Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Docket Number: (not applicable)

Location:
Rockville, Maryland

Date: Wednesday, October 18, 1995

Work Order No.: NRC-363 Pages 1-224/280-307

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers

1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON MEDICAL

USES OF ISOTOPES (ACMUI)

+ + + + +

WEDNESDAY,

OCTOBER 18, 1995

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 8:30 a.m., Barry Siegel, Chairman, presiding.

MEMBERS PRESENT:

BARRY A. SIEGEL, M.D., Chairman

DANIEL S. BERMAN, M.D., Member

WIL B. NELP, M.D., Member

ROBERT M. QUILLIN, Member

JUDITH ANNE STITT, M.D., Member

DENNIS P. SWANSON, M.S., B.C.N.P., Member

LOUIS WAGNER, Ph.D., Member

DAVID WOODBURY, M.D., Member

JUDITH I. BROWN, Member

Also Present:

Larry Camper
Josephine M. Piccone
Donald Cool
Sally Merchant
Torre Taylor
Manuel Cerqueira
Cheryl Trottier
Stewart Schneider
Trish Holahan
Cathy Haney
Jim Smith
Jim Clark
Mattew Combs
Susie Hoffman
Dennis Sering
Evelyn Watson
Peter Almond
Mel Griem
Carl Paperiello
Patricia Rathbun
Bob Ayres

A G E N D A

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

(8:36 a.m.)

MR. CAMPER: Good morning, ladies and gentlemen. I am pleased to welcome you to Rockville, Maryland and to the NRC headquarters for this public meeting of our advisory committee on the medical uses of isotopes. I am Larry Camper. I am the chief of the Medical, Academic, and Commercial Use Safety Branch, and I am the designated federal official for this advisory committee meeting.

This meeting -- this announced meeting of the advisory committee is being held in accordance with the rules and the regulations of the General Services Administration and the Nuclear Regulatory Commission. This meeting was announced in the Federal Register on the 25th of September, 1995, and that notice stated that the meeting will begin at 8:30 a.m. and we're just a little bit late.

The function of the advisory committee is to advise the NRC staff on issues and questions that arise in the medical use of byproduct material. The committee provides counsel to the staff but does not determine or direct the actual decisions. The NRC solicits the opinions of counsel and values the opinions of this committee very much.

The staff requests that the committee reach a consensus, if possible, on the various issues that will be discussed today but also values stated minority or dissenting

opinions. And we ask that you would clearly articulate those dissenting opinions as we discuss the specific agenda items. Our agenda today is once again full and I would request that you make your comments specifically germane to the topic under discussion and make them as succinct as possible so we can conduct as much business as possible.

As part of the preparation for this meeting, I have reviewed the agenda for members financial and employment interests. I have not identified any conflicts that based upon the very general nature of the discussion that we're having at this time. Therefore, I see no need for any individual to recuse themselves from the discussion. However, if during the course of our business you determine that you may have some conflict, please state that for the record and recuse yourself from the discussions.

What I'd like to do at this point before introducing the committee members for the record and so forth is allow Dr. Donald Cool, the division director for the Division of Industrial and Medical Nuclear Safety, to make some comments under the director's comments.

DR. COOL: Thank you, Larry.

I'm pleased to welcome you back once again for another meeting. For some of you, it was just like you were just here. Over the last few weeks, there were a number of subcommittee activities working on various modules and

activities related to some of our training. I was very pleased that the ACMUI was able to undertake that sort of endeavor and get into some of those details and provide us some assistance with that. So let me express my thanks to you for those special efforts and the work that was done.

I know one of the questions that was raised at that time or by some of those subcommittees was how does this now then fit into the overall structure with where the office of Nuclear Materials Safety and Safeguards is headed in terms of regulatory guidance and that process. You have probably heard at least rumor and innuendo, if not more so, associated with what has turned out to be a massive undertaking on the part of my staff to essentially re-engineer the licensing process for materials licensees. At a first, very superficial look, that seems, well, relatively simple. You go in and see what you're doing now. You see how you could do it better and you go and institute those changes. Unfortunately, as with all things, it's not nearly that simple, although we have been continuing to move through a rather substantial process which will continue over the next year or so.

One of the pieces of that process is a division of the whole way in which the guidance system that we use and put out for licensees and ourselves to use is formatted and organized. In some cases, it will also result in new guidance or changes to the guidance that exists there because of things

which are outdated, things which have been hanging around in drafts for long periods of time, and a variety of circumstances. That process is ongoing and in fact I will leave from here to go and meet with a management review team of NRC managers from the regions and headquarters that will be reviewing the efforts to date on that licensing guidance activity.

One of the things we have attempted to do is to build into that whole development process and outlining process a safety analysis of the system. The NMSS guidance for materials has grown up over a long period of time, 20 to 30 years. And with anything that sort of grows and evolves over the course of time, you get some interesting discontinuities and otherwise. And so we undertook a systematic analysis of the safety implied by the guidance activities and have now integrated that in the outline.

Fundamentally, the new guidance will deal with two areas. That kind of information which all, or at least substantial segments, of the licensee community needs to know. Fundamentals with regards to radiation protection. How to apply for a license. Securities of materials. Some of those sorts of things. And then from there, move into specifics for particular classes and types of licenses. So you can envision, and I don't care whether you draw the pyramid upside down or right side up, but moving from that which is very

general to that which is very specific such that if you are a particular licensee, and I'll pick radiography just to stay out of any of the groups that are here today. But if you were a radiographer and you asked the NRC, what do I need to know about this particular license. Or, if you were going to do mobile brachytherapy, or if you were going to intervascular brachytherapy, or any of a number of things that you have on your agenda today, you would be able to extract from that general and specific guidance that particular list of things that was directly applicable to you. We hope to have it all done electronically.

As a result, the efforts that you folks did in the subcommittee, and the ongoing efforts with a number of these modules, will fit, I believe, very nicely within this pattern because those are in fact the detailed specifics that will apply to any little particular class of licensee activities, and be dependent upon the other more general information which other people need to know.

I wanted to provide you with that brief synopsis. Later this afternoon we're going to be talking a little bit more about the re-engineering effort in general. But it is taking considerable amount of effort and time.

There are a couple other things that I just want to sort of note to you and then let you proceed on your way. You have a couple of topics on the agenda that I believe are

particularly important. One of them dealing with emerging technology and use. That is, the intravascular brachytherapy, which raises a number of questions with regards to ink packs, appropriate supervision, training, experience requirements, and otherwise for kinds of activities and perhaps kinds of individuals who have no previously been using sources, at least in this particular type of modality for treatment. So, that is something which I think bears considerable degree of attention because we are still on the front end of it enough so that we do not have to catch up. We can actually stay even with the power curve in this particular case.

One of the other things you have on the agenda is a discussion associated with medical consultants and how those consultants work in particular circumstances, what kinds of information that we might be looking for. And to try and get some clarity with what I've discovered over the past six months tends to be not necessarily very clear. And in fact, would almost lead you to believe that in order to be able to do your job you had to deny the request to act as a consultant because it was of relatively minor significance. Rather than making the statement for the record that based on the information that you had, this was of minor significance and being done with the job. It's a very strange perception although maybe perhaps you get to the same end point.

And so, I think that discussion in terms of how

you function as consultants, both you here on the ACMUI and of the other consultants that the agency retains for use in specific medical situations. That will be a very interesting discussion and hopefully we can get a little better clarity with regards to the sorts of things that can and should be done and the proper way to represent what was accomplished in that sort of thing.

Lastly, I want to simply mention the incidents that have been going on over the past few months. They are obviously not medically related in the sense that they involve the treatment of a patient with radioactive materials for diagnosis or therapy. However, I believe that what will come out of all of the efforts associated with the NIH contamination event where a female individual who was in fact pregnant at the time received internal contamination of phosphorus-32. There's been a great deal of publicity just of late associated with that and an event which the commission found out about just this week which was very, very similar at Massachusetts Institute of Technology. Again, phosphorus-32 internal contamination. Amounts of material at or very close to the regulatory limits for occupational exposure. Raising questions associated with the appropriateness of the rules and guidance that we have in place for security of materials. For functioning and authorities of radiation safety officers. For reporting and record keeping requirements.

And I bring these to your attention mostly for your information because there may well be a ripple effect that goes well beyond the simple broad scope license. Most of these broad scope licenses are liable to have medical problems associated with the problems -- programs associated with them as well as, perhaps, research reactors and other activities. And so, I would like you to at least have that in the back of your mind. If there is input that you might wish to make at some point during the conference, we'd be happy to receive that.

I have a minute or two to answer questions and try to keep you on schedule.

Barry?

CHAIRMAN SIEGEL: No specific questions. I'm quite interested in your last comment and I wonder what we can do to keep you all from over reacting. Because I am very concerned that extremely stringent security measures in reaction to what appear, at least initially, to be extremely unusual events, can really be very disruptive, not only of the daily conduct of business in a research university, but of the practice of medicine in a way that it can become very, very difficult to just conduct ones business.

DR. COOL: That is something that I am also concerned about. But you are right. That the pair of incidents, being as they are and coming with the timing that

they have, has resulted in a significant agency response. I should note that the NRC yesterday afternoon initiated an incident investigation team, it's highest investigation team effort which reports directly to the executive director for operations, to review the MIT action. We have been tasked by the chairman to review the regulatory aspects and the application of our regulations coming out of NIH and out of MIT.

And so, while I maybe can't give you specific items, were the committee to have some comments and suggestions about appropriateness of security in given situations and what some of those impacts might be, either generated during this meeting or perhaps separately as individual consultants, that input would be very useful. We are on a tight time frame. I would expect that we will need to be to the commission with our analysis and some recommendations by the end of the year or very early in next year. Typically, IITs are on-site for a week or two and then have 45 days to complete the report and provide the report to the commission. That will place it prior to the end of the year. And the commission will be expecting that the analysis associated with the regulations and guidance will be right behind it. So, we are in a very -- a relatively fast moving time frame.

CHAIRMAN SIEGEL: Given that time frame, consider

the possibility that one or more members of this committee might be asked to, not necessarily join the IIT team, but rather to come in at some point to hear what's going on and at least lend a perspective that you might not have within the agency.

DR. COOL: Certainly take that into --

CHAIRMAN SIEGEL: So, I'm sort of following two--

DR. COOL: -- as a thought as how to best try to accomplish that. That is an interesting idea.

CHAIRMAN SIEGEL: Judy?

MEMBER BROWN: I just had a question. I'm not familiar with the MIT incident. Does that seem to be the same deliberate internal action that the NIH was?

DR. COOL: We have nearly a matching set of allegations.

MEMBER BROWN: Oh, lord.

DR. COOL: And at this point, it's obviously way too early to tell what may or may not be truth. What generally happens is that the first reports of the events and everybody scrambling around, you usually figure that maybe 50 percent or more of what you just heard is wrong. That's part of what the team which is currently on-site is going to try and figure out. But there are statements to that effect and there is certainly some evidence which, if true, would lead you to believe that this was something besides accidental.

But, until the facts of the matter are ascertain with a lot more clarity, that is an open question.

Are there other questions I can answer?

If not, I wish you well in your deliberations. You have a very busy schedule. I will try to stop back by depending upon how much other activities with some of the incidents end up taking of my time.

Thank you very much.

MR. CAMPER: Thank you, Don.

All right. Let us continue with just a few more administrative items before we open business.

I want to introduce the committee members that are present today for the record. We have Dr. Woodbury at my extreme left representing the FDA. Dr. Lou Wagner who is a practicing physicist. And Mr. Dennis Swanson who is a radiopharmacists. And Dr. Judith Stitt who is a practicing oncologist radiation therapist. And Dr. Josephine Piccone who is a section leader for the medical and academic section. We have the esteemed chairman, Dr. Barry Siegel. And to my right, we have Mr. Bob Quillin representing the state regulator's perspective. And we have Dr. Wil Nelp who is a practicing research specialist and offers that perspective. We have Ms. Judith Brown who brings us the patient's concerns and advocacy types of concerns and issues. And we have Dr. Dan Berman who represents cardiology interests.

In addition to the committee members, later today we will be joined by several consultants who aid our agency in evaluating misadministration events when we talk about the use of medical consultants that Dr. Cool was referring to. We will be joined later today by Dr. Peter Almond, Dr. Mel Green, Dr. Petrovich, Evelyn Watson, and Dr. Richard Whittington. And at some point during the day they will join us.

I'd also like to point out to the members of the audience, and it very good, by the way, to see such a good turn out from the public. It's very encouraging to see your interest and I welcome all of you here. We do have a couple of requests to speak which Dr. Siegel will address shortly. And also, we'd like to draw to the attention of the audience the fact that there are several members of the medical staff available. We have Sally Merchant over here to my right, standing. We have Torre Taylor over here to the left. And we have Dr. Holahan, Trish Holahan. And of course, Josie, I've already mentioned. We have -- there may be some others around. I encourage you in the audience to chat with those individuals if you have questions about the medical program or processes. It may be easier to grab one of them than it is to grab Josie or I. But, we're also available if you have questions or thoughts and we encourage your questions.

Administratively, a couple of points. We do have restrooms to the rear of the room. Go down toward the

television, turn left or right. Unfortunately, there are no water fountains as Dr. Stitt has already pointed out on this floor. But I think she might have found one somewhere. And on the first floor there's a large cafeteria that has a very full selection of food and drinks. So, please make yourself available to that if you're so inclined.

So, with those introductions and administrative comments, Dr. Siegel, would you please chair the meeting for us?

CHAIRMAN SIEGEL: Thank you. Good morning, everyone. Short and sweet. I won't presume to say that the agenda for this meeting looks less onerous than the one we had for the last meeting which I thought we'd zoom through without much difficulty but it seemed to go on, and on, and on, and on. But, I think the issues this time look like they're relatively more focused and we ought to be able to get through each of them in the allotted time. And we ought to get rolling so that since we're already about ten minutes behind schedule.

We have three requests for public comments. Requests from the American Society of Nuclear Cardiology, request from ASTRO, and a request from Tri-Med. And rather than take the public comments as a block, I will use the chairman's prerogative to align those public comments with the corresponding discussion items so that they fit better with

what we're talking about. And consequently, the Nuclear Cardiology one will go with this first time this morning, the ASTRO one with the intravascular brachytherapy issue, and the Tri-Med one with the petition immediately following. And we'll actually take the Nuclear Cardiology comments following Sally Merchant's introductory comments so that the representative from ASNC can hear her material and help us focus the discussion.

I want to make clear, and Sally, I'm sure, will make clear in a moment, that we are not opening up for discussion the entire issue of training and experience criteria for licensure as an authorized user. That's not a topic of discussion that this committee is going to consider any time until after the National Academy of Sciences report has hit the street, until we've evaluated it, until -- and until the Part 35 rewrite gets going in earnest.

So, with that minor introductory comment, we will conduct our business today as usual. And we'll give everybody a chance to participate in consensus building.

Are there any other introductory comments from other members of the committee?

I'm told that ASTRO only gave us written comments and that no one's actually going to make a presentation. So we'll look at their written comments.

And with that, we'll let Sally take the floor and

tell us about review of training and experience exemptions by this committee.

MS. MERCHANT: As Dr. Siegel said, training and experience was an agenda item at the last meeting. As a result of that meeting, physicians who apply to be authorized users on NRC licenses but who do not meet, fully meet, the requirements of 10 CFR Part 35, Subpart J, require an exemption in order for that to -- for them to become authorized users. Exemptions requests will be reviewed by the ACMUI.

The purpose of this presentation is to develop some procedures for the advisory committee to use -- for the staff and the advisory committee to use. I've provided a strawman and I'm hoping that the committee will help me to fill it out so that we can come up with a really usable procedure.

Just for clarification, 10 CFR 35.920(b) is the other category for physicians who want to do diagnostic procedures and want to be authorized users to do the diagnostic procedures. And 35.920(b) requires 200 hours of classroom and laboratory training in basic radioisotope handling techniques and 500 hours of supervised work experience under the supervision of an authorized user, and 500 hours of supervised clinical experience under the supervision of an authorized user.

10 CFR 35.19 specific exemptions provides for those exemptions. And they say -- it says, in part, "The commission will review requests for exemptions from training and experience requirements with the assistance of the advisory committee on the medical uses of isotopes."

Applications to become authorized users on NRC medical use licenses are submitted to the appropriate NRC regional office. We're actually going into the procedure now. If, when reviewed, the submitted training and experience does not meet the criterion listed in 10 CFR Part 35, Subpart J, an exemption would be required to approve the request. The request for exemptions to Subpart J are forwarded to NRC's headquarters in the form of a technical assistance request which is a formal request from the regions for us to provide some guidance or -- does someone have a question? And we call those TARs. And you'll see them referred herein as TARs.

CHAIRMAN SIEGEL: Sally, real quickly, I think we've asked this question before I don't remember the answer. You are getting on average how many of these annually?

MS. MERCHANT: We don't have a number because as we discussed last time, there was some small overlap. So, if there was a small concurrence allowed, it -- between the 500 and the 500. And it varied and the license reviewer would review usually based on what they had done rather than hours. So all of them didn't come into headquarters.

Guidance is going out to the regions, and has gone out to the regions, to -- that all of them must come in now. So, up until now, we've only got one that needs to be reviewed by this committee. We expect it will be several. I really couldn't put a number on it.

What do you think, Larry?

MR. CAMPER: Well, I think the number that we actually get at headquarters is small. I think that probably 5 or 6 a year, perhaps one or two which makes it's way to this committee. But that's only part of the picture.

What we found when we queried the regions on this topic, we found that, in all candor, the regions were processing these types of applicants differently. Some of them were expecting more hours to be demonstrated. You might recall from Sally's first slide that there's 1,000 hours of experience with the types and quantities and clinical experience along with 200 hours of didactic. 200 hours of didactic is fairly simple and straight forward. It gets a little more complicated when you look at the 500 and the 500.

So, I think the bottom line is, is that at number of these applications, many more than the number I mention, probably on the order of -- I don't know exactly how many physician applicants apply to be authorized users per year, particularly for the limited use in cardiology, but I suspect the number's on the order of 50 to 100, something in that ball

park, I suspect, maybe a couple of hundred. But the numbers of hours that they have presented and the way in which they have been processed by the regions has varied and is different. And one of the things we're attempting to do, and there are several things, but is to try to lend uniformity and consistently to that.

You might recall that during the last meeting we discussed some of the problems that we were seeing and tried to developed a model for dealing with it more generically, if you will, although we weren't really talking about generic exemptions. We were talking about a model to use to process all exemptions, be it on a case-by-case basis.

So, I think the truth is as Sally says, we don't really know the exact answer but certainly there has been variability with regards to how they've been processed. And that's been part of the problem. We don't know just how many there are.

MS. MERCHANT: All right.

To apply for an exemption from Subpart J, the TAR must provide all supporting documentation including documentation of the applicant's classroom and laboratory training and documentation of the supervised work and supervised clinical hours the applicant has submitted.

The NRC's headquarters staff member who is assigned the TAR will prepare a package for the ACMUI with a

cover memo indicating the procedures of the review. The package will be provided to the NRC headquarters ACMUI coordinator who forwards it to the appropriate ACMUI members.

The procedure for the ACMUI review is as follows. The prepared package will be provided to the appropriate members with a cover memo indicating the time frame, typically two weeks, for review and procedures for returning responses. In order to comply with FACA meeting constraints, ACMUI members can't discuss the exemption request with each other and should submit their reviews to NRC in writing.

MR. CAMPER: Is it clear to all the committee members what Sally means by FACA meeting?

MEMBER NELP: No. No, it isn't.

MR. CAMPER: Sally, could you clarify that a little bit for them?

MS. MERCHANT: According to Part 7 of Code of -- of Title 10 of the Code of Federal Regulations, two or more members are a meeting. Meetings have to be noticed. Therefore, you can't really -- according to Part 7, you can't discuss this with each other. According to Part 7.

Are there any other questions?

MEMBER NELP: What's FACA?

MS. MERCHANT: That's FACA. Have we misinterpreted, Dr. Woodbury?

MEMBER WOODBURY: No, not that I'm aware of.

MS. MERCHANT: Thank you.

MR.CAMPER: Just point out, Sally will point out in a minute, Dr. Nelp. If it turns out that deliberation is needed, there is a mechanism for doing that.

MS. MERCHANT: We have that.

MR. CAMPER: She's not through that. But the problem is, if we disseminate the packages to committee members individually for your distinct and individual reviews, because of the sunshine provision associated with FACA, if you're going to deliberate with a colleague on the committee, we get into a noticed scenario. It's just public disclosure is the --

MEMBER NELP: May I be so bold as to ask what FACA means?

CHAIRMAN SIEGEL: Federal Advisory Committee Act.

MEMBER NELP: Thank you.

MS. MERCHANT: After the committee member has reviewed the package, the findings should be returned to NRC in the provided self-addressed envelope. I would ask that after you review the package, you either return the package to us or destroy it. Keep in mind that you, as well as your colleagues, would not like your private business publicized. So it's really better to -- these must be kept private.

Once all comments are received from the ACMUI members, the responsible NRC staff member reviews the comments

and determines a majority opinion. The staff, in consultation with the Office of the General Counsel's staff, makes the determination as to whether the exemption will be granted. The staff member maintains clear documentation of the ACMUI review and the basis for the final decision.

For applications for unusual or atypical use, the following procedure for a conference call may be followed. A time will be arranged by NRC with agreement from all participants for a conference call. And this would require a Federal Register notice. Minutes of the meeting will be prepared by the NRC staff and signed by the ACMUI chairperson or designee. The meeting should be scheduled within two weeks of receipt of the TAR.

CHAIRMAN SIEGEL: Sally, are you constrained by a 30 day Federal Register notice requirement, or can you shorten that?

MS. MERCHANT: I think that there is a provision for what I think is termed, and don't hold me to this, unusual circumstances such that Federal Register notices can go in with no time constraints.

CHAIRMAN SIEGEL: Torre, did you want to comment about that?

MS. TAYLOR: Yes, also it would be a closed session so we would definitely --

CHAIRMAN SIEGEL: In a way it's slightly

oxymoronic that you have a Federal Register notice to announce that you're having a closed session of an advisory committee. But I understand.

MS. MERCHANT: And then finally, the NRC staff member who was assigned the TAR provides a written response to the region. ACMUI members who participated in the review will be on distribution for the TAR so that you will be able to follow the outcome of what happened.

I have a series of questions. Could you excuse me for just a second. I don't know where they are.

CHAIRMAN SIEGEL: Do we want to take the questions now or do we want to wait and hear comments from the ASNC?

