the application of radiation. If the device is unable to deliver either excess or under-dose the patient, unless you alter the time, then this looks pretty straightforward from my simplistic point of view.

DR. VETTER: Dr. Nag. I'm sorry. Dr. Howe, and Zelac both had their hands up.

DR. ZELAC: Just for my own edification, I have a couple of procedural questions that I'd like to ask about what's actually done.

How do you actually place the tip of the device onto the lesion? I mean, what guides you? Are you simply looking through the eye?

DR. HEIER: So you're doing it through an operating microscope. There is a point mark on the

device which tells you what you treat as the point source. That is actually held .1 millimeters above the lesion. The device is angled in such a way that the very tip rests on the retina. To put that in perspective, the retina has the texture of wet toilet paper, so the ability to tear the retina is extremely high, which is why we say the training for this is highly retinal in nature, and not something that from a retina standpoint, you don't do without training.

DR. ZELAC: So the tip is actually making contact with tissue, and that's when you know you're in the right spot, as long as it's visually at the right spot.

DR. HEIER: Right, so that it's not the tip that you care about. That's where the analysis comes ahead of time, making sure that you align it in such a way that your entry point into the eye is such that the tip can be placed where it's not endangering important tissues, but the cross-hairs of the delivery is right over the main component of the lesion.

DR. ZELAC: I have two more. Is there time? The second question, with one entry, one surgical entry of the device, can you treat multiple lesions?

DR. HEIER: We never would. It's delivery

of 24 gray to one lesion. So if you have a patient who has -- first of all, you might have a patient that has a large contiguous lesion, and that might be something you're still ready to treat, but you would not treat multiple lesions with this device. If you have that type of patient, that's not a good candidate for this therapy.

DR. ZELAC: And third and final question, you mentioned in your presentation that the surgeon needs to hold this device in position for four minutes. That sounds challenging.

DR. HEIER: Not for an experienced retina specialist.

DR. ZELAC: Okay. Thank you.

DR. VETTER: Dr. Thomadsen.

DR. THOMADSEN: Sort of following up on one of his questions, one thing that concerns me about this treatment when you were saying you just give a fixed dose to -- fixed volume, et cetera, is similar in ways to the beginning of intravascular brachytherapy, which was driven by vascular cardiologists as opposed to radiotherapists. Without regard to the effect of the dose distribution, and the attempt was being given to just have a single dose regardless of the size of the lesion, and without

paying attention to the penumbra of the beam. And that accounted for many of the early failures. Whereas, the experience when brought in from radiation oncologists looked at the dose distribution compared to the lesion to adjust the dose to fit the lesion, as opposed to using one-size-fits-all. And I would think that after the trial is over, you wouldn't want to change this in the trial, it would probably be useful to be able to go from this fixed dose, fixed volume approach to one which would be customized to the patient to the size and shape of the lesion, or possibly number of lesions.

Similar arguments would hold for the Itrium-90 microspheres, which is driven by intravascular interventional radiologists; although, I will say that they have a lot more training in radiation, so they do have -- they fall not exactly towards the extreme.

I would hate to, at this point before the studies have come to their conclusion, and enough data has been gathered with respect to size, shape, positions of lesions, and the results of the therapy, to cut out those people who are very experienced in customizing radiation treatments to the patient.

MR. HENDRICK: If I could answer that. If

there is going to be a change such as that in nature, it would require that I would have to go back to the FDA and start a whole new IDD application and PMA. And if we were to have a product or a device that would say, for some example, allow us to have significant modifications, then, of course, at that particular time, we're talking about a different device. And we're talking about a device that has to have significant treatment planning protocols. But that's not the device that we have today, that's not the device, if we get through this current trial, that will have the labeling that will be very specific, that will say that this device has only one type of radiation -

DR. THOMADSEN: A question for Dr. Suleiman, if I may.

DR. VETTER: Okay.

DR. THOMADSEN: A follow-up question on that. Would this device, once it got through the trials and approved, be something like intravascular, which would not be allowed to be used off-label, or would this be something that could be used off-label?

DR. SULEIMAN: When you do a trial, you pretty much define what you're going to do. You go through, and it's your final exam. It either passes

or it fails based on your criteria.

DR. THOMADSEN: But afterwards, could a physician -

DR. SULEIMAN: Off-label use?

DR. THOMADSEN: -- use it otherwise?

DR. SULEIMAN: Yes. That's an easy answer.

DR. HEIER: If I may, I think, again, that's an important concern. From a practical standpoint, as a clinician, if that's what this treatment comes to, and I have to coordinate treatment patterns with a radiation oncologist, this isn't going to be a practical application, because the need to deliver this treatment quickly, coordinate the OR, coordinate sitting with the radiation oncologist, describing the lesion, going over -- I mean, we have two-year fellowships to learn to read angiograms, and OCTs, and how to determine what type of lesions they are. If it's going to require that, from my standpoint, that's not going to be a practical application. It may be that you'll do another study to find certain patients that it will, but you're not going to be able to do that practically speaking.

DR. VETTER: Dr. Welsh.

DR. WELSH: So what Dr. Thomadsen was

alluding to regarding the 24 gray to the center, 6 gray to the periphery, is a concept that we use frequently in radiation medicine, which is GTV, Gross Tumor Target, Gross Target Volume. The clinical target volume where you might want to provide a certain dose that would take care of anything that you cannot visualize, or know for a fact is diseased. And then, finally, the planning target volume, which is the dosimetric margin, which accounts for the penumbra. So in the clinical trial, what are the parameters? Are you saying 24 gray to the center, and 6 gray to the visible edge, or is there a dosimetric penumbra margin that is being accounted for, just for our education.

DR. HEIER: So there are -- there is a wide variety of lesion sizes that are eligible. There is no small size that would make it ineligible. There are large sizes that would make it ineligible. From the standpoint of the trial, there's no differentiation of those lesion sizes from the smallest to the largest that's allowed. And the delivery is based on the one fixed dosimetry. And the trial, the Phase II trial results were excellent based on this wide variety of lesions.

If you need to change that, I think you're

looking at an -- if it turns out that, say for 40 percent of the lesions work really well, and you do a sub-analysis, and you find that's the smaller lesions, which I think you could certainly assume that would be the case, 40 percent of the lesions working well with this will not get this treatment passed, because right now we can do that with our injections.

MR. HENDRICK: In our trial, though, we only allow treatment up to 5-1/2 millimeters, and so in our documentation, we will only have in our sheet that goes along with the product the ability to say you can treat up to 5-1/2 millimeters. That's the cut-off range.

DR. WELSH: My question is not so much about size per se, but minimum dose to the periphery of the lesion. So if you say minimum dose to the lesion periphery is 6 gray, you then say plus X number of microns, millimeters to account for dose fall-off to minimize dosimetric concerns.

MR. VERMEERE: Yes, I have developed target dose volume histograms that take us out to 10 millimeters, so we've done that analysis.

DR. WELSH: And that's 6 gray to that -

MR. VERMEERE: No, 6 gray, the definition is, John said is to 5.4 millimeter diameter. But I

did the calculations both with Monte Carlo and radiocarbon film, took that out, and then did the calculations for the dose volume histograms, and we ran those out to 10 millimeters, so we do have that database.

DR. WELSH: So in the clinical trial, what is the prescription?

MR. VERMEERE: It's 5.4 millimeter max lesion.

DR. WELSH: You ascribe 24 gray to that.

MR. VERMEERE: To the centroid, yes.

DR. VETTER: Dr. Nag. I'm sorry.

DR. WELSH: If, in your analysis of the trial, you get some disappointing results, surprising results, it might be over-simplifying by saying that it's due to the lesion size if the dosimetry to the periphery of those lesions hasn't been fully worked out in each and every case.

MR. VERMEERE: We've worked it. I'm saying 5.4 millimeters, you are working at a 6 gray level, and that's what we define as that outer perimeter.

DR. VETTER: Dr. Nag.

DR. WELSH: It would just be sad to see if it doesn't work because of something similar, but it

sounds like you -- something simple, but it sounds like you've put a lot of thought and effort into it.

DR. VETTER: Dr. Nag.

DR. NAG: Yes. A couple of points. Dr. Heier, you said they're difficult to coordinate, and you are not -- likely, you're not going to any of these further if radiation oncologists are involved. I have done not just -- you have done eight. I have done several hundred of interocular procedures with the I-125 plats with ophthalmologists. I don't claim to have the expertise of the ophthalmologists, so I let them do the dissection, and they don't claim to have the expertise with the radiation that I have. And they value my input tremendously. And it's because of our close interaction that we have been able to develop ocular brachytherapy to the level it is now, where you are having over 90 percent control rates. So that was one.

