UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES

OF IOSTOPES (ACMUI)

Nuclear Regulatory Commission

Two White Flint North

Room T2D3

Rockville, Maryland

Wednesday, October 20, 1999

The committee met in open session, pursuant to notice, at 2:05 p.m., Dr. Manual Cerqueira presiding.

MEMBERS PRESENT:

DR. MANUAL CERQUEIRA

MS. NEKITA HOBSON

MS. RUTH McBURNEY

DR. LOUIS WAGNER

P R O C E E D I N G S

[2:05 p.m]

DR. CERQUEIRA: Good afternoon. My name is Manual Cerqueira. In Dr. Stitt's absence, I'm going to be interim chair for today's meeting. I would like to turn the meeting over at this time to Cathy Haney from the NRC.

MS. HANEY: I am going to read the official opening remarks for the meeting.

I am pleased to welcome you to Rockville for the public meeting of the ACMUI. My name is Cathy Haney. I'm an acting branch chief of the Rulemaking and Guidance Branch and I have been designated as the federal official for the advisory committee.

This is an announced meeting of the committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the Federal Register in September and the meeting notice indicated that the meeting would start at two o'clock.

The function of the advisory committee is to advise the staff on issues and questions that arise on the medical use of byproduct material. The committee provides counsel to the staff but does not determine or direct the actual decisions of the staff or the Commission.

The NRC solicits the opinions of the council and

values the opinions of the committee very much.

I do request that whenever possible we try to reach a consensus on the various issues that we will discuss today or at any other ACMUI meetings, but I also do value stated minority or dissenting opinions. I do ask that if you have dissenting opinions that we read those into the record.

As part of the preparation for this meeting I have reviewed the agenda for members and employment interests based upon the very general nature of the discussion that we are going to have today. I have not identified any items that would pose a conflict. Therefore I see no need for an individual member of the committee to recuse themselves from the discussion. However, if during the course of our business you determine that you have some conflict, please state it for the record and recuse yourself from that particular aspect of the discussion.

At this point I would like to introduce those that are here today and those that we expect.

First, we are expecting Niki Hobson, who is representing patient rights, to join us.

Dennis Swanson is here, representing nuclear pharmacy. He is here as a consultant to the committee because Dennis did go off the ACMUI on September 30, I believe, but we are keeping him on as a consultant.

Dr. Cerqueira, who is representing cardiology as well

as background and diagnostic nuclear medicine. He will be functioning as the chair of the committee.

Dr. Don Cool, who is the director of the Division of Industrial and Medical Nuclear Safety.

Ruth McBurney, who is representing state interests.

Lou Wagner will be joining us shortly, and he will be representing the physicists.

I would like to make two other introductions.

Barry Siegel is off to my right. Barry has been a consultant to the Part 35 Working Group and has helped us with revising the rule.

Theresa Kendall, who is sitting over to my left by the pole, is providing administrative support to us. Also, she is the one that is handling your travel. If you need anything associated with travel, you can see Theresa.

With that, we will turn to Don.

DR. COOL: Thank you, Cathy. I am Don Cool, director of the division. Let me add my welcome to you for this afternoon's brief session.

As most you probably are both acutely and chronically now aware, we continue with the revision of Part 35. A good chunk of the agenda today is in fact to look at and be prepared to participate in the briefing of the Commission that will take place tomorrow morning.

By way of background on that, the Commission has had

in front of it since August a draft final rule for their consideration. They had requested the staff to provide the draft rulemaking language so that they could consider the entire aspect of the rule. Not only the major issues, but all of the bits and pieces to look at along with enough supporting information to allow them to understand why the staff had made the recommendations that it made.

They also asked that we provide them in a couple of specific cases with some specific information, one particularly being in the patient notification arena as result of some of their previous discussions. The package which they have front of them, which is publicly available, I hope each of you have had an opportunity to look at. That package in fact contains two different alternatives of possible rule text that the Commission will be considering.

Tomorrow's briefing of the Commission will be the public opportunity for the Commission to hear from the staff and from the advisory committee about the revision of Part 35 in particular and any particular issues that you might wish to bring to their attention.

I would expect that they will be very interested both in your particular views on a number of key issues and may well ask some rather pointed and focused questions to try and help them understand the basis for particular recommendations in support or changes that might be part of that, because the

Commission is in fact in the position where following that meeting it is going to want to be considering and voting upon that package in order to give the staff direction on how to proceed.

The game plan for this is that the Commission will complete its review with this public meeting and then any further follow-up questions that they may ask of us and then will provide the staff the staff requirements memo indicating exactly how it wishes the staff to proceed with finalizing the document. We would expect that they would give us specific direction to change or modify specific rule text.

Then we would be looking to provide back to the Commission approximately three months after that direction was given a final complete package, which at that point would have any of the adjustments that the Commission wanted to have to the rule language itself, to the supporting documentation, as in the statement of considerations, regulatory analysis supporting documents, as well as the corresponding guidance document which has not yet been provided so that we didn't spent too much time writing a document before the Commission was in fact comfortable with how it wished the rule to look.

That is where we are procedurally in terms of the activities.

The Commission has a number of areas that we have suggested to them that are of particular interest because they

have been the things that we have talked about and have come up in the whole series of public interactions that we have been going through over the last a little over two years with this process. I think those are very familiar to us.

Things like reporting levels for an unintended dose to an embryo/fetus. The reporting of information to the patient and to the Commission, which is in fact the specific place where the Commission asked us to give them some alternative language.

Training and experience, which has throughout this process been an area of great discussion and back and forth.

So I would encourage you to use this afternoon to look at those particular issues and to know how you would tend to respond and which one of the committee members might be the lead for that particular arena when the Commissioners start to ask questions.

I expect tomorrow that there will be three Commissioners at the table, Chairman Dicus and Commissioners Merrifield and McGaffigan. Commission Diaz is out of town, but, as they did today during the briefing by the Organization of Agreement States, he will be listening by phone. I don't know whether they by the time tomorrow comes around have sorted out some of the technology glitches that made it essentially impossible for Commissioner Diaz to actually ask questions during the course of the discussion. I hope they will have

that fixed and that he will be able to participate as well as just listen to the briefing.

The one other thing that I do want to mention is that there was a briefing today by the Organization of Agreement States. Dave Walter, who has been part of the Part 35 Working Group throughout this process and the head of the Conference of Radiation Control Program Directors State Reg Committee did make a presentation to the Commission on that task group's view of the rule, and in particular several places where that task group of the conference is looking at some recommendation which does not exactly match what is in the proposed final Part 35 that is front of the Commission.

I know Ruth McBurney has had a copy of that talk and the presentation that was made.

I should note that the discussion today did not reveal any new information that I was aware of. The topics which Mr. Walter discussed this morning in that public meeting were essentially the same topics which he had addressed during the Organization of Agreement States meeting in Austin, Texas, a month and a half or so ago.

There were a number of questions asked by various Commissioners in terms of the relationship between some of the more prescriptive proposals which the conference task group was considering and its interaction with the whole concept of the practice of medicine. There was a little bit of a discussion

back and forth of what might constitute practice of medicine.

There was some discussion on training and experience. In particular some back forth with regards to what data supports or doesn't support various segments of the training and experience both in terms of the event history that has been out there and the biological effects of different quantities of material, particularly in the unsealed therapy arena.

There was also some discussion on concepts of patient release and some discussion on the reporting criteria for the embryo/fetal dose, with Commissioners asking a couple of clarifying questions and getting some clarifying information.

In that respect, today's presentation paralleled in a number of ways the key issues that I expect to come out and may well give an indication to you as members of the committee of things that the Commissioners are likely to bring back up to you and ask you very similar sorts of questions to get the committee's view, and they are likely also to ask the staff that same sort of question, trying to understand as best they can before they vote the information that goes behind this, the kinds of considerations that have come into play, the facts and implications of the matter. I think it was very clear that the Commission is concerned about the implication for practice of medicine, for availability of care as part of their overall consideration of what to have in this rulemaking activity.

I think that concludes what I wanted to outline for

you. With that, Dr. Cerqueira, I will conclude my remarks and let you get on about the business of preparing for the meeting. Thank you.

DR. CERQUEIRA: Thank you very much. I think for some of the issues that you have identified, especially if the Agreement States have significant input, it will be very worthwhile for Ruth to give us whatever information she can recall from that meeting. The Agreement States right now, there are 30 of them --

MS. McBURNEY: Thirty-one.

DR. CERQUEIRA: Thirty-one.

MS. McBURNEY: We just added one.

DR. CERQUEIRA: The federal rule, unless it has wider application, may create some discrepancies and some further problems.

Cathy.

MS. HANEY: I would see we can just go on to the first agenda topic and address this one so we can focus on getting ready for the briefing.

This is the committee's self-evaluation. Let me give you a little bit of background for those that have not been with the committee for the last couple of years.

In 1998 the Commission came down with a request to all the advisory committees asking them to come up with self-evaluation criteria. We would always take about five or

ten minutes at one of the semiannual meetings and talk a little bit about the criteria and where we were.

As a result of one of the meetings we did come up with a list of criteria and that was forwarded up to the Commission. You have a copy of that memo under your tab.

After that, Commissioner McGaffigan came back and asked that we slightly modify two of the particular items and add in, I believe, an additional question. That is the list that you see in your book. You have a copy of what I have up on the screen. It's a listing of all the questions.

The other advisory committee have gone back to the Commission already with their self-evaluations. However, because the ACMUI has been so involved with Part 35, we went back and said we've really focused in on 35 and that is why we haven't gotten to you before, but the next meeting that we have, which happens to be this meeting, we will discuss it with the ACMUI members.

What I would like to do is work with the committee to provide support to you all. If we can go through these questions and come up with some answers to them rather than spending time correcting them editorially, if we can get some thought processes down, some brainstorming down, then we can come back and refine this for you and then put it out for the committee to look at as a whole and maybe hold a telephone conference call where you would actually get a second chance to

look at it. At this point we need to make the next step, which is maybe to spend 20 or 30 minutes going through some of these items.

The first one I would offer is, does the staff and the ACMUI interact in such a manner as to satisfactorily address issues before the Commission? Rather than me bias you, I will turn it back.

DR. CERQUEIRA: I can make my first comments. Probably being the most junior member of the committee, I think the whole Part 35 revision rulemaking has involved an extensive amount of interaction between the committee and the staff. I think we have provided a significant input in terms of the medical applications and the clinical setting, which is expertise that the staff do not really have. I think there has been extensive interaction and unique expertise that have been provided, and the mechanism for this interaction has been satisfactory.

Perhaps we should go around and take comments, perhaps starting with Lou who has been here a while.

DR. WAGNER: I guess my only comment would be the ACMUI has absolutely no inhibitions about interacting on any issues that are brought before it. I have been pretty satisfied with being able to address everything. I don't have any qualms about this issue.

DR. CERQUEIRA: Ruth.

MS. McBURNEY: Since the draft comments are mostly mine, I would say the staff has been very helpful in telling us what issues need to be addressed and what the issues are, what they want input on, and certainly with this volume of material that we are being asked to comment on on this significant rulemaking there has been, as you say, a great deal of involvement. That relationship with the staff has been very positive.

DR. CERQUEIRA: Dennis.

MR. SWANSON: Yes.

DR. CERQUEIRA: Niki.

MS. HOBSON: Certainly the experience of interacting with the staff has been thoroughly enjoyable for me. This has been an education for me sitting in on these meetings and hearing the learned discussions from both sides of the table.

Sometimes I wonder -- and there is probably some logical explanation -- when the committee takes a stand that is not necessarily reflected in the staff's input to the Commission. I am wondering why that happens. In particular the patient notification issue. We have been pretty unanimous in not wanting patient notification, and yet we keep seeing that issue come up. Are we not saying it strong enough, or is there something else going on that I don't quite understand?

MS. HANEY: Can I address that?

DR. CERQUEIRA: Yes, Cathy.

MS. HANEY: Your opinions are reflected in the minutes. We have the minutes after each one of the meetings. Those minutes are provided to the Commission. It happened to be that in this particular package they went up with the rule language. It doesn't always happen that way. In fact, usually it goes up under a separate cover, but in this one is made sense to give it to them so they could see it first hand out of the minutes.

When we do a rulemaking, what leaves us is not really what the ACMUI had recommended. We try at subsequent ACMUI meetings to come back and tell you what happened. That is a relatively new effort. The last two or three years before that I think there was a big gap on feedback to you. You might not like what we tell you when we come back and tell you, but at least now you know why it happened. But the minutes do go up.