MR. CAMPER: Well, what I would like to do is at least, if we --

CHAIRMAN SIEGEL: Pose the questions.

MR. CAMPER: Yes. I'd at least to pose the questions so the presenter is aware of the questions. And then we can then discuss them -- let them make their presentation and then we can discuss the questions.

CHAIRMAN SIEGEL: Dan?

MEMBER BERMAN: Can we ask questions just to clarify what she presented?

CHAIRMAN SIEGEL: Of course.

MR. CAMPER: Sally, Dr. Berman --

MEMBER BERMAN: Sally, I just want to clarify something that you had said which is on, I think, on your second overhead that had 10 CFR 35.920(b). Is this -- If somebody applies with all of these, 500, 500, and 200, does that have to come through this exemption?

MS. MERCHANT: No, you've met the requirement.

MEMBER BERMAN: Good. I needed that clarification. Because related to that, I think, then, we have to have some basis for determining, well, if they don't meet this, then what's enough.

MS. MERCHANT: Well, the first question is, which members will perform the reviews? Is this -- This is your decision. Do we need the entire committee? Should it be a subcommittee of some number of members? Should there be any qualifying criteria? Is it something -- I'm kind of going through the questions because they all kind of group together. DO you want to have rotating committees where four will do it from this date to this date, four more will do it from this date to this date. This is entirely up to you. What do you think? Who should review these?

MR. CAMPER: Let me point out. As you ponder that question, and again, after the presentation we'll go through the questions in more detail. But as you ponder that question, you probably should bear in mind that I would expect to see more of the exemption requests being processed by this

committee than has historically been the case. Because, as I said earlier, our findings have been that the regions have processed these applicants differently. And this really all gets back to this whole concept of the fact that the 500 hours of the types and quantities and the 500 hours of clinical experience can be obtained concurrently. And that's bene sort of a working concept for years, probably with not the degree of clarification and guidance from headquarters that I would have preferred as I go back and look at it.

So, as a result, the regions, and for that matter, applicants and professional organizations, have interpreted the concurrent concept differently. Some believe that 500 and 500 translate into one 500 hours. I mean, that's concurrent at a one-for-one ratio. I think most of us in the program have viewed concurrent training a little bit differently than that. But then you start getting into a situation when you begin to articulate just what you mean by that and you start involving the Office of General Counsel and you start to get a literal interpretation of the regulations which is what we were discussing with you last time.

So, given that we have instructed the regions to look at these closely, to process them in a fashion that we're going to come to closure on today, we'll see more of these. So, you might bear in mind how you want to structure your deliberations given that we might see -- again, I don't know

exactly what the numbers -- but we might see 25, 30, or 40 of these a year.

MS. MERCHANT: I would also add that this does not mean you can't revise the procedure at the next meeting if we find that it -- that whatever the procedure that we all agree on doesn't work for one reason or another, it wouldn't be a major thing to revise a procedure.

CHAIRMAN SIEGEL: You don't need to see 35 or 30 of these a year. What you need to do is to revise the training and experience criteria to make them rational. And that's the problem. And I recognize that that's not an item that's open for debate.

MR. CAMPER: I think you said that, didn't you?

CHAIRMAN SIEGEL: And I said it. Well, we're not going to debate the specifics. We're going to get the principle on the table which I've done over, and over, and over again. And I have a couple more -- two more meetings, at least, to do so.

MEMBER NELP: I'm concerned that you really can't give us the volume of the work. I mean, if it's one a year, it's not very much. If it's 200 a year that are being processed out in the field, that might be worthwhile. But you're devoting a lot of time and effort to --I realize there is a problem but I would sort of like to know what the magnitude of the work effort is for the NRC. Because if it's

really as small as it might be --

MS. MERCHANT: Let me say just for your information, and I don't believe that this is telling anything that is proprietary. I've been doing a study of training and experience involved in it, been looking at the 200 hour courses, and I can say with some confidence that they graduate probably about 1,000 a year 200 hour. I would suspect that some portion of them will apply for exemption. They do greater than 1,000 a year.

MEMBER NELP: These are proprietary evening, weekend type courses?

MS. MERCHANT: Yes. So that's -- I can tell you that's what the volume is as far as those people that are taking the 200 hour course. I mean, that's just off the top of my head rather than give you -- they gave me numbers. Everyone was very cooperative.

MEMBER NELP: Are the instructors in these programs highly credentialed by your criteria?

MS. MERCHANT: I wouldn't want to get into that before we release the report.

MR. CAMPER: Let me make a comment there for your benefit, Dr. Nelp, and that of the committee.

Sally's referring to a study that we have done, private sector programs providing a 200 hour didactic component. That's phase 1 of a three phase plan. Phase 2

will be to go look at some of the residency programs that are going on because there have been some fairly significant comments which have been made about the quality and the number of hours being provided in a residency program. So, whether they line up with out regulations and whether we think -- what is actually going on is what we think is going on, et cetera, et cetera. So at some point in phase 2, we're going to put in place a contract to go look at residency programs. That will probably begin to occur early in calendar '96.

Phase 3 will be to compile all these findings and at some point during the process of the major revision to Part 35 which will commence following the National Academy of Science report, we intend to have amongst a series of public meetings a public meeting that would involve the various professional societies that have a vested interest in this. The American College of Nuclear Physicians, the Society of Nuclear Medicine, the American College of Radiology, the group representing the cardiologists, and so forth and so on, endocrinologists, and there may be others that I haven't thought of.

And at some point, we'll sit down with all of those bodies and we'll say, look, this is the current training and experience criteria in our regulations. We went and look at how that training is occurring. Now, this is what the training is. This is what we found. Why don't you talk to us

about, (a), Dr. Siegel's point which he brought up a few minutes ago and that is, what about the appropriateness and adequacy of the existing training. If this is not right, what should it be? And secondly, the mechanisms by which it's being provided, the actual number of hours of training that occurring. What's right with it. What's wrong with it. And how do we fit it. Or, for that matter, is the concept of achieving a number of hours the entirely wrong concept. Is there a better alternative? If so, what is it? So forth and so on. Because all those professional societies representing the various types of physicians practicing that want to use byproduct materials in the course of practicing medicine, we think they're the ones who should help us figure out what it should be. Because obviously right now it's very controversial.

So, the study to which she's referring is just phase 1 of a three phase program.

CHAIRMAN SIEGEL: David.

MEMBER WOODBURY: Well, Larry, the thing that seems to me to be is getting some feel for what numbers we're talking about. It makes a difference if we're talking about 1,000 per year, 100 per year, or 10 per year in terms of answering the questions you've asked us. I think that's the question Bill and I want to get some feeling for.

MR. CAMPER: Again, I wish I could give you a

number. I really do. If I could, I would. But with regards to the 1,000 number, Sally's number is a very accurate number in terms of number of physicians that are completing the 200 hour program on an annual basis. Obviously all 1,000 of them don't process their applications in the same year. They take -- some of the, for whatever reason, don't go on to complete the 500 hour, 500 your components. Some of them do it over a somewhat protracted period of time, several years in fact.

Again, I don't know the exact numbers but I think it's reasonable to assume that in the regions we're seeing 200 or 300 of these a year. And of those, if I take a look at how the regions have processed them differently, and I look at this current focus and clarification of what concurrent means or doesn't mean depending upon how one looks at it, I would expect that you'll probably see, again, I think a good working number is 30 or 40 of these a year.

MS. MERCHANT: Yes.

MR. CAMPER: Maybe a few more but I just can't be more explicit. I wish I could.

MEMBER BERMAN: Based on what you said and based on the growth of the field in cardiologists, and the growth of the number of people interested, and the 1,000 people per year supports this. I think it's an under estimation to think it's going to be small. It would, of course, depend on whether or not the track record is that there are any exemptions that get

through. Be it if they don't get through, they'll probably stop applying and everybody will come up with 1,200 hours. And so, our discussion about what -- is there any flexibility in that 1,200 hours is going to be relevant to this. But if there is some flexibility, I think it's going to be more in the range of a couple hundred or a few hundred per year rather than 30.

MR. CAMPER: That's a good point. I was going to mention that a corollary, a fall out of this, you're right, is that as the word gets out that there's more scrutiny being applied, some of those that would have applied for exemptions will not. Some will simply say, okay, I've got to get 1,000 and that's it and be done with it. Others may test the waters for a while. And you're right. We don't know how that will play out. But the numbers could be that high. I acknowledge that.

CHAIRMAN SIEGEL: What we've most often done in the past, this committee, is that we've been asked to look at training that essentially met the required hours but was acquired in unusual training circumstances, such as in a practice environment as opposed to in a formal institutional training environment. And so, we've been asked to judge whether the quality of the training experience based on the documentation provided to us in that unusual educational environment was appropriate for approval. We have not been

asked to say this person only has 600 hours but he says he's a good guy and his preceptor says he's a good guy. Should we approve it. And frankly, I think that that would be an exceedingly unfair and dangerous thing for us to do. And the right way to attack that one, Dan, is not to allow exemptions while these rules are in place, but to deal with these rules in a logical orderly fashion as quickly as possible.

MEMBER BERMAN: I think, though, that if you do focus the discussion only to what you said, that you will have, I believe, excessively narrowed the scope of what could be done through this committee. It was -- That's why I clarified in my question what did 10 CFR 35.920(b) say. It says, 1,200 hours. What are being asked to look at? We're being asked to advise on exemptions. People who do not meet exactly what is there.

Now, your interpretation of what our scope might be was just now focused on whether it was done in a full-time training program or in a not full-time training program. Based on Mr. Camper's earlier discussions here, which was that in the past there has been -- and Sally Merchant mentioned that there has been a small amount of concurrence allowed, and Larry just referred to the fact that there has been some concurrence allowed, it's part of, I believe, necessary for this group to discuss the question of whether any degree of concurrence can be allowed in order to determine whether or

not an exemption is discussable.

CHAIRMAN SIEGEL: We've all -- the issue of concurrence is addressed in the regulations because it says all of the above can be accomplished in a six month training period. And we know that 1,200 hours is more than six months. That's the level of concurrence that's built into the regulations themselves. I think it would be exceedingly dangerous for this committee to deviate from that concurrence posture without the whole issue being really analyzed in great detail. And first of all, we don't have the time to do it today. We're already ten minutes over schedule and we haven't heard from the ASNC yet, and haven't answered the questions. And we -- to do it before the National Academy of Science's report would just be not right.

MR. CAMPER: A couple of points. Let me just interject here, Sally.

Barry, I understand what you're saying and I know why you say that. But let me bring a couple of things to bear that the committee must keep in mind.

The problem that we -- where we are today is today is that the concurrent issue has been dealt with informally historically. What has happened though is that as a result of increasing interest the staff has been forced to deal with this issue in a logical approach and understand exactly what needs to be done to process these. When that

happens, you then get into an interpretation of your existing regulations. The more there is pressure applied, and the applying of pressure is okay, we don't mind that. That's part of the regulatory process. But what happens when that occurs is that you then are forced to deal with things literally and to put in place a procedure accordingly.

Now, our dilemma then, having said that, is as follows. You have a couple things. 35.19 talks about specific exemptions. The gist of 35.19 is that exemptions will be entertained by the Commission. It goes on to conclude by saying that the Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes.

Now, what that means for you, unfortunately, ladies and gentlemen, is that it's not just about whether or not it's been obtained in a formal program or an informal program or a private hospital or whether it seems to pass the smell test. It's more than that. It's evaluating and assisting the staff in any exemption request and that could be as simple as 500 hours versus 1,000 hours.

Now, you also cannot come to a conclusion ahead of time that you will not entertain anything but 1,000 hours because you must evaluate each exemption on a case by case basis. Now, Barry's point, Dr. Siegel's point

about really entertaining less than 1,000 hours at a time when we know the real issue is to look at the training experience requirements is obviously a very logical approach and it makes sense. But the problem is, unfortunately, you can't give yourself the luxury of doing that approach because you simply must help us entertain any exemption and we must look at them on a case by case basis.

You may in the final analysis conclude through your Committee deliberations that you're not prepared to let Dr. X submit less than 1,000 hours and your rationale is, or Dr. Y or Dr. B or Dr. Z. But again, you must entertain it on a case by case basis.

CHAIRMAN SIEGEL: And my major concern is that it would be inappropriate for this Committee to exercise its perhaps whimsical judgments day by day on a case by case basis when there are fundamental principals that need to be established first and that we're not going to be able to establish until the whole set of arguments are on the table.

The correct community response to what you just said, Larry, is for every cardiologist who wants to do this, but simultaneously every radiologist, every person with any other kind of training, and every radiation oncologist who wants to be able to become certified to do this with only one year of residency instead of four years of residency to instantly put in a request so that the ACMUI can

spend its full time doing nothing but evaluating those requests.

I'm making a reductio ad absurdum here intentionally to point out the fact that it's wrong for this Committee to deviate very much, if at all, from the rules that are currently in place until the basis for these rules have been reevaluated thoroughly, carefully and rationally. I acknowledge that you've got procedures here and we'll take those exemptions as you get them and we'll duke them out. Depending on who's in the room on a given day, you may or may not get outcome A versus outcome B. That really to me seems a terrible mistake.

MR. CAMPER: Well, I understand again why you say that way, but that's exactly what we'll have to do because there is a mechanism for exemptions in the regulations. It's explicit that if it deals with training and experience we'll use the Advisory Committee to aid us. We do that because as physicians and as physicists and radiopharmacists, et cetera, et cetera, the concept is that you're in the best position to aid a regulatory staff. None of us are physicians, but many of us are physicists and so forth. But you're in the best position as practitioners to aid us in determining whether or not the training and experience presented is adequate or if it should be grounds for an exemption. Unfortunately, the simple truth of the

matter is whatever we end up doing, whatever it might be with regards to adjustments in the training and experience criteria, and no one knows at this point, but whatever it is it will take a substantial amount of time for that process to play out given the public due process that's associated with rulemaking, et cetera, particularly one of the magnitude of the planned revision of Part 35.

What that means is that probably over the next three or four years, I suspect, there will be many exemption requests that this Committee will need to review under the current criteria. I understand and I know why you feel the way you do, but that will be the challenge before the Committee. Unfortunately, we have to deal with the rules we have now until such time as they're changed.

MEMBER BERMAN: Barry, I think that given the fact that what Mr. Camper has told us is that these exemptions will be entertained, that there will be, I believe, many applications that are going to come before the Committee. Now, one possibility would be that we're going to just adhere to our time schedule. We're not going to even discuss what are going to be the various people who might sit on these committees attitudes towards this concept of concurrence or we could have at least a discussion at this point so that we can understand what kinds of issues should be dealt with as we're going to be dealing with these exemptions. I think that it's

wrong to eliminate discussion at this point in this morning's meeting because of the fact that we are going to have to go ahead and evaluate these exemptions requests.

I am a cardiologist and a nuclear medicine doctor. I sit on this Committee because of my representation of both sides and I need at least a few minutes to be able to discuss a view about what is behind this issue of concurrence. I guess there's a request from ASNC to present.

So, it seems to me that there are several minutes of discussion that need to take place this morning for us to have a good concept of what to do over the next year in terms of these exemptions.

MR. CAMPER: I would suggest that -- again, I certainly understand your concerns and Barry as the chair can orchestrate this. But again, I think the point that Barry made in the beginning is the one to focus upon. To the extent that you can focus your discussions upon the process for the handling of exemptions requests and the process of this Committee reviewing those exemption requests as opposed to the question of whether the training and experience is right, the level currently in our regulations is appropriate or not, you need to focus upon processing of because you'll never resolve the other issue at this point and there will be an opportunity to do that.

MS. MERCHANT: May I suggest that if there is some discomfort with the procedure of independently reviewing and not concurring, we could probably set up conference calls with those members that you all decide would be appropriate and resolve several at one time. That's another way to approach it. The B method for unusual or atypical applications. If it would make everyone have a higher comfort level, it could be arranged. It would not be something that we couldn't do.

CHAIRMAN SIEGEL: I think we should deal with the procedural issues and we're going to because those are the questions you've asked us. I think we really can't deal with the specific exemption issues. I've said that 19 times and I'm saying it again. In part, I think having this Committee look, as directed by the regulations, on a case by case basis will help focus this Committee's thinking when it comes time to advise the NRC on the overall redo of the process.

MEMBER BERMAN: But the problem that I see is this, Barry. You as the Chairman have said that it's your view that the degree of concurrence that it would be acceptable would be to go from 6.92 and from 1200 hours down to 6 months, which is a reduction of some amount of time. Your opinion is that -- if I interpret what you said earlier, the way you read it, we should be looking for that 1,000 hours

and the 200 hours, look for the 1200. If they're not there, then we don't even consider it. I believe that we need to understand are you correct in giving that as your opinion? Is that the way it is or, in fact, is there some flexibility that you have not expressed? If you're prepared to say that you say it's 1,000 hours and that's as low as it goes, then that would be the end of the discussion. If not, we need to discuss this.

MS. MERCHANT: Let me put something else in here rather quickly. You all once reviewed a physician's training and experience who did not meet the 1200, decided that the experience that he had had was excellent and you suggested what else he needed to do in order to meet. It was not -- he actually had not gone through a formal procedure. What you suggested was very doable for him. So, in some of those cases, although you may not accept what's submitted, after reading what the physician has done, we would hope you'd make suggestions that this physician would meet if he did whatever you found appropriate.

CHAIRMAN SIEGEL: Dan, I completely understand what you're saying and I'm just telling you that I think that for us to open this up in the mechanism you suggest will create a free for all. I don't think that that's the way federal licensure should occur. For us to simply sit down and look at Part 35 and say, "You know, what we really think is

that you can really do all of this in three months," and let's come right out and say that, a lot of work went into the creation of these regulations. Obviously a lot of political pressure in multiple directions went into the creation of these regulations. For this advisory committee to sit here in ten minutes, we're way over time now, and think that we're going to open this up when this is going to need to be a multi-day discussion after much evidence is on the table doesn't make sense.

I'm willing to do whatever the Committee believes and we'll juggle the agenda if that's what we need to do.

MEMBER NELP: I'd like to make a comment. It seems to me that you're dealing with a problem out in the field and you want us to help you with it. If you have people out there that you're granting exemptions to and you don't think that they're qualified or it's questionable or you don't know how -- bring us to date. I haven't seen one such situation. So, we're talking about a rather nebulous area as far as our own personal interaction with these individuals.

I would be happy to review them in light of the guidelines. Enough said. But go ahead and do it. If your people in the field are feeling pressured, then fine, I'd be happy to look at it. But I agree with Barry, the

regulations are in place. If I want to be qualified or certified to do something in the medical sphere that doesn't have anything to do with radioactivity, if I want to be a certified oncologist or a certified endocrinologist or a certified cardiologist, I have to get the training and follow the rules. There's no -- there's some flexibility, but not a whole lot.

MS. MERCHANT: Yes. I do not believe -

-

MEMBER NELP: So that's how we look at it. That's my advice.

MS. MERCHANT: I don't believe that we have granted authorization for anyone who is unqualified. I believe that the license reviewers --

MEMBER NELP: That's fine. I'm not perceiving the problem to be -- I don't understand exactly where the problem is. If you have a problem with your people in the field, we'll be happy to assist them in evaluating credentials.

MS. MERCHANT: Larry would like to answer this.

MR. CAMPER: Let me make something clear. We don't have a problem with people in the field, Dr. Nelp.

MEMBER NELP: Okay.

MR. CAMPER: We don't have a problem with authorizing unqualified users. Let me try to articulate what the problem is.

MEMBER NELP: I would like to know what the problem is.

MR. CAMPER: All right. Let me tell you what the problem is. Our regulations, if you read them, are very explicit. Two hundred hours, 500 hours and 500 hours. That totals 1200 hours.

MEMBER NELP: It also, I believe, says this can be condensed to the equivalent of six months.

MR. CAMPER: No, actually it does not say that.

MEMBER NELP: Oh, I'm sorry.

MR. CAMPER: It says something a little different than that. There is the board certification pathway. There is a pathway which we refer to as the "or" pathway, which is the one I just described which is 200 hours, 500 hours and 500 hours, and then it has something else which literally is not correct also. It says, "has successfully completed a six month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience and supervised clinical experience in all the topics identified in Paragraph B of this

section." That doesn't exist.

What happens is that that group approves programs, some of which contain within them a six month program. But we're not aware of any literally six month programs as described in that language that are approved by the Council. Okay? So, the language is off base also.

MEMBER NELP: I'm sorry. I thought that meant if they came and trained with Dr. Berman for six months in his approved program and they focused on, in this case say, nuclear cardiology, that that was the intention of that statement. I believe that's what happens frequently.

MR. CAMPER: Let me try to articulate for you what the problem is. It's not a question of our people in the field being able to review these. The problem is this. For years there has been a working concept and my predecessor, for example, Dr. Glenn, is on record as saying that training can be obtained concurrently. But that's all that was said.

Now, some people interpret that to mean concurrently with regards to the types and quantities experience and the clinical experience as being one for one. Therefore, 500 hours resulting in a total of 700 hours, whether they do it in three months or six months or two years, 700 hours.

Now, the problem is as attention has

continued to be focused upon this and as it became aware to us that there was interpretations of concurrent differently than we perceived it and we ourselves have never set down and said, "Okay, exactly what do we mean by concurrent?" We know that some of these things from receipt of package to administration to the patient are done on a continuum. There's a concurrent effort going on there.

So, as we attempted to articulate in guidance space for use by our regional reviewers just what we meant by concurrent, we developed and brought to this Committee a model. The Committee resoundingly said, "We do not want to entertain a model that could be used as a guideline by your regional reviewers for the granting of exemptions because we think that that, in essence, is a de facto way of creating a different set of regulatory criteria." Rather, we want to see each one on a case by case basis and we'll aid the staff in achieving the exemption possibility and pathway allowed in the 35.19.

Where we are today is to say, "Okay, we heard the Committee. We, in this case, chose not to go against the Committee's advice but rather to embrace the Committee's advice. We're now discussing with you a mechanism to achieve that."

MEMBER NELP: And we said if you have a problem with those applicants, we would be happy to review

them and assist you in evaluating their training, experience and credentials. That's a pretty simple solution. I bet you it wouldn't take me or Barry or anyone around this table very long to assist in a single evaluation.

CHAIRMAN SIEGEL: Judy?

MEMBER BROWN: After the NAS report is received and the revisions are done, will you also be granting exceptions under those new revisions?

CHAIRMAN SIEGEL: Almost certainly.

MEMBER BROWN: So you'll still be making it up as you go along.

CHAIRMAN SIEGEL: That's one way to characterize it.