And you said it was hard to do it in the outpatient setting. I have done these both in hospital settings, and in outpatient settings, so there is no reason why radiation oncologists cannot come in the hospital setting, as well.

The third point I would like to make, that radiation dosimetry, especially at close distance, you

are distant in the order of millimeters, sub-millimeters, the dosimetry changes so rapidly that unless you have someone who knows all of the different things about how the dose is spreading in the longitudinal direction, the vertical direction and so forth, you are not getting the full benefit of the treatment. And I think for NeoVista, I would like to say I think you are being short-sighted, that you have the convenience of having this time over it, and having a higher turn over basin, you are more likely to fill the procedure because if a certain dose is not effective, you don't know what is the reason, was it because of placement it retained, or the angle it retained, or the distance it retained, or whether you needed to have multiple applications. All of these, you are going to lose all of this, and in the long run you are going to be shooting yourself in the foot.

DR. HEIER: I think if it comes to that, and if it turns out that the study shows that we need that degree of coordination, it may be that that's something that has to be looked at. The large majority of retina specialists in this country will be unable to deliver it in that manner. And I'm speaking solely from a practical application. From the previous study where we had people very gung ho about

looking at that study, could never coordinate all of those schedules within a week, and that was in the hospital setting. In an ambulatory surgery center, which are often separate from the hospitals, I would be surprised if a radiation oncologist is going to be willing to take a two or three hour gap out of his day, because that will be the time frame there, come over, wait in the ambulatory surgery setting for what is going to be a five-minute application of radiation, and take that time and arrange that in a couple of days span. So if this requires the degree of collaboration that you are discussing, and I understand. I'm waiting to see the results of the study. If it does, you may be absolutely right, and I fully recognize that that may be the case. The results of the Phase II have given us hope that for the majority of patients, delivery of these exact parameters will work. And if they do, this is something that we'll be able to practically offer to a number of our patients. If they don't, I think you're looking at a whole different paradigm, and that will need to be worked out. And it will certainly be different than what's been proposed today.

DR. VETTER: Dr. Howe.

DR. HOWE: I think one issue that hasn't

really been addressed yet is the fact that it's very difficult to measure the activity in the dose from the source in an accurate method. And one difference between this device and the eye applicators that we see for the external eye, is that the authorized user for the external eye applicator has an eye applicator, uses it to a medical endpoint, and continuously uses that applicator. So once they're familiar with it, they don't change eye applicators.

This particular device gets changed out at a routine frequency, and so your experience with it - first of all, the dose is not as accurate as being said, so you have a potential for one coming in at a high dose level, the next one that you get comes in at a low dose level, a lower dose level, so there really is a big range here.

MR. VERMEERE: Excuse me. Let me speak to that, if I could, please. We have a clinical device that we've designed for the clinical study, and we've made sets that are at 45 different institutions around the world. Every set will be there for the full period of the study. Every device has been analyzed. Chris Kasors and I have been working dosimetry. Chris has created the standards for us. Also, DNK in Germany has made their standards, and we've cross-

referenced to that. Everything has been done with radiocarbon film, everything is done with Monte Carlo coding, making sure that all the dosimetry is accurate. We go through and do every six months an update in the decay function, so we give them an accurate time. They get two sources at each location in case they drop one. As you'll notice, that little 20-gauge needle is fairly fragile, to push on it might break off, but each pair is matched, and so there's no change-out, there's no routine change. The decay of the Strontium is 1 percent every five months. We do a six months correction just to make sure we're staying accurate, so those aren't quite right.

DR. HOWE: I think what I'm saying is that during your clinical trial, yes, you have that control. When your clinical -- but we have to regulate for the long run. And in the long run, once you're beyond the clinical trial, just as Dr. Welsh is alluding to, and Dr. Nag is alluding to, you're going to be seeing different patients coming through that you'll want to treat. Then you're going to have your change-out of sources. You're not going to have the matched sources each time, so you're going to have more variability. And that's all I'm bringing in is the -

MR. HENDRICK: Let me answer that for a second, Ma'am.

DR. HOWE: And I know you have the precision that you're trying to get, and you have the best you can for what's available.

MR. HENDRICK: One of the ways that we control this specific thing is that these devices are never sold. The reusable portions are in control of the company forever. We do not allow a hospital to buy them. And the reason for that is specifically that, is that we keep absolute control of the dosimetry that is out there in the devices, so there can't be any of that kind of issue, where a device might go someplace else, or they start to use it, and they don't do the proper validation of the device after a year. And the devices that we send out, we always make sure that they are within a couple of seconds of each other at each site, so there isn't a significant difference there.

DR. HOWE: So you're matching the sources for the site.

MR. HENDRICK: Absolutely. Absolutely.

DR. VETTER: Dr. Suleiman.

DR. SULEIMAN: Just to clarify, I think some of the suggestions you've heard from the

Committee probably are valuable, but your trial has already been launched. And it's obvious to me that you seem to know what you're doing, so you've put all your eggs into this basket, and let the trial finish. And it may succeed, it may not. That, I don't think, is the issue here, necessarily. I think the issue here is the training that's appropriate for the Strontium-90 applicators, sufficient to address the radiation safety issues that you would want for your device.

The off-label question, just to clarify, when FDA approves a medical product, it allows it to enter commerce. It's been shown to be safe and efficacious according to some standards depending on our various regulatory authorities. After that, how it's used in the field of medicine, it can be used for other indications. That's a different issue. But a lot of the scientific points you're making I think are valid, and would be useful to you, but I think at this point isn't really relevant to this discussion.

DR. VETTER: Dr. Eggli.

DR. EGGLI: I would like to ask another irrelevant question then. I don't remember hearing what you said about the number of patients in your Phase II trial, and your success rate in your Phase II trial.

DR. HEIER: There has been a Phase I and Phase II. The Phase I was NeoVista device only. The Phase II was in combination with anti-VEGF therapy. In that study, there were 34 patients, and we've got 18-month follow-up on them. And the most interesting part about that is, what we're looking at is overall success rate. The success of that has been comparable to what we saw with the anti-VEGF patients who were delivered monthly therapy for a year in terms of significant visual gain.

DR. EGGLI: That's approximately?

DR. HEIER: Right. Because you can't compare the -

DR. EGGLI: What's the number that goes with that roughly?

DR. HEIER: Thirty-four. Oh, no, 30 to 40 percent.

DR. EGGLI: Okay. The 30 to 40 percent that you see here.

DR. HEIER: A three-line gain.

DR. EGGLI: Okay.

DR. HEIER: More important is that roughly 70 percent of patients at 18 months had not required further therapy.

DR. EGGLI: There was no progression of

the lesions.

DR. HEIER: Not only no progression, but stabilization and in case improvement where fluid dried up. If that's replicated in the Phase III, and the Phase III study is going to be 450 patients. That's a large study, 450 patients, 300 in the treatment arm, 150 in the Lucentis arm. It's being compared to standard of care, Lucentis.

DR. VETTER: Dr. Thomadsen.

DR. THOMADSEN: One thing that hasn't been said here is that the authorized user, as far as coordinating, the radiation oncologist doesn't have to be in the operating room. This has come out in the other Part 1000 treatments that we've been discussing, so the coordinating doesn't have to involve having a radiation oncologist in the operating room. But it is involved -- so then, again, I'm not sure what -- as it's designed here, I'm not sure what the coordination is. There's a fixed dose delivery. The positioning is determined solely by the retina specialist, as you suggest. If we require that modification of dosimetry, that's going to require coordination, but that's going to be an entirely different study, an entirely different approach.

DR. THOMADSEN: Right. But right now, if

you were to change anything about your study, like the use of a radiation oncologist, that's a different study, too. You really can't change that in mid-study.

DR. HEIER: What would -- and I'm truly not trying to be difficult on this, but what would that gain the patients?

DR. THOMADSEN: At the moment, only finishing your study. As you've described, I'm not disinclined to say that there is really no role of the radiation oncologist to be the authorized user. I don't think we're quite ready to decide that yet. I think you need to analyze in your study what has happened to the patients, what might be a variable that could be changed, and what the future is going to look like. The future may or may not look like exactly your trial, and as such, I don't know that we can say, but in the middle of your trial, you can't stop and say these patients have had the involvement of radiation oncologists suddenly, these patients don't. I don't think you can. That would have to be an amendment to your trial.