One thing if I could get you to comment on. The bylaws right now call for two meetings. Last year we had the ACMUI meetings, but we did cancel the November meeting. Because of the Part 35, there was no reason for you to get together.

Under this particular item, you might want to comment on the frequency of the meetings. Maybe additional use of telephone conferences. We did find out that if we do have a telephone conference which involves the entire committee and decisions are being made, that does need to be made public. We

need to give a call-in line for any of the public that would want to come in. So that would affect how whether we would really want to go that way.

And use of e-mails. NRC is getting into all this IT stuff. If you would want to comment on how that would help or how it does help the committee to address issues and whether you feel like you are getting enough information from us. We could send you more e-mails if you want them, but you might be getting enough of them already.

DR. CERQUEIRA: Cathy, I guess the Federal Advisory Committee Act does mandate how some of this communication can be handled. I'm sure we have to stay within those guidelines. I think some of these alternative methods would certainly be valuable as a way to get information from the committee and feedback from the members of the committee and staff. I think we would be willing to explore some of these possibilities.

I would like to make one comment about some of Niki's statement. We are an advisory committee. We can feel very strongly about things, but there is no obligation upon the staff or the NRC Commissioners to take action on the recommendations. That's a little bit of a reality check that I had to go through when I got here.

Would anybody else like to comment?

MR. SWANSON: Just a question, Cathy. Since it seems like final decisions on a lot of these issues lie with the

Commission, how does the staff and the Commission interact so that you have full understanding of where the Commission is coming from on various issues such as patient notification so that you can bring that back to this committee?

MS. HANEY: I will answer it from personal experience, and this is more less just a couple of years. I feel especially with Part 35 that the Commission really does have a good understanding for where the ACMUI is, because I've had the opportunity to talk either with the Commissioners directly or with their technical assistants on a one-on-one basis. I have been quite honest with them about where we stand, where staff is. Even within staff there are differing opinions. Where the ACMUI is, where the states are. I have tried to keep them informed of all the different interests that are out there.

It was easy to do with a rulemaking like this that has as much visibility as it has. On some of the other rulemakings we have done in the past on Part 35 they have not been as visible. So it has really afforded someone in my position the one-on-one contact with the TA's or with the Commissioners themselves.

What we try to do is in any of the Federal Register notices we have to address that it was discussed in an ACMUI meeting and this is what the ACMUI said. So it is going to them in writing. I have no problems with that. Sometimes when

you get the opportunity to meet one-on-one you can get a point across a lot better than you can by just reading it in a draft Federal Register notice.

MR. SWANSON: Do you feel as a staff member meet with them enough to have a good understanding of where they are coming from on this issue, Part 35?

MS. HANEY: On this one, yes. I think this one has gotten enough visibility and the way that it has been handled internally with a little bit more of a streamlining process as far as management. As any government agency, we have our management chain. I haven't had to go through as many of those steps with this rulemaking. That has helped a little bit.

Also, NRC as a whole is going through a bit of a change where we are looking more for stakeholder involvement and stakeholder opinion and what are the implications on stakeholders. It is almost like everything is kind of changing for the good at this point.

DR. CERQUEIRA: If we are going to finish on time, we probably should continue. Following Dr. Stitt's lead, she was a very good taskmaster on time.

We have enough information here in terms of the interactions between the staff and the committee.

Question 2 of the self-evaluation criteria: Do the committee members clearly define issues for staff and provide timely, useful, objective information to the staff when

requested?

This is almost a comment from the staff rather than the committee.

MS. HANEY: We will get our opportunity to respond to these too.

DR. CERQUEIRA: Any comments on this, Lou.

DR. WAGNER: I think the statement that is made there is somewhat pejorative and should be struck. It tends to indicate that people are biased. I think the whole idea here is we have to represent different professions. The whole intent is to represent the different sides, and I don't think that should be presented in a pejorative way. That is planned; that is the way it's supposed to be.

As far as I'm concerned, within my experience and interactions that I've had, the answer is yes. I don't know of any cases where we have not been able to communicate with the staff well enough to provide objective information and clearly define the issues. I think the statement as it is written is too pejorative and should be struck.

DR. CERQUEIRA: Ruth.

MS. McBURNEY: It really wasn't meant to be pejorative. To be objective, you have to look beyond not only the group that you are representing, but to try to provide the most accurate information. I think the committee members do try to do that.

DR. CERQUEIRA: I would like to comment that this is a forum for input from various groups that are involved, both physicians as well as physicists, radio chemists. I think the composition has been carefully thought out. We obviously don't always agree on some of these issues and we have very strong opinions on them.

Certainly in the interactions that I have had people have managed to put aside some of their real core issues in a spirit of compromise to come up with a consensus which has overall safety of patients in mind. Rather than seeing this as a negative, I think it is a positive.

Dennis.

MR. SWANSON: The only comment I might make is I think the committee does a good job defining issues in response to items or regulations or proposed regulations that are put in front of the committee. One could also interpret this to mean that the committee members themselves are bringing issues to the NRC for discussion, and we probably haven't done that as much as perhaps we should be doing it.

DR. CERQUEIRA: Good point.

Do you have sufficient information?

MS. HANEY: Maybe "the forum for providing comments from different perspectives," and then I will delete what is written there. Are you okay if I delete this and then just go with those bullets?

DR. CERQUEIRA: I think that is fine. Question 6 also addresses some of this, all elements of the medical community. I think we will revisit that again.

Does the staff have any comments for us? Are we timely?

MS. HANEY: Yes, I think so. The experience has really been with 35, and I think everything has run very smoothly with 35. When we have needed you, you have been there for us. I think the use of the subcommittees has been wonderful. In fact, we got a tremendous amount out of the subcommittees.

Also, I haven't had a problem in calling any one of you and saying I've got this particular issue, you're the best one to answer this, can you give me the advice, and getting timely advice. When we go back with our staff review of the interactions with the committee, that is what I am going to emphasize.

I personally think there is a tremendous value to this committee and my ability to access radio pharmacy, physicists. Everyone always says, what does the patient rights advocate say? They don't care what Dennis says.

It has been great. That's what I'm going to bring up.

Are you okay with number 3?

DR. CERQUEIRA: Any additional comments?

MS. HANEY: I would like to get your comments on the subcommittees and whether this is a particular question or not. Maybe we can put some bullets here, and then if it's not, when we get to it, we can put it in another place. Did you find the use of the subcommittees beneficial as compared to just waiting and presenting the big bulk of the material at a full meeting?

MS. McBURNEY: I think that is going to be addressed in number 9.

DR. CERQUEIRA: My experience on the committee has all been related to Part 35 revisions and it has been very intense, with frequent meetings and interactions.

DR. WAGNER: Are we addressing 9 now?

MS. HANEY: No. We can come to that. I didn't realize the subcommittee was on there.

DR. CERQUEIRA: Any additional comments on 3?

Let's move on to item 4. Does the committee provide expert advice which is not available from within the agency?

MS. HANEY: Let me read it into the record. The answer that we are looking at is:

Yes, the members of the committee represent those being regulated as well as medical, physics, and pharmaceutical expertise not available on the staff. It also provides input from the state regulatory perspective which is to some extent different from that of NRC, and input from radiation safety officers who must implement the final rules and guidelines.

DR. CERQUEIRA: It's a very concise statement. I think it sort of summarizes some of the things we have said earlier.

Does anyone wish to make changes or additions?

MR. SWANSON: The main point is you are getting input from people that actually have to put your regulations into practice.

DR. CERQUEIRA: The regulated community.

MS. HANEY: Question 5. Want to go ahead?

DR. CERQUEIRA: Sure.

MS. HANEY: Does the committee meet frequently enough to address issues in a timely manner. The answer is yes.

I would say if we could elaborate here. This is really getting at what I was starting prematurely to talk about. For right now semiannual is working, but looking back to where we were last November, were you in agreement with canceling that November meeting because of where we were with the projects? To the best of my knowledge, that was first time we had actually canceled one of the big meetings. It didn't seem practical to have it.

Would like us to continue to consider that when we are having a meeting whether the timing is right and whether there are sufficient issues to bring everyone together?

DR. CERQUEIRA: I think that is totally appropriate. To just have a meeting for the sake of meeting is not in

anybody's interest. We spent all this time working on the draft rule. I think over the next several years we are going to have to deal with the fallout of that, and there may be more issues than we care to address.

MS. McBURNEY: There are also those special topics that we put aside until this rulemaking was finished.

DR. WAGNER: I would say that I think it is important that this committee meet at least twice a year and try to make every effort to do so.

I think last year and last November was an exception, mainly due to the fact that the staff was so overwhelmed that organizing and putting together a meaningful meeting was difficult. I think we should make every effort to have a meeting twice a year to keep up to date with what the issues and principles are. It's just very important.

Whether we are going to address it or not, I also like the issue of having subcommittee meetings in there, because they seem to be extremely productive meetings where a lot of fresh ideas come forth.

I would not want us to get into a cavalier attitude toward having meetings. I think we absolutely should have at least two a year.

DR. CERQUEIRA: Good points. If we don't have enough issues, then you'd have to question the value of the committee.

Any additional comments for 5?

Cathy.

MS. HANEY: Number 6. Do committee members bring issues from all elements of the medical community to the attention of NRC staff. The answer that we are looking at:

Yes. Usually for those issues that involve other aspects of the medical community consultants are brought in for the committee meetings to provide expertise and information for decision making in those areas. I was pleased to see that a radiation safety officer position has been added to ACMUI since this position plays a key role in implementation of rules and sees issues more clearly from a radiation safety standpoint.

DR. WAGNER: Who is "I"?

MS. McBURNEY: That was the one person that responded to this.

MS. HANEY: It wasn't me, Lou. I didn't write these answers.

DR. CERQUEIRA: Any additional changes or deletions?

MS. HANEY: Number 7. Does the committee facilitate and foster communication between the public, medical community and NRC?

Yes. This gives greater opportunity for the NRC to listen to input from the public and the medical community as well as for representatives of the medical community to better understand the regulatory philosophy that goes into standards and policy.

DR. WAGNER: Is this a question mostly answered by staff about the committee and rather than us about ourselves?

MS. HANEY: No. This is really for you to look at yourselves. The question is, are you providing a link or a way of getting information from your professional organizations to us? And vice versa. Are you able to take information that you get from being on this committee and go back to your professional organization and help them to understand why we do things the way we do things.

DR. WAGNER: We have to be very careful, though. As you know, we cannot speak as ACMUI members when we are talking to any of those other groups. This question is a little dicey for me to get into because of the way it is worded and phrased. I would hope that our most important role is to give the staff a perspective on regulation so that its communication with other areas outside of the ACMUI is more fluid and more communicative.

DR. CERQUEIRA: Dennis.

MR. SWANSON: It goes the other way too. I routinely do presentations before the nuclear pharmacy community as to where we stand with the regulations, et cetera. So, yes, it is working the other way also. I clearly announce that I am not doing a representation as a member of the ACMUI. It provides a mechanism to keep these people up to date, because obviously they are not in this room.

DR. CERQUEIRA: I think the way the meetings have been set up, if there are other interest groups that are out there, they have the opportunity of making presentations and presenting other viewpoints that may not necessarily be directly represented in the community. That option exists out there to make certain we get communication from all the parties.

Any additional comments for 7?

Why don't we go on to 8. I will read it while Cathy is typing.

Does the committee consider current resource constraints of the NRC when recommending new or enhanced regulatory programs?

Yes, I feel that it does. One example this year was the initial proposal for an exam to be included in the training requirements for authorized users. The review of exam programs would have been resource-intensive for NRC. This was one of the reasons it was removed as a proposed requirement. This measure was concurred in by the ACMUI.

Comments?

MR. SWANSON: To the same extent that the NRC considers resource constraints of the medical community when recommending new or enhanced regulations.

You don't have to put that down.

MS. HANEY: I'll get it in there somewhere.

MR. SWANSON: In all reality, I think that is something that is in the back of our mind that goes both directions.

MS. McBURNEY: What's it going to cost the community to implement and what's it going to cost the regulators.

DR. CERQUEIRA: Other comments?

We can go on to number 9. Does the committee make effective use of subcommittees to assist the staff on specific tasks or projects?

Yes. I felt that the diagnostic and therapeutic subcommittees were very effective in addressing issues specific to those areas during the development of changes to Part 35.

DR. WAGNER: I really like the subcommittee. They have been extremely productive. They are very intense and well focused sessions. So I would encourage the further use of subcommittees on issues, meeting between the staff and the ACMUI on these issues. It was great. It's terrific.