MR. CAMPER: Well, Judy, we would hope in the best of worlds we would come up with a set of criteria, although you'll never get total agreement. You hope that you'll ultimately develop a set of criteria that is reasonable, that is fair, that is obtainable and that the community helps us come to closure on. But despite that, there will always be a possibility for exemptions. There has to be an exemption possibility in the regulations.

Now, when you develop regulations, what you're trying to do is develop the type of regulations that won't require a lot of exemptions, the granting of. But there will always be some.

CHAIRMAN SIEGEL: The notion that the concurrence equals six months, there is some historical precedent for that in terms of the fact that the assurances provided to the NRC by the American Board of Radiology such that it achieves deemed status under the regulations is based on the ABR's assurance that its candidates will have received six months of training and the ACGME acts accordingly. Now, whether six months is the right number, four months is the right number as many argued ten years ago, or whether three months or a week with the right kind of preceptor statement is the right number I think can't be open for debate right now, but I think must be debated carefully, thoroughly and changed in the future.

Dan, I know we're disagreeing on this issue, but you actually realize that I agree with the posture that the construct that is currently here doesn't make sense and that the NRC's role needs to be focused on the radiation safety aspects of this and the training requirements need to be much less to be an authorized user under an NRC license and be divorced completely from the clinical training requirement. I believe that, but I'm not willing to change it in ten minutes at this table.

Now, having said that, we're way over schedule. We have a request from Dr. Cerqueira to make a statement on behalf of the American College of Cardiology and

the American Society of Nuclear Cardiology. Five minutes is allotted. He can make the presentation.

But Manny, I would ask you please to limit your comments to the procedural issues that are before us. If you tell us that cardiologists only need three months of training, I don't want to hear it because we know that that's what you're going to say and we may even agree with you, but it's not germane to what we're talking about today. So, try to focus. If you do it in less than five, we'll appreciate it.

DR. CERQUEIRA: Well, I'll certainly try.

On behalf of the American College of Cardiology and the American Society of Nuclear Cardiology, I'd like to thank the esteemed Chairman Siegel and the rest of the --

CHAIRMAN SIEGEL: I don't mean to interrupt you. Esteemed chairman. I remember a few years ago when the name of one of our major corporations was -- people started to think it was known as ailing Chrysler. I'm starting to wonder whether esteemed chairman is --

DR. CERQUEIRA: Well, I'm just following up on Barry's -- and the rest of the Advisory Committee for giving me this opportunity to address the issue of training and experience criteria for authorized user. My

comments will be general rather than trying to deal with the specifics that have been discussed during the last half hour.

The mission of both the College and the American Society of Nuclear Cardiology is to foster the optimal medical care for patients through professional education, development of standards and the formulation of health care policy. We are in complete agreement with the Committee about the importance of radiation safety in the use of nuclear cardiology procedures. Stipulating a certain number of hours or months for training was developed as a vehicle to ensure an adequate level of training necessary for public health and safety.

Our organizations have always maintained that a nuclear cardiologist is concerned only with the imaging of a single organ system, that is the heart, and in maintaining a radiation risk to the patient that is as low as is reasonably possible.

We believe that the previously acceptable practice of allowing physicians to concurrently complete their required supervised clinical and work experience has worked well and is sufficient to assure radiation safety and the practice of nuclear cardiology. To change this policy is potentially arbitrary and restrictive. Furthermore, we have no knowledge of any serious violations of radiation safety among nuclear cardiologists who are licensed

under the current interpretation of the regulations.

Our concern is that the ACMUI reviewers may experience a conflict of interest in judging the applications that are brought before the Committee. A discussion of turf, as happened at the last ACMUI meeting, clearly demonstrates the validity of this concern. The College and the American Society of Nuclear Cardiology strongly recommends that the Committee maintain the current method of licensing that recognizes concurrent training as a viable and accepted standard. However, if the Committee decides to move forward with their review of each exemption that is presented to it, we would support the review of nuclear cardiologist's credentials being done only by individuals with board certification in both cardiology and nuclear medicine and/or radiology.

We look forward to the review of the current regulations by the National Academy of Sciences. The American College of Cardiology and the American Society of Nuclear Cardiology also look forward to working with the NRC staff and the Advisory Committee on the most effective training for our members that will ensure the highest level of radiation safety both to the physicians and to the general public.

Thank you very much.

CHAIRMAN SIEGEL: Manny, thank you.

Let me ask you a question.

DR. CERQUEIRA: Sure.

CHAIRMAN SIEGEL: Your statement about who should review, repeat that again?

DR. CERQUEIRA: Well, it's our feeling that basically we should have a cardiologist and somebody who is also board certified in nuclear medicine and/or radiology to review it to avoid some of the turf issues that were clearly obvious during the last discussion.

CHAIRMAN SIEGEL: Yes. I think the notion that we would entertain as this Committee an application from a cardiologist for an exemption and exclude Dr. Berman from the discussion is incredible to me. Under no circumstances would I allow that to be conducted. If we were planning a conference call review of such a thing and Dr. Berman was unavailable, I would insist on it being rescheduled.

So, the suggestion that this Committee's activities would be designed to restrain trade I find a little bit offensive.

DR. CERQUEIRA: Yes.

CHAIRMAN SIEGEL: We want to state for the record that the approach that this Committee would take so long as I help to guide what it does will be as fair as possible, as fair as reasonably achievable. That's AFARA.

DR. CERQUEIRA: Well, that's very reassuring information. We certainly weren't implying that the Committee would in any way deal with the issue in any manner other than what you've just described very eloquently.

CHAIRMAN SIEGEL: Bob?

MEMBER QUILLIN: Since I represent the Agreement States which actually will look at more of these than the NRC will look at, and since I have a role of trying to be a liaison between this Committee and the Agreement States, I also think somewhat umbrage at the comment that only two groups should look at this and these kinds of applications because it's really necessary for me in my role on this Committee to let the Agreement States know what the ACMUI is thinking.

DR. CERQUEIRA: You're right.

CHAIRMAN SIEGEL: So, having heard that and having heard your comments, let me suggest the following, and this is not a position I had until I've heard this discussion. I would suggest that the way we ought to handle these exemptions is that we ought to do it as a committee of the whole so that we have all the representation and we have the full wisdom and expertise of all the people on this Committee, that we should do that as many as possible as part of our biannual meetings as we can cram into those meetings and when we need to do more that we do it by noticed

conference call meetings so that we can have participation of all of us who are available at that moment to participate in the discussion.

I'm concerned that the paper reviews will deny each of us from the wisdom of the other person's point of view and assessment of the training and experience of that individual. I also believe that the desire for having the whole Committee involved is motivated by bringing the whole Committee up to speed for the major debate which is going to be --

DR. CERQUEIRA: My only comment to that, Barry, would be that you'd like to get a procedure that would have a relatively good turnaround time. What you're proposing would be somewhat cumbersome in the sense of getting --

CHAIRMAN SIEGEL: We all have telephones. Most of these individual exemptions can be dealt with. In past experience they've been very short meetings.

DR. CERQUEIRA: But the Committee has what, 17 members?

CHAIRMAN SIEGEL: What?

DR. CERQUEIRA: How many members are on the Committee?

CHAIRMAN SIEGEL: There are actually only 12 or 13 at the moment and we need, therefore, more than

half for a quorum according to our rules. We would make certain that a quorum would include individuals with the-- and we can discuss this procedurally, but if we were doing a radiation oncology one, we wouldn't want the quorum to exclude both Dr. Stitt and Dr. Flynn. I don't think that's procedurally complicated and I think that there is real benefit to having the whole Committee involved. But I'd be willing to see what other people think.

MEMBER SWANSON: I would agree with you. In lieu of a specific set of criteria to evaluate the exemptions, if you start farming these out to groups of individuals you have the opportunity to enter bias into the decision making process or unevenness into the decision making process. Therefore, I think it has to be reviewed by the total Committee.

MEMBER WOODBURY: I agree that the Committee as a whole would be the way to go. The problem I have is the same question we raised earlier is the volume. For instance, if you have 500 of these to do in a quarter or half year or even at one of these meetings, it would take up the whole meeting. Nothing else would get done. So, that's why trying to assess the volume that you're talking about is --

CHAIRMAN SIEGEL: I'm willing to take that risk.

MEMBER BERMAN: But you're really talking -- I believe, as I mentioned before, you're dealing with potentially a few hundred of these. I believe it's going to take a tremendous amount of time. I also believe that if we try to do this by telephone conference call, it's going to be very difficult. What Dr. Cerqueira mentioned, which is that because of that difficulty that this might just add another impediment in the process, you'd think that what could end up happening is that people who are applying for licenses might end up with six month to a year's extra delay because of the process that we're now putting in place.

CHAIRMAN SIEGEL: I don't think that the process has required that time in the past when it's been involved. But tell me what you would propose -- which of the strategies you find more executable, Dan?

MEMBER BERMAN: Well, it has to come out on the table. I think that at some point in time this Committee of 12 needs five minutes, 10 minutes, 15 minutes of discussion so that they'll be able to process 25 or 30 applications. We are dealing with a concept that there are 500 hours of work experience that deals predominantly with radiation safety, a concept that doesn't even apply to nuclear medicine residents or to radiology residents. Nobody spends that much time monitoring packages. If that concept is just going to be not discussed, I think we are closing off

discussion unnecessarily.

CHAIRMAN SIEGEL: This Advisory Committee does not have the authority to change the Code of Federal Regulations.

MEMBER BERMAN: I'm not asking for that. What I am saying -- but 1200 hours is equal to 6.92 months. It's more than six months. 1200 hours at 40 hours a week is not a six month time. There already is, as you've pointed out, evidence that some degree of concurrence on this training is acceptable. What we're trying to define is how much is reasonable. Sally recently told us that during the time that you've had tenure on this Committee this group has met, has reviewed applicants who did not meet the 1200 hours, looked at the training and said it was adequate. So, this exception has already been taken in the past by this Committee. I think it's unrealistic to assume that the cardiologists of the world who are interested in training who do 700 hours, which is four months, and that would be with complete concurrence, would do that four months of training, it would be unrealistic to assume that they're not going to apply. So, they're going to apply based on past precedent and we're going to have to evaluate them. I think we need to do it as a Committee as a whole, but I think we need some kind of understanding as to what might be an appropriate minimum amount of time that's acceptable.

MEMBER NELP: I perceive you can't take exemptions and set rules for exemptions. I thought Manny's statement was a very reasonable statement. It seemed to be in line with the current regs. and we can't change the regulations, but we also can't sit around and say, "Okay, we're going to agree as a Committee as a whole that three months is it."

MEMBER BERMAN: Three months is not even on the table.

DR. CERQUEIRA: We didn't talk about times.

MEMBER NELP: I'm not referring to Manny's statement. I'm referring --

MEMBER BERMAN: But you and Barry both referred to three months and three months is not even up for -- nobody is asking for that.

MEMBER NELP: That's merely an expression. That's an off-the-cuff remark. I don't know what it should be. But it would seem very difficult for us as a Committee to come up and set guidelines for exemption. I think they should be handled -- I haven't seen -- I'm a new guy on the block. I've been here what, a year and a half? I haven't seen one of these items come to the table.

DR. CERQUEIRA: That's a good point in the sense that the way the procedure is being carried out by

Larry's committee with the interpretation has not resulted in any problems or any violations. We're not aware of any serious misadministration or radiation risks. So, I think Larry is trying to get clarification and I don't see what was wrong with the method that was being used.

MEMBER NELP: You're saying that he's been doing a fine job.

DR. CERQUEIRA: He's been doing a great job.

MEMBER BERMAN: But the problem is that we changed it our last meeting. When Larry brought to the table the fact that concurrence was allowed to varying degrees in the field and wanting some clarification of that, that's when our Committee rejected that, except for my vote. What we found out now, they're going to be coming forward and that's what we're dealing with.

DR. CERQUEIRA: And I think we're sort of potentially burdening this Committee with a lot of problems that have not really been problems.

MEMBER NELP: I think what Barry has said is let's don't change the rules until you go through this very critical review that's going to expose the whole system of regulations and see how it fits because we'll just be --

DR. CERQUEIRA: But in the meantime it would be reasonable to let Larry's committee continue to do as

they've done in the past, which is to basically deal with the issues.

MEMBER NELP: We didn't advise them in any way that they couldn't do that.

MR. CAMPER: No. Actually, I think you did. What you have here is a classic situation where the sleeping dog is no longer asleep.

MEMBER NELP: Oh, come on.

MR. CAMPER: The dog has been kicked. The truth of the matter is that for years we have processed these applications. I've already acknowledged unfortunately that there was some lack of uniformity in how they were processed amongst the various regions. I'm not critical of the regions for doing that because I think, in fact, there hasn't been adequate guidance from Headquarters on the subject.

But as time has marched on and there is more interested in physicians becoming authorized users, as the question of what does concurrent mean as it gets interpreted, the dog was kicked awake. Then we found ourselves in a situation of trying to develop a model to facilitate the processing of these applications for the very reasons that are being talked about now. We've brought that model to this Committee. The Committee had a resolution that it did not want to entertain that model, rather it wanted to

have these things reviewed on a case by case basis.

So, the concept of our regional personnel continuing to review these things in the absence of further guidance is history.

CHAIRMAN SIEGEL: Okay.

MEMBER NELP: Now, wait a minute. We're an advisory committee, Larry. You can accept our advice or not and you can go ahead and run your program as you see appropriate for the issues and the problems.

CHAIRMAN SIEGEL: Big risk.

MEMBER NELP: Dr. Cerqueira just told me and he told you that you're doing a very fine job.

MR. CAMPER: Well, thank you, sir. We appreciate that.

MEMBER NELP: And I would say continue to work as you have been.

MR. CAMPER: Let me just make a record real quick. The problem that we have though is you're absolutely right. This Committee makes recommendations to this Agency. We could have chosen to ignore or to entertain bits and pieces of your resolution. We could have continued to do it the way that we did it. You're absolutely right.

The problem with that mindset though as a regulator is this is about training and experience for physicians. To ignore or to select only in part the

recommendation of this Committee that deals with such a sensitive issue as physician training and experience when this Committee is comprised primarily of physicians I think would have been a very unwise thing to do as a regulator.

MEMBER NELP: I agree. Your wisdom is well recognized. We've said bring it to us and we'll help you. That's all.

CHAIRMAN SIEGEL: Judy?

MEMBER NELP: Until this --

CHAIRMAN SIEGEL: We need closure here.

MEMBER NELP: -- Academy of Sciences thing is reviewed and we're fine.

CHAIRMAN SIEGEL: And I'm going to try to give us closure.

MEMBER BROWN: Is NRC expecting a big increase in the number of exemptions --

CHAIRMAN SIEGEL: Oh, you bet.

MEMBER BROWN: -- permitted because word is now on the street that there are these exemptions and why wouldn't anybody apply for a lower standard if they could?

DR. CERQUEIRA: I don't think the word on the street has changed in any way.

CHAIRMAN SIEGEL: The mail trucks are outside right now.

MEMBER NELP: I think Larry kicked the dog.

DR. CERQUEIRA: Well, we're in a situation where we have people who want to come into the field. We have no evidence that they are misadministering radioactive compounds, so we should be happy that people want to get into it.

MR. CAMPER: Let me make, again, one comment for the record so there's no confusion.

MEMBER BROWN: So it's only the people in the know that can apply for these exemptions and get in under the lower standards. Other people are just kind of --

DR. CERQUEIRA: Well, I wouldn't call them lower standards. There's been no evidence that people are coming in unqualified.

MEMBER BROWN: Well, they wouldn't be applying for an exemption if they had more than the required training, right?

DR. CERQUEIRA: Well, that gets back to Dr. Siegel's point as to the basis upon which those standards were established. It may be that it's overkill.

CHAIRMAN SIEGEL: Let me suggest the following.

DR. CERQUEIRA: Sure.

CHAIRMAN SIEGEL: Let me suggest first of all that the procedure by which this Committee ought to develop an approach for granting exemptions with really figuring out what we want to do while you're still worrying about how you're going to change Part 35 at some distant time in the future, if

you really want us to do that and you want us to have this debate, that you should schedule some time in the spring, and we've already got one meeting on for the spring plus the other regular one. Let's schedule another meeting. Let's schedule a full two or three day meeting to include public testimony from all the interested parties like occurred at the Holiday Inn Bethesda 12 years ago, whenever that meeting was, when at the time the current regulations got cast in concrete and then let's create a set of exemptions based on that meeting that we can use as our operating posture for 1996 while you work forward to a rewrite of Part 35, ideally based on the information that came out at that meeting.

So, I put that suggestion on the table. We need another meeting like we need a hole in the head and I need that meeting on my watch like I need a hole in the head. But nonetheless, I think that that will satisfy the concerns that have been expressed if we really debate the issues fully.

Procedurally we have a more important question to address. It seems to me we need to consider whether we want to do this one of three ways. Way number 1 is to accept the idea that we do paper reviews. On the other extreme, number 3 is to go with the concept of Committee as a whole which has some advantages, a learning process, but admittedly is chunky.

Way number 3 is for us to design right this

moment basically two subcommittees. Subcommittee one relates to nuclear medicine and subcommittee two relates to radiation oncology. I would propose that the nuclear medicine subcommittee be composed of Dr. Berman, Dr. Nelp, myself, Dr. Woodbury, Dr. Wagner and Dennis Swanson, Bob Quillin who should sit on both subcommittees. The radiation oncology subcommittee should be Dr. Flynn, who is not here, Dr. Stitt, the new radiation oncology physicist and Mr. Quillin. Judy can sit on either or none or both, whichever she prefers, and we can do it.

That will be -- it will be easier to organize conference calls of a smaller group of people than it will be of a larger group of people. It will meet the requirements for Federal Advisory Committee Act and we can do it. So, I think we've got three strategies.

DR. CERQUEIRA: I'd propose there be a fourth also in the sense that the NAS recommendations are going to be coming. So, any sort of conference to make changes may be influenced by what happens. Why change what has been working? Why not continue what was being done in the past until you get the NAS recommendations and then at that point review the process?

MEMBER NELP: I would like to make a motion that we accept Barry's number 3 suggestion of having two subcommittees to, on an interim basis, deal with the issues.

We'll see what the issues are and then we can be flexible. If we need to change that, that's fine. I so move.

MR. CAMPER: I have a clarification question, Barry. You're saying -- for the record, you're looking at two committees, two subcommittees that would review the actual requests for exemptions or review submitted training experience, right?

CHAIRMAN SIEGEL: Correct.

MEMBER NELP: As you see fit. We only want to review the things that you feel are problematic. We don't want to do your work for you. We want you to bring to us issues that you or the people in the field think need additional attention.

MEMBER BERMAN: But could I clarify what you're saying? Its seems to be a little discrepancy.

What they were doing up until recently was -- Larry, I wanted you to catch this. Up until recently what they were doing was accepting at a certain degree of concurrence and that was -- as you're pointing out, that was working. What we decided at our last meeting was we were going to say, "No, you can't do that anymore."

MEMBER NELP: No, we advised them of our opinion. They have no constraints about following that advice and I imagine they've continued to operate as they have.

MEMBER BERMAN: I don't think so actually.

MEMBER NELP: And in the regulations, they can grant exemptions and if they have problems with that in terms of the qualifications of individuals, then I think it's very reasonable that we could help them --

MEMBER BERMAN: But on the interim basis, until we have the meeting, the excellent meeting that Barry suggested --

MEMBER NELP: That won't change the regulation. That meeting will just vent a lot of expression and give a lot of direction, but it won't change any regulations.

MEMBER BERMAN: Right. But the meeting that Barry described will actually, I think, get a lot of discussion that will clarify how the subcommittees might work. But until that time, are you suggesting that our subcommittees, you're going to look at everything or would you be willing to let Larry's group or to advise them that--

MEMBER NELP: I think Larry has a responsibility as the director of a certain component of the NRC and one of his responsibilities is to look at these things and if he has a problem that he feels he can't deal with, we'd be happy to assist him. But I think he's very capable to grant exemptions and my motion is if he feels that our advice is so strong that he wants us to look at them, then a subcommittee evaluation would be appropriate.

MEMBER BERMAN: Okay.

CHAIRMAN SIEGEL: He's required to get the ACMUI to look at exemptions by Part 35 as it currently stands.

MEMBER NELP: But he hasn't done this in the past.

MR. CAMPER: Because we didn't grant exemptions.

MEMBER NELP: Oh, I thought you did.

MR. CAMPER: No. What we did was --

MEMBER NELP: You granted concurrence.

MR. CAMPER: Our reviewers reviewed the submitted training and experience of an applicant and they came to closure given the guidance that they had to work with, which I've already indicated was minimal on this question of what constitutes concurrence. Now, what has happened is as this issue has continued to escalate, we have now recently been provided with an interpretation by the Office of General Counsel that the regulations as currently written require 200, 500 and 500. If you're going to authorize a physician user who presents less hours than that, you will do so through the mechanism of an exemption.

Now, if I turn to 35.19, it tells me that if I'm going to grant -- if the Commission is going to grant exemptions that deal with physician training and experience, I will grant those exemptions in concert with assistance from the Advisory Committee on the Medical Uses of Isotopes. The assistance that the Advisory Committee has offered in your

last resolution in your last meeting was we do not want to entertain a model for establishing concurrence. Rather, we want to see each and every application. That's the assistance that you've offered.

MEMBER NELP: Correct.

MR. CAMPER: We have accepted that assistance and we are proceeding to develop the procedure to implement your recommendation.

MEMBER NELP: And I made a motion that we would like to provide that assistance through the use of subcommittees. We'll evaluate the problem, come up with a working solution and I look for a second.

CHAIRMAN SIEGEL: Was there a second?

MEMBER WAGNER: I'll second that.

CHAIRMAN SIEGEL: Okay. Lou, you've been chomping at the bit for awhile.

MEMBER WAGNER: I would like to see the Committee move on with its business. We are not going to solve this issue at this meeting. We are an hour behind time and the facts are that I personally would not want to make any decisions until I start reviewing some of these cases. Sally has said before that we can change these rules midstream if we want to in terms of how we're going to review these things. At this time, I don't think this Committee wants to go ahead and make a whole lot of ideas about what we're going to do

until the whole Committee sees some applications and can make some decisions.

CHAIRMAN SIEGEL: The motion has been made and seconded that the process for review of exemptions be by subcommittee. At least for the moment, let's say that the subcommittee composition is as articulated by me a few moments ago. Is there further discussion on this motion?

All in favor of the motion, indicate by saying aye.

(Ayes.)

CHAIRMAN SIEGEL: All opposed?

(No response.)