MR. HENDRICK: Currently, there is no requirement in the trial -

DR. THOMADSEN: For a radiation

oncologist?

MR. HENDRICK: For a radiation oncologist.

DR. THOMADSEN: You need an authorized user. Correct?

MR. HENDRICK: Yes.

DR. THOMADSEN: So you've had an involvement of a radiation oncologist so far.

MR. HENDRICK: We were following the laws of the NRC, or the regulations of the NRC, in which the NRC -

DR. THOMADSEN: That is correct.

MR. HENDRICK: -- at that point in time, we said that we're an optical applicator, and they said yes, you're an optical applicator. That's how Dr. Heier was able to fall into that realm. And so, we have hospitals where they have radiation oncologists, sometimes they are, sometimes they're not. In his particular case, he has his radiation safety officer there, so we have kind of a lot of combinations.

And what I want to emphasize is, I don't want to change any of the regulations. I just want to make sure that we're in the right regulation, so that we aren't impacting the fact of -- as CMS was talking to me two weeks ago, it is clear, in my industry, in

our industry, we have to -- we must develop products, but also reduce the cost. That must happen, and it's going to force us into that scenario if we choose, if we choose to ignore it, those companies won't exist. And so, what we're trying to do here, and that was the whole purpose of trying to focus in on what could give us the highest probability, that could also minimize the cost, but give us the best clinical output. And yes, if something comes along in the trial that says maybe we should do something different. Certainly, as a company, we would probably look at that. But, again, we still have to focus on the fact, is that I have to deliver to your families, and to the hospitals, and to the patients a treatment that is going to be cost-effective, but that is also clinically significant. And if we don't allow an ASC environment to operate, and also like a hospital or university to operate, and we start to enforce other restrictions on it, it will start to impact the patients.

DR. VETTER: Mr. Lieto.

MR. LIETO: A quick question. How much activity is roughly in one of the devices, millicuries?

MR. VERMEERE: The nominal activity is 555

mega becquerel, which translates to about 11.1 millicuries for reality. It would be 15 millicuries at 555, and right now with the chemistry we're at 11.1.

MR. LIETO: And each site has two of these. Correct?

MR. VERMEERE: That's correct.

MR. LIETO: How many sites in the U.S. are you expecting to use this in your Phase III? Because you say 45 globally -

MR. HENDRICK: Thirty.

MR. LIETO: Thirty in the U.S.

MR. HENDRICK: Thirty sites now have the device.

DR. VETTER: Dr. Eggli.

DR. EGGLI: It seems to me that this device is designed to deliver the therapy one way, and one way only. And that modification of the therapy would require modification of the device, with the exception of, you can't move it around because of the approach to the eye. All you can do is change the time that you expose the retina to with this device.

DR. THOMADSEN: Not so.

DR. EGGLI: You can't -- we've already heard him say you can't move it around.

DR. THOMADSEN: You can. You can position it differently. They have to be able to position it differently to hit the target.

DR. HEIER: You can position it differently, but how would that change -- the decision for positioning is based on the lesion characteristics.

DR. THOMADSEN: And that's exactly the point, that if the lesion were elongated, or if it were circular, just like with the pterygium, you may have a different treatment pattern.

DR. EGGLI: But how is the presence of a radiation oncologist going to change that?

DR. THOMADSEN: In the planning of where the device would be to cover the target.

DR. HEIER: I don't think so. That I truly do not believe.

DR. THOMADSEN: That's what we do.

DR. VETTER: So in an elongated lesion, how would you do the treatment?

DR. HEIER: You would try to place it in the borders of that elongated lesion, but your going to have other parameters which are going to guide that. So we always look at that. We always look at the characteristics of the lesion, and try to base the

device based upon that. But we're guided by other things, we're guided by entry into the eye, we're guided by vessels, we're guided by the nerves, so that's something -- that's what we've been looking at for years in terms of our fellowship with angiograms. That's what we train our fellows to do, and so it's how we look at laser application, it's how we look at photodynamic therapy applications, it's how we look at other approaches to the eye.

And, again, I truly am not trying to be -- I recognize the value of radiation physicists, and oncologists, and if this has to be modified, they're going to play an instrumental role, and it's going to completely change the dynamics of this procedure, from my standpoint. I can apply it when it's delivered like this. And if it turns out that the parameters you're talking about are important, those are going to become manifest in the outcomes of the trial. And if the trial shows success, as it did in Phase II, then the means we're applying it are fitting these dynamics.

DR. VETTER: Dr. Nag.

DR. NAG: From what I'm hearing, I think if you are using this tool more like a laser, you apply on the surface, you burn it, and that's all you

are doing, then you are using it more or less blindly. Whereas, if you are going to be able to modify it, and you are able to sculpt it, then you would need to know more details about not only the isodoses, but also the details of what happened at the sub-millimeter level, so it depends. I think right now if you are -- are you trying to use it just like a laser, a burning tool, or more like a radiation device that can be modulated? If you need the modulation portion, then I think having it in the hands of an ophthalmologist may not be to the best advantage to the company.

DR. HEIER: Then that will be manifest in the outcomes of the trial.

DR. SULEIMAN: I think it's more the form. I don't think -

MR. VERMEERE: There is no intent to modulate the beam, shape the beam, or use IMRT, but it's placed in a single location, there's a single field, calculate the field dynamics which is going to be X dimension at 2.5 millimeters from the surface, and get a set field, and those values are all calculated.

DR. NAG: That's why I'm saying, I think you are being short-sighted, and you are using a highly advanced tool in a very simplistic way, and you

are sort of hindering the growth potential of this device.

MR. VERMEERE: Right now, we try to use the device under the 491 clause as a surface applicator, which restricts us from doing a lot of other things. And we felt this is the level that we need it from the early Phase I, Phase II study. We got the results that we were hoping for, and the Phase III will confirm those results, using a simple field as we've defined, and providing us 24 gray centroid value.

DR. VETTER: Mr. Mattmuller.

MR. MATTMULLER: It seems like a lot of this discussion has been based on how they can improve their product, or its use, and I don't know if that's appropriate. I'm thinking we ought to be focusing on what they're proposing is safe, and the training they're proposing that the ophthalmologist has is adequate for the use of this device.

DR. VETTER: Dr. Fisher.

DR. FISHER: I agree. Just to finish Steve's thought. He reminded me earlier how important this is from a patient perspective. And I think we need to consider that first and foremost. If this is a successful, workable solution, then that should take

some priority. And, again, as my role as patient rights advocate, I may need this device some day. And my father needed it at one time, and it wasn't available, and he's blind as a result, with this disease. I think that's what's important here. We need to keep that in mind.

DR. VETTER: Any other questions or comments? Dr. Eggli.

DR. EGGLI: I would like to second what Steve and Darrell just said. We're not here to help the company design a product. We're here to determine whether the product as presented can be used safely from a radiation safety point of view. And I think, to me, the answer to that, again, from a very simplistic point of view, is already obvious.

DR. VETTER: So the question really before us is, do we, as a Committee, feel that the training as specified in 35.491 is adequate for use of this device. Dr. Eggli.

DR. EGGLI: I would like to move that the as providing in 491 is adequate for the use of this device.

DR. VETTER: Is there a second?

DR. FISHER: Second.

DR. VETTER: Dr. Fisher seconds. Further

discussion? Dr. Howe.

DR. HOWE: Dr. Vetter, if you make that statement flat out, then that means anyone using the external eye applicator is now good to go with this eye applicator. And I think there are differences between the external applicator and the internal that you may want to apply the same topics, but you want to make the topics specific to the device.

DR. VETTER: 491 does not talk specifically about the external applicator, or internal applicator, or anything. It talks about -

DR. HOWE: But what you're saying is that once a person has authorization for 491, and we have a number of people out there with 491 with the external applicator, those people now can use this device without any additional training. I don't think that's your intent. I think your intent is to have maybe the same level of training with the same topics that are focused on this device and its use.

DR. EGGLI: I would like to modify my motion to include with specific device-appropriate training.

DR. VETTER: Is that -

DR. FISHER: Yes.

DR. VETTER: Okay. So motion now reads -

can you review that for us, again?

DR. FISHER: That 491 is an appropriate training requirement for the use of the NeoVista Strontium-90 device, accompanied by appropriate device -specific training.

DR. VETTER: Dr. Nag.

DR. NAG: You were mentioning that 491 does not mention superficial and deep, because at the time when that was written, there was no deep device. And, in fact, it is now in the rulemaking that these are going to be separated, and this would now be called - 491 would be called for superficial ophthalmic use, so 491 will be superficial ophthalmic application.