DR. CERQUEIRA: Lou, right now the breakdown as sort of diagnostic and therapeutic, which was sort of a risk-based pairing. Will this be the type of subcommittee that we would have in the future? What subcommittees do you envision?

DR. WAGNER: I think that is an obvious breakdown. Now since the focus is going to be more oriented toward therapy there should be some focus on subcommittees within therapy for different items and different issues. That will break down and

get some of these issues addressed and drawn out.

DR. CERQUEIRA: Dennis.

MR. SWANSON: I think that question probably should read, does the committee make effective use of subcommittees and individual ACMUI members. Then you can bring in your issue where you routinely call up people if you have got specific questions.

I think we probably have made the most effective use of subcommittees over the last two years, but prior to that there were things where individual members were brought in as consultants. That is what I am trying to get back into this because I think that has also been very effective.

DR. WAGNER: I think the most important point is to state that the subcommittee use is a more effective and efficient use of ACMUI committee members' time, and hopefully it is also more effective use of NRC staff time. That's a very important issue, because we don't have to meet as a full committee and a few people can really intensely get on with the issues. It certainly doesn't drag things out in a full committee meeting and have things belabored with discussion that just never ends.

DR. CERQUEIRA: A very positive response for the subcommittee program, and it is encouraged in the future.

MS. HANEY: One more.

DR. CERQUEIRA: Number 10. Does the scope and size

of the committee meet the current needs of the NRC?

Yes. I think the scope and size are appropriate. I would hope that all positions can be filled in a timely manner so that the level of expertise remains consistent.

Lou.

DR. WAGNER: This has been an issue since I've been here and it has not been solved. I believe it is one that should be addressed before the Commission. I am very disappointed in the fact that there are lots of positions that don't seem to get filled in an appropriate time when they are vacated. I don't know if we still have the radiation safety officer position officially filled. Is that filled?

MS. HANEY: No.

DR. WAGNER: Then we use nuclear medicine people and other individuals who should be representing things and we have these large gaps at times with people not filling these positions. When we know a position is going to be vacated, it should be announced well before it is vacated, and there should be a replacement coming in right after it's vacated. The person who is going out should know who the replacement is going to be.

I don't know what the rules are with regard to all these things, but it seems to me that a more effective lead time to get those positions filled promptly would make the ACMUI more effective. It also would make the ACMUI more

efficient, because the subcommittee then would have a full staff or complement of representation in order to get their jobs done.

This has been an issue since I have been here. It has never gotten resolved, and I am still disappointed to see how this whole process is going.

MS. HANEY: Let me ask one thing that I would like under this question for the committee to put something on the record for. Last year when we went up to the Commission with who was on the membership, there were some positions that were cut, one of them being a radiation oncologist position, which would take us down to one oncologist on the committee.

We are in the next step of the process for filling some of these positions. It is a long administrative process to get someone seated.

One of the things that we asked the Commission to reconsider was having two oncologists back on the committee. The rationale that we gave for that was that the oncology profession is so diverse. Basically, we said it is very hard to find one person that can address everything.

I guess I would like your comments on whether you agree with that.

DR. WAGNER: Are you saying that Judy Stitt's and Dr. Flynn's positions be combined into one?

MS. HANEY: Last year they were combined to one.

However, we have gone back to the Commission from a staff level saying that we would like two positions. Actually, Dr. Flynn had also written a letter to Chairman Jackson at that point saying that it was not wise to do that. Some of the reasons that I just gave you is what Dr. Flynn had given.

Since we have got this topic before us, if they decide to against that, I could also say in the October 1999 meeting the committee reinforced the need for two oncologists on the committee. I don't want to put words in your mouth, but if you would like to say that.

DR. WAGNER: Absolutely. The facts are you are looking at risk, and that is where the risk is. That is where the doses are delivered; that is where the radiation levels are high. There is where you have such a wide variety, and it is expanding in its scope in terms of applications. There is no way in the world you can have representation from one person who knows it all. That's impossible.

I think that two people is absolutely essential to the proper function of this committee from that standpoint. That is the biggest area that really needs representation from the medical community.

MS. HANEY: Thank you.

DR. CERQUEIRA: Right.

MS. McBURNEY: I agree with that. With all the things that we are going to need to be addressing at least in

the near future on the emerging technologies, the labeled antibodies, intravascular brachytherapy, and so forth, there is probably not a single oncologist that is doing a lot of all of that, plus teletherapy as well as the radiopharmaceutical therapy and so forth.

MS. HANEY: There is definitely one oncologist. If the Commission goes the preferred route, there would be two oncologists, the radio pharmacist position, the radiation safety officer. The research position was one of the ones that was cut last year by the Commission. I have a paper upstairs, but off the top of my head that's it.

Dr. Alzeraki is still on the committee. She unfortunately had jury duty, so she could not come today. So we do have diagnostic represented. They are just not here today. And John Graham is also still on the committee but because of death of one of his supervisors there were some responsibilities he needed to pick up.

John is here for another year. Lou, you are here for two more. Does that sound right?

DR. WAGNER: I thought it was one, but maybe it is two.

MS. HANEY: I think you are two, because I think we renewed you.

DR. WAGNER: If you can put with me for another year.

MS. HANEY: Sure. You're going to help me implement

this rule. As long as we can continue to argue the 5,000 millirem reporting threshold I need you around.

DR. CERQUEIRA: Those are some very good points. I guess one of the things that does come up is how wide a group do you need. Talking about the radiation oncology, with the emerging technologies some of the cardiology community feel somewhat under represented in the sense that we have sort of a diagnostic cardiologist, but as that representative I am certainly not an expert in any way in intravascular brachytherapy. So there is some expertise within the cardiology community that is not represented, and I certainly don't quality to represent.

You can't every opinion, but at the same time if this is going to be an important area in the future, then I think that consideration should be given as well.

MS. HANEY: We always have the option of inviting someone to the meetings. I would just say that when you do see the agendas coming out, if you think there is someone that we do need to invite, if you can give us feedback, we can do it. I think we are going to get to the point we are going to need to bring in some of the cardiologists that are working in the therapy area to sit in as an invited guest. That is probably going to be an obvious one, because I think we will be dealing with T&E issues for them soon.

If there a particular meeting that you think we

should invite somebody, please let us know. We can do that. We've never had a problem with bringing in an invited guest.

What we will do is take these and refine them a little bit just to help you out some. Then we will send it back out to you. If you want to change it, feel free to change it. My intent is not to put words in your mouth. If you don't like what you see, make sure you tell us.

DR. CERQUEIRA: Cathy, this is not going to be presented to the Commissioners tomorrow; is that correct?

MS. HANEY: No.

DR. CERQUEIRA: This is sort of an ongoing process.

MS. HANEY: This is a separate action.

DR. CERQUEIRA: I think it might be a good idea to send it out to people. For some people this is first time they have seen this, and it might be worthwhile for them. I am sure that people will add specific comments and input.

MS. HANEY: Even on your flight back, if something comes to mind and there is more information, just send me an e-mail and we can incorporate it right away.

MS. HOBSON: Can I just make one comment?

DR. CERQUEIRA: Sure.

MS. HOBSON: Earlier you were talking about using e-mail and conference calls, and I think that is a great idea. I have benefited greatly from the face-to-face meetings and hearing the interaction between the committee members and among

the committee members, because each of you come from an area of expertise that I don't know about. So it's really very beneficial to me to hear all this discussion. Conference calls are fine as long as everybody is hooked up and I can eavesdrop in on these conversations. But one-way e-mails would not be real beneficial to me.

MS. McBURNEY: You don't have the group dynamics.

DR. WAGNER: All e-mail should be copied to everybody on these communications.

MS. HANEY: I think we are doing that. I hope we are doing it.

DR. WAGNER: I think it is.

MS. HOBSON: As long as I get everybody's input.

DR. WAGNER: There shouldn't be any private conversation going on with these kind of issues.

MS. HOBSON: I need it probably the most of anyone.

DR. CERQUEIRA: I was just appointed to this HCFA committee which is now under the Federal Advisory Committee Act, which has very strict rules. I don't think you are allowed to have conference calls because it constitutes a public meeting without public access.

MS. HANEY: We did check into that. Like the meeting we had where we had a couple of members. We went through our lawyers. My understanding was that we could do a meeting by phone except it would have to be noticed as a public meeting

and the phone lines would need to be made available to the public to call in. That would be a meeting where we were making decisions. Just an informal one-on-one or two-on-one where it is almost like scoping early things like --

DR. CERQUEIRA: Does it require a Federal Register notice?

MS. HANEY: Diane, was it Federal Register or just a public meeting notice?

MS. FLACK: I'm not sure about that. But you have to provide a room that people can go to.

MS. HANEY: I don't think we will go that way. That would almost be if there was something we needed an answer on in two weeks and we knew we couldn't bring you in. My intent is not to go to that. I agree with Niki. There is a big benefit of sitting around a table and talking about it.

MR. SWANSON: I think it goes beyond that. I think there is probably something to be said for body language.

[Laughter.]

MR. SWANSON: For example, Office of Protection from Research Risk for IRB activities mandate that if you have a local research context, which means that if you are doing research someplace else, you have to have a representative from someplace else. They will only allow video conferencing. They will not allow telephone conferencing because they believe there is something to be said about body language. In reality,

there probably is something to be said about body language.

DR. WAGNER: What am I saying right now?

MR. SWANSON: I know what you are saying all the time.

DR. CERQUEIRA: Let's take a five-minute break.

[Recess.]

DR. CERQUEIRA: I would like to welcome everybody back for the start of the next session, which is going to be the preparation for the October 21 Commission briefing on the revision of Part 35, Medical Use of Byproduct Material.

Cathy and Diane have provided some overheads which are under Part 35 Vugraphs, ACMUI.

MS. HANEY: These viewgraphs have already gone to the Commission. So we really don't have the option of changing the text. We could change it if we absolutely had to, but my recommendation is not to.

DR. WAGNER: Cathy, we meet tomorrow at 2:00 with the Commission; is that correct?

MS. HANEY: No, at 9:30. It's on the One White Flint building, the other building, on the first floor. If you just come in and say you are going to the Commission hearing room, there are there. Be there before 9:30, because they do start promptly at 9:30.

The format is that I will do a half hour presentation. Then they will ask me questions or drill me for

30 minutes. Then you guys will switch seats. You will come up to the table. I would plan for a half hour presentation, no more than that. Then you get drilled for a half hour.

Chairman Dicus is trying very hard to stick to schedule. The other thing that she is trying to do is to let the individuals go through the entire presentation before asking questions. If you remember from previous ones, the tend to jump in. But any thing is open. That is what they are trying for.

You should have copies of my viewgraphs, the ones that I will be using.

DR. CERQUEIRA: Cathy, do you want to go over yours and then go to ours?

MS. HANEY: I can.

DR. CERQUEIRA: What we should try to do with today's meeting is go over the specific material that we want to cover, but also to assign somebody from the committee that will be making the presentations.

DR. WAGNER: Could you brief us quickly about the composition of the Commission as it stands today?

MS. HANEY: Right now Greta Dicus is still chairman. She will be chairman until next Friday. Next Friday we will get a new chairman. I think Dick is his first name. Dick Meserve will become the new chairman.

Tomorrow you will just have Chairman Dicus. You will

have Commissioner McGaffigan, who you have met with before. Commissioner Merrifield, who when you briefed him in March last year -- he'll be off on your right -- this was the first time he had heard anything about medical.

That will be it sitting at the table tomorrow. Commissioner Diaz is not here. They did try to tie him in by a phone line to a briefing this morning and it didn't work real well. So they are probably going to try it again. You may hear this voice, and that's Commissioner Diaz. You have met with him also. So until next Friday we are with a four-person Commission.

DR. WAGNER: It keeps changing.

MS. HANEY: It does. Once Chairman Jackson left we needed a chairman. We can't have an acting chairman. That's why they moved Dicus in. Now we have the new one. It keeps us on our toes.

What I could do is go briefly through what I'm going to say, and I'm going to tell you some places where I think maybe you could help and some comments that you might want to add. When we get to that specific area on your viewgraphs, you will have an idea of where we are going.

Page 1 is just the briefing outline.

DR. CERQUEIRA: This under the Part 35 viewgraphs for staff, which is the last tab.

MS. HANEY: I am not going to go much into the

background because of the time, and they have heard a lot of before, but I will be stressing continuous interaction. You may want to comment on the interaction that you know of that has taken place and how effective that has been.