CHAIRMAN SIEGEL: Okay. So, the motion is passed. That's the procedure we've adopted and I take that to mean that we choose not to do paper reviews and we choose not to act as a Committee as a whole. I suppose it's conceivable that the subcommittees may find that something is sufficiently contentious that they'll want to refer it to the whole Committee.

MEMBER NELP: I think the subcommittees will fully inform the Committee.

CHAIRMAN SIEGEL: But I think they'll do it.

Now, let me ask the Committee before we move on how the rest of you feel about my suggestion for more work, that rather important political battle and it gets to the

heart of the philosophy of an important regulatory issue. It was debated at great length 12 years ago. There are certain elements on the sides of the different turf battles that will still feel the same way they did 12 or 15 years ago. I think there are others who taking an approach for reengineering the government and deregulation will argue for less role for the NRC in this. We just need to have the debate.

MEMBER BERMAN: I think it's an excellent suggestion. What Larry just told us a couple minutes ago of about now the counsel saying that you need 1200 hours means that all the radiologists who are being trained with their six months aren't meeting the 1200 hour requirement. So, really you've got -- you have a big problem that has opened up.

MEMBER NELP: That was a piece of advice. We didn't change anything.

MEMBER BERMAN: No, no. I'm not suggesting we change anything. What I'm suggesting is that this debate is really needed and I strongly support Dr. Siegel's suggestion.

MEMBER NELP: And I would like to add one more thing, Barry.

The next time we meet, Larry, I would like to have the data. I would like to know the numbers. I would like to know the position of your people out in the field. We're dealing with some nebulous figure and I'd like you to try to quantitate the extent of the situation so we know what

the heck we're dealing with because it's sort of nebulous.

MR. CAMPER: All right. We can certainly do that.

MEMBER NELP: I know it's there and you have a better feeling for it than I do.

MR. CAMPER: We can certainly attempt to do that. Let me just make one more closing comment about this. I think, frankly, if we do add on a day to discuss this training and experience issue as a follow-on to the meeting talking about the NAS, I like the idea that when we go to talk to the professional groups that have an interest, the endocrinologists and the cardiologists and the radiologists, et cetera, et cetera, that we will have pulsed the ACMUI and can say, "The ACMUI, we shared this information and this was generally their recommendations and their perspectives." I think that would facilitate that discussion frankly. So, we can think more about that.

CHAIRMAN SIEGEL: Good.

DR. CERQUEIRA: I'd like to thank Dr. Siegel and the Committee for hearing our request. We'd like to be actively involved in future discussions.

CHAIRMAN SIEGEL: I don't doubt that you will be.

DR. CERQUEIRA: Thank you, Barry.

CHAIRMAN SIEGEL: Yes. We are going to take a break. The rulemaking update probably will only take about a

half an hour. We're behind schedule, but we're going to do some catch-up. So, a ten minute break.

(Whereupon, at 10:19 a.m., the proceedings went off the record.)

CHAIRMAN SIEGEL: We have a quorum and we have at least one federal -- now we have both federal officials, so we can proceed.

We are going to go on with the update on rulemakings and guidance. And then we are going to continue directly changing the agenda with the petition for rulemaking, 1130 item and we're going to shift the intravascular brachytherapy to follow. Jim Smith said that would work for him.

And so, Cheryl Trottier, go for it.

MS. TROTTIER: Thank you. First, I feel like I should warn you. I found out about this yesterday morning. Because at the beginning of this session, I think Dr. Cool explained the situation at MIT and that we were doing this IIT team. Well, unfortunately, John Glenn who is our normal branch chief, is heading up that team. And so now I am branch chief and I get to come to you and explain rulemakings that I know next to nothing about because I haven't been in the office for the last four months. But, we'll get through it. I do have some of the staff here. So, if there are any questions that I can't deal with, I'm sure they'll be able to.

The first rulemaking is really just a real quick update for you. You may already be aware of this, that wrong patient was published in the Federal Register. The date is there on the slide, September 20th. I did not make any overheads, again, because of this short notice. And we did make some extra copies of the slides so anyone from the public who doesn't have access to the slides that the committee has, can pick them up in the back.

Anyway, that was published in the Federal Register in September. So we are done with that.

CHAIRMAN SIEGEL: Any comments on that item, folks? That was pretty much per our recommendation and concurrence.

MS. TROTTIER: Yes, it was.

CHAIRMAN SIEGEL: Yes.

MS. TROTTIER: All right. The next rulemaking is patient release. It's been changed somewhat since the last time you saw it and what we have put together on the slides today is to show you what some of the changes are.

I will tell you, first of all, it's current status that it is on its way to our commission. It is currently in our executive director's office. I would anticipate that within a week, if all goes well, it should make it up to the commission. But of course, it went to the executive director's office in May and it's been back several

times. So anyway, I'll just run through some of the changes that have been made to it as a result of his concerns.

On the first slide, you'll notice there is a proposed rule language and the previous proposed rule language. The main change there was to remove the phrase in parenthesis, including a breast feeding infant. It doesn't really make a significant change in the rule but we're dealing with the breast feeding infant in guidance space more than in rule language space. But when I get to the next slide, I think you'll see that.

Then on the next slide, you'll see, again, the proposed rule language is slightly different from what you saw before. Around the middle of the paragraph, after the ALARA statement, it says, "if the does to a breast feeding infant or child could exceed 1 millisieverts, assuming there were no interruption of breast feeding, that the instruction should include guidance on interruption of breast feeding and information on the consequences of failure to follow the guidance." That is the change that is in the package that is currently in the EDO's office.

MEMBER WOODBURY: Consequences to whom?

MS. TROTTIER: Consequences to the infant, or a child, in either case. The breast feeding individual.

CHAIRMAN SIEGEL: Dennis?

MEMBER SWANSON: I had a comment on the second

part which is actually added. I think the information on the consequences of failure to follow the guidance. As chairman of the radiation safety committee at our institution, human use subcommittee, I've been trying to come up with statements of risk associated with radiation exposure. And to be honest with you, I'm not sure what information on the consequences of failure to follow the guidance I can give to a mother. If their infant is exposed to 200 millirems of radiation, what are the consequences of that in consideration of the fact that their annual radiation exposure is 300 millirems? And so, I think I mean, you're kind of leaving us there with a difficult situation to try to explain in many cases. I mean, I can explain 5 rads exposure but I'm not quite sure how to deal with that.

MS. TROTTIER: I understand. Now, again, as I said, since I was not here, maybe -- Larry, do you have a view on why we chose the phrase that we chose on this?

CHAIRMAN SIEGEL: This has been in again and out again a couple of times.

MS. TROTTIER: In again and out.

MR. CAMPER: I would ask Dr. Holahan. She was actively involved in that.

Trish, do you recall exactly why?

CHAIRMAN SIEGEL: Or Stuart may know.

MR. CAMPER: Or Stuart may know.

MR. SCHNEIDER: Has to do specifically with the thyroid in the breast feeding infant.

CHAIRMAN SIEGEL: Right, Stuart, and I recognize that. That was Stuart Schneider, by the way, for the record.

The problem is, is exactly what Dennis said. Clearly, if someone being treated with I-131 who had been breast feeding, and I chose those words carefully, I would tell that mother, you may not breast feed any longer because if you do, you will wipe out your infant's thyroid gland.

The problem, on the other hand, though is if someone's going to have a study with technetium pertechnetate where most tables would recommend that ceasing breast feeding for 24 hours is the strategy to get the effective dose below 100 millirems, I would have trouble saying now, listen, if you don't follow my instruction, here are the consequences. And so, if you insist on this language, then the NRC has to be willing to accept the following in written instructions. We recommend that you discontinue breast feeding for 24 hours because we subscribe to the policy of maintaining doses as low as reasonably achievable. If you do not follow these instructions, it is unlikely or it is impossible to prove that any adverse consequences to your infant will result. Because I would insist on wanting to write that because I can't honestly tell a patient that 140 millirem dose to her infant will harm that infant any more than I could tell that patient

that the 300 millirem effective dose to her from the study will harm her.

MS. TROTTIER: Correct.

CHAIRMAN SIEGEL: And that's why I had objected to this phrase in this part of the rule previous. And I guess I'm objecting to it again.

MR. CAMPER: Trish?

MS. TROTTIER: Trish?

DR. HOLAHAN: It is my understanding that in the reg guide basically what you're saying there, Barry, in terms of that as much could be done in terms of the consequences, we recommend that you discontinue for 24 hours to avoid, otherwise your baby may receive some unintended exposure, or even to go as far as to say there are no expected consequences if you don't stop breast feeding. And that is what was meant in terms of consequences. Because no consequence is also a consequence.

CHAIRMAN SIEGEL: Why not change that? Why not say information on the consequences or lack thereof of failure to follow the guidance?

See, I'm concerned that license -- I know you're not going to put those words in because OGC will never let it stand. But I'm concerned that licensees, and more importantly, inspectors, will interpret this to mean there better be a statement about the consequences and they better -

- it better be based on the linear hypothesis rather than the linear quadratic or I could include a consequence based on a hermetic hypothesis which would say this will benefit your infant.

MS. TROTTIER: Yes. Well, I think, in fact, when I first looked at this slide yesterday, that this is a subject that we probably need to include in the regulatory guide. It's not in there now but I do think there's some guidance and the staff is telling me inspection guidance also. So, there are mechanisms that we can use to make it clear to both inspectors and licensees what the staff intended by those words. Hopefully that will solve that problem.

MEMBER SWANSON: As a committee member, I'd just like to make the recommendation that the sentence end, guidance on interruption on breast feeding, period, which could certainly include consequences if there are expected consequences of that.

CHAIRMAN SIEGEL: Are you making that as a -- I'm not sure whether we've got any option at this point, given the way this package is. But that doesn't prevent us from making the motion.

MR. CAMPER: No, it does not.

MS. TROTTIER: No, you can make it.

MEMBER SWANSON: I would like to make that motion.

MEMBER WOODBURY: I second it.

CHAIRMAN SIEGEL: Is there a second?

MEMBER WOODBURY: Second.

CHAIRMAN SIEGEL: Is there further discussion?

Judith?

MEMBER BROWN: I'm going to abstain. I haven't really given this enough thought to make a quick decision. Sorry.

CHAIRMAN SIEGEL: I think -- Let me speak on your behalf, even without -- Because I -- No, having understood --

MEMBER BROWN: I trust you on that, Barry.

CHAIRMAN SIEGEL: Yes, well, having understood some of your concerns about this issue in the past, I think we are really all of a like mind here because I think everybody on this committee, and I think the vast, vast majority of medical licensees will not go out of their way to harm infants who are breast feeding. And the notion that you have to explain to someone the radiological risks when there is no scientific basis for making those statements is what we're trying to avoid here.

MEMBER BROWN: But it doesn't say radiological risks. It just says consequences. So in the little box, you say no consequences, right? They just want to make sure somebody paid attention to this aspect.

CHAIRMAN SIEGEL: The trouble, and I guess in a

way, I would -- by forcing me to describe consequences, it actually sort of limits my flexibility as a practitioner. In a way, I'd like to be able to say although we really don't have any reason to think that this will harm your child, we recommend keeping doses as low as possible and as low as reasonable. And we strongly encourage you to stop breast feeding for 24 hours. Well, Doctor, what will happen if I don't? If then pressed with that question, I said, there's really no scientific evidence that anything will happen. I think if I have to put all of that complex language in my written instruction, which I would be inclined to interpret that this will then translate into what has to be in the written instruction, that that's going to start confusing patients. And I would --

MEMBER BROWN: I don't think anybody's going to be confused by that. I think that just documents that you paid attention to it. And, of course, you're going to pay attention to that because you speak on my behalf. But I'm not sure anybody else is. I mean, everybody else is.

MEMBER SWANSON: But let me emphasize something. By putting in a written instruction that there are no consequences, I'm concerned that that will distract from the precautions I've asked the patient to take. I would rather simply explain the precautions and not have to go on and say there are no consequences associated with this because I

actually think, as I said, by saying that there's no consequences, that might distract from my precaution statements. So you might get a negative impact there to what you're trying to achieve.

CHAIRMAN SIEGEL: In other words, do what I say but please note that there will be no benefit to doing what I say. I'd rather not have to say that. What I'd really like to say is, I'm the doctor. Do what I say. That's very paternalistic of me but in this case, I'd prefer to encourage the woman to do the right thing and not to spend a half an hour getting into which hypothesis we're using of radiation risk.

Lou, do you --

MEMBER WAGNER: No, I fully concur with what you're saying. The idea that there won't be any confusion on the interpretation of on the consequences I think is wrong. I think there will be tremendous confusion as to what that means, not only on the patient's part and the physician's part, but also on the regulator's part. This kind of a very nebulous phraseology is extremely susceptible to misinterpretation.

MEMBER WOODBURY: I had no idea what it meant. And if I'm a practitioner and I don't know what it means, then I'm in trouble.

MR. CAMPER: Well, I think the problem is, if you

look at it, I think that the logic was, you have in step 1 instructed interruption to breast feeding. The patient may or may not -- may or may not grasp the consequence of not following your instruction to interrupt breast feeding. And point two asks you to explain what that consequence might be if you don't follow the instructions to interrupt breast feeding.

Now --

MEMBER WAGNER: But, Larry, consequences is a very strong word. And the thing is, maybe something lighter like -- and the reason for this guidance, would be a different interpretation. But consequences is so ominous. That's the problem. It's how ominous consequences means. The reason or --

MR. CAMPER: The importance of following the guidance or the rationale?

CHAIRMAN SIEGEL: That's better.

MEMBER WAGNER: Yes, that's much better.

MEMBER WOODBURY: Call the question, Mr. Chairman.

MEMBER SWANSON: To me, it's incorporating the word. When I give guidance to my children, I try to explain the reasons why.

MEMBER WOODBURY: Call the question, Mr. Chairman.

CHAIRMAN SIEGEL: The motion been called. There were some other -- there was some other discussion. But, we can either take the question or we can go through the motion to answer the question call. Do other people feel they need to make a comment before we proceed?

All right. Question has been called. So, the motion was, is that we're recommending that you truncate that sentence after the word breast feeding and delete the item 2.

MEMBER BROWN: I thought the question -- I thought the recommendation that you substitute a word such as rationale?

CHAIRMAN SIEGEL: No, that was not Dennis' motion.

MR. CAMPER: Not the motion.

MEMBER WOODBURY: The motion is to --

CHAIRMAN SIEGEL: Now, we could come up with an amendment or a substitute motion.

MEMBER BROWN: I'd vote for that one, the one to change the words since consequences seems to be such a sticking point and have such a negative connotation.

CHAIRMAN SIEGEL: So let's to try the following just for the purposes of discussion. I guess the question has been, can we table motion to call the question while we continue to discuss this? Does the motioner allow that? And the committee go with that? We're not getting too formal

here.

How about the instructions shall also include, (1) guidance on the interruption of breast feeding, and (2), the rationale for interrupting breast feeding.

MEMBER NELP: Why don't you -- I'd like to make a suggestion in the language. Say, assuming there were no interruption of breast feeding -- I'm not sure of the English of that.

CHAIRMAN SIEGEL: That's correct. It's called for.

MEMBER NELP: Yes, I guess that is subjunctive. Thank you, Doctor, esteemed Doctor.

MR. CAMPER: Esteemed Chairman.

MEMBER NELP: Assuming there were no interruption of breast feeding, the instructions. I would say the licensee should provide guidance for the patient, period. Just make it very simple.

CHAIRMAN SIEGEL: Well that's the original motion.

MEMBER NELP: If there's no interruption, the licensee should then provide appropriate guidance for the patient.

MEMBER BROWN: I think given -- just as a practical manner, given how much this has been debated and where it is in the process of becoming a final rule, that this

committee would have a lot better luck changing one word than dropping two. And I would vote for changing the word to something less objectionable.

MEMBER STITT: I like Judith's idea. The -- I'm sitting here listening to the discussion and I grew up in the era of Truth or Consequences. And that tells you something about why that word is such a harsh word here. Because either you've got the truth or you've the consequences. And I think that if we try to make a major change in this, we're going to get absolutely no where. But that's a hostile word, at least in my generation.

CHAIRMAN SIEGEL: We've got several different approaches on it.

MEMBER WAGNER: Well, what we have is we have a motion and then we have motion to amend. So we have to look at the motion to amend first and then look at the motion.

MEMBER NELP: Could you state the motion, please?

CHAIRMAN SIEGEL: Well, the motion was that we recommend that the final sentence of proposed (b) be truncated at breast feeding. The motion to amend was that we recommend that item 2 --

MEMBER NELP: The first motion eliminated item 2, is that correct?

MEMBER WAGNER: That's right.

CHAIRMAN SIEGEL: The first motion is to

eliminate item 2. The second --

MEMBER NELP: The second?

CHAIRMAN SIEGEL: The amendment or the substitute motion would be to come up with a different language for item 2. And did someone write down what I said? Because I didn't.

MEMBER WAGNER: Information on the rationale to follow the guidance.

MEMBER BERMAN: Wouldn't it be simple to say guidance on and rationale for the interruption?

MEMBER BROWN: That's fine.

MEMBER BERMAN: That would be fine. And could it be guidance on and rationale for the interruption or discontinuation of breast feeding, based on what you had said, Barry? You might want to add that.

MEMBER BROWN: I don't think we have too much license to edit given where this is in the process.

MEMBER WOODBURY: We have license to advise.

MR. CAMPER: We certainly will take your advice.

MEMBER BERMAN: Interruption suggests they can go back on it. Whereas if it's I-131, as Barry was saying, he's want to tell them to discontinue.

CHAIRMAN SIEGEL: Well, that is spelled out in the regulatory guide. That's spelled out in lots of scientific documents that we would be expected to refer to as

practitioners. But tell me what you just said, Dan?

MEMBER BERMAN: Guidance on and rationale for the interruption or discontinuation.

MEMBER NELP: I like it.

MEMBER BERMAN: Of breast feeding, period.

MEMBER NELP: I like that very much.

CHAIRMAN SIEGEL: Now --

MEMBER WAGNER: I second that motion.

CHAIRMAN SIEGEL: Good. So that really now becomes the substitute motion and I guess there's an option for the --

MEMBER SWANSON: I will withdraw the initial motion.

CHAIRMAN SIEGEL: Excellent.

MEMBER BROWN: And I withdraw the amended motion.

CHAIRMAN SIEGEL: Excellent. So we now have a substitute motion. And let me read it based on what I think it says. The substitute motion would be, is that the ACMUI recommends that the final sentence of proposed -- what is this -- 35.75(b)?

MS. TROTTIER: Right. Just (b) is good enough.

CHAIRMAN SIEGEL: Be amended to read, If the dose to a breast feeding infant or child could exceed 1 millisievert (0.1 rem), assuming there were no interruption of breast feeding, instructions shall also include guidance on

the interruption -- no, guidance on --

MEMBER BERMAN: And rationale for.

CHAIRMAN SIEGEL: Guidance and -- No, it should be --

MEMBER BERMAN: Guidance on and rationale for.

CHAIRMAN SIEGEL: And rationale for the interruption or discontinuation of breast feeding, period. That's the motion.

MEMBER BROWN: That's good.

MEMBER BERMAN: And you're taking out the when parenthesis also.

CHAIRMAN SIEGEL: Is there a further discussion on that motion?

MEMBER NELP: Has it been seconded?

MEMBER WOODBURY: Yes.

CHAIRMAN SIEGEL: It was seconded and 13 prior motions were withdrawn.

MEMBER NELP: Call for the question.

CHAIRMAN SIEGEL: All in favor?

(An oral vote was taken.)

CHAIRMAN SIEGEL: Opposed?

Let the record show that the -- and I vote aye. Let the record show that the ACMUI unanimously recommends that even though this package is sitting with the EDO, that we go back to that language.

MS. TROTTIER: Actually, we have it. So --

CHAIRMAN SIEGEL: Super.

MS. TROTTIER: We will discuss this with the EDO's office.

CHAIRMAN SIEGEL: Good. Continue.

MS. TROTTIER: On the next slide, then, this is the record keeping part of the rule. And I know a lot about this because I was in the EDO's office when he rejected this rulemaking the first time. And it was because the language that was previously proposed in his mind was very confusing. It's down at the bottom and you can see it. He really got caught on attenuation of radiation by body tissue, blah, blah, blah. His view was only health physicists understand this and, anyway.

What we ended up with, I think, will probably be acceptable to him in that it is in more plain English. So that's really what the purpose of this change was, to make the record keeping requirement easily read.

CHAIRMAN SIEGEL: Dennis?

MEMBER SWANSON: Afraid I have a comment there, too. What is meant by using an activity other than the activity administered? Is this as in making a error in the calculation, an error in the administration? What is that in reference to?

MR. CAMPER: It means -- it's a conservative

approach. We're using the original amount of activity administered to the patient as opposed to any consideration of biological elimination at some point in time. You may certainly do that. You may certainly use the approach where you bring to bear biological elimination and so forth. But if you do that, it requires a record.

CHAIRMAN SIEGEL: Don't 1 and 3, though --

MEMBER SWANSON: Hand in hand.

CHAIRMAN SIEGEL: -- capture the same thing?

MS. TROTTIER: Yes, it does.

CHAIRMAN SIEGEL: Although they capture it in a slightly different way. One -- the component in 1 allows for a very rapid initial elimination component that quickly reduces the body burden to some relatively small number. And then 3 uses an effective life of the remainder as opposed to just the physical life.

Now, either one could be captured by either 1 or 3. In a way they're redundant. But I personally can live with this. Especially if regulatory guidance explains what's going on here.

Anybody terribly troubled by it?

MEMBER SWANSON: Even if you used the biological half-life, how can you base it on an activity other than that which was administered? It just doesn't make any sense to me unless you're talking about errors.

MEMBER BERMAN: Maybe it should say using activity less than the activity administered.

MEMBER SWANSON: No, why would you do that?

MEMBER BERMAN: Because what was stated about rapid excretion.

MEMBER BERMAN: I tell you, that statement just doesn't make any sense.

MEMBER WOODBURY: The thing that disturbs me, if the language is written that the committee can't understand, how do you expect the licensees to understand? And I'm totally confused.

MEMBER BROWN: Right.

MEMBER STITT: It reads like a misadministration. You gave something that you didn't mean to.

CHAIRMAN SIEGEL: Actually, why do you need item 1 at all?

MEMBER SWANSON: Right.

MEMBER WOODBURY: That's right.

MEMBER SWANSON: Just eliminate it.

CHAIRMAN SIEGEL: Because I think the concept that we went through when we discussed this rule at length was, basically that the NCRP-37 approach says, here's a point source of I-131. Stand at it from a meter. Allow for 25 percent occupancy. And here's your external exposure. We've addressed issues of the leaky patient in prior discussions.