DR. EGGLI: That actually doesn't have to happen. And that's what we're talking about right here, right now, is that doesn't have to happen. 491 does not have to be changed.

DR. VETTER: Mr. Lieto.

MS. GILLEY: Was there a second? I'm sorry.

MR. MATTMULLER: There was.

MS. GILLEY: Okay.

MR. LIETO: Do we need to be concerned in terms of who the team -- terms of who is going to be

the authorized users for this? I mean, I guess what I'm kind of looking at, does this need to kind of -- I know I'm going to hate for saying this, moving this into 1000 to specify that there are certain authorized user credentials to be -- well, I guess what I'm trying to think about is, it would be like -- I'm looking at Dr. Heier's credentials, and I'm thinking could some optometrist or somebody come in with an authorized user credential, in terms of wanting to use, because we're looking a lot at the situation I think that you're talking about, of doing this in an ambulatory setting.

DR. EGGLI: There has to be a retinal surgeon.

DR. HEIER: Yes. So there are credentials already to get credential to do retinal surgery that require a certain level of training, which is a minimum of a one-year fellowship, most require a two-year vitreoretinal fellowship, so the requirements to do those, to be able to deal with the complications of this are extensive.

DR. VETTER: Dr. Nag.

DR. NAG: No.

DR. VETTER: Dr. Zelac.

DR. ZELAC: Kind of a question I'm just

putting out to the floor. If the retinal surgeon is the authorized user, who's the radiation safety officer?

DR. HOWE: It would be the same person.

DR. ZELAC: I understand that. We're talking about this 10 or 15 millicurie Strontium source in a rather delicate needle. There is the possibility, if not the likelihood, that this is going to break off at some facility, so my question is, who's the radiation safety officer?

MR. VERMEERE: Every facility that we currently use has a staff medical physicist, such as Dr. Thomadsen or Dr. Vetter, or has a RSO, somebody who has been recognized by the Nuclear Regulatory Commission or an agreement state. Some of us are professors in radiology, some of us are medical physicists and board certified, but there is a class of people who have been recognized, either through the American Health Physicists Society, or the AAPM, or the NRC by grandfathering, or the states by grandfathering. So those people will be involved. You've even stated such in your initial guidance document, that either an oncologist or a medical physicist, or radiation safety officer will be there. And we would expect that the support team would always

require to have such trained individual along with the authorized user if it's a retinal surgeon.

DR. VETTER: Mr. Lewis.

MR. LEWIS: Dr. Vetter, given the motion on the table, and recognizing some of the comments of Dr. Thomadsen and Dr. Welsh before he left, about the different techniques that might be used for different shaped or sized lesions, wouldn't the -- and I'm not well-informed, so I guess my question is, is the Committee really in a position to judge the radiation safety before the results of the trial? I recognize the radiation safety issue of the users may not be an issue, but there is also the radiation safety issues of the patient.

DR. VETTER: Dr. Eggli.

DR. EGGLI: I think the Phase II study with 18 months of follow-up provides that level of reassurance. And, again, we're not talking about what Dr. Welsh was talking about, which is modifying or modulating the therapy. We're talking about a very rigidly constructed therapy. And I think 34 patients with 18 months of follow-up, given the time course of typical radiation complications, is adequate to demonstrate the safety from a patient use point of view.

DR. VETTER: Dr. Nag.

DR. NAG: Yes. A couple of points. I think -- in fact, I know the new ophthalmic applicator under 35.1000. Am I right?

DR. HOWE: Yes, it is. It's under 35.1000.

DR. NAG: Therefore, you would now move it to 35.491? Is that -

DR. EGGLI: I think the motion says that the training as prescribed is appropriate training. It doesn't say to move the device from Part 1000 to Part 400. But what it's saying is that as you develop training requirements, if you leave it in 1000, then these are adequate training and experience requirements.

DR. VETTER: Dr. Thomadsen.

DR. THOMADSEN: One of the issues that's coming up, which may be that's subtle on this, is administratively, once the person is an authorized user, at the moment, they can't not be allowed to be radiation safety officer. That's adequate, if they're listed on there. So if you have a clinic, an outpatient clinic somewhere that's open, that the ophthalmologist is the authorized user, they can also then designate that they are the radiation safety

officer, even though they do not have the training that most radiation safety officers would have.

MR. VERMEERE: That's not quite right, because you and I both know that the radiation safety officer position has to be a recognized position. To get yourself written onto that line 12 of the license, normally there's a recognition either by training, past experience, or meeting the obligations of the various radiation safety -

DR. THOMADSEN: Or by being listed on the license as the authorized user. Is that correct? Once you're on, you're on.

DR. HOWE: Yes. Once you're recognized as an authorized user, you're eligible to be a radiation safety officer for the same types of uses.

DR. VETTER: If someone signs the preceptor statement.

DR. HOWE: The preceptor statement, yes.

DR. VETTER: And right now, that might be difficult.

DR. EGGLI: Identifying the training requirements for an authorized user, leaving the device in Part 1000 does not exclude the requirement of the presence of a radiation safety officer, or someone who provides that functionality. All we're

talking about are what the training requirements for an authorized user, so I have no problem leaving this in Part 1000, saying for the time being it requires a radiation safety type skill present. But what we're talking about is defining the training and experience requirements for an authorized user as that will be constructed within the confines of Part 1000.

MR. VERMEERE: And I think we totally agree with you.

DR. HEIER: I have no desire to be a radiation safety officer.

DR. VETTER: Ashley, did you happen to capture that motion? Oh, you didn't. The earlier one by Dr. Eggli.

MS. TULL: Oh. I have 491 is an appropriate training requirement for the use of the NeoVista Strontium-90 device, if accompanied by appropriate device-specific training.

DR. VETTER: Okay. That's the motion before us.

MS. TULL: Yes.

DR. VETTER: Any further discussion? Dr. Nag.

DR. NAG: Now, you are saying that you are having a radiation safety officer when you are doing

your treatments. And at the same time you are saying that you would not be able to get a radiation oncology back-up person. Now, how is it your are able to get the radiation safety officer in the outpatient setting, but not the radiation oncologist?

DR. HEIER: They're cheaper, and more plentiful. They're readily available to whenever we say.

MS. GILLEY: They have patients that they're seeing every hour, every half hour, like a radiation oncologist is.

DR. HEIER: And think that's infinitely easier.

DR. VETTER: Okay. Are you ready for the question?

(Chorus of yeses.)

DR. VETTER: All those in favor of the motion, please raise one of your hands. One, two, three, four, five, six, seven. Opposed, raise your hand. One opposed. And abstentions? Two abstentions. And we're down one number because Dr. Welsh has left, so the motion passes.

Dr. Heier, recognize please that we are advisory, so we simply pass the motion advising the NRC that we would recognize the training as

equivalent, basically, but device-specific, so that doesn't necessarily change anything. It's advice that we are providing to the Agency. Dr. Thomadsen.

DR. THOMADSEN: I just wanted to explain, I'm not adverse to the change at all. I just think it's a little premature to make this decision. That's all.

MS. GILLEY: One more question. I think there's some guidance document that came out on this. Will that be reconsidered?

MS. FLANNERY: Yes, the guidance is published and posted on the website, so what happens in a case like this is we take ACMUI's recommendation and make a decision whether we want to change the guidance, and consider it under 491. So a decision will have to be made on that.

DR. VETTER: Ms. Flannery wanted to make a statement before we go on break. Is it related to this subject?

MS. FLANNERY: No.

DR. VETTER: Okay.

MS. FLANNERY: So I'd rather just wait until this discussion is closed.

DR. VETTER: Yes. Dr. Howe.

DR. HOWE: This is Dr. Howe. I'd just

like a clarification. In 35.491, it is a physician who. Is your recommendation to be any physician who, or are you thinking in terms of a -- not an ophthalmologist, but a retinal surgeon?

DR. EGGLI: I guess, if I might speak to that.

DR. HOWE: Is that too prescriptive?

DR. EGGLI: It is -- no, I think that's presumptive, because in any institution you're not going to get the credentials to open up an eye and get down to the level of the retina unless you can prove that you have the credentials to be a retinal surgeon. So I don't think there's any risk that me, as a diagnostic nuclear medicine physician, is going to go to the OR and open up an eye, and try to stick a device down to the retina. So that I don't -- in any one institution, you have to be credentialed to do retinal surgery.

DR. THOMADSEN: Would that be true in a freestanding office?