Then just the purpose of the SECY paper, which is that four inches of paperwork that we mailed you.

Key issues for Commission consideration. The idea here is, these are the big ones that we are bringing to you, Commission. At the same time there are probably about 300 other little ones that are in this package, but I don't have enough time to go through all of those issues with you.

These are here because either they were concerns of the Commission where they asked us specific questions, or they were concerns of the stakeholders that I thought really needed to come to their attention in this sort of this meeting.

The first thing that we discuss on page 5 is the need for a formal risk assessment. The Commission had asked us to come back with the pros and cons of doing a formal risk assessment. I will be emphasizing here that the rule is risk informed, that we have made significant reductions in the unnecessary regulatory burden in the diagnostic area; there there are still some prescriptive requirements for the therapy, but we believe that is warranted by risk.

Page 6 is the Radiation Safety Committee. I will be explaining that the comments were fairly well split on the

Radiation Safety Committee. Health physicists, radiation safety officers tended to believe that the committee should not be deleted at all. Hospital administrators, physicians did not necessarily see the need for the committee and felt that it was better to give the licensee the flexibility on how to manage their program.

We took a risk-based approach in developing the draft final rule. We went ahead for the sake of the slide and used the subparts. Subpart E would be your unsealed therapies; subpart F is your manual brachytherapy; and H is your therapy devices. If you have two or more in that area, you would need to have a radiation safety committee.

The other condition is that if you have two or more types of units under subpart H, like if you have a remote after-loader in a gamma radiostereotactic unit, you would need a radiation safety committee. The idea here is that we would bringing the different disciplines together to discuss issues.

Viewgraph 7 is your training and experience requirements. I need to focus here on the fact of why we are no longer going with approval of training programs, because in March I was pitching no exam, we'll approve training programs. We have evolved from there to the point where we don't think we should get into the approval of training programs. Rather, we are going to be relying on the preceptor to certify that the individual is competent to function in their particular

position, whether it's a radiation safety officer or an authorized user.

We did increase the hours in some areas over the proposed rule, especially in the diagnostic areas.

DR. CERQUEIRA: One point here. On page 8, the CRCPD committee concerns, are you going to bring up some of the issues? I guess the Commissioners met with the Agreement States.

MS. HANEY: Right. This would be one area where I would identify the fact that, Commission, I'm aware that you heard yesterday that there were some differences, but in this particular area there was a difference, the SR-6 Committee believing that the training and experience for use of I-131 should be higher than what is in the draft final rule.

The kick-outs here in the rule the use of I-131 are almost specific to the endocrinologists. I would mention that the track record of use of I-131 by endocrinologists has been very good, and that because of that, we could not justify an increase in the hours. However, we did increase the hours in the 35.300 area, which is the unsealed byproduct material, because that section is not just limited to I-131 use.

That was the argument probably a year and a ago that Dr. Flynn made about some of the pharmaceuticals that are being used under 35.300 can get into bone marrow suppression, and the risk is higher. Therefore we increased the hours there.

DR. CERQUEIRA: I guess the one comment I would like to make is with 31 Agreement States just in terms of training people who don't come in through boards, it would be very important to have uniform federal policy at least for the diagnostic.

MS. HANEY: You have got some viewgraphs that are specific to training. That is the area where you probably want to bring that up.

DR. CERQUEIRA: Does the staff support this?

MS. HANEY: That is a tricky question. I guess I personally don't disagree with you. However, when we take a rule and we decide what level of adequacy or compatibility should be assigned to the rule, there stepping stones that we go through, and we call it a management directive. Using that management directive is how we arrive at the compatibility. Training came out at a C.

In order to get it to a point where the states would have the same requirements, we have to either say it is equivalent to Part 20 sort of issue, a dose limit or definition. The only other one that would kick it out higher is if we could say this is a matter of interstate commerce. I don't think we can argue on that.

Then you go to the next tier, which is where you are right now, that the states have to have the option of being more restrictive if they want to.

So this is a matter not so much with Part 35. The issue is with the adequacy and compatibility policies that we use.

The Commissioners are aware that this is an issue. This is getting back to what Dennis had said. This is one of those ones I have talked with them about, and their technical assistants know. I think you should use this as your opportunity for you to make that pitch about the differences. Even this morning Commissioner McGaffigan questioned Dave on the I-131 training and said you may be fighting this on 31 fronts or 32 fronts as compared to just with NRC.

I don't want to say that they are happy where we are, but I haven't heard that they aren't. Again, the states have the option of being more restrictive on this. So they are aware of this issue.

DR. CERQUEIRA: I think if this were a category B instead of a category C, it would certainly be greater simplification for people that are out there.

Dr. Siegel is expressing some body language. Barry, do you have any comments?

DR. SIEGEL: Only that states have different medical licensure requirements. I don't see how you could ram one down their throats. The Constitution didn't give this particular power to the federal government.

DR. CERQUEIRA: Good point.

Ruth.

MS. McBURNEY: That's true. The comments made by Mr. Walters were those representing the Suggested State Regulations Committee. It did not represent the whole Organization of Agreement States' position. They have not taken a position. The states have not had an opportunity to review those suggested state regulations. You couldn't do a brush that all the states are going to want to go that way.

Would this be a good opportunity for me to clarify something from the minutes of the last briefing? I was quoted as being an endocrinologist and having to do with the training and experience on that. Apparently that was not my quote. It was someone else. I'm certainly not an endocrinologist.

I would concur on the 80 hours being adequate for an endocrinologist for the single isotope that they use.

DR. CERQUEIRA: We will have an opportunity to bring up some of these issues. It would be helpful if the staff also could anticipate some of the things we are going to say.

MS. HANEY: Number 9 is the threshold for the unintended exposure to embryo/fetus/nursing child. In the paper we have recommended that the rule have a 50 millisievert threshold for reporting. There are those that are still arguing the 500. I would say this is an area where I think you guys really need to get some technical facts on the table about the effects of the difference between 500 and 5,000 millirem

exposure on an embryo, fetus or a nursing child.

We have a backup slide that references some AAPM and NCRP information. It's on page 25. What I would like to have happen tomorrow, if I get the more technical questions directed to me about the statistics, the percentages, what effects you see, I'm going to defer to the ACMUI. Back in the March meeting, Lou, you did the presentation, and it was wonderful. I think even though it's almost a repeat of some of the things you said back in March, we might want to consider that type of presentation again.

This is one where what you are fighting against is good rems and bad rems. NRC is in constant discussion with EPA over whether dose limits at Yucca Mountain should be 15 millirem or 25 millirem, and, Cathy, you're saying embryo/ fetus can get 5,000 millirem. Does you see a problem here, Cathy?

That is some of the perspective of where these comments are coming from. Then you look at the Part 20 limits where the public dose limit is 100 millirem and the limit to declared pregnant women is 500. It is like, why are you such an order of magnitude off?

This is what you are working against or with.

The next one is the notification following a medical event or exposure. After the March briefing when we received the SRM, the Commission asked us to come back with an

alternative rule language. That alternative rule language would only have the licensee certifying to us that the patient or responsible relative was notified.

I have pointed out that the committee has voted against any notification. I think that is one of the items in your viewgraphs. However, I think you might want to consider how much do you want to support this.

It is kind of like if I can't have exactly what I want, is this one step better? Is this one step in the right direction?

All the Commissioners have different views on this particular item and some feel stronger than others.

The additional CRCPD SR-6 Committee concerns have to do with the criteria for release of individuals containing -- well, 35.75. There are two things here. One is they would like the authorized user to sign the record of the release.

The other thing is they would like a statement in the rules that says that once the patient is released, goes home, if contaminated material triggers a landfill monitor they want a statement in the rule that says the state could still hold the licensee responsible for that material.

From NRC's standpoint -- I am not sure of the legal situation with this -- if you have made a release in accordance with our regulations, how can you go back and say that it was not an adequate release?

In this area the states can be more restrictive. This may be just one of those situations were we back off and say, states, you can be more restrictive, but we are not going to go there because you don't see this in our rule.

The other particular item has to do with brachytherapy treatments. We have in our rule that you can house or quarter two patients together that have had unsealed therapy, and you can house two together that have manual brachytherapy. The states will probably not authorize two unsealed patients being in the same room. Our position is that the dose that one is receiving from the other is inconsequential in light of the amount of that they are receiving from their particular treatment.

DR. CERQUEIRA: Cathy, one question about the release and the releasing institution being held liable. Is this a safety issue or a financial issue from the states?

MS. HANEY: I think you will hear both arguments. It's obviously financial, because it's the states that have to go out to the landfills. When the alarm goes off, they have to go out. In some cases is tech waste; in some cases iodine waste, but you might find that manual brachytherapy seed that is out there too that a facility has lost. So they need to go out and check. Then you have got the state physicists out there going through garbage at the landfills. It is a financial, it is resource drain.

Then there are those that will argue that it is a safety issue. In the early 1990s when the ACMUI discussed this rule, it was, is the patient the leaky source? The documentation we used to support the rulemaking was that the patient was not a leaking source and that if the licensee considered the maximally exposed individuals, any doses that anyone other than that received would be well below that limit.

DR. CERQUEIRA: Is there a consistency within the states at what level of activity these systems are triggered? Is it possible that they are set too low?

MS. McBURNEY: There is not a real consistency now. There has been some guidance put out by the Conference of Radiation Control Program Directors. Landfill operators can set levels on their own.

DR. CERQUEIRA: My concern is if you are going to hold these hospitals liable for non-dangerous levels of radiation, that is a fairly hugh liability for the cleanup if there is no safety issue involved. If you have adequate thresholds for detecting dangerous radiation levels, then I think that would be appropriate. Otherwise these institutions are going to assume large liabilities without any safety risk to the users or the public. I'm not sure we want to necessarily impose that.

DR. WAGNER: I'm very confused about this issue. I don't understand the points that you brought up in regard to

this. I don't know if this is the time to talk about this or not. It seems to me that the issue of trying to make a user responsible for a legally released substance is silly.

The problem is that you have to be able to distinguish for the landfills what is a source that needs to be investigated and what isn't a source that needs to be investigated. That needs to be solved. That is the issue that needs to be solved. We don't solve this from a regulatory point of view, trying to throw the responsibility back on the user who legally released the patient. That's silly.

MS. HANEY: That's why we differ in this area, because we did not put a corresponding requirement. If we get into this tomorrow, hopefully the representative from our legal counsel will be there to address the legal aspect of it as compared to the safety aspect of it. This is one of those issues where you may have to fight on a state-by-state level as compared with NRC.

DR. SIEGEL: Just a question, Cathy. The underlying regulations that are causing this problem are EPA regulations that preclude disposal of radioactive materials in these landfills?

MS. HANEY: I don't know if it's an EPA regulation per se, but I know that the states do have regulations that say no radioactive material in the regular sanitary landfills. Therefore, the alarms are being set very low to catch it, and

as soon as the alarm goes off, then you have to respond to it.

MS. McBURNEY: Cathy, we are one state that allows certain levels of short-lived isotopes to go to the sanitary landfills. Certainly we have this problem of the detectors going off. A lot of times it's material that is being allowed to go there. Not only from released patients, but also material from hospitals that we under regulation have allowed.

They have to set those detectors low enough so that they would pick up like a sealed source in a big truckload of material. That is what we don't want to get in there. So we have to accept that there are going to be hits on those detectors for other material as well.

DR. CERQUEIRA: Dennis.

MR. SWANSON: I doesn't make any sense to me. You are not concerned about us flushing all the stuff down the sewer?

MS. McBURNEY: That's not the point. We tell them to put it down in there if that's what it is, but we have to respond not knowing what it is and where it came from.

DR. WAGNER: There has got to be a technical solution to this.

MS. HANEY: From 35's standpoint it's a non-issue. It's not a non-issue for any of the regulators across the board.

Let me tell you about 15. The emphasis here is going

to be that we are going to continue to use a specific license for Part 35 licensees. We have made a significant reduction in the amount of material that needs to come in in support of a license application. There have been those that have commented and said, fine, you're not going to look at it at the time when you license someone, but you are going to get into a detailed review of procedures at the time of inspection. The answer to that is, no, we are not going to go into detailed review of procedures at the time of inspection unless it is warranted. For example, like we are going up to follow up on a medical event.

Then we only expect minimal changes to the enforcement policy, mostly because of changes in terminology and some of the thresholds in there. The whole issue of what is going on with the enforcement policy is a separate effect.