And then the things you can do to modify NCRP-37 are to assume a different model for elimination as opposed to no elimination. To assume that there is attenuation of the activity by the patient and to assume a different occupancy factor. Those are the three variations. And I don't think you need to say that with four items. One item captures it.

Does anybody -- staff, have a concept that's different on that?

Stuart? I'm looking at you.

MR. SCHNEIDER: The reason we put that in was if the number in the -- if the activity was less than what was in our release table, then it was using the activity administered. But if you had a value that was greater than the release table, you may have to hold the patient until that activity was less and it no longer was the activity administered.

CHAIRMAN SIEGEL: So you're implying that a patient would get 6.8 millicuries of I-131 and the release table say 6.6. And you just keep him for an hour and it's down to that level and then you let him go home?

MR. SCHNEIDER: But it's still based on --

CHAIRMAN SIEGEL: But your release table is actually also going to include some -- substitute measurements based on external dose rate as well. So the licensees are going to have an out from there as well.

MEMBER NELP: That's going to be the determinant, isn't it? Or either/or?

CHAIRMAN SIEGEL: It's still going to be a little bit of either/or.

MR. SCHNEIDER: In the case where it's either/or, then if you use the release value based on the dose rate, then you have to have the record of the survey. And that's explained in the guidance attached to that.

MEMBER WAGNER: Barry, would the wording -- since what they want is the retained activity rather than the administered activity, it seems to me that that's the change that you need in number 1 to satisfy what they want.

CHAIRMAN SIEGEL: Well, it's retained --

MEMBER WAGNER: It's the retained activity.

CHAIRMAN SIEGEL: Retained when?

MEMBER WAGNER: Well, it doesn't matter. I mean, it's retained at any point that they want to release the patient. If it's based upon the retained activity at the time of release rather than the administered activity.

MEMBER NELP: I'm confused.

CHAIRMAN SIEGEL: That actually is the basis for releasing someone who got thyroid cancer therapy, right?

MEMBER WAGNER: Right.

CHAIRMAN SIEGEL: You really are basing it on retained activity.

MEMBER NELP: Rather than monitored exposure? I'm confused.

CHAIRMAN SIEGEL: Well, it's either/or.

MEMBER WAGNER: Yes, it's either/or.

MEMBER NELP: It would seem to me that if someone gives more activity to the patient than is in the table, then they ought to go the release criteria by monitoring the patient.

CHAIRMAN SIEGEL: Cathy?

MEMBER NELP: That's -- you have a choice, wouldn't you?

MR. CAMPER: No, remember, it's purely dose driven now.

CHAIRMAN SIEGEL: And it's --

MR. CAMPER: It's 500 millirem absolute limit and you also have the 100 millirem consideration.

CHAIRMAN SIEGEL: Right. It's dose driven but it's dose driven with the ability for licensees to refer to tables if they don't want to calculate doses. And the tables provide lot of conservative room --

MR. CAMPER: I understand. But I think Dr. Nelp was referring to the current criteria where you're measuring a meter, 5 mr per hour the other or that currently exists?

CHAIRMAN SIEGEL: But the table actually -- the tables as we last saw them included both dose rates and

retained activity, as I recall.

MEMBER NELP: Isn't that correct?

CHAIRMAN SIEGEL: And I have this in the regulatory guide.

MR. CAMPER: The tables do that. That's right.

MS. TROTTIER: Right. I believe they still do today.

CHAIRMAN SIEGEL: Cathy.

MR. CAMPER: That's right.

CHAIRMAN SIEGEL: Cathy, did you want to comment?

MS. HANEY: I was just going to say that the reg guide tables, the way they're set up right now, are set up as administered activity and that's why the -- one of the reasons why the rule language, it was in there base don administered activity. However, if you're taking into account at the time of administration, then you are looking at the dose that is retained in the body. So, it depends upon -- both are right but it depends which way you're attacking the problem. Which way you're attacking.

MEMBER WAGNER: It seems to me what you're getting at, though, is the idea that you'd use retained activity which still would be beyond what the table is.

MS. HANEY: It is. But the values -- the simple way to look up the table is to look at the administered activity.

MEMBER WAGNER: Right. I understand. I understand. And if they wanted to release him based on retained activity, they'd have to go through a calculation to judge that -- to justify that.

MS. HANEY: Right.

MEMBER WAGNER: So, a solution to your problem is to say, using the retained activity, not the administered activity. So if in their justification they used retained activity as opposed to administered activity, they can justify it. I mean, I think that's the issue that you're getting at.

MR. CAMPER: The problem is, if you go back why was C put in at all? And if you -- for example, if you read it and it said the licensee --

CHAIRMAN SIEGEL: You don't really want to raise that question.

MR. CAMPER: I think I just did.

MEMBER WAGNER: Kick the dog again, Larry.

MR. CAMPER: But if you were, for example, to say, the licensee shall maintain a record of the basis for authorizing the release of the individual for three years after the date of release, period, that's a problem. We felt that was a burdensome record keeping requirement because it would require every release to have a record. And we didn't want to do that.

So, what we attempted to do was to establish a

conservative criteria that if followed, and this is where you get into you're treating it as a point sore, you're treating at a specified distance. You're using the original amount of activity administered. If you release considering those kinds of considerations which the tables describe the amounts, then no record keeping is required. But if you deviate from that, then you find yourself in record keeping space. So it was an attempt to reduce the amount of record keeping.

MEMBER WAGNER: I understand that.

MEMBER NELP: I'd like to comment.

Larry, you know, if I take your chest X-ray, I'm obligated to keep it in my file for X number of years. If I treat you as a patient, I'm obligated to put in your medical record what I've done and that medical record is a permanent file for your life. And for a number of years. So, it's really not very burdensome, and I do this routinely and I'm sure other people do, when I treat you, I will say how much I gave and I can put in there released with such and such activity, period. I mean, it's a matter of current procedure.

MR. CAMPER: But I don't think that the documentation of chest X-rays and the like have anything to do with the possible dose consequence to a member of the public.

MEMBER NELP: No, but I'm saying even now I keep this record permanently. It isn't a burden for me to keep this record for three years. That was my point. I keep this

record permanently now.

MR. CAMPER: I agree. I don't think the keeping of the record is the problem. I think the development, the need for the development of the record is the problem. What we attempted to do here was to establish a threshold below which you would not have to develop a record using conservative practice.

MEMBER NELP: Even below your threshold I keep a record permanently.

MEMBER WOODBURY: Is keeping the record appropriate?

MR. CAMPER: But do you want -- You don't want the NRC to impose that on all --

MEMBER NELP: Yes, I think that's very reasonable. You know, if --

CHAIRMAN SIEGEL: We've had this discussion. You're retro --

MEMBER NELP: Am I, really? Because this is a routine form of medical practice. If you come to my office, I enter that visit in my medical record on a permanent basis.

CHAIRMAN SIEGEL: I'm not sure you keep those records in an NRC readily inspectable format.

MEMBER NELP: I think I do. I could access those very readily.

MEMBER SWANSON: Isn't what you want to say is

using an activity that results in an exposure rate of less than 0.1 millirem, assuming an occupancy factor of .25? Because what you're really trying to do is -- your problem is you're trying to allow people to release based upon your guidance document but you can't refer to your guidance document and regulation, right?

MR. CAMPER: That's right.

MEMBER SWANSON: So, you've got to refer back to the criteria used in your guidance document as your regulation. And so that's what I'm saying, using an activity that results in exposure rate less than 0.1 millirem, assuming an occupancy factor of 0.25, which is what your tables are based on. Or something in that kind of wording.

MR. CAMPER: Well, you're right on the mark with what the problem was, that's right.

CHAIRMAN SIEGEL: Right. Because you can't reference the guidance in the rule.

MEMBER NELP: But isn't this related to keeping of the record?

MS. TROTTIER: Well, it's which records you have to keep, that's the concern. Rather than keep records of every release.

MS. HANEY: Can I just say something?

CHAIRMAN SIEGEL: Yes, Cathy.

MS. HANEY: we felt that it was important in the

case of number 3 to have it in there because of all the discussions that took place about having a table that would allow for release by taking account biological considerations. And again, we were trying to keep the record burden down. The required regulatory record burden in the license down by making sure that that statement was in there.

CHAIRMAN SIEGEL: I'm a slow learner here. Give me one more example that focuses only on item 1. I give a patient 30 millicuries of I-131, or 100 millicuries of I-131. When would I release the patient using some other activity? Give me an example. I'm having trouble understanding an example that is not -- that's just based on using a different number as opposed to using one of these other assumptions to get to the different number. That's where I'm confused.

I mean, I might say it's okay for me to release patients over 150 pounds when they have 50 millicuries because I've considered occupancy factor. But that's not using a different activity administered. I might do it on the basis of biological elimination. I mean, not occupancy factor, shielding. I might do it on the basis of occupancy factor. But I don't understand how I would ever use a different number other than the starting number unless you mean what Dennis and Lou were driving at which is the retained activity at the moment of release based on some measurement.

MR. CAMPER: But you see, under that scenario,

that wouldn't require a record.

MEMBER WAGNER: It would if it's still beyond the tables, wouldn't it?

MS. TROTTIER: Right, if it's not the value on the table.

MEMBER WAGNER: That's the point that we're trying to make. And that was what I thought the issue was. If you're still beyond the table but you're still justifying a higher release activity.

CHAIRMAN SIEGEL: But then you're going to be doing it on one of these other factors, not juts on the fact that it's a different number.

MEMBER WAGNER: Right. But the point -- that's exact -- Well, no. I think the --

MR. CAMPER: No, you are. Because the reality of the matter is you could release patients with substantially higher activity. And the thing that would let you do that, of course, is item 3.

MEMBER NELP: May I ask --

MR. CAMPER: And in that case, you will create a record because you opt to release that patient at a much higher activity level.

MEMBER WAGNER: Well, that's only if you want to follow the tables. But my point is, is that if you don't to -- if you still want to release at a higher activity beyond

what the tables are, then you would still have to justify it on the basis of the other activity, also.

MR. CAMPER: I understand. But the table, the one basic table is about physical decay.

MEMBER WAGNER: I understand what you're saying. All right. Yes. I agree. I agree. You can eliminate 1 and it won't change anything.

MEMBER NELP: May I ask a question again?

CHAIRMAN SIEGEL: Sure.

MEMBER NELP: If I release a patient with some of these exceptions based on my own judgment, I'm going to make a record of it. If I release a patient according to the guidelines without any exceptions, I'm going to keep a record of it.

CHAIRMAN SIEGEL: That's your choice.

MR. CAMPER: Not for us you're not.

MEMBER NELP: No, but in the practice --

CHAIRMAN SIEGEL: It's no longer an NRC required record.

MEMBER NELP: But in the practice of medicine, because of my role as a physician, my medical malpractice insurance, my ability to bill appropriately, and my professional career, I am going to keep a record of it.

CHAIRMAN SIEGEL: But I'm just telling you that if you send people home who got 5 millicurie imaging doses of

I-131, assuming they're not breast feeding, you don't have to put anything down on paper for anyone --

MEMBER NELP: Yes I do. Yes, I do.

CHAIRMAN SIEGEL: NRC requirements.

MEMBER NELP: That's exactly correct.

CHAIRMAN SIEGEL: You can make whatever record you choose to based on the way you practice medicine.

MEMBER NELP: If I'm in the practice -- anybody in the practice of medicine --

CHAIRMAN SIEGEL: But NRC won't --

MR. CAMPER: With the exception of the patient dose record. We do have a requirement.

CHAIRMAN SIEGEL: I understand.

MEMBER NELP: Let me complete this, Barry.

CHAIRMAN SIEGEL: Please.

MEMBER NELP: If you kept a record on everything, it wouldn't be a burden to anyone because the record exists. You see? The record exists. There's no way that you're going to treat a patient without a record.

CHAIRMAN SIEGEL: We need to have a chat about deregulation.

MEMBER NELP: I understand.

CHAIRMAN SIEGEL: And about getting the government out of our face and not about giving them more to do.

MEMBER NELP: Thank you. I just wanted to be sure that you understood my opinion.

CHAIRMAN SIEGEL: I guess.

Do we want to recommend that 1 disappear because it seems like it's irrelevant?

MEMBER WAGNER: I second that motion.

CHAIRMAN SIEGEL: I didn't make it but I guess I did. Do you guys have a strong argument why it has to be in there? Please explain it to me.

MS. TROTTIER: See, I'm staying out of this fight because I recommended about one or two things. And so --

MEMBER NELP: It's totally redundant.

MR. CAMPER: In the side bar, I was just trying to understand if we pulled out that element within the tables, what would that do to the entire table?

CHAIRMAN SIEGEL: Not much. But the tables are based on the assumptions that with a given administered activity, that the dose will be either less than 100 or less than 500 with an occupancy factor of .25 at a meter with no biological elimination and with no shielding.

MR. CAMPER: That's correct.

CHAIRMAN SIEGEL: And consequently, 1 is irrelevant, I think. I don't want to -- if you've got a carefully articulated reason for 1 being in there, I want to hear it before we vote on this motion. Because I don't want

to mess something up that you've really thought through very carefully. But I'm happy to destroy something if you don't got a good reason for it.

MS. TROTTIER: I'm going to be bold and say I don't think we have a really strong reason.

CHAIRMAN SIEGEL: In that case, shall we call the question?

MEMBER WOODBURY: Call the question.

CHAIRMAN SIEGEL: All in favor of the recommendation from the ACMUI that item 1 be eliminated in paragraph C --

MR. SCHNEIDER: One second, Barry. When this was out in July, there was an instance where it came about, which I can't remember now, where the lack of this phrase was very important that it be there. And I just can't remember right now that specific example.

MR. CAMPER: Well, it becomes the basis for the following elements. You have to assume some activity to begin with.

MEMBER WAGNER: How can you administer an activity that's not administered?

MEMBER SWANSON: Exactly. Unless it's a misadministration.

MR. CAMPER: But that wouldn't call for the elimination of 1 entirely.

MEMBER WAGNER: Using an activity other than the activity administered.

MR. CAMPER: Yes, but how are you going to address the point? You must have some basis of activity to begin with.

MEMBER WAGNER: Right.

MEMBER BROWN: It's activity administered.

MR. CAMPER: Sorry. Say that again.

CHAIRMAN SIEGEL: A zero has got to be the starting point. Differential equation we're going to solve here. I mean, I could be giving people 100 millicuries and let's just say, what I'm going to do is just say I gave him one. Let's just do that. That's using an activity other than the activity administered. That's willfully falsifying the records. I don't get it.

MEMBER NELP: But you have to keep that falsified record for three years.

MEMBER WAGNER: Could you possible have a situation where you administer an activity and for some reason it doesn't get into the patient? It falls on top of the patient or something?

MR. CAMPER: It triggers the creation of the record.

CHAIRMAN SIEGEL: This is goofy.

MEMBER WOODBURY: It doesn't make any sense,

Larry.

CHAIRMAN SIEGEL: What triggers the record?

MR. CAMPER: Using some number other than that amount of activity which was actually administered.

CHAIRMAN SIEGEL: No. But the only basis for using a number other than the number administered is because you did calculations related to 2, 3, or 4.

MR. CAMPER: Right.

CHAIRMAN SIEGEL: Because you can't say, well, i really gave this patient 100 millicuries but let's just say we only gave him 10 and we'll release him based on that. You can't say that. What you can say is, we gave them 100. This patient weighs 600 pounds. He attenuates a lot. He lives alone in the mountains and we're going to let him go home. Okay? Not because we didn't really give him 100. Because we gave him 100.

I think we should call the question to eliminate 1.

MEMBER WOODBURY: Call the question.

(Whereupon, an oral vote was taken.)

MEMBER BROWN: I'd like to abstain since I don't have the special knowledge to judge this.

CHAIRMAN SIEGEL: Let the record show that with the one abstention, that we unanimously recommend --

MEMBER NELP: The only knowledgeable person

abstains.

CHAIRMAN SIEGEL: You want to try (d)?

MS. TROTTIER: Yes, let's try (d). I really think (d) is probably pretty easy.

Yes, go ahead, Torre.

CHAIRMAN SIEGEL: Don't you dare say that.

MS. TAYLOR: I need to say that everyone that's speaking off the main table needs to say their name for the transcript so we know who's speaking.

MS. TROTTIER: Under (d), which is the last slide on this rulemaking, this is simply the addition that addresses the instructions for the breast feeding woman. And that it's to retain the record for three years. Previously we didn't have that provision in there at all because it wasn't in the previously proposed rule version you saw.

MEMBER SWANSON: I need to ask a question about that.

MS. TROTTIER: Sure.

MEMBER SWANSON: Excuse me. You've got providing instructions if the exposure could exceed .1 rem but your requirement for the written documentation is at .5 rem. Do you really mean that?

CHAIRMAN SIEGEL: Yes.

MS. TROTTIER: Yes, they say yes.

MEMBER SWANSON: So, you're saying --

CHAIRMAN SIEGEL: Breast feeding.

CHAIRMAN SIEGEL: Dennis, here's the --

MEMBER SWANSON: Let me just understand this as a licensee. I give instructions at the .1 rem level but you don't require that I have to document it unless it's above .5 rem?

CHAIRMAN SIEGEL: Right. And from an inspection point of view, what that means, I'm hoping, is that the inspector will come in and say what do you tell breast feeding women who are having thyroid scans with technetium pertechnetate. They might ask the technologist or they might ask the radiologist, or the nuclear medicine physician, or look through the brochure that's handed out. On the other hand, they might say have you treated any patients with I-131 for thyroid cancer who were breast feeding, or for hyperthyroidism in the last year. And then they'll want to see the actual record that says the patient was instructed that it is necessary for her to discontinue breast feeding. And that's in the chart. So that's the difference.

MEMBER BERMAN: But shouldn't that then say, in line 2, instructions regarding interruption or discontinuation rather than just instructions? Instructions were provided to breast feeding women.

CHAIRMAN SIEGEL: That instructions were provided.

MEMBER BERMAN: It's instructions regarding discontinuation of breast feeding.

CHAIRMAN SIEGEL: Well, it's discontinuation or interruption.

MEMBER BERMAN: Or interruption, that's right. But instructions regarding interruption or discontinuation of --

MEMBER NELP: You can maintain --

MEMBER BERMAN: I'm saying you should insert the words instructions regarding interruption or discontinuation of breast feeding.

CHAIRMAN SIEGEL: That would make it clearer.

Cathy, you had a comment on that?

MS. HANEY: I just wanted -- this is Cathy Haney. I just wanted to say at least preliminary inspection guidance, what we plan on saying is, having the inspector look at were instructions given, yes or no. Our intent at this point is not to have the inspectors looking at the instructions.

MEMBER NELP: That's reasonable.

MR. CAMPER: Amen.

CHAIRMAN SIEGEL: Doctor Berman has suggested, though, that clarification might require adding the following phrase, if I captured it. The licensee shall maintain a record for three years after the date of release that instructions regarding interruption or discontinuation of

breast feeding were provided to a breast feeding woman if the radiation dose to the infant of child from continued breast feeding -- that's getting to be a pretty legalistic phrase here -- could result in a total effective dose equivalent exceeding 5 millisieverts. And I think that clarification doesn't hurt. I think it helps.

So, we could entertain that as a motion, too?

MEMBER NELP: But haven't you already required those instructions to be given about breast feeding and this is specifically -- It's already gone through that scenario.

CHAIRMAN SIEGEL: I understand. This is just a different part of the rule and it's just to make it imminently clear.

MEMBER BERMAN: It's simply a clarification.

CHAIRMAN SIEGEL: It's simply clarification. I don't think it hurts at all. It's not redundant in this case.

Can we have a motion to make that a change?

MEMBER SWANSON: So moved.

CHAIRMAN SIEGEL: Second?

MEMBER BROWN: Second.

CHAIRMAN SIEGEL: Further discussion?

MEMBER BERMAN: Question.

(Whereupon, an oral vote was taken.)

MEMBER SWANSON: Mr. Chairman, can I make one comment on this subject? And item of concern that I think

this committee needs to look at. There's still a fair amount of concern in the nuclear medicine community that the new Part 19 and 20 regulations that define training requirements for the general public and for occupational workers may be inferred to mean that patients exposed, let me go on, to patients released -- or, excuse me. Family members exposed to the patients released may have to receive instruction. There's still some concern on that.

I think that what I would like to recommend is that how that is going to be addressed in Part 19 and 20 be brought specifically back for discussion at this committee at the next meeting.

CHAIRMAN SIEGEL: You're referring to 201301, Dennis?

MEMBER SWANSON: Yes.

CHAIRMAN SIEGEL: Those limits for individual members of the public?

MS. TROTTIER: Part 19 applies to workers' instruction, it's not for the public.

MR. CAMPER: That's correct.

MEMBER SWANSON: The problem is it says "Occupational dose does not include dose received from background radiation as a patient from medical practices from voluntary participation in medical research programs or as a member of the public.

CHAIRMAN SIEGEL: Correct.

MEMBER SWANSON: It doesn't say or from a patient, okay.

CHAIRMAN SIEGEL: But occupational dose, it does in fact include the dose from a patient.

MEMBER SWANSON: Absolutely.

CHAIRMAN SIEGEL: Yes.

MR. CAMPER: Every day.

CHAIRMAN SIEGEL: But remember occupational dose isn't at 100 mili-rems. Occupational dose is cut at 5 rams, right? So the fact that I work around patients who are treated with 100 millicurie doses of I-131 is very much relevant to my occupational dose, and my occupational dose isn't limited at 100 mili-rems per year and, therefore, I don't need an exemption to get it up to 500 mili-rems per year because because it's already 5 rems per year. fortunately I always get minimal, but that's where it is. Are you with me? So occupational dose and public dose don't mix in this scenario.

There has been some concern expressed that public dose was going to be tricked by this release stuff, but I've been assured in discussions that I've had with Mr. Camper and others that 35.75 will rule the day on this. And much as we've seen in other discussions were 35 provides more specific information that applies to a medical situation than the

generic information in 20, then 35 wins. That's been the general ruling made by the Commission on a couple of these questions.

MEMBER SWANSON: And I agree with you and I am aware of that from sitting on this committee, but I can tell you the way the regulations are currently written it remains a concern in the nuclear medicine community.

MR. CAMPER: Well, you have two things to bear in mind. If you go back to the wrong patient rule, 20.1002, "The scope," was modified so that it now reads "The limits in this part do not apply to dosage due to background radiation, due to any medical administration the individual has received."

The patient release rule further goes on to clarify "Or doses from an individual who has been administering material."