DR. EGGLI: If you don't want to spend the rest of your life broke from the first malpractice suit.

DR. THOMADSEN: Well, we never let tort be the defining -

DR. EGGLI: And I understand. I don't know the answer to that question, but if the freestanding clinic is associated with any kind of an institution, then there would be a credentialing process. I would assume that the American Board of Ophthalmology has guidelines as to who can and who cannot perform retinal surgery. Is that correct?

DR. HEIER: Every surgery center that I've ever -- every accredited surgery center, and that's all we can attest to, are accredited surgery centers, every accredited surgery center I've ever been aware with, has very specific requirements as to the training that you go under before you can do any retinal procedure.

DR. THOMADSEN: What is your reticence to including those qualifications in the motion?

DR. EGGLI: I'm not reticent to include those qualifications. At this point, since the motion passed, we would have to do an amendment, and I'm happy to do that. I'm happy to amend my prior motion to say that the authorized individual must be a qualified retinal surgeon. I'm happy to add that modifier to that.

DR. VETTER: So that's -- we'll take it as a new motion then.

DR. EGGLI: All right.

DR. VETTER: Dr. Nag.

DR. NAG: Yes, I think we are going to relish the principle. We haven't reviewed the entire 491 to see what other unforeseen consequences we are going to land into. I think it would be wise of the Committee to look over -- to table this for the time being, look over the entire section.

DR. EGGLI: It's already passed.

DR. THOMADSEN: Except for defining what physician would qualify.

DR. VETTER: You're going to make it more restrictive. Ms. Gilley.

MS. GILLEY: I simply want to ask a question of NRC. How many licenses do you have out there for ophthalmologists that only do 491? If I have five out of 1,700 I would be surprised, and none of them are general practitioners. They're all people with board certification in ophthalmology, so I wonder if we're not opening up a can of worms that doesn't really exist by the nature of what we've already got going on. The commitment to have a license to do Strontium-90 eye application requires all the other requirements of a license, not just the T&E of the individual. There's inventory control, there's

radiation safety, ALARA, occupational -- I mean, this is not a fly in the dark-type operation. There is serious consideration when you get radioactive materials in the eye surgery-type environment.

DR. VETTER: Mr. Lieto.

MR. LIETO: I would speak against the motion, and I think we've done enough, and I don't think we need to add any more -- there's not any indication that we need to add more restrictions at this time. My recommendation to the Committee is to vote against this, this added restriction.

DR. VETTER: Any other comments? The motion is to add another requirement to the training, that it only -- that the individuals must be retinal surgeons.

DR. FISHER: Was that seconded?

DR. EGGLI: It was by Dr. Thomadsen. I'm willing to withdraw it, if Dr. Thomadsen is willing to agree.

DR. THOMADSEN: No, I'm not. I'm not willing to withdraw that.

DR. VETTER: All right. All those in favor of the motion raise your hand. One, two, three, four. All those opposed? One, two, three, four, five. And abstentions? So the motion fails. Are we done with

this discussion for now for this meeting? Okay. Thank you very much. We appreciate your coming.

Ms. Flannery has something to say.

MS. FLANNERY: Thank you. I'm hoping that this will be quick, because I know everybody is ready for a break. This just has to do with the discussion right before we broke for lunch. I think there was a concern by ACMUI about the supervising AUs and the preceptor AUs, that the current regulations don't allow them to be -- don't allow grandfathered supervisors and preceptors. And I guess i just wanted to make a clarification here. Right now, we are seeking a higher level opinion from OGC, so we're going through that right now, and still trying to get this issue straightened out.

Now, we just want ACMUI to realize that you can still continue your practice for supervising and preceptoring the proposed authorized individuals while we still work with OGC on this matter. Now, when this issue is resolved, and we find that we do need to do a rulemaking, something like this can be expedited. So I know that there was a concern here that this would take years, and the issues that would be involved, but there are certain circumstances, and I think this would qualify, where we could expedite

it. And it wouldn't have to go through normal rulemaking, so I just want to clarify that. But I also want to state for the record that we're still trying to get this issue straightened out.

DR. VETTER: Dr. Eggli.

DR. EGGLI: In a sense, this is a technical error with respect to the intent. Did this go through the administrative rulemaking process?

MS. FLANNERY: We're still trying to get that straightened out with OGC. OGC would have to answer that question, and we have posed that question to them, so we're still trying to get that resolved.

MS. GILLEY: Could I just request the urgency that when you all do get an answer to correspond with us, and let us know. The agreement states, a lot of them are in the process of rulemaking and rule developing, and instead of recreating the same mistake, it would be good for them to be able to go ahead and make some of those administrative changes, so they're not having to go back through the rule promulgation process in two years.

MS. FLANNERY: Absolutely.

DR. VETTER: Okay.

MS. FLANNERY: Thank you for giving me a minute.

DR. VETTER: Yes, you're welcome. Thank you for clarifying that for us.

So we have an hour and a half left on the agenda with a break here. It looks like we're bumping up against 6:00. Are there any concerns with flights or anything like that?

DR. EGGLI: I'm concerned that Marriott is going to tow my car.

DR. VETTER: Send the bill to Mr. Lewis.

MR. LEWIS: I have to leave. I have to get to the day care.

DR. VETTER: You have to leave. Okay. So I think we need to have a break, but we just need to recognize that the remaining agenda is going to take us a little while. We may lose a few people along the way.

MS. TULL: Can I ask who does have a flight this evening? Are all of you staying here?

MS. GILLEY: Somebody say yes, so we can get out of here before 8:00.

DR. VETTER: So let's -- can we get by with a five-minute break? Will that work?

DR. EGGLI: Just a bio-break.

DR. VETTER: Just a bio-break, so we can keep things moving along. Okay. Please try to be

back, we'll make it quarter after. You get seven minutes.

(Whereupon, the proceedings went off the record at 4:08 p.m., and resumed at 4:17 p.m.)

VICE CHAIRMAN VETTER: I'll call the meeting to order. Okay. Do we have a quorum here? One, two, three, four, five, six, seven, eight. Do we still have eight? All right.

MS. GILLEY: This is higher math, I'm not sure.

DR. EGGLI: Yes, we're ready. Yes, we have a quorum.

VICE CHAIRMAN VETTER: We're at ten now?

DR. EGGLI: Yes, we have a quorum. We're speaking to ourselves but we have a quorum.

VICE CHAIRMAN VETTER: Okay. We have the next item on the agenda, the last item on the agenda. Dr. Fisher is going to provide us some information from a patient's perspective on a patient's needs, concerns, and rights.

DR. FISHER: Thank you, Dr. Vetter.

This presentation is informational and does not request any action or changes on the part of the Nuclear Regulatory Commission but primarily for the benefit of this committee.

I appreciate the opportunity to work with you and serve on this committee. It is a real honor. And my special role is as a patients' rights advocate. And there are some important history associated with this role.

And as I will show you, there are some other concepts that are critical to this committee that have evolved over time, including the concept of the Human Subjects Committee and the Institutional Review Board. They are all kind of tied together in an interesting way.

Patients want the best possible medical care when faced with illness and disease. A good example of this is a friend of mine whose funeral is being conducted at this very hour, one o'clock Pacific time, very close friend died of metastatic prostate cancer with extensive involvement to the skeleton, multiple skeletal lesions.

One of the drugs that he wanted more than anything else for his particular condition was alpha radiating radium-223 chloride, which is not available yet in the United States as clinical trials are just beginning at two institutions this year.

And it wasn't possible for him, because of lack of availability, to get perhaps the one treatment

that could have helped him the most. And so that's kind of what this position is all about.

DR. NAG: Dr. Fisher, can you tell me what the isotope was?

DR. FISHER: Radium-223.

DR. NAG: As what form?

DR. FISHER: Chloride. And I won't go into that particular isotope and treatment at this time but it is in extensive clinical trials in Europe.

In particular, patients want access to the latest scientific advances. They want protection from poor health care practices. They don't want to be ripped off.

They want to understand their options for treatment and they want good clear information. They're not specialists. They don't understand the medical jargon. But they do want to know what is best.

They want to be treated with dignity and respect. And they are concerned about the long-term consequences of their disease, in particular about the financial aspects.

The role of the patient rights advocate is quite important. And if you look at the first four bullets on this list, these are the same

responsibilities that each of you have as members of this committee. And I'll try to make this presentation, in the interest of time, I'll shorten it up just a little bit so that we can be finished soon.