Page 16. The estimate is 3 FTE to complete the rulemaking, medical policy statement and the NUREG, which is the guidance date. As far as our best guess of what we are looking at when we would finished, if we get a staff requirements memorandum in November, we will have three to four months to finish everything we need to finish. Then OMB has 90 days to give us an OMB approval for any of the recordkeeping requirements. We would probably publish in the Federal Register mid-2000 with an effective date of six months out.

There are a couple backup slides here that if you

want to reference or use, you are always welcome to.

The first five pages is just a chart where we went through to show what regulations applied to what type of use in the unsealed material area. On the first page it looks like there are a lot of checks there. You have the purpose and the scope section, the definition section. Most of this is just your paperwork sort of stuff. There really aren't any requirements there.

As you get into subpart B, the first couple set up a radiation safety program and supervision, and then you have the training issues at the end.

It isn't until you really hit subpart C that you are looking at the requirements that really cause the licensee to do something in their day-to-day operation.

The take home message here is that in the diagnostic area, the 35.200, while they do have the requirements to comply with others in the general nature, there really are very few requirements in the diagnostic area.

Page 23 is just the training and experience requirements that are in the draft final rule. That is two pages.

Then we have a little bit of backup on the recommendations for the exposure to the embryo, fetus and nursing child. If they want to go more into a projected schedule, this is more detailed.

The last two pages are something that should have been in front of you when you sat down. This is something that the specific Commissioners had asked that we incorporate. This is a comparison of what the draft final rule says and the current Part 35. You can go down and see where the differences are.

Page 28 is the alternative rule text that we put forward for the report notification of the medical event. This is gets into if you would only be requiring certification versus getting more detailed and getting into the reports that are required.

That is my spiel tomorrow.

DR. CERQUEIRA: Any questions for Cathy on any of this?

Barry.

DR. SIEGEL: This certification for medical event, was it proposed that that also apply to the pregnancy breast feeding as well?

MS. HANEY: Yes.

DR. SIEGEL: Then the question for Dr. Cerqueira is whether the committee ever actually officially voted to endorse that as a better than nothing alternative. The committee is on record as saying no notification is what we think is appropriate because it is already being done and you don't need a federal rule.

DR. WAGNER: No regulation for notification.

DR. SIEGEL: I think Cathy asked the question earlier whether the committee would want to take a stand on this as an alternative if you can't have exactly things the way you wished them to be. This might be better than the current language.

MS. HANEY: Page 7 says that. We can always talk around things if we have to. If we have to change a viewgraph, we can change it.

I think if you aren't prepared to discuss it, you will get asked, what are your views on the alternative rule text?

DR. SIEGEL: Actually, the question I was asking was, has the committee ever actually voted on that?

MS. McBURNEY: I don't think we have met since then.

MS. HANEY: No, they haven't met since then.

DR. SIEGEL: I am sort of suggesting you might wish to.

DR. CERQUEIRA: Dennis.

MR. SWANSON: I think if you look at our viewgraph on this, it says ACMUI does not support any regulation requiring notification of physicians and patients as this is redundant to existing standards of care.

Then it has on here "alternative rule language provided by staff preferred over existing requirements."

So your viewgraph sort of does comment on that or

leave it open for discussion.

DR. CERQUEIRA: If we have to support that, we can do it individually, but we don't have any sort of committee formal vote on it.

DR. WAGNER: Can we address that when we address our viewgraphs?

DR. CERQUEIRA: That's fine. Any further questions for Cathy on the staff presentation?

DR. WAGNER: In regard to the training issues, are you going to be saying anything different than what was said in previous meetings? I'm very confused.

MS. HANEY: There are a couple of things. One is that I do not believe NRC needs to approve training programs. I said that in March.

The other thing I will be saying differently is that we have split out the training and experience requirements for the use of strontium 90 eye applicators. In the proposed rule we recommended that the hours go up to match that for that for a radiation oncologist.

Based on continued discussion and the impact on the use of these devices, if we were to up these hours, we reconsidered whether we should make any changes in this particular area.

We went back and looked at why we did it, which was all the misadministrations we have had with eye applicators.

The root cause is really that either the sources were not calibrated an untraceable to NIST, or else the sources were not decayed properly. So rather than put in a training requirement an up to three years and possibly patients couldn't use it because there wouldn't be physicians that were qualified to use it, we put a requirement in the rule very specific to this that said the sources have to calibrated to NIST and only an authorized medical physicist may decay the sources.

We used a slightly different approach with this, but my believe is that this will fix it more than requiring a physician to have the three years of training just to use the strontium 90 eye applicator. So that is different than what I have told them.

MS. McBURNEY: Which training and experience?

MS. HANEY: 491.

MS. McBURNEY: So it's back to 24 hour.

MS. HANEY: Yes. It's back to 24 hours.

The other thing that the Commission has not heard before but I believe you all have is that under 290 and 390, the 700 hours. We are no longer breaking down the classroom and laboratory and the work and clinical experience. It's basically physician complete a 700-hour training program and cover these specific issues. It still says physics and math and all that, but the hours are not there. Then these are the things that we want you to master under the handling of the

material.

Off the top of my head, I think that is all that they haven't heard before.

From the standpoint of ACMUI, it's about the same thing. All these hours were agreed to at the last meeting with the exception of the 491 going back to 24 hours.

DR. WAGNER: I understand the not approving training programs. You are going to recognize various board certifications in the programs.

MS. HANEY: Right. We are still going to do that. What we have asked the Commission to do is to give us permission to start that recognition process now so that everything is in place by the time the rule becomes effective. The nice thing about doing that, Lou, is it took away the two implementation effective dates of the rule because we were having to keep subpart J on the book until we got boards approved, and no one understood why we had subpart J requirements plus the requirements in the modality base sections. We said, well, once we got rid of the exam, what is keeping us from implementing this immediately, and it became the recognition of the boards. We though if we start that right now, the boards have almost 18 months to get their requests into us.

The last two pages of that four inches of paperwork that you have is a model letter, and it says, dear board, we

are doing this rulemaking. We are going to start the recognition process now. All you need to do is send us a letter that says, dear NRC, I certify that in order to sit for my board the individual must complete the alternative training pathway, would have at least had so many hours and have a preceptor form. Sincerely yours.

DR. WAGNER: What about alternative training pathways other than boards?

MS. HANEY: The alternative is what you see on page 27. You still need a preceptor.

DR. WAGNER: There is no examination required.

MS. HANEY: Correct.

DR. CERQUEIRA: There is no hourly specifications for any specific components the way it used to be.

MS. McBURNEY: In the diagnostic. There is in 490 and 690.

DR. CERQUEIRA: Further questions for Cathy?

Lou.

DR. WAGNER: I am still trying to recall all the rationale and the reasons. I know the boards all have examinations. That's how you become board certified. You have to pass the examination. It's pretty stringent, and it really is an incentive for people to study. In the alternative requirements you don't have that. You have a preceptor statements, which seems to me to be a cushy little way to go.

Why did we remove the examination requirement from the alternative pathway where they don't have one? You wouldn't have to approve it, but you could require it.

MS. HANEY: One of the reasons we removed was when we increased the hours for the diagnostic users over what was in the proposed rule -- in the proposed rule we proposed only 120 hours of training. So when we increased the hours we figured that the individual was getting more training, and therefore there wasn't that much of a need for the exam.

Then there were a lot of implementation issues associated with the examination that came into play. Also we looked at the history. The easiest one is to look in the radiation oncology area. Right now we have physicians that are coming in through the alternative pathway, which is basically three years and 200 hours of training.

We don't have a history to show that that has not provided adequate radiation safety handling of the material. So without the justification of why is there a need for the exam, I really couldn't justify it. The same thing for users. In the 35.390 we actually increased hours.

Does the exam automatically guarantee that someone knows how to handle a material safety? What we heard was, no, it doesn't. We started looking for tradeoffs by increasing the hours, by adding this increased burden on the preceptor form. We felt that provided adequate assurance.

DR. CERQUEIRA: Dennis.

MR. SWANSON: One of the questions I have is, should this committee specifically go back and take a look at the changes that appear in the current draft final for 390, 392, and 394 since there were some changes made there?

Personally, I have some problems with the interpretation of some of that language.

MS. HANEY: Specific to training?

MR. SWANSON: Yes.

MS. HANEY: Okay. I don't know if you want to do that or not.

DR. CERQUEIRA: We have got the time. Not everybody has the actual language. I don't.

MS. HANEY: We have copies. Let me say this. What you might want to do is focus on your viewgraphs first and maybe everything but training and experience, and then come back to that. I think some of these viewgraphs, as soon as you decide who is going to say what and some key points, we can move real quickly through them and we wouldn't be rushing through it at the end of the day, and then we could have a little more time to focus on the T&A.

DR. CERQUEIRA: Why don't we do that. We will go to Part 35 viewgraphs, the ACMUI. There is a total of 8 pages there.

I guess we are going to have to delete John Graham

from the people listed on the front.

MS. HANEY: You can just say why he's not there, because they will be looking for him.

DR. CERQUEIRA: If we go to page 1, we have sort of a briefing outline, which basically goes through what we are going to do.

If we go to page 2, we have the general comments.

Dennis is not going to be with us, is he?

MS. HANEY: No. Dennis had a conflicting engagement this week.

DR. CERQUEIRA: We are going to talk about what is there, what we are going to say, and who is going to say it.

Does anybody have any disagreement with any of those bullet items?

MS. McBURNEY: I think it's pretty much what we had last time.

DR. CERQUEIRA: Yes.

MS. McBURNEY: I would still concur with that.

MS. HANEY: Chairman Dicus will hand off to you.

DR. CERQUEIRA: I could do these general comments. It doesn't take much input.

MS. McBURNEY: The outline and the comments.

DR. CERQUEIRA: Then we go to the next item, which is the Radiation Safety Committee.

MS. McBURNEY: I did that last time.

DR. CERQUEIRA: We can have Ruth do that.

DR. WAGNER: I don't see what we are going to say that is any different.

MS. McBURNEY: Did this change?

MS. HANEY: No. Lou is right. The safety committee is not an issue. They may ask questions based on do you think that two is the right number, should it be three or more. I honestly don't think they will get at that level of specificity. This is more going on the record, saying again what you said.

In essence, there is very little that I'm saying that is new too. Maybe about five minutes worth of what I'm saying is different from March.

DR. WAGNER: So there are going to be less Commissioners that we are going to be talking to this time.

MS. HANEY: Yes.

DR. WAGNER: There are not going to be any different Commissioners, are there? Are there going to be any Commissioners there who weren't there last time?

MS. HANEY: No, unless Meserve is in the audience.

MS. FLACK: They are really still interested in this issue.

DR. WAGNER: About the Radiation Safety Committee?

MS. FLACK: Yes.

DR. WAGNER: I wish we had some perspective on their

concern.

MS. HANEY: I will tell you their concerns. One could be this is a prescriptive requirement, that we are telling a licensee you have to have a committee. That is one side of it. There are those that are arguing we should not have prescriptive requirements. Then you have all the public comments that came in from the physicists community saying that the Radiation Safety Committee is very good and serves a useful purpose.

So they are trying to balance a quasi-prescriptive requirement because we have made it much simpler than what it is right now. Basically it says meet once a year and look at your program as compared to meeting four times a year and all of that.

This is a risk-informed approach to the Radiation Safety Committee, recognizing that if you only have diagnostic nuclear medicine, you don't need a committee.

The buzzwords of the day, if you can get all of these into every viewgraph, you get your travel reimbursed.

[Laughter.]

MS. HANEY: These are the buzzwords of the day: Maintain safety, reduce regulatory burden, public confidence, and efficiency and effectiveness.

We weren't using those words back in March, Lou. Any time you can incorporate these words without saying Cathy told

me to say this.

DR. WAGNER: That flows very well with the recommendation.

DR. CERQUEIRA: Certainly for the Radiation Safety Committee. Basically we have allowed the single use physician who can act as his own radiation safety officer.

Ruth, do you know what E, F and H are? When Cathy did her presentation she basically identified.

MS. McBURNEY: I wrote those down.

DR. CERQUEIRA: If you are doing dangerous, multiple source radiation, then you do need the committee.

MS. FLACK: Cathy mentioned early on that the Commissioners were especially interested in the effect on the stakeholders.

DR. WAGNER: Maybe it would be good to mention to the Commission that administrative law is when you have the higher risk situations. Administratively it is much easier for the physicists and the radiation safety individuals, who are mostly the ones concerned about this, to justify the establishment of a committee. When you don't have the regulatory requirement behind that, they don't have the administrative authority to get that done.