MEMBER SWANSON: Right, but will there be language in Part 20 to say that the patient release rule takes preference over the Part 20, Part 19 and Part 20 in a similar vein?

MR. CAMPER: Well, we do have some language. Where is the language that clarifies that the more specific part applies?

MS. TROTTIER: Are you talking about in patient release, Larry?

MR. CAMPER: Yes.

MS. TROTTIER: I don't have the rule in front of me, but there is no training requirement in Part 20 for members of the public.

CHAIRMAN SIEGEL: How could you train the general public? You can interpret that question on many levels.

MR. CAMPER: First of all, Dennis, let me, that information that was published in early '94 in which the Commission was explaining that. The more specific part, in this case Part 35, ruled more than the general requirements, Part 20. Subsequent to that, in the wrong patient rule under the language in 20.1002 "The scope," that has been further clarified that it does not apply to any exposure that the individual has received as a result of a medical administration.

In the language in the patient release rule, and I don't have that in front of me, it goes on to further indicate that it's also exposure to members of the public from an individual undergoing a medical procedure. So we have already been on record as saying that the more specific regulation applies, and we have further gone on to clarify even the scope of Part 20 in each of the two rulemakings.

But then the occupational worker part of it doesn't apply to members of the public. It only applies to occupational workers.

MEMBER SWANSON: I don't have a problem with

anything you're saying --

MR. CAMPER: Okay.

MEMBER SWANSON: -- to this committee. I understand your intent.

MR. CAMPER: Okay.

CHAIRMAN SIEGEL: I am concerned again that the regulations in Part 19 and 20 have been interpreted by the members of the nuclear medicine community, and more than one is saying that it could mean that patients -- excuse me, family members of patients receiving radioactive materials would be required to have training, okay. And for a couple of reasons, number one, they kind of fall out in between, okay. Public dose means the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, okay.

So basically I'm a licensee, I release a patient, okay, so it falls into that criteria. It says it does not include occupational dose or doses received from background radiation as a patient from medical practice. It doesn't say "from a patient from medical practices", it says "as a patient" or from voluntary participation in medical research programs.

All I'm saying is where is the specific language where Part 35 release criteria will take preference over Part 19 and 20 statements, that's all I'm saying.

MS. HOLAHAN: Dr. Siegel?

CHAIRMAN SIEGEL: Yes, Cathy or Trish?

MS. HOLAHAN: Okay, Trish Holahan. I just wanted to say that as part of this rule package there are changes to Part 20. One of the changes is to the definition of public dose to exclude doses received from patients released in accordance with 35.75. Also there are similar changes to 20.1301 in terms of the public dose limit.

MEMBER SWANSON: Thank you. And I think those need to be brought back out again.

MS. HOLAHAN: And they are in the rule package.

CHAIRMAN SIEGEL: Okay, good.

MEMBER WAGNER: May I make one comment please?

CHAIRMAN SIEGEL: Sure.

MEMBER WAGNER: On the pamphlet that was passed out, the regulatory guide 8.39, in your tables please make sure you distinguish appropriately between capital M's and small m's. We don't want people getting megacuries of activity.

MS. TROTTIER: Before you say anything further about the regulatory guide, I just want to make one important point. I'm giving you copies of the regulatory guide. I will put that in the public document room for individuals who are in the room and would like to get copies of it. It is a very rough draft. It has not been approved by anybody, so

therefore you can look at it, you know, taking it into account, it's status. Hopefully it will be soon out for publication, for comment. I don't anticipate this process taking a long time, but I don't believe it will go within the next couple months. So, you know, certainly your views are welcome, but as I said, you know, remember this is a very rough draft.

CHAIRMAN SIEGEL: And I've been kind of pushing hard over the last month or two to see if we were going to get this draft regulatory guide before the meeting so we could review it. We obviously haven't. The concern I've had is that when we discuss this rule the first time we really started seeing some real language, much of our concern related to the content of the draft regulatory guide. And so my question to you is, how do you wish to hear back from ACMUI about what's in here given that no realistic meeting time will allow us to discuss it at a meeting?

MS. TROTTIER: Because I'm putting it in the public document room, we can take written correspondence on it from anyone.

CHAIRMAN SIEGEL: Okay.

MS. TROTTIER: And, you know, as I'm trying to say, I'm giving it a couple of months because I don't anticipate it getting out of here within the next two months, but, you know, six months is probably too long to get back to

us.

CHAIRMAN SIEGEL: In the event that members of this committee worked hard tonight and we thought that there were some issues that needed to be raised while we're here, I'd guess I'd reserve the right, unless you tell me I can't, that we might try to address some of this tomorrow.

MR. CAMPER: I think that's fine, if the agenda allows it.

CHAIRMAN SIEGEL: Okay. So I would encourage all of you to try to look at this --

MR. CAMPER: Let me ask you another question, Barry.

CHAIRMAN SIEGEL: Sure.

MR. CAMPER: As Cheryl pointed out, these guides will be published for public comment. And what's the time line on this particular guidance document for public comment?

MS. TROTTIER: You mean how long?

MR. CAMPER: Yes.

MS. TROTTIER: We don't have one set. I mean I don't believe there is, you know, an urgency to have a short review period.

MR. CAMPER: You might want to ponder, Barry, whether or not a subcommittee may --

CHAIRMAN SIEGEL: Why don't I just move in?

MR. CAMPER: -- public comment period. I only

offer that as something to think about, and we would entertain that.

CHAIRMAN SIEGEL: Yes, great. It's not all that entertaining, but maybe.

Okay, continue.

MS. TROTTIER: Okay, now I did, you know, obviously tell a fib, that I could be done here in an hour, so we'll move on.

I believe the next topic will be fairly simple because I really don't have much to tell you. This is the guidance for the radiopharmacy rule. You reviewed it the last time you met, I believe, and we have taken some additional comments and we expect the guides to be issued for public comment shortly. The public comment period will be 180 days, so there is going to be a long period of time, but I think it's pretty close now, so.

CHAIRMAN SIEGEL: Yes, Dennis?

MEMBER SWANSON: Question?

CHAIRMAN SIEGEL: Yes, Dennis.

MEMBER SWANSON: Was it still your intention to conduct a workshop on that in the involved part?

MR. CAMPER: Yes, I wanted to make two comments. I wanted to, as Cheryl pointed out, this committee has seen this before. And also there has been a great deal of effort exhorted by Dennis Swanson and Marc Ratman. I think Marc is

still here. Dr. Ratman is one of -- is our ex-medical visiting fellow. And a great deal of work has gone into these guidance documents. Also Dr. Pollycove too has made a significant contribution. I want to thank them for that.

But, yes, we do intend, we have previously committed on the record that we would have a workshop, a one-day workshop, with representatives of the radiopharmaceutical industry, and we had hoped to do that before the guidance documents were published. That hasn't happened or won't happen for a number of different reasons. But, yes, during the public comment period there will be a one-day workshop here, and we'll allow representatives of the industry to take a look at the guidance as well, absolutely.

MEMBER SWANSON: Thank you.

MS. TROTTIER: Okay, the next rulemaking that we had on the agenda was the pregnancy and breastfeeding rule. That's currently on hold for a number of reasons. We're still waiting for information from our contractors as well as the decision to just hold off until we get the National Academy of Sciences study completed. But I believe the staff had actually come up with some questions.

In an effort to move this along, we could defer these really. I mean I don't believe there is an urgency, Dr. Siegel, if you would like to defer them. I think we had them on the agenda, but we're really not going to make any

decisions on this topic until the next meeting.

CHAIRMAN SIEGEL: This is not a five minute discussion.

MS. TROTTIER: Yes, I realize that.

CHAIRMAN SIEGEL: And I think when we do it, we ought to do it in a fashion to revisit the stuff we talked about three years ago --

MS. TROTTIER: Yes.

CHAIRMAN SIEGEL: -- and do it so we can really analyze it in depth and not in two minutes.

MS. TROTTIER: I would prefer to do that. So unless you object, I'll not --

CHAIRMAN SIEGEL: And I'm saying not just in the interest of our schedule, but in the fact that this really needs to be aired with more than a little bit of time.

MS. TROTTIER: Yes.

CHAIRMAN SIEGEL: Any disagreement? Okay.

MS. TROTTIER: Okay. Well, then I will jump to the petition and --

CHAIRMAN SIEGEL: Excuse me, Cheryl.

MS. TROTTIER: Yes, sure.

CHAIRMAN SIEGEL: We theoretically have about an hour and a half's worth of work to do and it's now 11:30, before we break for lunch. We don't know how long this petition will take. Larry was just looking to see if there is

any logical way to juggle this. I would propose that if we can get through all of it in an hour, that we work through until 12:30 and then not break for lunch until then. But does anybody feel hypoglycemic?

MAN: I've gotten pretty --

CHAIRMAN SIEGEL: You can leave.

MR. CAMPER: Another alternative would be to do the intervascular brachytherapy issues now and break at lunch.

MS. TROTTIER: We could go back and do it the way it originally was on the calendar, because --

MR. CAMPER: If you do that, you probably can cover the intravascular.

MS. TROTTIER: In 30 minutes.

CHAIRMAN SIEGEL: The only question I would ask is if there are representatives here from Tri-Med who would feel betrayed if they to stay until after lunch? The real question is whether you're going to miss your airplanes if we do it right after lunch?

MAN: Yes.

CHAIRMAN SIEGEL: Then why don't we take Larry's suggestion --

MS. TROTTIER: That's fine.

CHAIRMAN SIEGEL: -- delay it until after lunch and let's go on with intravascular brachytherapy.

MS. TROTTIER: Okay.

CHAIRMAN SIEGEL: We haven't even begun to consider the turf issues on this one yet.

MS. TROTTIER: Thank you very much.

CHAIRMAN SIEGEL: Thanks, Cheryl.

I announced earlier that we were going to get oral comments from ASTRO and I'm told we only have written comments from ASTRO, and you have copies of them before you.

Jim, go ahead.

MR. SMITH: Yes, the topic that we want to discuss today is something we see is coming on the horizon and it's probably a very large application of brachytherapy and a non-cancer modality.

We first got wind of this back in May when Trish came back from, what was it, the International Conference on Brachytherapy, down in Palm Beach. And we first heard that there was the proposed treatment of brachytherapy for restenosis.

From some of the information we received from one of the local vendors of sources it appears that in 40 to 60 percent of patients who undergo balloon angioplasty, that they're liable to -- they're possibly going to have restenosis later in the future. Various medications and mechanical methods have been used in an effort to prevent restenosis with very disappointing results. There is evidence that a proliferation of smooth muscle cells causes restenosis in

response to stretch and stimulation by a variety of growth factors. And this comes into play also because they are now using stents and they're finding that the stent itself also causes restenosis.

It's been hypothesized that local radiations to the angioplasty treatment site may result in a reduction of the incidents of restenosis due to the growth and inhibitory effect of radiation on vascular smooth muscle cells.

There have been two studies that I'm aware of. One is being done at Scripps Institute, and currently today they are having a conference to present some of their results. And there is another trial that was conducted in Germany, and they've had promising results. Animal and human studies using these treatments in Europe have demonstrated promising results. So there is a great interest.

Currently at the AAPM they decided to prepare a task group to deal with this issue. They plan to put out information regarding the modality in a newsletter, and they're also planning on doing a task group report on the subject.

It's estimated that approximately 400,000 patients a year will be candidates for this procedure, so this can well outshine any radiation treatment or brachytherapy treatment of cancer patients. With this number of treatments it's anticipated that the use of brachytherapy may be used

more by cardiologists than by oncologist. I know we've always had issues of training experience with cardiologists here in the nuclear medicine area, and this may be another area for the training experience issue to come up again.

Additionally, in recent months, ever since we found out about this, we've been approached by several manufacturers, some that are suggesting that we use permanent implants in the microcurie range, some are currently using or plan to use HDR treatment for these treatments.

The activity sources ranges from microcurie for the permanent implants up to the curie range for the HDR treatments. Since the goal is to deliver a dose of radiation to the smooth muscle cells and vessel and to limit the dose to the rest of the patient. Some manufacturers are suggesting that they use a beta emitting coated stent under 10CFR35400 intravascular brachytherapy is not an approved use, nor is the use of this unsealed source.

Trish? I know each of you has these questions in your handout, but for the benefit of the people in the audience?

MEMBER BROWN: Is it necessary for me to know what restenosis is, or just to know it's a bad thing and you don't want it?

MR. SMITH: It's following balloon angioplasty I believe there is a growth of cells inside the vessel wall, and

it basically it occludes the vessel within a few months following the treatment.

MEMBER BROWN: Okay.

CHAIRMAN SIEGEL: Buzz, please use the microphone so people can hear you.

MEMBER BROWN: Thank you.

CHAIRMAN SIEGEL: Okay. Did you get any of that? Doctor Nelp tried to say that it was a tightening up of the coronary arteries so that blood flow is impaired again following angioplasty.

MR. SMITH: We understand that it also goes to femoral arteries too because there have been some peripheral treatments and they had the same results.

The first question we have is, should NRC consider changing its training experience requirements to allow cardiologists to perform these treatments? We have discussed this matter with our office director, and his statements to us, although they're not written down, is that regardless of who performs the treatment, they should have the same training experience as a radiation oncologist currently required under our regulations.

MR. CAMPER: Yes, I was going to point that out. I mean it's not so much allowing cardiologists, it's that currently the training requirements in Part 35 are so extensive for the use of brachytherapy that it may or may not

be compatible with the practicing cardiologist's ability to leave their practice to go get that training.

You have a similar situation, although on a much smaller scale, with the didactic training requirements in 35.920. I mean currently it's on the order of three years to be able to use brachytherapy. But by the same token one can envision that if this is something that fits readily into cardiology practice there could be an interest in cardiologists, and that might translate into an effort to reduce the number of hours.

MR. SMITH: Especially when you consider the fact that there is a wide range of treatments that they are planning. There is the permanent implant where you're dealing with microcurie amounts of activity, so there's really not a whole lot of radiation safety involved as far as the occupational exposure to employees and exposure to members of public. However, you're going to get the same dose to the patient's vessel wall.

MEMBER BERMAN: Just a point, it's probably not just cardiologists, it's cardiologists and radiologists who are not radiation therapists because these are not only for the coronary arteries, so it's a broad issue.

CHAIRMAN SIEGEL: And vascular surgeons.

MEMBER BERMAN: And vascular surgeons, okay.

CHAIRMAN SIEGEL: It's a fairly broad rule.

MR. SMITH: We can leave that one up there.

And that's the next question here. Should someone who is conducting this treatment using a permanent implant have the same training experience requirements as somebody who is doing it with HDR? I guess it depends on how you view the training experience requirements. Are we there looking for the safety of the patient, are we also looking for the safety of the individuals who are conducting the treatments?

CHAIRMAN SIEGEL: This seems to me like a technology eminently in need of partnership during its formative years.

MR. CAMPER: I want to come to that at the end. I have some questions. I have a concern about supervision along the lines of what we previously discussed with the urologist/therapist connection for the prostate implants. You might recall we discussed that not too long ago.

I can readily see where this question of adequate supervision and interfacing could be a problem for these procedures.

Are you going to go back and revisit each question?

MR. SMITH: Well, I was hoping we could visit these questions right now, but we can present them --

MR. CAMPER: Because I'd like to get the

committee to come to some kind of --

MR. SMITH: Okay, all right.

CHAIRMAN SIEGEL: We should go back to number one?

MR. SMITH: This is number one here.

MS. HOLAHAN: Do you want to go back to slide one?

MR. SMITH: No, let's just go through them first and then we can go back and try to get comments.

MR. CAMPER: Oh, I see, okay.

MEMBER NELP: May I inquire again, you said for an individual to be qualified to use brachytherapy now, it's an approximate --

CHAIRMAN SIEGEL: It's three years.

MEMBER NELP: -- three years of appropriate training.

CHAIRMAN SIEGEL: Basically a radiation oncology residency.

MEMBER NELP: A three year residency equivalent.

MR. SMITH: And also another issue that's come up with this that we've never seen before, brachytherapy, I believe, is traditionally done with sealed sources. Now, in order to use a beta emitter inside of somebody, we've had recommendations that they have a beta emitting coated stent. Now, the problem with the stent is that when it expands, part

of the coating is going to break off and go to the rest of the body. Now, we don't anticipate that the doses anywhere else in the body will be high as where the stent is localized, but should we have some sort of criteria from this administration.

CHAIRMAN SIEGEL: You're way ahead of the curve. In fact it seems to me that you're also -- but it's good to know that you're thinking of that as the first thing on your plate. Where is CDRH in these discussions?

MR. SMITH: We've had joint --

CHAIRMAN SIEGEL: Because it seems to me that before any of these things are going to get used, they're going to be in the loop pretty early in the game.

MR. SMITH: -- I think I can say the following, and if I don't say it, if I say something that is proprietary, Ralph, just jump up and scream. Ralph Shupin is in the back there. And let me see if I can remember her name --

MS. RYAN: Tara Ryan.

MR. SMITH: Tara Ryan, and Graham Zuckerman from CDRH are here, and we've had joint meetings with them with three manufacturers. Currently I believe FDA's position is that this is an intervential treatment with significant risk, therefore, even though you have a broad scope license and you have an IRB approve it, FDA is going to have to approve your IRB's review of this treatment before you can proceed.

CHAIRMAN SIEGEL: So these devices clearly need

an IDE in order to be used per FDA's viewpoint?

MR. SMITH: Ralph is shaking his head, so yes I guess that's correct.

CHAIRMAN SIEGEL: I'm sorry for all the abbreviations.

MR. SMITH: Okay.brachytherapy CDRH was Center for Devices and Radiological Health. IDE is Investigational Device Exemption.

MR. SMITH: Now, Scripps Institute has conducted these trials. Now, I don't know whether or not they received approval from FDA, but I don't believe they did. Today they are doing a conference on their results. It's been kind of difficult to get any information out of them. I believe they believe their treatments are proprietary right now. I don't know how much longer they will be conducting their treatments though.

Okay, we can go to the next one.

MEMBER BERMAN: Do you know if they involved radiation therapists or if it done by cardiologists?

MR. SMITH: We don't know anything about it. They've pretty much kept it quiet. We've heard some rumors. It's been really quiet. Although the manufacturer of the sources for these treatments has promised me that after today he will give me some information on the trials.

Also, this is another issue that's come up, as

far as FDA is concerned, intraluminal does not mean intravascular. However, at least one HDR unit is approved for intraluminal use, and that manufacturer has stated that in his opinion or its opinion that intravascular should be included in intraluminal. And we'd like your comments on that, what do you think? I personally see some differences in sticking a catheter in somebody's heart, but I'm not a medical physician, so. I think we can go on to the next question.

CHAIRMAN SIEGEL: It's no worse than magnetically steered sources going into the brain.

MR. SMITH: And, again, this is sort of just a catchall, are there unique radiation safety concerns associated with this? If you're conducting this treatment and the source should happen to break off and lodge in someone's heart, you're going to have to have a team go in and remove the source. And I'm not sure how complicated open heart surgery is, but I imagine staring at a 10 curie source would be kind of a difficult situation to deal with.

CHAIRMAN SIEGEL: It's more complicated than lancing an abscess I can tell you, especially with a 10 curie source on board.

MR. SMITH: Yes. Now, I believe that everyone got a copy of the written statement from ASTRO. And it's their conclusion, I believe just from summarizing it, that we shouldn't change any of our regulations, that we should keep

our requirements the same and view the training experience requirements as the same for radiation oncologist regardless of who is performing treatment.

And that's the last question I have. And then I guess we can go back and run over each question individually.

MR. CAMPER: Jim, before we actually go through each of the questions, I would like to afford the opportunity for the representatives from FDA, if you have any comments that you'd like to make about the procedure, the modality, or where you stand in your review process, or anything you think might be of use to the committee, if you'd like to make some comments, please feel free to do so.

MR. SMITH: I think earlier they called me to let me know that we got in touch with them a little too late and they wanted a prepared written statement and it was a little late to do that.

MR. CAMPER: All right, I just wanted to afford the opportunity.

CHAIRMAN SIEGEL: So let ask a clarification question. Do you have any license applications?

MR. SMITH: No, we don't have a license application for the medical use, but we do have ongoing discussions with the device and source manufacturers to try and see what we're looking for and what FDA is looking for. Currently FDA is a the big hurdle because they've made the

statement this is a significant risk device and treatment, so we currently don't have anything to worry about. Nobody has got approval from FDA, and until that happens, we're not going to see any treatments done at an NRC licensee.

CHAIRMAN SIEGEL: It would strike me, and I'm curious to see, I'm told that we have a manufacturer's representative here who would like to make some comments. Let me just speak for a second here and then we can perhaps do that.

It strikes me that this is an emerging technology that involves some issues that unequivocally require the expertise of cardiologist and/or cardiothorasic surgeons intervential radiologists and/or vascular surgeons, people who are trained in steering catheters in the vascular system and understand how to treat the complications related to the presence of the catheter, the administration of contrast agents, and understand how to interpret the significance of vascular stenoses and whether and how they need to be treated. That's one group, one level of expertise.

It also seems to me that there is a substantial opportunity here for problems related to radiation safety, and they include both permanently implanted low dose rate sources and certainly include the high dose rate sources that would need the expertise of a team of individuals that might include physicians, radiation oncologist, but also would very likely

include medical physicists with expertise in brachytherapy and the rest of the team that's normally assembled in a radiation oncology department.

And I would think that rather than us trying to give glib answers to your very complex questions, that urging you to do initial licenses by way of a team approach as the basis, that you'll accept this going down, is the right way to start to emerging technology off and then let's watch it evolve.

I think to say right now that we should say well, but cardiologists who take six months of training in brachytherapy ought to be able to do this without the aid of anyone else in his medical center. I think that would be a mistake. First of all, that individual couldn't get that training. It's not clear where it would come from right now, or it might be difficult to get that training. And I think just as we encouraged with the prostate cancer seed implantation that this warrants a team approach to medical care.

And in some ways, you know, there's going to be a concern, everybody is concerned, you know, Medicate will only one physician for this procedure, but I think having this committee and the NRC and the FDA take the posture that this warrants a team approach is at least one way to encourage HCFA to think that there might be the need for more than one

billable physician involved in this procedure. And I'd be curious to see what the rest of you think about that.

MEMBER NELP: It isn't clear to me what sources of radioactivity or what amounts of radioactivity are being used or proposed to be used in these --

MR. SMITH: It ranges the gambit. We have beta emitters in the microcurie range for permanent implants.

MEMBER NELP: What species of nuclides?