But I did want to add that in addition to the four responsibilities we all have, the patient rights advocate must be cognizant of the impact of NRC actions on patient access to health care and, therefore, represent the concerns of patients and patients' rights stakeholders.

Regulations have impact on patient care and access to best health care practices. The factors that may impact on patient rights are the tradeoffs between regulations that restrict or limit the availability to or patient access to new treatments.

For example, in the case of the presentation that we just had. I was quite agitated during that entire discussion because I'm genetically disposed to the disease being discussed. It's a family trait in our family and so I really -- I have personal interest in it.

But I'm also aware of other people who have interest in these and other treatments. Incidentally, I spend about four hours a week in a patient rights advocacy role as a volunteer. And so

I have a passion for this subject that extends beyond my professional responsibilities.

It is obvious that the slow process for new drug or device regulatory approval impacts on patient access to best health care. Regulations that restrict hospitals and physicians ability to provide the most effective treatments do not work in the best interest of patients.

So the patient rights advocate must pay particular attention to rulemaking process to ensure that NRC regulations do not adversely impact patient access to health care.

The history of patient rights advocacy parallels the history of this advisory committee. I'm not sure to the degree you are aware of this but the concept of patient rights did, in fact, evolve as a fundamental part of the operating philosophy of this committee, which dates back to the Manhattan Project.

The next few slides show the evolution of federal regulations concerning patients' rights in the context of radio isotope research and the practice of medicine. This goes back to -- actually the experimentation with radiation predates the 20th century but specifically there was an important event in 1946 when recognizing the value of radioisotopes in

medicine, the Manhattan Project announced the availability of radioisotopes for medical research and, in particular, the treatment --

MS. TULL: Oh, I'm sorry. I just grabbed the wrong one.

DR. FISHER: -- the treatment of disease. And there was first a memorandum from Colonel Stafford Warren, the Medical Director of the Manhattan Project, who was at that time at Oakridge National Laboratory.

It was followed up by a journal article June of 1946, published in science written by Paul Abersold, on the availability of radioactive isotopes in an announcement to universities, hospitals, and clinicians.

In 1946, the Manhattan Engineering District formed the Interim Advisory Committee on Isotope Distribution Policy. That's the predecessor to this committee.

The Atomic Energy Act of 1946, you are all familiar with the Atomic Energy Act or the enabling act that started the Atomic Energy Commission. But really the first act was in 1946. In 1947, the Atomic Energy Commission formed its committee on isotope distribution policy, which was a slight change in the

form it formed in 1946. It had two parts. It had a subcommittee on allocation and distribution and a subcommittee on human applications. It is really interesting how this was set up.

The first subcommittee decided who would receive isotopes and for what purpose. And whether the government should make an investment in their production for that particular research. And the second subcommittee determined whether it was appropriate to use those in human subjects.

In 1950, this committee's name changed to the Atomic Energy Commission Advisory Committee on Isotope Distribution. In 1953, we had President Eisenhower's famous speech on atoms for peace to the United Nations in New York.

Then we had the Atomic Energy Act of 1954 with focus on nuclear power, nuclear weapons, and the third leg of the Atomic Energy Commission was peaceful applications of isotopes. That was the third important mission of that agency.

In 1974, the Energy Reorganization Act split the Atomic Energy Commission into two parts, the Nuclear Regulatory Commission and the Energy Research and Development Administration. This committee stayed with the Nuclear Regulatory Commission and today the

Advisory Committee, of which you are a member, provides advice on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. Short history of this committee.

Back to 1946, this particular slide indicates recognition that radiation therapy is not without risk of normal tissue injury. Local isotope committees were formed to review the use of radioisotopes. It was a two-tiered system. It had both local review and federal review or federal oversight for each project.

Experimental protocols were reviewed at the local level before being approved at the federal level and receiving permission to receive isotopes through this national distribution policy.

And in the documents that I have reviewed on this subject, patient safety was of "paramount importance." And also I found that risk-benefit analysis was an integral component of the policy on the use of isotopes in humans.

I found this statement, "it is not wise in any way to inhibit investigators with ideas." In other words, let's try to utilize this new tool as best we can. And yet the safety of the patient must

come first.

The concept of patient informed consent originated with this committee. In 1949, the responsibility for the use of radioisotopes was assumed by a special committee of at least three competent physicians belonging to the institution where the work was to be performed.

The rule said that a subject must consent to the procedure and there should be no reasonable likelihood of producing, through this experiment or this treatment, manifest-producing injury by the radioisotopes to be employed.

Paul Abersold was the AEC Director of the Isotope Program and this is part of the minutes of the Subcommittee on Human Applications in 1949. These rules on human use of isotopes were first codified in 1951, part of 10 CFR -- what was then 10 CFR 30.50, a supplement to the 1949 edition.

And these contained not the full set of rules but a very primitive set of rules with administrative facility and personnel requirements for receiving and using isotopes. It did not include dose limits or patient consent requirements. A very crude set of rules at that time.

In 1956, the Atomic Energy Commission

issued guidelines for the use of isotopes in terminally-ill patients. The interesting part of this was the requirement for preclinical studies in laboratory animals before isotopes could be tested in humans.

And the use of isotopes was limited to patients suffering from disease conditions with a life expectancy of one year or less with no reasonable probability of the radioactivity employed producing manifest injury. So here we had the concept of compassionate use, which is common today in FDA nomenclature.

In 1956, there was a more formal statement presented on patient informed consent in research subjects. And guidelines for informed consent became more formal. Informed consent was required for all use of radioisotopes in normal, healthy subjects.

A radioactive tracer could not exceed what was under ICRPT the permissible body burden. Experiments should not normally be conducted on infants or pregnant women.

Subjects were limited to volunteers to whom the intent of the study and the effects of radiation had been outlined. And that these guidelines required that both the purpose and the

effects of radiation be explained to volunteer subjects.

Also in 196, the Medical Isotope Committee became more formal and these requirements updated the 1949 requirements, again three or more physicians plus a qualified radiation physician were required to serve on the Medical Isotope Committee. This committee reviewed and permitted the use of radioisotopes within the institution from the standpoint of radiation health physics.

The committee prescribed special conditions that must be used, such as physical exams, the training requirements, designation of limited areas or locations of use, disposal methods for waste, et cetera. Records and reports were to be provided by the radiation safety officer.

The committee recommended remedial action when a person failed to observe the safety recommendations and rules. And these guidelines also required that medical isotope committees maintain adequate records.

So just another comment, in 1965, the Atomic Energy Commission produced its guide for the medical use of radioisotopes. This document described the application process and specific policies for the

non-routine medical uses of byproduct material.

It reiterated the exclusion of pregnant women as subjects, required that subject selection criteria be clearly delineated, and, again, required the consent of human subjects or their representatives except where this would not be feasible or where consent would be contrary to the best interest of the subjects. A little caveat there which we don't any longer have.

The 1960s were characterized by the emerging role of the Food and Drug Administration which developed, at this time, a more active role in supervising the discovery, the development, and the commercialization of radiopharmaceuticals. And through this process, the oversight of radioisotopes research began to change.

And the history of this shift in regulatory authority from the Atomic Energy Commission to the FDA is complex and beyond the scope of what I want to say other than that the FDA now has assumed many of these roles.

So we jump forward 30 years in time to the Clinton administration in 1997. President Clinton created the Advisory Commission on Consumer Protection and Quality in the Health Care Industry and charged it

with recommending such measures as may be necessary to promote and assure health care quality and value and protect consumers and workers in the health care systems, laid the foundations for the Patient's Bill of Rights in medicare and medicaid.

And he asked the commission to develop a Patient's Bill of Rights. So the commission did. And this Patient's Bill of Rights was codified in 42 CFR 482.13 on medicare conditions of participation, dated 1999.

The federal statement on patient's rights -- I'm going to go back -- the goals of the bill of rights were to strengthen consumer confidence that the health care system is fair and responsive to consumer needs, to reaffirm the importance of a strong relationship between and health care providers, and reaffirm the critical role that consumers play in safeguarding their own health.

The main aspects of the patient bill of rights are usually adopted by most medical institutions. The seven or eight primary aspects of the patient's bill of rights from 42 CFR 482 are the right to information, the right to choose, access to emergency services, being a full participant in health care decision, care without discrimination, the right

to privacy, and the right to speedy resolution of complaints.

In addition, the commission added one responsibility for the patient. And that was to maintain good health. In a health care system that affords patient rights and protections, patients must also take a greater responsibility for maintaining good health.