I think it is something that is needed in this case. So it's a very reasonable to do to satisfy that need, because it says it's something that is important.

MS. McBURNEY: As was mentioned earlier, there are probably not oncologists that do all these things. It is good to have them come together and talk to each other.

DR. CERQUEIRA: Exactly right.

Dennis, any comments on the Radiation Safety Committee?

MR. SWANSON: No.

DR. CERQUEIRA: We are going to skip the training and experience, page 4, and we will come back to that.

Then we are going to go to medical event. Lou, you did that last time?

DR. WAGNER: I don't think so. That was done by Dr. Stitt.

DR. CERQUEIRA: Yes, Barry.

DR. SIEGEL: Suggestion. Reject it immediately if you disagree with me. I have a concern that splitting this up so much in terms of the formal presentation of the slides is going to come off looking like a dog and pony show as opposed to you just doing it fairly quickly, making the point that what you are largely doing is reiterating important issues that you brought to the Commission's attention at the last briefing, and that you and the other members at the table are prepared to address their very specific questions on some of these issues at the conclusion of the presentation.

I think that if you keep passing the baton, it is

going to look peculiar. That is just my sense listening to you talk about how you are going to do it.

DR. CERQUEIRA: We could certainly do it that way. That would give them the opportunity to focus on the specific issues that they have raised which we are not fully aware of.

DR. WAGNER: I would much rather do it that way. Then we could address their concerns.

DR. SIEGEL: That is especially true if what Cathy said is correct, that Greta Dicus will let you get through your presentation before you start getting interrupted. If you are going to get interrupted at every slide, then there is some advantage to identify who the appropriate respondent is, but if you are going to get through it, then when there is a question about the pregnancy stuff, you can say, I'd like to let Dr. Wagner address that question because he is the world's renowned expert on radiation exposure of a potentially pregnant female.

DR. CERQUEIRA: That's fine. I would be very happy to do that. I guess if we go all the way through it, would it help to bring back the viewgraphs, or should we just let them basically do a free form question and answer session?

MS. HANEY: After you do your presentation, Dicus will open it up. She goes first and asks all of her questions. Then she will turn to McGaffigan. McGaffigan will jump you all over the place. Then Merrifield will do the same thing.

DR. CERQUEIRA: We don't know if Diaz is going to be

asking.

MS. HANEY: If the phone line works, he will actually come after her. They go in ranking order, seniority order.

DR. CERQUEIRA: That would be a good way to do it, because they will already have the viewgraphs ahead of time, and I'm sure their staff has sort of brief them.

MS. HANEY: They already have these.

MS. McBURNEY: They probably already have their questions.

MS. HANEY: They do.

DR. WAGNER: So the idea would be that we won't be addressing this individually, that you are going to be going through the slides as a brief overview, and then we are to say that we are here to answer for the ACMUI any of the concerns that you may have regarding our position on these topics.

DR. CERQUEIRA: Okay.

DR. WAGNER: That really is good, because that cuts to the chase.

DR. CERQUEIRA: Excellent suggestion.

MR. SWANSON: One comment would be, do you want to specifically comment on any changes since we last talked?

DR. CERQUEIRA: Am I going to remember that?

Cathy, what did we change?

MS. McBURNEY: We need to go through them.

DR. WAGNER: I don't see anything we changed on the

Radiation Safety Committee.

MS. HANEY: The T&E, there was a change.

Then on viewgraph 6, in March when we briefed the Commission we said 5 rem. We were pushing it to go into Part 20. Regardless of whether it went in part 20 or not we wanted it at a 5 rem level. I guess that really isn't a change.

I can't emphasize enough that you emphasize the impact on medical practice in this particular area based on what is really happening out there. That's the public comments that we received.

Viewgraph 7 is a change because this alternative rule text came into being. Say you haven't changed your mind on the first one; you still believe that, but whatever you want to say on the second bullet.

Implementation challenges is really the same thing with the exception of this early recognition of medical specialty boards, and you all are in the right place to say we really think they should move ahead because we want this in place by the time the rule becomes effective.

DR. CERQUEIRA: Right.

Niki, there are two items where your input would really be helpful to the Commissioners, and that is the unintentional exposure to the fetus or the embryo and the notification. They kind of see us as professionals who to some extent have a vested interest or an agenda to promote.

Earlier today you expressed some strong feelings about the notification, and I think if you could make some of those points, it would actually have much more of an impact coming from you than coming from us.

MS. HANEY: I think they will ask directly. My guess is there will be a question directed directly at Niki about that.

I think when you do introduce the members sitting with you, Dr. Cerqueira, it probably is good to say the perspective that they are coming from so that they are aware that Niki is patient rights and Ruth is state and Lou is physics.

DR. WAGNER: Shall we go through the slides and see what we are going to say?

DR. CERQUEIRA: Yes. I will go through and then I will give them the opportunity to ask questions.

We have identified minimal changes other than the training and experience in terms of what we presented last time and this time.

I am not going to make additional comments on these things.

MS. HANEY: At the same time, you don't need to read them the viewgraphs either. Ruth is right. They have had your viewgraphs for other a week now, and they pretty know what you are going to say based on these viewgraphs. I would pick a

couple of things out of each one of these viewgraphs that you want verbally on the record. A lot of the briefing is getting things on the record.

On page 2, for example. I think you could probably say the ACMUI does believe that the draft final rule is risk-informed and more performance based, and we do see where there is a focus on the higher risk procedures. That almost covers that first bullet.

On the stakeholder involvement -- I'm not making you say these words -- we endorse the Commission's efforts to involve the public in this through the entire process. We recognize that there have been several public meetings.

This is one where you might want to hit the public meeting aspect. Involving the regulated community, you do recognize that the rule has changed for the best because of this involvement.

DR. WAGNER: I don't suspect the Commission is going to have any direct questions with regard to these general comments.

MS. HANEY: They won't, but I will tell you, Lou, they have really been pushing the stakeholder involvement. That is all I would say about this viewgraph, and I would move on.

DR. WAGNER: So Dr. Cerqueira should just make sure he emphasizes that stakeholder involvement issue.

MS. HANEY: Yes.

DR. WAGNER: It's the other slides that are really the meat, because the Commission has to come back and say, okay, now we have a question about the ACMUI's position on this issue.

MS. HANEY: Yes.

DR. CERQUEIRA: Right.

DR. WAGNER: Are there an issues with regard to the Radiation Safety Committee other than what we already discussed? I don't think so.

MS. HANEY: I don't think so.

DR. WAGNER: We are going to come back to training and experience. Is that true, Dr. Cerqueira?

DR. CERQUEIRA: We keep saying we are going to come back to it. Should we just do it now?

MS. McBURNEY: Let's just do it.

DR. WAGNER: Let's just do it.

DR. CERQUEIRA: We said before clinical environment; the alternative pathways in addition to the boards; the preceptor statements.

Do we want to emphasize some of the changes that we have put in here, getting into the details?

MS. HANEY: I don't think so. I think it's sufficient to say that you endorse the alternative pathway, period. That is at least what we heard at the March from you

guys. Then just drop it there and let them come back and ask any specific questions.

We have a letter from the American College of Radiology, saying that they are happy with the 700 hours. That is about the only letter that we have received since the draft final rule was made available to the public on the hours.

The American College of Nuclear Physicians S&M did submit a letter to us that commented on several areas in the rule but it did not specifically address the duration of the training program.

I am assuming that everyone is more or less happy with where we are because they haven't sent me any letters.

DR. CERQUEIRA: Either they are happy or they are just tired. We've worn them out.

I have a pretty good handle on this. The things that we said we wanted to emphasize during the discussions we had the other day was basically the national standards. I can make some good points there, I think.

DR. WAGNER: Is there anything that we should be concerned about with regard to Commission queries or rumblings or issues with regard to training and experience?

MS. HANEY: They may ask you about the I-131 endocrinology use, because that is something that they heard from SR-6 Committee.

DR. WAGNER: The issue being the 80 hours of

training?

MS. HANEY: Yes. Do you believe 80 hours is sufficient or do you believe that it should be raised to 700 hours?

DR. WAGNER: I think the committee's answer to that is we agree with the 80 hours.

MS. HANEY: Correct. That's what you have told me.

DR. SIEGEL: And the safety record that has been presented.

I think you would also probably want to emphasize on that last bullet that even though this is Part 35 and you are doing a lot, the Commission is not off the hook, because it is going to need to grapple with what to do with training and experience requirements for intravascular brachytherapy and other emerging technologies in the very near future.

DR. CERQUEIRA: Right. I think the FDA is about to approve one of the devices for intravascular brachytherapy for cardiac use.

I think we are pretty much in agreement from the committee in terms of the regulations that have been proposed.

The medical event, endorse the final draft rule.

DR. WAGNER: This is one we are going to have trouble with because we don't have good representation on the committee from oncology. What should we be on our guard about here?

MS. HANEY: Actually, I have not heard anything from

the Commission with a concern about medical events at all. That doesn't mean they won't bring something out of the woodwork on us, but I think this is basically we like where the threshold is.

This one I did not talk about in my presentation. At this point it is one of the lesser issues with the rule. We did include it here because the ACMUI addressed it back in March. We felt that this would be something more that you might want to endorse again.

DR. WAGNER: I can't remember exactly what all our criteria were. I know we endorsed it, but I can't remember about the adequately capture events of concern and the dose thresholds. I couldn't recite those right now.

DR. CERQUEIRA: Can you do that, Ruth? I don't think I can.

MS. HANEY: I don't think we are going to that level of specificity on this. The big issues were patient intervention and wrong treatment site. I think if you just say that the changes to the rule adequately address those two issues, they are not going to go further than that. I may be eating my words at 11:30 tomorrow.

DR. WAGNER: We can only prepare to the extent that it's reasonable.

DR. CERQUEIRA: I will have to do a song and dance. If I am really stuck, if people know some of the information,

please volunteer.

Six is the unintentional exposure to embryo/fetus/nursing child. I think that is pretty self-explanatory in terms of the threshold.

DR. WAGNER: The thing that I am going to address there, which apparently you tell me is their concern -- I must admit I really get disappointed when people try to compare this situation with the embryo as being a member of the general public. That is just so inappropriate. You can't compare this to an embryo of a working mother. That embryo is clearly a member of the general public. You can't compare this to an embryo of a member who is out there walking on the street or walks by your facility or even works as as secretary within your facility. That clearly is a member of the general public.

This is a woman who is sick and happens to be pregnant. You cannot separate those two biologically. You cannot treat those two independently. You always have to do it with the full recognition that that woman is pregnant. Therefore, this is not a member of the general public, and quit comparing it to that. That's the problem.

Then from there on we have to discuss the level of reporting. That's the point.

DR. CERQUEIRA: Okay.

DR. WAGNER: I don't know whether there is anything else I should be aware of on this issue.

MS. HANEY: Somewhere is going to come up the impact on medical care. What I will have said already is that this possibly could lead to an increase in pregnancy testing because there are several diagnostic tests that will trip the 500 millirem level. Barry gave me some information about the different diagnostic tests that would trip the level, and there are several, eight or nine or so. Are you going to pregnancy test as a result of it?

The other issue would be the preferred provider issue, that the nuclear medicine facility may not be the same one as the laboratory as far as preferred provider, so now you've got an issue with the patient having to go multiple places.

Somewhere along the line we heard that there was a chance that HCFA might not reimburse for this type of pregnancy test, but I don't know if that is true or not. Maybe someone here knows.

DR. SIEGEL: HCFA is not entirely relevant since very few pregnant people are 65 or older.

MS. HANEY: You never know.

DR. SIEGEL: It could be Medicaid.

MS. HANEY: Insurance. Somebody said it.

These are not in order of importance. The other big one is that physicians may start ordering other types of diagnostic tests that would be less effective. Therefore you

are impacting the health care to the female population.

MS. McBURNEY: The other one that might come up is, is there a level greater than 500 millirem that will not have an impact?

MS. HANEY: That may come from Merrifield. As I said, Barry went through this and I should have Xeroxed this for you. It looks like most of the diagnostic tests, if the threshold was a 2 rem -- we talked about this before. I think you said, if I had to live with something less than 5, I could go with 2. Two might be pushing it a little bit. We might want to go up to 3 rather than 2. Split the difference.

DR. WAGNER: The issue has to be based upon something that is solid and something that is real. It can't be something that is fictitious or artificially made up.