MR. SMITH: Well, I don't know that I can tell you. I know that there has been a publication at least on P-32 coated stents. I know that there are one or two other isotopes that have been I guess given to us in confidence, I don't believe that we can release that information right now in the public forum.

MEMBER NELP: Judith, are you aware of what materials they're using and what levels of activity they are using?

MEMBER STITT: The iridium-192, 10 curie source is one of the ones that are, what was it again, Eminent Chair, Esteemed Chair?

CHAIRMAN SIEGEL: Esteemed, Esteemed.

MEMBER STITT: Is so clever because he sent to all of us who have E-mail, and those who don't have these articles, which is probably everybody but me, the Helicobacter pylorie group of articles as well as the HDR, and the animal

research is being done with iridium-192 and the German trial that was published in the Red Journal was also with the high dose rate, 10 curie source. So that's a common source, it fits into the lumen.

Let me make some comments. I think the questions that you've put together are far more detailed than our knowledge, and it's a good question base to start with. In my opinion number five is probably the most important question of all of them. The others are specific detailed questions But this procedure is a unique radiation safety concern, and I don't think it matters that it's treating benign disease, it's not benign in the sense that it's a very lethal disease. It's not a neoplasia type of disease, but as we've all sat through our discussions, committee meetings regarding particularly the use of high dose rate sources, it requires tremendous expertise, exactly as you put it, Esteemed Chair, from a team of people.

Well, certainly the cardiologists bring things that radiation oncologist bring different, and our physics colleagues, without whom we could have no idea of what we're doing or where we're doing it, when you look, if you would just white-out vascular stenosis, it reads just like a cancer article as far as the doses, the dose rates. The total doses are exactly what I give for endometrial carcinoma. These are high doses with high risk procedures, and have to be done very

very carefully.

We'll have misadministrations expediential with little numbers up in the corners that we haven't even seen before without a team approach. This is not a small amount of a low energy isotope that's being used for a nuclear medicine study.

I think that maybe we're ahead of the game in the sense that in some of the other isotope technologies we, as a group of professionals looking at safety saw it coming after it happened, and I think maybe we're ahead of time and potentially are leaders. So I appreciate the work that you've done. I would have to be called a biased observer because I'm a member of the subcommittee that put together the ASTRO intravascular document.

The fourth paragraph makes a statement that likens it to a lot of the other collaboration that radiation oncology is involved in, that is we cannot do endobronchial therapy which intraluminal and intravascular is a sub type of intraluminal, they're just body lumens, but we could not do that procedure in radiation oncology without the pulmonologist. And I think there is no reason to think that this technology is not going to be evolving in a direction that would be different than that.

MEMBER NELP: Can you tell me what dose rates you're delivering, they're delivering to the --

MEMBER STITT: Dose rate?

MEMBER NELP: -- to the lumenal walls?

MEMBER STITT: 300 --

MEMBER NELP: Not rates, I mean total doses?

MEMBER STITT: Total doses, well most of the articles are all in pigs. There's one in humans, but -- and the fractionation is variable, from a single fraction to multiple fractions, but 2000 centigray to a small volume. I have to go back to the old fashioned 2000 rad.

MEMBER NELP: That's nice, very good.

MEMBER STITT: Me too. When the numbers get in the decibel points and start moving I have to go back to the olden days.

MR. CAMPER: I'd like to make a comment.

MEMBER STITT: Okay.

MR. CAMPER: I'd like to put this entire discussion into perspective. There is much to do in the future obviously about this, and we will come back to the committee from time to time with specific questions or issues about this modality as it emerges. What we're attempting to do in various, and if we couched it adequately, and that is this is a very complex issue and we will explore it specifically, but what we're trying to do in keeping with the effort over the last three or four years certainly is to come to this committee earlier and earlier with conceptual

problems, and layout at least a framework for you to begin to think about the fact that we're going to visit this in more detail.

And one of the things that I think that we're going to have to explore more clearly as we move in any revision of Part 35, is this question of supervision. Supervision was changed significantly in 1987 when Part 35 was last revised, and it's a fairly loosely worded issue in the statements of consideration. And I think that there are modalities and practices which have emerged or are emerging where this team approach needs some attention. And we'll call upon you ultimately to help us articulate what that team approach should be like or what does constitute an adequate level of supervision, so we will get back to that at some point.

But we're just trying to say this is coming, we're aware of it, and we're going to be talking with you about it in more detail. But any thoughts you have at this point in time about these specific questions will be helpful to us at least for formulating ideas to look at for the future.

MR. SMITH: Okay, did you want to go back over the questions one at a time, or let's talk now?

CHAIRMAN SIEGEL: I'm going to allow this even though it was not announced. Do we have a representative from

Nucleotron who wants to make a couple of comments, and if so I'm going to let him do so? You can go to the mic if you'd like to. And please announce who you are, who you represent for the record, and try to keep your comments down to a couple of microseconds.

MR. TEAG: Is that like a couple of microcurie? My name is Steven Teag, I'm a representative of Nucleotron Corporation. And item four of the agenda discussing the definition of intraluminal to include intravascular came from a proposal that we offered to FDA recently.

I believe most of the people at the committee know who Nucleotron is and the product line that we developed. I'm not going to flatter anybody by using esteemed and distinguished to address the committee --

MEMBER NELP: Could you please tell us who Nucleotron is?

MR. TEAG: Okay. Nucleotron is the largest manufacturer of remote afterloading brachytherapy devices. We currently hold a 75 percent market share of this technology, and we have been the vendor that has developed all new technologies related to this specialty of uses of sealed radioactive sources in treatment of diseases in humans.

My first comment is concerning the regulatory space. And from the previous discussions we've heard this morning on training and experience, and I'll start with 35

Part 940 describing the T&E for brachytherapy. There is an exception to that in 941 for the ophthalmic use of strontium 90 applicators as a source, specifically by non-radiation oncologist with that sub specialty. I offer that since 35 is being rewritten in its entirety in the next several years. The time is right to consider more medical specialty related items under training and experience rather than these global, you know, credentially by certain professional organizations.

My second comment is one, and I hate to say this in front of Dr. Stitt who I know well and admire intensely, but I am objecting to the very narrow view that ASTRO has taken in their prepared document, that only radiation oncologist have the T&E to use any sealed sources safely. I believe that -- I won't go any further down that line right now.

The third question that I'd like to address is number five on Mr. Smith's list of questions to you, was the area of radiation safety. Since the Nuclear Regulatory Commission, or from Mr. Quillin's standpoint, the agreement stated equivalents, authorized and licensed each device that uses radioactive materials including the radioactive sources themselves, this is a form where radiation safety issues regarding the technology can be well and appropriately addressed in the design and testing requirements prior to an agreement say or the NRC authorizing the licensing of a device

for use in humans.

I believe that the engineering design and the testing thereof can prove the inherent radiation safety of a device or of a radioactive source. Supplementing, that is adequate training and experience, for the authorized users of this device will suffice to serve the public needs for radiation safety both in the patients that are treated with this technology, the staff and physicians and paramedical personnel that will be involved with this, and global view of radiation safety to the public as a whole. Thank you very much.

CHAIRMAN SIEGEL: Dr. Nelp?

MEMBER NELP: I presume this translates into the corporate entity that you represent and probably also into the economic entity of the corporation. And the corporate position is that other users could use the device, and I presume you see this as a better economic pathway or a more facile pathway for you to follow than to market the device say through radiation oncologist. I'd like some feeling for what the company thinks about when they are marketing a device of this sort in terms of the user. You want to broaden the user base, but you imply that the user base will be bigger if you let more people in rather than channeling it through the current channels. Is that correct?

MR. TEAG: Currently there is no marketing

strategy that my company is proposing to use because there is no approved device either through this Commission or through the Food and Drug Administration to market any device for this indication of treating vascular diseases with radiation.

Certainly I echo Dr. Siegel's comments that this will be a multi-specialty use device in that the catheter twister is the intervential cardiologist, or in the peripheral area the intervential radiologist who has the training and experience to manipulate a catheter safely within the body. The application of radiation within an existing catheter is currently the prowess of the radiation oncologist, or other medical specialties that the Commission has previously defined as suitable for using certain specific isotopes and delivery systems, i.e. the ophthalmic applicator by ophthalmologists.

We see a public health benefit nationally to this whole treatment of vascular disease with radiation and a reduction in overall health care cost for vascular disease, which we all know is escalating almost exponentially. And that's basically the end of my prepared statement.

MEMBER NELP: Thank you.

CHAIRMAN SIEGEL: Does anyone have any other questions? Thank you very much.

MEMBER BERMAN: But related, it seems logical that if the use of a new technique for a very broadly, very prevalent condition like restenosis becomes something that's

out there, it will be inhibited if there is the need to involve two specialists compared to involving one from the growth of that technique.

I think that Dr. Stitt's comments are appropriate. I mean we do all this discussion about the use of diagnostic radionuclides and how much training a cardiologist needs, and at the same time we tell the NRC don't even regulate the field because nobody dies from these small diagnostic doses, and that's a discussion we'll have next February, but this one is larger. Now, we're talking about really sizable doses that could have potential major impact on the patient, and I think that it is an important area for us to try to help at an early stage, get involved in the early stage to define a joint pathway for doing this appropriately.

MEMBER STITT: And the other thing that will help us along the way is that we will be gaining a medical physicist with a brachytherapy background at some point in time. And I think the cardiologist and the radiation oncologist could find some common ground. I think the most important person in the whole event is the radiation physicist, the medical physicist because that's the radiation safety of the staff and the patient, and having some idea of where that dose is and where that dose isn't, so.

MEMBER BERMAN: But as that evolves over time then it's perhaps possible for the future, but a cardiologist

collaborating with a very strong radiation physicist would be able to do this -- that an exemption or some kind of training reduction from what an radiation oncologist goes through might be appropriate for a cardiologist if they're doing this in conjunction with the appropriately trained radiation physicist.

MEMBER STITT: Well, again, I think we need to look at the safety. Safety to me of the patient and the public is where we need to start this whole procedure. The bodies will come. We don't want to modify training, we want to start with the overall picture.

CHAIRMAN SIEGEL: I've been waiting to see what your comments were on this because you actually have two potential conflict of interest positions on this one, and I'm saying this jokingly. One is you could want to encourage cardiologists to be able to do this, speaking for them, but on the other hand you should remember that if this things works you're going to be doing a lot fewer thallium scans to look for restenosis in patients who had angioplasty three months ago, so it's going to have a big impact on your business. Just remember that.

Now, I think the discussion focuses exactly on what we were already talking about earlier this morning, and it focuses on the thing I've been telling you for four years, which is you need to change the paradigm. Instead of starting

with existing medical specialties and trying to make the training and experience criteria more or less fit the models of those existing medical specialties who think they're doing an adequate job, each of the various things you should license, we should figure out what the training and experience really is that's necessary to do that irrespective of where you come from and what your other background is, and divorce the radiation safety aspects of this from the medical aspects. And then it will be easy.

Then we won't be thinking along specialty lines. It is possible that, having defined those requirements, that some specialties will be able to come and request deemed status and say our specialty training program already routinely incorporates all of these elements, therefore, board certification in our specialty should be sufficient to document that we have fulfilled the training experience.

In the past I think this was developed based on how can we make what we're going to put on paper fit the existing specialties as opposed to literally starting from the other end and do a ground-up approach to developing training and experience criteria.

MR. CAMPER: I think that's true, and I think as part of that deliberation when we get to it is, again as I have said before on the record, it's the concept of what is an authorized user in 1995. You know, you have using radiation

and radioactive material in the course of the practice of medicine, that means something and it may carry with it a particular level of training, but on the other hand you also have radiation safety in its pure sense for the objective of maintaining radiation safety, and that may carry with it some different level of training or meaning.

And the truth of the matter is, is that is what authorized users historically have been may not be the same thing today or in the future, and we need to explore that as part of that process.

MEMBER BERMAN: In terms of the precedent, the comment was made that ophthalmologists are allowed to use an ophthalmologic application without being radiation oncologist. Could you explain why it is that that particular exemption exists?

MR. CAMPER: Well, it's not an exemption. In 35.941 --

CHAIRMAN SIEGEL: It exists, it exists because at the time this was created a substantial amount of that was being done by ophthalmologists. In fact probably more of it than by radiation oncologist. And the regulations were designed to capture the amount of training that ophthalmologists were currently getting in order to do this. It was a top-down regulatory approach from existing medical structure versus a bottom-up approach based on safety

considerations.

MEMBER STITT: And if you look at the practice of medicine, that is what are the safety issues and what are the medical issues, the strontium applicators are sort of black magic. No one can calibrate them, no one knows what dose you're giving, you kind of wave them around, and I'm being silly, but that's actually true, and depending on if your stopwatch works or doesn't work or, you know, if you whack the thing on the table, you may be exuding some radiation. But the medical issues and the safety issues are at absolutely opposite ends of the spectrum.

And we kind of laugh about the strontium because it seems to show up on our agenda every time we have one of these meetings and people roll their eyes because it really is a bit of a black magic sort of thing. And I think that Dr. Siegel described it well, top-up versus bottom-down type of thing. So we have two real different agenda items if you're comparing the --

MEMBER BERMAN: But is it also true that the radiation exposure potential, the potential hazard to public safety or the patient safety is much less with the ophthalmologic application?

MEMBER STITT: Yes, there's essentially no--

MEMBER BERMAN: -- So given that then, aside from the ophthalmologists are there any other kinds of exceptions

to radiation oncologist kind of training being required for this kind of application on the body? I think it would help if we can say no, there are not.

MEMBER STITT: Not a thing that I can think of. That's a real out --

MR. CAMPER: No, we only have the two at this point. We have the 940 which is the full spectrum of brachytherapy sources, which is the three years or certifications and the other one, of course, is 941 which is the ophthalmologic of strontium 90, but those are the only categories of brachytherapy therapeutic use.

MR. SMITH: But you also want to keep in mind that there are other proposals beyond HDR treatment. I mean there is the permanently implanted stents with radioactive materials on it. And from a radiation safety point of view, it's nowhere near HDR.

MR. CAMPER: Well, I think one message I'm hearing here as we go through this T&E issue in the future, I think we're going to be taking a long hard look at each of these modalities and what is the appropriate level of training or nature of training for each of these modalities. We have quite a bit of work to do, don't we?

MR. SMITH: Well, I think there are other people out there who believe we have a lot of work today too. Like I said, AAPN has already formed a task group for this, and there

is a lot of talk about it amongst other groups too.

MR. CAMPER: Do you want to go one by one to the questions.

CHAIRMAN SIEGEL: Dr. Wagner had a comment first?

MEMBER WAGNER: I just want to make the comment that I am fairly chagrined at the idea that item number three is placed at item number three. I think item number three should be way back in everybody's mind, and what we should be worried about is whether or not we've got proper training for people to minimize anything that may occur because ill trained people are using these devices.

I think the mind set of putting number three in the priority status it was given here, although these may not have any priority status, it's just an ill focused idea. And that we ought to focus more on items one, two, four and five as the prominent issues to be addressed at this point.

MR. CAMPER: Lou, we agree. They're not prioritized. But by the same token having said what you just said, and I agree with you, I can assure you that at some point discussions about misadministrations associated with these kinds of problems will become an extremely volatile issue. And it's good to at least at this point in time plant the idea in your minds that we need to deal with this at some point, because nothing inflames like misadministration. So this if food for thought.

CHAIRMAN SIEGEL: But of course the National Academy of Sciences is likely to tell you to decriminalize the misadministration issue and then it will be a whole different approach in your mind set as well.

MEMBER NELP: To answer --

CHAIRMAN SIEGEL: Having said that, I can only hope that that's what they're going to tell you.

MEMBER NELP: To answer your question about going through your questions, I as a advisor would much prefer that you go through your questions and then answer them, and I'd rather look at your solutions than your questions

MR. SMITH: Okay.

MEMBER NELP: You know how your approach will be, then we can construct more from that, I believe.

MR. SMITH: Well, basically I think the questions are leading themselves.

CHAIRMAN SIEGEL: We can do the questions.

MR. SMITH: Okay.

CHAIRMAN SIEGEL: We can do it. Do you want to project them real quickly for the audience.

MEMBER NELP: Thank you, Esteemed Chair.

CHAIRMAN SIEGEL: Thank you, Esteemed Committee Member.

Should NRC alter its training and experience requirements to allow cardiologists to be named as authorized

users for the modality? And I think the answer we have essentially given at the moment is, it would be premature to do so. And in the same breath we would encourage that once FDA has got far enough to start considering having these devices out with IDEs for clinical testing, that the NRC and state licensing posture for the use of these devices should be based on a team approach where all the kinds of expertise are in place necessary to develope the technology properly.

Because we're really in the evolutionary phase of this approach, and I think the problems that could arise, you've thought of some of them, but I'm sure we haven't though of all of them, and the best way to capture those problems is to make sure that people with all the right kinds of expertise are playing the game.

MR. SMITH: And we've tried to stay pretty close with the FDA and some of the manufacturers on this so that we're abreast of what's going on in the community.

CHAIRMAN SIEGEL: So do you all agree that recommending a Part 35 change as a quick fix for this would clearly be inappropriate?

CHORUS: Yes.

CHAIRMAN SIEGEL: Okay.

Next, should the microcurie range permanent implants require less training than the HDR treatments even if each is designed to deliver a total dose of 10 to 20 gray to

the vessel wall?

MEMBER NELP: I think that's a detail that I would refer back to your first answer.

CHAIRMAN SIEGEL: But I think once we know what's involved, the answer is likely to be yes. But because the radiation safety issues to the team involved, occupational exposure is going to be much less of a problem than if a 10 curie iridium source breaks off in a coronary artery.

MEMBER BERMAN: I'd just like to say that I think in the development of the kinds of modifications of training requirements it's going to be important to have a multi-specialty representation at the table and public comment in the deliberations.

CHAIRMAN SIEGEL: Oh, I agree completely, Dan.

I mean I think, if I were the FDA and I'll make this comment for them, and I were working with the manufacturer to design the kinds of people that were going to be involved with the clinical protocol, I would probably insist that the protocol, that the people involved have expertise in both brachytherapy and in steering catheters in coronary arteries, and that there be a team approach and monitoring clinical outcomes. Okay, so, yes, but premature to item two.

Number three, Dr. Wagner I think has already addressed how we feel about item three. You know, if FDA

writes the package insert that anticipates the dose to the other tissues based on flaking of the seeds or migration of activity then it won't be misadministration.

But I think that we really are ahead of the game on worry about how you're going to define a misadministration on this emerging technology.

MR. SMITH: We've never used an unsealed source before for these treatments, so we're not really sure we have a requirement that you check for leaking sources, and if you have a leaking source during a brachytherapy treatment, that's a misadministration. We know these things are going to leak to start out with.

MEMBER SWANSON: Again, I think this is an area where you really need to cooperate with the FDA to, as they evaluate these devices, to try to make sure that that doesn't happen, okay, up front. I mean that needs to be something that they're looking at as part of the device development process.

MR. SMITH: Okay.

CHAIRMAN SIEGEL: And question four is, at least one HDR unit is currently approved by FDA for intraluminal brachytherapy and the manufacturers argue that intraluminal includes intravascular. Should NRC interpret intraluminal as including intravascular?

I think the implication of that question is that,

if you simply make that interpretation, then people can go forward and start using this clinically today with no further thought. And my sense is that this committee thinks that this technology needs to be evaluated.

MR. SMITH: Okay.

CHAIRMAN SIEGEL: Do you all agree that we wouldn't want this turned loose in clinical, routine clinical practice tomorrow simply because of interpretation of a meaning of a word?

MEMBER STITT: That's exactly right.

MR. SMITH: I think FDA has made the same conclusion, that it doesn't include intravascular.

CHAIRMAN SIEGEL: Any disagreement on that? Okay.

Question five, are there unique radiation safety considerations associated with this modality, for example where is the most likely location within the medical institutions for such implantation?

The second part is easy, it's going to be in the cath lab or in the intervential radiology suite, sometimes in the operating room, but less often. It is much less likely to be just down in the basement with average radiation oncology departments.

MR. SMITH: It's still going to require shielded treatment.

MEMBER STITT: Or extraordinary shielding for high dose rate sources. So again we've got a new plant facilities here that most places will not have.

CHAIRMAN SIEGEL: But the average HDR room isn't currently equipped for cardiac catheterization either.

MEMBER STITT: No, our's would come close because we do everything under flovro, etcetera, etcetera. But you're right, there's probably no location in anybody's --

CHAIRMAN SIEGEL: Biplanar flovro?

MEMBER STITT: Yes. But that's unique, that's just our place. You're right, most cardiology suites, nor most HDR suites could do this procedure. And I think the other radiation safety aspect is we all have to find a friendly cardiac surgeon to agree to be the one that goes swimming for that source that just left its tether.

CHAIRMAN SIEGEL: That's a key issue.

MEMBER STITT: Right. And we keep bringing that up at our meetings here, and it's not a small issue. We do have to be prepared, and I believe that's the regulation that we were looking at three weeks ago, the guidelines say, if you're going to submit a license, you have to show that you are prepared to deal with these radiation emergencies.

CHAIRMAN SIEGEL: I mean here is the scenario, the source just broke, the source was sitting comfortably in the proximal left anterior descending coronary artery where it

was eradicating the area that had been angioplastated. The source is now sitting in the distal left anterior descending coronary artery where it has caused an acute myocardial infarction, created ventricular arrhythmias that have made the patient very unstable, and a cardiac surgeon is asked, at risk to his own life, to go in and remove the radiation source in a patient who normally would not be a candidate for any form of surgery because he's too unstable. I think that's a pretty significant safety problem.

Do you agree, Dan?

MEMBER BERMAN: Yes. The only thing that I'm still unclear about, and I need clarification maybe from Judith, is the difference between the beta emitting coated stent and the high dose radiation?

MEMBER STITT: Yes, and we're talking about a broad category. A beta emitting coated stent is totally different than radiation safety-wise and interstitial implants where you could get the source activity wrong and then totally different than a 10 curie source that's the size of a grain of rice that has been known to become disconnected.

MEMBER BERMAN: And the reason that I'm asking is, I think from what I'm just hearing here, there's a tremendous amount of -- we've focused a lot of attention on the high dose radiation rate approach.

MEMBER STITT: Right.

MEMBER BERMAN: And that has a lot of implications for safety. I think the cardiology community may actually be going more in the direction of the beta emitting stent approach. And if that's the case, shouldn't we be further discussing this question number two, that if you were to ignore the high dose rate approach for a second and come back to the discussion of the beta emitting stent, are all of the things that we're talking about in terms of hazards still relevant so that this is something that needs to be put on to the back burner until it's worked out, or are they so irrelevant it becomes more like a ophthalmologic application?