In summary, by recognizing the importance of patient rights advocacy and by sustaining the position of the patient rights advocate on this committee, the U.S. Nuclear Regulatory Commission continues the pattern established more than 60 years ago by the predecessors of this committee.

The NRC demonstrates its longstanding commitment and sensitivity to issues that are of concern to patients. So this position has its foundations in the historical development of this committee.

Concerns for protection of patient rights are based on that history that parallel the evolutionary history of this committee. And the most important elements of patient rights are established in federal law.

And with that, I would open it to the

committee or the audience for any questions.

VICE CHAIRMAN VETTER: Dr. Fisher, may I say first of all that the committee appreciates the importance of the patient rights advocate. And we appreciate your presentation on patient needs, concerns, and rights. And I think we've heard that before. It is very helpful to us. And we also appreciate the role that you serve in that regard.

So questions or comments for Dr. Fisher from either the committee or the audience?

(No response.)

VICE CHAIRMAN VETTER: Thank you very much.

And to the last item on the agenda, the one we've been working real hard to get to, Ashley, the administrative closing.

MS. TULL: I have several things to go over. The first is for the presentation -- for Cindy's presentation on F-18 infiltrations that we skipped today, we have some background information that came in from the regions.

We are moving that item to a teleconference. And we'll discuss teleconference dates here in a minute. But if you want to read over this, you will have some prep time before the

teleconference.

Okay, the first thing I'm going to do is go over the recommendations that the committee made during today's meeting. I'm going to pass around a one-page sheet and I'll wait for these to go around before I start. And on all of these, these are just a draft. This is what I tried to frantically type while the committee changed its mind repeatedly and revised recommendations.

MR. EINBERG: Ashley, we only have -- we ran out of the recommendations. Oh, are they coming around that way? Oh, okay.

MS. TULL: Half and half.

PARTICIPANT: We all had three over here.

MS. TULL: Okay, so these are draft recommendations from today's meeting. When I get the transcripts, we will put together the official recommendations per ACMUI's exact wording in those transcripts.

So for number 18, this actually wasn't a recommendation but we took it as an action item. NRC staff should transmit information from the ACMUI fingerprinting subcommittee report to licensees. A good example would be through the Q&As on the website.

Number 19, NRC staff should accept the

permanent implant brachytherapy subcommittee report recommendation on pre-implantation. This was recommendation number one of the bullets that were listed. And it had to do with medical events based on the written directive at the time the patient leaves the postoperative treatment area.

Number 20, NRC staff should accept the second, third, fourth, and fifth recommendations of the permanent implant brachytherapy subcommittee report, as indicated on the slide.

And 21, NRC staff should accept the sixth recommendation of the permanent implant brachytherapy subcommittee report. This recommendation was later amended to read when a written directive is required, administrations without a prior written directive are to be reported as regulatory violations and may or may not constitute a medical event.

Number 22, ACMUI should form a subcommittee to draft a set of proposed qualifications to be satisfied by interventional radiologists to become authorized users for Yttrium-90 microspheres. Dr. Thomadsen will be the chair. And Drs. Eggli, Nag, Welsh, and Mr. Mattmuller will all serve on that subcommittee.

Number 23, there was a recommendation for

NRC staff to move the Yttrium-90 microspheres from guidance to regulation space.

Number 24, ACMUI endorsed the permanent implant brachytherapy subcommittee report as a whole.

Number 25, ACMUI strongly encourages NRC to continue supporting exportation of highly-enriched uranium material from moly-99 targets used by international producers and to provide support for development of U.S. producers of moly-99.

Number 26, ACMUI should form a subcommittee to develop recommendations for individuals to achieve authorized user status using the board certification pathway. The subcommittee will provide feedback to the full committee during a future teleconference. The subcommittee includes Dr. Eggli as the chair, Dr. Guiberteau will provide technical assistance, and Dr. Nag.

DR. VAN DECKER: I'm not convinced that this engenders the theme of what was talked about. But Dr. Eggli can help me. I think the concept was to discuss the specific problem of somebody completing training until the time they take the board and their ability to be an authorized user in that interim period.

I believe that is the specific question

that is to be addressed. And if that is the specific question to be addressed, then I think I also need to be a piece of this.

DR. EGGLI: And you were.

MS. TULL: Okay. So I will add Dr. Van Decker. And then I'll make a note to specifically look at the transcript on this one to get a good subcommittee charge. And send that to you guys.

DR. VAN DECKER: Right. Right.

MS. TULL: Okay?

Number 27, NRC staff should revise 10 CFR 35.30, 35(b) as proposed. All of the following are going to come from Donna-Beth's presentation so they are kind of vague and out of context. But I'll put them into better words when you get the formal recommendations.

Number 28, NRC staff should revise 10 CFR 35.40 to clarify that the authorized user should sign and date that the pre-implantation and after-implantation portions of the written directive for all modalities with two-part written directives.

Number 29, NRC staff should revise 10 CFR 35.65 to clarify it does not apply to sources used for medical use; however, NRC should not require licensees to list the transmission sources as line items on the

license.

NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by authorized users meeting the training and experience requirements of 10 CFR 35.590 or 35.290.

Number 30, NRC staff should revise 10 CFR 35.204(b) to read that a licensee that uses molybdenum and technetium generators for preparing technetium-99m radiopharmaceuticals shall measure the moly-99 concentration of each eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section. Okay?

Number 31, NRC staff should add reportability to the regulations when moly breakthrough is measured.

Number 32, NRC staff should --

MR. LIETO: Wait a minute.

MS. TULL: Yes?

VICE CHAIRMAN VETTER: Ralph?

MR. LIETO: I think you mean when moly breakthrough limits are exceeded.

MS. TULL: Yes. That exceed limits -- the limits. Okay?

Number 32, NRC staff should approve the proposed change for grandfathered authorized users as

supervisors and preceptors for the purposes of T&E. This is the urgent issue that we are dealing with with OGC as well.

NRC staff should revise -- this is number 33 -- NRC staff should revise 10 CFR 35.40 to clarify that NAU has to sign both the pre-implantation and after-implantation portions of the written directive for all modalities with two-part written directives. Dr. Nag will include this clarification in the permanent implant brachytherapy subcommittee report.

Okay, 34, the ACMUI subcommittee should review events and provide analysis to the full committee in the spring meeting instead of the fall.

If you'll turn the page over, number 35, 10 CFR 35.490(1) is an appropriate training requirement for the use of the NeoVista strontium-90 device if accompanied by appropriate device-specific training.

Number 36, NRC should add another requirement to the training that the individuals must be retinal surgeons. This is in reference to the previous recommendation.

VICE CHAIRMAN VETTER: That was withdrawn. Oh, no, I'm sorry. Oh, no, I'm sorry.

MS. TULL: It did not pass, yes, I noted

a four-five-one vote so the motion --

VICE CHAIRMAN VETTER: Failed.

MS. TULL: -- didn't carry.

VICE CHAIRMAN VETTER: Yes, thanks.

MS. TULL: Yes.

Number 37, NRC staff should notify ACMUI when OGC makes a determination on the availability of grandfathered authorized users to be supervisors and preceptors for the purposes of T&E.

Any questions or comments on the recommendations?

(No response.)

MS. TULL: Okay.

VICE CHAIRMAN VETTER: Excellent. Thank you. Very good.

MS. TULL: Last year, we had over 50 recommendations. So 30-something, I'm happy with. I can follow 30.

Okay, next we're going to set dates for the upcoming teleconference and meetings. So I'm going to pass around some calendars so you can actually be looking at days and we're not guessing what is a Monday, what's a Wednesday.

DR. EGGLI: You don't, by chance, have a copy of my calendar?

(Laughter.)

MS. TULL: No, I don't have copies of your calendar. I'll call Debbie really quick.

(Laughter.)

MS. TULL: Oh, actually I need one, too, please. Thanks.

MS. GILLEY: Oh, good, you took care of all of May.

MS. TULL: Yes. So for the December teleconference, typically we do one to two hours, 1:00 to 3:00 p.m. east coast time has worked. For those on the west coast, that's 10 a.m. We don't want to go much earlier.

Are there any preferences in December? I talked to Dr. Welsh before he left and he said the first week of December was out for him.

MS. GILLEY: The second week is out for me.

MS. TULL: Okay. I was actually going to say if we could start with looking at the third week, the 15th, 16th, 17th, and 18th? Dr. Welsh had a preference for the 18th. But that's just a starting place.

DR. NAG: I have a preference for the 18th as well.