MR. SWANSON: Let me ask you this question. I understand the congressional reporting requirement of 5 rems. What is the NRC going to do with reports between 2 and 5 rems?

MS. HANEY: We could do a couple of things. We could look at the circumstances of why the event occurred. We could get information out to other licensees under an information notice of don't let this happen to you.

MR. SWANSON: Is that in turn going to lead to you coming back and saying, well, you should have pregnancy tested this individual? What are your alternatives?

MS. HANEY: Right now we are pitching this as a

reporting limit and not a dose limit. I don't want to tell you if you call me and tell me that you had somebody at 3 that we wouldn't come out and do an inspection. Just because you trip this level does not mean that it's a violation or it doesn't even mean that it is a violation.

We are gathering this information and we would compare it against what the standards of practice would be. For diagnostic tests it is just ask the question. As long as your techs are just asking the question and if the patient lied, there is nothing your techs can do about it. If you get into the therapy area, the standards are the pregnancy test.

DR. WAGNER: This whole issue is going to get extremely complex. In reality, if you want to deal with this on the perfect level, you have to go into what is the gestation age and what is the dose and what is the risk associated with that, and all these other things. That is not something at the reporting level that we should be getting into. It is just too complicated. Those are all medical issues. What we need to do is make sure that this thresh old applies to all stages of pregnancy, from even prior to conception, at the ripening of the follicle. Go all the way back, and then from there on out.

It is very difficult to address this in an appropriate way, because from a regulatory basis it shouldn't go there. So we need a threshold that is proper for reporting, that takes into account all those issues. That is why we have

been emphasizing the 5 rem issue. That basically covers it from the reporting point of view.

DR. CERQUEIRA: Is this controversial with the Commissioners?

MS. HANEY: Yes, it is.

DR. CERQUEIRA: We have presented this to them before. Do you think they will have specific questions?

MS. HANEY: Yes.

DR. CERQUEIRA: Given that we have already made recommendations?

MS. HANEY: If I had to guess, this and patient notification is what you are going to spend your half hour talking about.

DR. CERQUEIRA: Here is where Lou can certainly provide all the factual information.

Niki, do you have a strong feeling on this, or do you fully understand the issue that is involved?

MS. HOBSON: On the 50?

DR. WAGNER: 50 millisieverts versus the 500 millirem.

DR. CERQUEIRA: Part of the implications of this is that you would basically almost have to do a pregnancy test on every woman within childbearing age who is getting these studies done, which would have tremendous financial implications, but more importantly, really would not reduce in

any significant way the risk to the fetus.

MS. HOBSON: If she does happen to be pregnant, you are going to scare the woman out of her wits. The popular culture of any exposure to radiation is that it's going to produce three-headed monsters. That is the image.

MS. McBURNEY: This is a reporting level to NRC that we are talking about now.

DR. WAGNER: Right.

MS. McBURNEY: You would not have to tell?

MS. HANEY: It's both, Ruth. That is part of what Lou is getting at. The importance there is that once you report to NRC, then you are also notifying the woman, and you may be notifying her at this very low threshold. If it is the 500 millirem threshold, are you unduly alarming this woman?

DR. WAGNER: I think the other issue that is very important is the coverage of the very early pregnancy and how the reporting level of 500 millirem essentially conflicts with standard of care in regard to the pregnant woman who is sick and how we manage those issues. Clearly this 500 millirem is in conflict with that. Therein lies our dilemma. We have to make sure that the reporting threshold is appropriate for all the stages of pregnancy.

MS. HOBSON: What happens you know a woman is pregnant and she also has a fatal disease?

DR. WAGNER: That is not unintentional. This only

refers to the unintentional issue.

DR. CERQUEIRA: Barry has got a comment.

DR. SIEGEL: That is the entire problem here. The problem is that the current standard for the vast majority of diagnostic tests is to use a variety of mechanisms to try to determine whether or not a patient is pregnant short of doing formal pregnancy testing on everyone, which still misses pregnancy in the first ten to 14 days. So you can't know about that even if you did pregnancy testing.

The only way you could do that is do what has been recommended in some European countries, which is actually in order to perform radionuclide therapy is to do a pregnancy test, then provide the patient with careful instructions regarding birth control and/or abstinence, and then 14 days later do a repeat pregnancy test, and then administer the therapy, which is insane. Just insane.

Since you are dealing with a patient population where the standard of care is just to ask the responsible question, then once you know whether or not the patient is pregnant -- let's assume the patient is pregnant -- for the vast majority of these diagnostic tests you now say to yourself, is there a better non-radiation diagnostic test that could answer this question? If there isn't, you do the test anyway. So even knowing that the patient is pregnant doesn't change your behavior as a physician.

That is in some ways, Manny, the point that I think you need to make most importantly, that this has the potential to really interfere with the way we make decisions from moment to moment, because it is putting the NRC in this reporting requirement in the position of maybe telling us that we shouldn't be going ahead and doing this test based on our best belief that this patient is not pregnant because of concern that we might later find out that she was pregnant.

DR. CERQUEIRA: That is a good point that I could make.

Ruth, do you have any comments that might help Niki?

MS. McBURNEY: I think setting it at 5 as a reporting level does address what Lou is saying. At that level, from a regulatory standpoint, then you might want to go back and look at were there any procedures that weren't followed.

DR. CERQUEIRA: We will go through this. Lou, I think we will depend heavily on you if there are specific questions related to this. Basically it doesn't change very much from the position that we said before.

MR. SWANSON: Is there any way we can tie the buzz words into this argument?

DR. WAGNER: I will do my best.

MS. McBURNEY: What were those again?

DR. CERQUEIRA: Maintain safety, decrease regulatory burden, increase public confidence, and efficiency and

effectiveness.

MS. McBURNEY: It's consistent with what you are reporting to Congress.

MS. HANEY: What they may do is argue public confidence. If you take those that have the idea that any radiation is going to produce a three-headed baby, how does NRC setting a reporting limit at 50 millisievert increase public confidence?

DR. WAGNER: I think at this point the answer to that is quite clear. It's not a matter of public confidence; it's a matter of patient confidence.

MR. SWANSON: Congress has set a reporting limit at 5 rem.

DR. SIEGEL: No. The NRC set the reporting limit at 5 rem.

MS. McBURNEY: To Congress.

DR. SIEGEL: The Congress didn't tell them where to set the number.

MS. McBURNEY: But it's consistent.

MR. SWANSON: Now we are arguing about defining a lower reporting limit. Why are we even arguing that point? NRC has already set it at 5 rem.

MS. HANEY: I think what you are arguing though, Dennis, is we have the reporting requirement to Congress at 5, but every other one of our reporting requirements is lower in

the regulation. So our policy in the past has been we want to hear about things before we have to tell Congress. This would be the only AO reporting requirement that we would not hear about until it hit the threshold that we needed to report to Congress.

MS. McBURNEY: The difference is that this is a patient versus a normal member of the public.

MS. HANEY: That is actually what got us down this path. About two years ago we revised our abnormal occurrence criteria, and this was one of the items that was caught up in that revision, and the Commission came back and said, well, it's a great AO criteria, but if you don't have the requirement for a licensee to report to us the information, then we are not going to be able to tell Congress about it. So the direction was to incorporate this into the regulations.

It is almost something that should go into a more general requirement, either our Part 20 or Part 30, 40 or 70, which are specific to the use of the material. This is not just limited to medical. We considered a lot of things, and the best thing was let's just fix 35. Where most of these reports are going to come from are going to be the medical environment as compared to non-medical. Once we get this all done, we will go back and look and see if we need to do rulemakings in any other areas.

DR. CERQUEIRA: Dennis.

MR. SWANSON: I can't seem to get my point across. It seems like the NRC has set as the reporting limit to Congress that there is a safety issue here at 5 rem. It seems to me like the only reason why we are reporting them at 500 millirems is to satisfy an advance notice situation for the NRC, which has nothing to do with safety. In fact, it erodes the patient-physician relationship, so it is eroding public confidence. It increases regulatory burden if we go the 500 millirem reporting requirement.

You have established a safety level already. This is just advance notification. That's all this is.

DR. CERQUEIRA: Those are very good points.

DR. WAGNER: Another case of a regulation written for the sake of a regulator.

MR. SWANSON: Right. So what are going to do with this information?

DR. CERQUEIRA: Those are good points. I will try to make some of those and let Lou handle the more detailed questions.

Niki, if you could make some comments on this, it would help.

Page 7 is notification following medical event or exposure to embryo/fetus/nursing child.

MS. HANEY: What you are battling against here is what level of assurance does NRC need in order to assure that

the patient was informed.

DR. WAGNER: This is where we have to go back and address what we were addressing earlier about whether the ACMUI is now take a position on this alternative rule that might come as a compromise. Is that right?

DR. CERQUEIRA: What page was that?

MS. HANEY: Let's try just looking at the last page of my viewgraphs. It should be number 28, which is alternative rule text. The notification part stays the same. You still have to notify the referring physician and the individual. That's the same.

Under certification, you are actually certifying that the licensee notified the individual. We would get a letter that said, "I certify that the patient was told," period. That's all the information NRC would get.

The business about the copy of the report and a description of the event, we would stay away from that. The concern from the Commission is going to be, are physicians telling their patients when medical events or misadministrations happen?

There have been just as many articles published that say, no, they are not, as there have been saying, yes, they have been. You can't go article against article on it.

At the March briefing the committee was asked in other areas of medicine are you telling the patient. If the

answer is yes, then I think you need to come across and say yes, we are telling the patients. Just kind of leave it there. They are looking for that assurance that it is happening.

DR. WAGNER: Are you saying there is no change to the rule itself except the enforcement issue?

MS. HANEY: Lou, in the draft final rule text we kept the requirment as is. We had no reason to change it at that point, because everything we have gotten officially from the Commission says continue to require patient notification.

In the March SRM they gave us a little bit of a window and said, however, you can give us alternative rule text that would allow for certification. This is what this is. They have it as an attachment to the rule package.

What you want the Commission to do is to replace the rule text that is in the draft final rule with this alternative rule text if they will not delete it.

If they will not eliminate the requirement, you can do your pitch for why it should be eliminated, and you can even stop there and let them come back an ask questions on the other one. Like I said, you don't need to say everything that is on the viewgraph. They may come back and say, but on your viewgraph you said. Then I think you can say, well, as a compromise the alternative rule text is better than what you have right now.

DR. WAGNER: Tell me if I'm wrong. If we go that

route, then the notification issue would be basically eliminated and replaced with a certification issue.

MS. HANEY: No. You would still have the notification. E would still stay in the rule text.

MR. SWANSON: What she is basically saying is that would still have the requirement in the rule text that you have to notify the patient. What you are doing away with is the requirement that you have to give the patient a copy of the written information. You can verbally notify the patient. Then what the NRC wants to see is a certification statement that says "I notified the patient," period.

DR. SIEGEL: That gets to the heart of one of the problems, which is that you go and you talk to the patient on the day the event occurs and you say, we did this, it was a mistake, we're sorry, we have to reschedule your test because we gave you the wrong stuff, the radiation dose is not a problem. Then 15 days later the patient gets a very formal looking letter and they say, you know, maybe that doctor wasn't telling me the truth. I'd better call my lawyer.

That is what doctors are fretting about. As it turns out there is almost no case history that indicates that this leads to malpractice litigation, but by the same token it is just one more thing. To use Dennis' term, it erodes the patient-physician relationship when it's just a face-to-face conversation about this is what we did and these are the

potential consequences.

DR. WAGNER: So this does eliminate the written notification?

DR. SIEGEL: It gets rid of the written notification.

MS. HOBSON: If there is no possibility that harm was done to the patient, what is the purpose of the notification? Why should you tell them anything unless there is real potential for harm? I think the patient does deserve to know.

MS. McBURNEY: I think the patient deserves to know.

MS. HANEY: NRC has taken a position that the patient should be told and the patient needs to know.

MS. HOBSON: But it is so frightening. If you are a cancer patient, you are already fighting for your life. Then you have this additional burden put on you, which doesn't solve any problem at all.

MS. HANEY: Niki, that is what they are going to look to you tomorrow to say. They were saying specifically were you going to be at the meeting. I think tomorrow you need to say that to them.

We have had previous patient rights advocates that were very much in support of the rule. But you are coming at it from a different perspective.

DR. SIEGEL: You are addressing the issue of therapeutic privilege, which is a very important one. In general, the ethical principle says that if a doctor makes a

mistake, you should tell the patient you made a mistake even if it's inconsequential.