MS. TULL: Okay. Does anyone have a conflict on the 18th? Okay. So we're going to set it for December 18th from 1:00 to 3:00 p.m. east coast time. And we'll be discussing the F-18 presentation --

PARTICIPANT: I'm sorry, 1:00 to when?

MS. TULL: To 3:00 p.m.

PARTICIPANT: 1:00 to 3:00 --

MS. TULL: East coast. And we'll be discussing the F-18 infiltration that Cindy was going to talk about.

And also for item number 27, which was -- actually it is not 27 anymore. I changed them. There was a subcommittee that was going to report back to us -- item number 26. Will this give the subcommittee enough time to get some things together to discuss that issue? I know it's only about six weeks.

PARTICIPANT: It's a start.

MS. TULL: Okay. Maybe a draft or something?

PARTICIPANT: Yes.

MS. TULL: Okay. So you guys will be prepared to talk as well during that teleconference?

(Laughter.)

MS. TULL: It's either that or wait until

after the holidays and then all of a sudden, we're really far out. Okay?

All right. So if you will turn the page to April, this is for the spring ACMUI meeting. And this room that we're in right now is not going to be available. It's going to be completely renovated. And we need to find a different room.

The best option is the NRC auditorium. And as you can tell by the Xs all over the calendar, we are very, very limited on when the auditorium is available.

PARTICIPANT: So the 23rd and the 24th?

MS. TULL: Yes.

MS. GILLEY: Do you not want to move it into June?

MS. TULL: Preferably not.

MS. GILLEY: Okay.

MS. TULL: We have to coordinate the commission briefing for April or May as well preferably.

MS. GILLEY: Okay.

MS. TULL: And also if we start pushing to June if we try to keep April and October and all of a sudden we push to June, June-October becomes very close. It's hard to get a teleconference between

those two dates.

Is there any opposition to a Thursday/Friday meeting? The auditorium would be available on those days.

DR. EGGLI: I'll be out of the country the 23rd -- the week of the 19th.

MS. TULL: Okay. Would everyone be available April 30th and May 1st?

DR. NAG: No.

MS. TULL: No? Okay. The last option --

MR. LEWIS: Was that a no or an I don't know?

MS. TULL: That was a no from Dr. Nag. The next option is May 7th and 8th.

DR. VAN DECKER: I, unfortunately, don't remember when the International Conference in Nuclear Cardiology is but it is one of those two weeks. I'll have to figure out which of those weeks it is.

MS. GILLEY: Does it have to be this venue?

MR. LEWIS: I think we have to explore our options.

DR. NAG: When will this room be available again?

MR. BROWN: It may be available in May. It might -- it might.

VICE CHAIRMAN VETTER: That needs to be determined.

MS. TULL: It's very difficult to -- a commission meeting needs to be scheduled. And if you would like to meet with the commission and be on their calendar, we really need to pick a date.

VICE CHAIRMAN VETTER: That needs to be a high priority for us. If we don't have a meeting with the commission, our visibility goes way down. We need to have a meeting with the commission.

DR. SULEIMAN: Which dates in April are the least conflicted?

MS. TULL: I had one conflict on the 23rd and 24th from Dr. Eggli and one conflict on the 30th and May 1st from Dr. Nag.

DR. SULEIMAN: Can we take a vote on both of them?

DR. VAN DECKER: I can do the 7th and 8th, I don't know.

MS. TULL: Then on the 7th and 8th --

PARTICIPANT: There is a computer over here with internet access if you want to check on your meeting for a date.

MS. TULL: Yes, or Gretchen, could you do just a quick Google search on the National Cardiology --

DR. VAN DECKER: International -- ICNC.

MS. TULL: ICNC. No, that one is not hooked up to the internet. That's my personal.

MS. GILLEY: Well, with the Commissioners, if we would meet in their chamber for their actual briefing, would it be possible to meet across the street at the Marriott for the meeting?

DR. NAG: No money. Very expensive.

MR. LEWIS: Well, with the Marriott, the problem is getting a room that is big enough for a variable public audience. They charge by the person so we can't tell them how many people will show up.

MS GILLEY: All right. Okay. I just thought there might be another location.

DR. SULEIMAN: We could probably work something out at FDA but you guys have too many people coming in and out. I think you'd probably want it here.

MR. LEWIS: Ashley, what is the 22nd? It's not Xed out but it is question marked.

MS. TULL: Is it in Spain? The 10th through 13th is your meeting.

MR. LEWIS: Why does the 22nd have a question mark?

MS. TULL: The 22nd has a question mark because I called the people who currently have the auditorium reserved and begged and pleaded for them to give me that day so that we could have a Wednesday/Thursday meeting but I do not have confirmation that their meetings would be canceled. And that would have to be something that management would have to --

VICE CHAIRMAN VETTER: That wouldn't help us anyway.

MS. TULL: And I think there was a preference to not have a Wednesday/Thursday meeting because it is in the middle of week which means you miss two days on either end. And there was a preference to go ahead and have the Friday for the Saturday travel day.

VICE CHAIRMAN VETTER: Well, could we work this out -- with your putting a meeting with the commission -- I don't know when you can confirm that meeting with the commission --

MS. TULL: I have to give them the date of our meeting. And then hope that they reserve a slot. And then we find out about 30 days before that it is

confirmed. But our dates have to be firm.

Just to go back to the 7th and 8th of May, no one actually had a conflict then. Dr. Van Decker's meeting does not conflict.

DR. NAG: One question, can we ask the Commissioners if between some of those dates they are not available? Then we can throw away those dates right away.

MS. TULL: It doesn't work that way.

MR. LEWIS: You can ask them anything.

(Laughter.)

MS. TULL: Yes. We need to set our meeting date and then I need to contact the commission and say here is our meeting date. Can we please get the commission briefing set up on that date? And that's how we get to talk with the commission.

VICE CHAIRMAN VETTER: So you have no information now that would suggest that one date might be better than another for a meeting with the commission?

MS. TULL: You can consider them available. We need to pick our meeting based on our dates.

VICE CHAIRMAN VETTER: Okay.

MS. TULL: So the 7th and 8th there are no

conflicts. Is there any reason not to have the meeting on that day -- those two days? In the NRC auditorium, no traveling.

DR. FISHER: Seventh and eighth of May?

MS. TULL: Yes.

DR. NAG: I would say yes. You all can send an e-mail to Dr. Malmud and Dr. Welsh who are not here.

MS. TULL: I'll talk to him. Dr. Welsh, I've already talked to him about these dates. And I will talk to Dr. Malmud after the meeting.

DR. SULEIMAN: Okay. It works for me.

MS. TULL: Okay. We will tentatively set the next meeting for May 7th and 8th. Please block off your calendars and call the Marriott today.

MS. GILLEY: I'll make those reservations today.

MS. TULL: If you want to walk back over there and make those reservations, that would be great.

MR. MATTMULLER: You know maybe we can have a tent put up in the parking lot and have our meeting there.

MS. TULL: Okay, two more quick things. Time for your meeting and time for your travel will be

-- Shayla Glass is our secretary now. She will e-mail you next week. Be sure to turn your time in. I think it will be due on Thursday. You can claim eight hours for travel on Sunday, eight hours for each day. And eight hours again if you are traveling tomorrow. Or up to eight hours I should say.

Travel vouchers, I'll do what I did last time. I'll send you examples of if you took the train, here is what your travel voucher should look like.

If you took a flight and you paid for it on your own, that's done differently than if the NRC paid for your flight. And also if you took the train. I'll send out four examples. Pick the correct example.

And I'm going to have you mail those directly to me so that I can review them because they go to the Department of the Interior now and they are being very heavily scrutinized.

So hopefully you'll get you your money as quickly as possible. Payments have been processed much more quickly now that we've gone through DOI. So it's a work in progress.

DR. EGGLI: Okay. We've actually had eight hours of meeting today.

MS. TULL: Yes.

DR. EGGLI: I will be traveling two-and-a-half hours yet today.

MS. TULL: You can claim up to eight hours.

DR. EGGLI: So it's just eight?

MS. TULL: Yes.

MR. LEWIS: For your time. That has nothing to do with your travel voucher.

DR. EGGLI: No, I'm driving.

MS. TULL: No, he's just asking for time in general. Eight hours max each day.

DR. NAG: Now you can sleep here tonight and leave tomorrow. Then you can claim the other two hours.

UNKNOWN MEMBER: There is no way he'd get a room at the Marriott.

(Laughter.)

MS. TULL: Okay. And the very last thing please take off your name tags and set them on the table. Thanks everyone.

(Whereupon, the above-entitled meeting was concluded at 4:59 p.m.)