What you were just addressing was if my telling this patient may actually put this patient less at ease overall or may -- I don't want to use the word "harm", but may in fact make this patient's anxiety level higher inappropriate, with no benefit, then my therapeutic privilege as a physician acting literally in that patient's best interest is to just keep on going and not bring it up.

On the other hand, if I'm always acting in my own best interest, I'm better off getting it right out on the table and saying, I made a mistake. The court records on that are eminently clear. I am far more likely to have major damages assessed against me if I tried to cover something up

MS. HOBSON: It isn't my purpose or agenda to try to protect the physician. If a physician does something that is wrong, that is malpractice or against medical ethics, et cetera, they should pay the price. But if it's within the tolerance that we have been talking about where no actual harm has occurred, I think the act of notifying the patient is harmful because it increases the stress level. As Dennis says, it erodes the patient-physician relationship. It makes the patient less confident that the world is going to be okay, that the medical community can take care of my illness.

MS. McBURNEY: But there are levels. It is not

within those tolerances. It is that that falls outside that tolerance.

MS. HOBSON: But aren't those levels set so conservatively that you can really predict whether or not that is going to cause harm? Unless there is scientific documentation that this misadministration or medical event is going to cause harm to the patient, I feel very strongly that it is harmful to drag them through this notification process, because it just raises all kinds of other worries in their minds, and they have got enough worries already.

DR. CERQUEIRA: That is a good point. I think the staff's alternative basically makes certain that you don't have physicians that are doing this repeatedly, because now they are still required to notify the NRC.

MS. HOBSON: I don't have a problem with notifying the NRC.

DR. CERQUEIRA: Yes, but the patient would also receive this notice. Even though the patient has been reassured and everything, it would create a whole lot of other problems.

Dennis.

MR. SWANSON: I think you also need to understand the regulations do allow at the advice of the referring physician not to notify you if they do think it's stressful. I think Dr. Siegel pointed that out. If it is viewed that it would be too

stressful for you, the regulations say that you don't have to tell them, except for the responsible relative.

DR. SIEGEL: Which is a mess, because the current interpretation of the responsible relative issue means that you can't get out of notifying because you think it will actually harm the patient. It has to also harm the responsible relative.

DR. CERQUEIRA: I think these points have been made in previous meetings. Pretty much the Commissioners are somewhat concerned about this, because they don't want to give the appearance of covering up anything by not notifying patients. I think the committee feels very strongly that we do need to make this point, and we will reiterate it.

Dennis.

MR. SWANSON: One comment about your alternative rule language. You have a regulatory requirement to notify the patient and you have a regulatory requirement to notify the referring physician, but you only have to certify that you notified the patient. I hate to add additional certifications, but it doesn't make sense why you wouldn't also certify that you informed the referring physician if that is part of the regulatory language. The current language focuses on the problem, which is the patient notification issue.

MS. HANEY: Probably (vii), certification that the licensee notified the referring physician and the individual.

DR. WAGNER: I would actually word it entirely differently. I'd say that you certify that you complied with item E, period.

MR. SWANSON: You could do that, too.

DR. WAGNER: That takes everything out of there. That you complied with item E. That way you might not have notified the patient because the referring physician may have said, don't do this, she's too high strung right now, this is going to be too much of a problem. I'll take care of it.

MS. HANEY: Lou, I don't think that would be an issue to change that, but I think the issue is whether we would accept certification at all.

DR. WAGNER: Is the committee going to take a stand on this? I would vote that the committee agree with the alternative ruling with regard to notification, with the requirement that the licensee certify that item E has been complied with.

DR. CERQUEIRA: Right, and the referring physician and individual have been notified.

DR. WAGNER: By saying item E you have already said that you have carried it out. With that change in the phraseology to indicate that the certification will simply state that the licensee complied with item E, I would move that the committee endorse that change as a potential alternative to our original position.

DR. CERQUEIRA: Do we have a second? I guess there are only four voting members here presently. Does that constitute a quorum?

MS. HANEY: Yes, because we are down so low on the members.

MS. HOBSON: I'll second.

DR. CERQUEIRA: Any further discussion?

MS. McBURNEY: Although I did abstain on the position that the advisory committee took not having that notification be done at all, I could support this alternative language. I think it still gets at a rule that says that you will notify. It is just a different way of doing it.

DR. CERQUEIRA: All those in favor of supporting the alternative rule text, as modified.

MS. HOBSON: I guess I should make one final comment. I haven't change my position that I think patient notification in general is a lousy idea. The alternative is definitely better than what is in the current draft. So reluctantly I would support this. If we have to say one or the other, then I would say this.

DR. CERQUEIRA: All those in favor.

[Show of hands.]

DR. CERQUEIRA: It's unanimous.

DR. WAGNER: Did you vote, Dennis?

MR. SWANSON: I can't vote.

DR. CERQUEIRA: He's not a voting member. There are only four voting members, Lou.

MR. SWANSON: If you want my opinion, I think what you ought to do is restate the previous position of the ACMUI.

DR. CERQUEIRA: Do you want me to do that during the presentation?

MS. HANEY: I think during the presentation you should say that the ACMUI continues to believe that there should be no requirements for patient notification, and it is up to you if you want to go on at that point and say, however, if there are going to be notification requirements, we support the alternative rule text over that which is in the existing rule, and then just go on at that point to the next viewgraph. That will come back as a discussion.

DR. CERQUEIRA: The version that they have is different than what we have approved.

MS. HANEY: I wouldn't worry too much about that, because that level of specificity is something that I can work with. When the staff requirements memorandum comes down, I can do that informally.

DR. CERQUEIRA: It sounds good.

The last two are the implementation challenges.

MS. McBURNEY: You already talked about early recognition.

MS. HANEY: You may get a question on the guidance

document and about your review of it. I got a question: did the ACMUI review it? I said that you had seen the early drafts of it, but it has changed significantly since then because the rule has changed significantly again.

You might want to spend a couple minutes talking about if asked, committee, do you want to review the guidance document again, what your response to it would be. We all know it, but a lot of this is to get it on the record. "The guidance document should not be used to implement de facto regulation." Those are some words you might want to get out.

You think that there is a benefit to having model procedures out there for licensees that are less sophisticated than some of the other licensees, some of the larger licensees. However, you believe the NUREG should be as flexible as possible to allow use of multiple different types of procedures.

Those are some of the things that you might want to spend a couple minutes talking about if asked.

DR. CERQUEIRA: Okay.

When will this document be coming out?

MS. HANEY: You're not going to see it for another three months. We haven't worked on it because we want the rule finalized before we make any more changes to the NUREG document.

The draft that went out, we went through it as

carefully as we could given the time constraints to make sure there were no de facto regulations in there. We still got criticism that we were using the NUREG as a de facto regulation.

A lot of that had to do with just interpretation how to use it. We use the terms "should" and "shall." If we use the term someone "should" do something, that means it's a nice idea but you don't have to, there is no regulatory requirement to do it. If we say the licensee "shall" do something, then there is a regulatory tie for it.

I think a lot of the comments that came back is people just didn't understand the difference, but we have got that in the verbiage up front, the difference between the use of the terms.

Our plan is to broaden it a little bit more with the model procedures than what went out with the proposed rule.

DR. CERQUEIRA: Lou.

DR. WAGNER: I have a question with regard to the issue of enforcement and the fact that a mind-set change is going to be required to be able to adequately enforce these rules because of their lack of prescriptiveness now. It is performance based. That is going to be a difficult challenge for the NRC and also for the Agreement States.

I can't predict what is going to happen, but I guess one of the pet peeves I have with regard to some of the

enforcement regulation is that when you write your policies and procedures about how you are going to do things and then a regulatory comes in and says, well, you didn't do it exactly the way you say right here, you didn't use this disinfectant, you used this other disinfectant, but that's against your policies and procedures, so here is a citation because you didn't follow your policies and procedures. That has happened.

It is that kind of thing that becomes a problem. Now we have this flexibility in here, and you are being held to a different kind of standard. What we have to really reinforce to the Commission is the challenge it is going to be for enforcement to be able to look at the performance and based it just on performance and not into the nit-picking issues with regard to what is on paper, what are we writing down here, and all these other issues.

This is where we have got to emphasize that. I think, Manny, we have got to come in and discuss that with them. They have a big task ahead of them here. This is not going to be a small task.

MS. HANEY: This is a good place to pitch continued ACMUI involvement with inspection procedures.

DR. WAGNER: The use of subcommittee would be wonderful with this.

MS. HANEY: This is the place to pitch it. Continued employment for ACMUI.

[Laughter.]

DR. CERQUEIRA: Not that they need it.

Ruth.

MS. McBURNEY: We had our annual meeting with the regional Nuclear Regulatory Commission state program staff yesterday. They were stating that they are already implementing a pilot program for performance-based inspections in the medical area.

No?

MS. HANEY: No. We're not doing it yet. It has not been approved yet.

MS. McBURNEY: Okay. They told us wrong.

MS. HANEY: Unless they were talking about some other program. We have considered doing a pilot program in the medical area that would focus on performance where the inspector would go in and look at big picture things, were there misadministrations, were there overexposures. That has not been approved by the Commission yet. They signed off on it, but it hasn't made it to the Commission.

Actually, we started it back in January of last year. We had a meeting with regional inspectors and came up with what the criteria should be. Then we held a public meeting on it. I think it was January, because I couldn't come because I was snowed in. We discussed the issues with the public that came and then further refined it. Just because of different changes

in the paper and everything it has not gone to the Commission.

It ties in very much to what Lou is saying, but it is the going in, looking at the big picture thing, not getting down at the nitty-gritty unless there is cause to. The classic would be the procedures for written directives. If we are investigating a misadministration or a medical event, we are going to ask to see those procedures. Then we may say, you said you are going to do this and this and you didn't do it, and then more than likely there is a going to be a violation.

On a routine basic in a medical facility, we are not going to go in and say, let me see those procedures. We might say, do you have them, and then say, great, and then just not even ask to see them.

It is a different mind-set, but this is a very difficult change for the program. If you want to go so far as the ACMUI wants to work closely with the implementation of the rule, there are a lot of challenges with this. Our plan is once we get further along we will go out and do training with the license reviewers and the inspectors. Hopefully, once the violations start coming in we will scrutinize things more than we would for a normal sort of violation.

It's a big change, but it's the way NRC is going. Not just in the medical area, but in all areas.

DR. CERQUEIRA: We are pretty close to our ending time. We have gone through pretty much all of the viewgraphs

that Cathy is going to go over and that I will present and then take questions and direct it to our experts from the panel.

Any other points?

Lou.

DR. WAGNER: Can we address with the Commission perhaps the issue of membership of this committee and the filling of the positions in a timely manner, and just at least get our point across that this seems to be a chronic, nagging problem that has not gotten solved over the years although it has been an obvious problem and we have brought it to their attention?

If we could address that issue, I would just like to know that the Commission is aware that there is a problem here with getting these positions filled in a timely manner and having people and representation on this committee. This committee works real well when you have got full representation, but if you don't and you have a certain key person absent and they are not there because there is nobody filling that position, the voting ability and the consensus ability, everything just deteriorates.

DR. CERQUEIRA: I think those are good points. I guess just trying to politically decide whether this is the forum to do it or not is something.

Barry, what do you think? You've been through these things more than any of us. Is this the right place to bring

it up? Can you do it incorrectly?

DR. SIEGEL: It depends a little bit whose head is going to roll once they realize that -- I probably wouldn't. If you are going to do it, I would do it right at the beginning. I'd say, you know, there are only four of us here today, and let me tell you why.

I wouldn't. I'd save it for a different forum, different time. I think you need to stay focused right on Part 35.

DR. CERQUEIRA: That is what I worry about. We have got this evaluation process which has been instituted.

MS. HANEY: I will put it in the self-evaluation. How about that?

DR. WAGNER: That's good.

MS. HANEY: That is going to the Commission. So we'll get it in there.

DR. WAGNER: That's great.

DR. CERQUEIRA: I think it would sort of diffuse the issue a little bit.

If there are no other comments, we will end exactly on time.

Dennis.

MR. SWANSON: I have specific comments on the draft language, but I will just point them out to Cathy and you can take it from there.

MS. HANEY: If Barry doesn't split, we can look at.

DR. WAGNER: Do we need a motion to adjourn?

DR. CERQUEIRA: Yes.

DR. WAGNER: So moved.

DR. CERQUEIRA: We are officially adjourned.

[Whereupon at 5:00 p.m., the meeting was concluded.]