MEMBER STITT: Well, I think that each circumstance is unique, and there are specific relative hazards depending on which isotope and which technique, and again where, to kind of restate what we've said, we're at the beginning of the differing technologies, and if the beta emitting stents are going to be up for FDA review and accessible to the medical community soon, that can be worked on. But it still requires a collaborative input, but there are some issues of radiation safety that are different as well as medical safety.

CHAIRMAN SIEGEL: Since you did not have E-mail at the time that I distributed this, I sent everybody on the committee who has E-mail a literature search that I did on this. And I actually, and we can make copies for whoever

wants it, I actually did not find any articles that have used, in the published literature, low dose stents.

MR. SMITH: I have a set of articles that was given to me by a source manufacturer recently, and one of those is regarding a P-32 coated stent. And I have 15 copies, so whoever wants one can have one later.

CHAIRMAN SIEGEL: Okay.

MEMBER WAGNER: Is that on animals?

MR. SMITH: Yes, they were doing it with pigs.

MEMBER WAGNER: Yes, that's why you don't see it in your literature.

CHAIRMAN SIEGEL: No, my literature includes animal studies, and --

MEMBER BERMAN: In our institution the beta emitting stents are now being readied for study in humans. So I believe what we're talking about is something that is going to become, more likely to become, the focus.

CHAIRMAN SIEGEL: I actually think that when we know more about what the devices really are, we know more about what the radiation safety considerations really are, as well as the other safety applications, then I think the answer to question two will be yes. And we've already said that it's probably going to be yes, but I think we need to know a little bit more about what's going on and then we can build the requirements from the bottom up based on the safety

requirements.

MR. SMITH: Well, currently all of these proposals are proprietary and even though they were proprietary, they didn't give us a whole lot of information. I think basically they were fishing to find out what might be approved and proceed from there with their design. But we know that at least one manufacturer is going the way of a coated permanently implanted stent. And I believe there are some radiobiological basis for it also, but supposedly, if they deliver the dose over a long period of time following the angioplasty, they have a better result. But I'm not a radiobiologist, so I don't really know if that's true or not.

CHAIRMAN SIEGEL: Okay, we've answered them about as well as we can.

Does anybody have any other comments about this item?

MEMBER NELP:

MEMBER NELP: I liked your answers, they were very good.

CHAIRMAN SIEGEL: There was consensus, right?

CHORUS: Yes.

CHAIRMAN SIEGEL: Just checking.

Why don't we then adjourn for lunch and we should re-adjourn at 1:20.

(Whereupon, at 12:22 p.m., the proceedings in the

above-entitled matter were adjourned to reconvene this same day at 1:20 p.m.)

A-F-T-E-R-N-O-O-N P-R-O-C-E-E-D-I-N-G-S

(1:25 p.m.)

CHAIRMAN SIEGEL: If the members of the committee would please take their seats so we can readjourn, having been caught on that word, reconvene.

The Chair has a request before we begin, namely that you all stop referring to me as "the esteemed chair." Your majesty will suffice.

All right. We are back on the record and we are now going to discuss the petition for rule making, exemption for commercial distribution for in vibo testing, excuse me.

MS. TROTTIER: In vivo. Okay. Actually, I don't remember the date, although I have it somewhere. It doesn't matter. We received a petition for rule making from Tri-Med Specialties.

The petition is basically requesting the commission to consider one of two ways to amend our regulations, either to permit distribution under a general license or an exemption to the regulations to permit production of capsules containing one microcurie of carbon-14. That would be used in diagnostic testing in vivo.

What we are currently doing, right now, is we have an evaluation ongoing because we don't have -- there is no provision in our regulations that would allow this request to fall under a categorical exclusion.

An environmental impact assessment or an environmental assessment, not an EI, will have to be done. That is going on -- oh no, we are about to do it.

We are in the process now of getting the contract in place so that we will be looking at that, and really what this does is it brings a question of the different ways that this could be handled if a decision were made to grant it.

The position that the commission is in right now is that we haven't made a decision in any regard either way, whether we are going to grant the petition, whether we are going to -- if we were going to grant the petition, which direction we would go, and I guess one of the reasons for bringing it before you today is primarily to discuss the petition and the pros and cons associated with going either way.

CHAIRMAN SIEGEL: But currently, if this were a licensed product from the FDA and a physician wished to use this product in his or her practice, eh would have to be an authorized user under 35.910 in order to do so. Is that right?

MS. TROTTIER: I believe that is correct. Yes.

CHAIRMAN SIEGEL: It is uptake dilution and excretion.

MR. CAMPER: And through a limited specific license.

MS. TROTTIER: We did receive a lot of public comment on the petition. The petition was noticed -- I thought I had it here, but somehow in my moving papers around I lost it, but anyway, the petition was noticed in the Federal Register, and we received 300 comment letters.

The majority of those letters are supporting that petition, and as I said before, we still have our own analysis to do.

So we are at least probably three to four months, minimum, away from making any decision in-house on whether we would grant the petition or not, and again, the last slide shows you the two options that they are requesting.

One would be distribution under general license, and that would fall under part 32, then, and the other one then, would be -- and then it would be exempt, but the other one would be to permit medical use under a general license, under part 35.

That was previously in the regulations, and in 1987 when part 35 was revised, that provision was dropped. Primarily I think, at that time, because there was no real use. No one was using it so it was dropped for that reason.

So then, the question now would be if we decided to grant the petition, what would be the best way to do it.

I think in your packets you probably do have a discussion of the petition, and did we also include the

articles that -- okay, all right. So they have all of the information on the petition.

CHAIRMAN SIEGEL: Okay. Perhaps before we go on is someone from the company here to make a presentation? Is that correct?

MS. TROTTIER: I understood they wanted to.

CHAIRMAN SIEGEL: Please use the microphone and identify yourself.

MR. COMBS: My name is Matthew Combs. I am with Tri-Med Specialties, and we have given you two written statements from two representatives of our company that further elaborate on what we feel is the need to grant this petition.

I can read those aloud or if you have any questions about what we are trying to do, we will certainly entertain those questions, if you all have any need for further information.

CHAIRMAN SIEGEL: I think we will just reserve the right to ask you some questions as we proceed.

MR. COMBS: Sure.

CHAIRMAN SIEGEL: What would be the mechanism, assuming you all decided that is what you wanted to do for reestablishing general licenses?

What would that require mechanically?

MS. TROTTIER: It would simply require us to

publish a proposed rule with the decision to do that. There is nothing unique about doing that. We could go ahead and do that, I believe.

CHAIRMAN SIEGEL: If you were going to, is it likely you would do it for this specific -- in response to this specific petition or would you rethink the existence of general licenses in anticipation of future tritium and C-14 diagnostic tests?

MR. CAMPER: That is an interesting question because what we would do is we would prepare a commission paper, as Cheryl is pointing out, and we would go back to the commission and recommend -- it really is a policy issue, that the general license category that existed previously in 35.31 of the old part 35 could be reestablished. That is an option.

Now, then you have to ask yourself, "Well, okay. If you go the route of the general license, is it worthwhile to pursue that when you have identified only one procedure?"

At least my initial blush on that is -- and this is not a conclusion -- is that is a jump. That is a reach because if you go back and you look in the statements of consideration that accompanied the '87 rule change you will find some things that say the following: "NRC believes it is no longer efficient to issue medical general licenses that allow the administration of by-product materials to humans.

"The tests authorized under 35.31 have been

superseded by newer procedures with greater diagnostic accuracy.

"These developments have been reflected by a significant decrease in applications for general licenses."

To determine the status of general licenses, the staff performed a telephone survey of 10 percent of the then-current registrants.

The survey results indicated that less than 9 percent of all of the current registrants still use material for medic use under general license.

Now putting that differently, is that of the registrants at that time, and I don't know the total number, 9 percent were still using, but the commission opted to move away from the concept of the general license.

So then you have got to ask yourself, "Okay, if we go back and suggest the option of reestablishing it, and you are doing it on only one test, one modality, is that worthwhile?"

I don't know. It is a reach I think, but by the same token, if there were other procedures, then there could be more validity to that.

Another option would be the idea of the exempt distribution, but that poses some problems that really we would like to get at from this committee; not the least of which is if you did it under an exempt distribution bear in

mind that at least regulatorally, in terms of our parlance, you would not have to be in a position that administered the material.

MS. TROTTIER: Right. Anyone has the ability to use exempt material.

CHAIRMAN SIEGEL: All right.

MEMBER SWANSON: If I could ask somebody from the company, how is this being regulated by the FDA?

MS. HOFFMAN: Hi. I am Susie Hoffman with Tri-Med. The application for the NDA is currently in front of the FDA for approval, and the test would be prescribed by a physician, according to FDA regulations.

MEMBER NELP: And it is in what committee? Is it in radio pharmaceuticals?

MS. HOFFMAN: It is under GI.

MEMBER NELP: Under GI?

CHAIRMAN SIEGEL: Yes, but so it is not going to medical imaging drugs advisory committee.

MR. COMBS: They are to reviewing portions of it that are relevant. So it is being evaluated by several different --

CHAIRMAN SIEGEL: I am sorry. You have got to use the microphone. Good point. Actually I think the comment you just made about distribution is really less of a problem because this would be a product approved by the Food and Drug

Administration as a prescription drug.

Consequently, that drug can only be given to a human being upon the prescription of a licensed physician, and although it could be administered by a non-physician, you can't get your hands on the drug without a prescription.

MR. CAMPER: Right. The other thing that is interesting in this regard is I am unaware of any other exempt distribution that we authorized that is for administration to humans.

MS. TROTTIER: That doesn't mean it wouldn't be approved, but I mean currently it is --

MR. CAMPER: I understand. We have things like smoke detectors and certain other detection devices and things like this, but not for human use.

CHAIRMAN SIEGEL: So the reason for making its distribution exempt is so that it can be distributed to other than licensee's?

MS. TROTTIER: Correct.

CHAIRMAN SIEGEL: You are still covered by the fact that it can only be -- well, it can't only be distributed to physicians but it can only be administered upon a physician's prescription.

Am I correct on this?

MEMBER SWANSON: Correct.

CHAIRMAN SIEGEL: Okay, but you are right. It

could be held by a clinical laboratory where no physician was physically involved in running the clinical laboratory.

Well, it is an interesting question. I can tell you the average nuclear medicine department in the United States isn't prepared to do this test because they don't have a liquid scintillation counter.

MEMBER NELP: Do they send the collected samples back to a central location?

MR. COMBS: Again, this is Matt Combs from Tri-Med. Maybe I will describe a little bit about the test.

The test is expected to be performed by sites that have liquid scintillation counting facilities. We will offer the service of counting the samples by Tri-Med in either regional counting centers or through Tri-Med.

So for instance, a radio pharmacy in, say Baltimore, may set up a counting facility as well. So when they deliver their doses every morning, they would pick up balloons from yesterday and analyze those, because we utilize just a mylar balloon in the kit that the patient blows up, and then extract the CO_2 out of that breath in the balloon.

CHAIRMAN SIEGEL: So just out of curiosity. Why did you choose a mylar balloon rather than a hyamine to trap the CO_2?

MR. COMBS: That is a good question. It is patient safety, actually, because the hyamine is caustic and

it is possible, not likely, that the patient could somehow inspire hyamine directly.

Whereas, here we remove the patient from the -- from handling the caustic hyamine.

MEMBER NELP: What if the balloon breaks? Then you have to repeat the test. Right?

MR. COMBS: Well, first of all --

MEMBER NELP: Or do they get more than one balloon?

MR. COMBS: You can have more than one balloon if you so choose. We found that one balloon is sufficient. These balloons are very tough.

We haver performed a lot of experiments on the balloons. They don't break very easily. It is pretty hard.

CHAIRMAN SIEGEL: If you have ever gotten one as a present you realize that they stay on the ceiling for weeks on end and you can't do anything about it.

Another regulatory question, and that is: If a laboratory chose to perform this test, what level of complexity will this test be classified with respect to the clinical laboratory improvement act?

I can see -- we are all sitting here worrying about the average physician wanting to do this -- this gastroenterologist -- wanting to do this test in his own lab, but if right now he is only doing a urinalyses and an

occasional hematocrit and he is classified as a low complexity lab under CLIA, and this converts him to a high complexity lab under CLIA, that physician is going to choose to say, "Thanks, but I am going to let somebody else do that test."

MR. COMBS: Yes. This test hasn't been classified by CLIA, but we believe it will be a moderate complexity test.

MEMBER NELP: Moderate complexity?

MR. COMBS: Yes. Especially if the site does not perform their own counting, because that is where most of the complexity comes from.

The other part of the test is you just take a pill, and 10 minutes later you blow up a balloon.

MEMBER NELP: Quite simple.

MR. COMBS: Yes. It is very, very simple.

CHAIRMAN SIEGEL: It is pretty straight-forward. It is the counting mode that is the problem, and currently CLIA regulations for moderate complexity tests are fairly onerous.

There are things going on, on the hill, people are trying to back physicians offices out of CLIA as we speak, maybe not today, but there is a lot of activity and pressure from the AMA to get things to back off a bit on CLIA, and I don't know whether any of that will go down.

MEMBER SWANSON: Larry, if this is done under a

general license rather than an exemption, is there any problem with the physicians' office sending the C-14 balloon back for analysis?

MR. CAMPER: No. No.

MS. TROTTIER: That would be evaluated during -- while they did the safety analysis anyway, but I can't imagine.

MR. CAMPER: Yes. That is a good point. No matter which way we were -- either approach, exempt or general, there would have to be a safety analysis to accompany it.

CHAIRMAN SIEGEL: If it is exempt is it likely that there will be a possession limit? Is that built in to the exemption?

I mean, what I am trying to think about, let's think about what could go wrong. Why would we not want this safe drug in the hands of gastroenterologists, internists, pediatricians, for that matter.

MS. TROTTIER: The safety analysis would address possession of multiple dose kits, say, or capsules. I mean, whatever this is.

That would be done. It would be considered in the transport and all of that. You know, that multiples were being shipped, but I don't -- it wouldn't be in the regulations.

CHAIRMAN SIEGEL: What I am driving at is the issue -- I think most of us would agree that the radiation exposure from one microcurie capsule of C-14 urea is negligible, that we are not worried about the radiation safety aspects of that to the patient.

One could conceive, and especially given some recent activity of someone trying to o.d. on C-14 urea, which is going to be tricky; and so if a practitioner has thousands of these capsules, such that it is possible to ingest a millicurie of C-14 urea, then there might be an issue of concern to the NRC.

On the other hand, if the way this stuff is going to be distributed is that no one practitioner could have in his possession more than 20 of them at a time, it is kind of a no-brainer from a radiation safety point of view.

MR. CAMPER: On your question on possession, there is no specification of a possession limit.

What happens under our E-distribution, there is a category, there is a product that is categorically provided an E-distribution vehicle.

CHAIRMAN SIEGEL: Okay.

MR. CAMPER: In the course of having that product approved for E-distribution they present certain information that is designed to satisfy safety analysis requirements in part 32, and they make assumptions about the population of the

product and present some scenarios --

CHAIRMAN SIEGEL: Right. So if I choose to build my house out of smoke detectors --

MR. CAMPER: Right.

CHAIRMAN SIEGEL: I would be 92 standard deviations from the mean in terms of smoke detector density, but I suppose there is no way to regulate that?

MS. TROTTIER: Right. You can build your house out of smoke detectors if you want to.

MR. CAMPER: You certainly can.

CHAIRMAN SIEGEL: Now, what would my dose be if I did, just out of curiosity.

MR. CAMPER: Not much. You wouldn't have to worry about fires.

CHAIRMAN SIEGEL: Matthew?

MR. COMBS: I would like to respond to the possession. I don't know whether this is relevant or not, but we have requested a limit of 150 of these capsules at any one site.

That is based on physicians being able to order them in lots of 100, and when they get halfway through their first lot of 100, if they buy them that way, to be able to order another one. So they wouldn't run out.

MEMBER WAGNER: Who would regulate that?

MR. CAMPER: Pardon?

MEMBER WAGNER: Who would regulate that, having 150 on site? No one.

MS. TROTTIER: Not if it was exempt.

MR. CAMPER: Again, the 150 is something that the petitioner has specified, but we would not put that limitation, an E-distribution doesn't work that way.

It is the individual product is approved under an E-distribution scenario.

MEMBER NELP: The FDA doesn't have any role in limiting the amount of any material in possession of a physician. Is there any way you can?

MEMBER WOODBURY: Not unless the amount given would exceed acceptable limits. With the amount given here I don't think that that would be a problem.

MEMBER NELP: No, but in terms of the number of pills, I could write a prescription for 1,000 pills if I wanted to.

MEMBER WOODBURY: Right.

MEMBER NELP: I would make the company happy, but you don't have any way of limiting my ability to prescribe? For instance, if I went into the drug store and ordered 1,000 tablets of codeine, they wouldn't sell them to me.

DR. SIEGEL: With good reason.

MEMBER NELP: Exactly, I always order small amounts and say, "What's up?" There are some internal

controls in the drug distribution.

MEMBER WOODBURY: Usually the label insert, if the FDA approves it, the label insert will give recommended doses or recommended ranges, but this would not preclude you from ordering.

MS. TROTTIER: I have question that is non-regulatory. Can I ask it?

CHAIRMAN SIEGEL: Sure.

MS. TROTTIER: It is informational. What is the cost to work up the diagnosis of duodenal ulcer using this technique, which has to be considerably less expensive than endoscopy, biopsy, et cetera.

Can you give me ball park figures?

MEMBER NELP: Within $100.00?

CHAIRMAN SIEGEL: Well, inverse is the strategy of just treating.

MS. HOFFMAN: I think that the ACG, the American College of Gastroenterology has put a lot of work into this recent, and the NIH recently had a consensus conference and stated that the breath test was the most accurate way of diagnosing iliohypogastric pilary and that all patients with ulcer disease should be tested for iliohypogastric pilary and treated.

Basically it is going to be a lot less expensive than endoscopy.

CHAIRMAN SIEGEL: What about the competing technology which I uncovered in my literature searches of using mass spec --

MS. HOFFMAN: The carbon-13?

CHAIRMAN SIEGEL: C-13.

MS. HOFFMAN: Well, neither test is out on the market at this point, but we believe that the carbon-14 is going to be less expensive.

Initially, if you have your own counter, your own scintillation counter, you can do you own analysis. A lot fewer places have their own mass spectrometer, which is required to analyze the carbon-13.

MEMBER NELP: Do you have a cost projection for a capsule?

MR. COMBS: We don't at this time because a lot of this depends on how long it takes to get approval, and there are a lot of factors.

So I don't want to say what we think it will be because I don't want to be held to that.

CHAIRMAN SIEGEL: Can you tell us whether we are talking about tens of dollars, hundreds of dollars, thousands of dollars or millions of dollars?

MR. CAMPER: There are some numbers in your petition.

MS. HOFFMAN: Right. For the capsules themselves

we are looking at tens of dollars.

MR. CAMPER: In their petition under the paragraph identified as, "Benefits of the Test," they point out that the C-14 urea breath test could be done by most doctors for less than $100.00 cost to the patient.

"This is a considerable cost savings over endoscopy and biopsy. The benefits to the public are that curative therapy for ulcers will become available to all, saving the United States an estimated 500 million dollars per annum over conventional therapy."

That is pretty much where you -- do you still feel the same way today?

MR. COMBS: Yes, but whether it is $50.00 or $150.00 or $200.00, we can't say at this time, but it is approximate.

MEMBER NELP: The longer it goes divided by the government, the more expensive it becomes.

CHAIRMAN SIEGEL: That's correct.

MR. COMBS: But the idea here is to offer something as low cost as we can because we are committed to that.

CHAIRMAN SIEGEL: Do you all have a sense yet about where the environmental impact analysis is going to go down?

Does this strike you as a particularly great

environmental impact concern?

MS. TROTTIER: No.

CHAIRMAN SIEGEL: During the time we have spoken here more C-14 was generated in the atmosphere by cosmic rays than is likely to be used over the next decade for this test.

MS. TROTTIER: Yes. The biggest issue right now is simply that this work has to be done. We can't do anything as far as making a decision without the work being done.

CHAIRMAN SIEGEL: I understand. I think we can - -

MR. CAMPER: Barry?

CHAIRMAN SIEGEL: Yes, sir.

MR. CAMPER: I have a question, just a thought. I think that is an excellent point. The environmental impact here is really not the deal.

CHAIRMAN SIEGEL: No. I'm not focusing on that.

MR. CAMPER: I understand that. I think the issue that concerns us the most is this regulatory philosophy issue.

Do we move back toward the general license in part 35, which was removed in '87 for the reasons I said or conceptually how does the committee feel about the idea that something would be distributed under the exempt distribution scenario for human use.

Those kinds of things are ticklish.

CHAIRMAN SIEGEL: And I want to tackle that in a slightly different way. Given that we don't know the answer to the environmental impact, but we can assume that it is not likely to be a deal breaker here.

I would then pose the question whether any of us feels that the use of this radioactive drug in a diagnostic test requires the level of training and experience laid out in 35.910, and requires institutional or practice licensure under 35.100 in order to be able to do this test safely from the viewpoint of patient safety, occupational safety, and ultimately environmental safety.

MEMBER BROWN: And that is given that it will always be prescribed by a physician.

CHAIRMAN SIEGEL: It will be a licensed prescription drug.

MEMBER NELP: I feel very comfortable with having it be exempt under those conditions because it will be or should be in the hands of responsible people, and its certainly innocuous --

CHAIRMAN SIEGEL: And it is not like -- the real issue here is radiation safety. It is not like the use of this drug as a diagnostic test will be unregulated.

There is FDA licensing for test performance. It will be interesting. I am wondering, in discussions with the FDA has physician laboratory proficiency testing as part of

eventual distribution come up as something, as a service the company is thinking of either offering or being forced to offer by the FDA?

There have been some recent imaging drugs, for example, where interpretation is so complex that the FDA is including in the labeling, like in order to be able to use the drug you have go to have some training under company tutelage in order to play the game.

MR. COMBS: Once again, wouldn't that fall under CLIA as far as the level of complexity for the testing?

CHAIRMAN SIEGEL: That was my third level of regulation. CLIA will be regulating this also. I am also wondering whether discussions with FDA have included anything specific in labeling.

MR. COMBS: Not at this time.

CHAIRMAN SIEGEL: Okay. So given that this test will be regulated at several levels, it is regulated as a prescription drug by the states.

It is regulated by CLIA -- its use will be regulated by CLIA. The chit will be regulated by FDA. I don't think that any of us think that radiation or occupational safety is likely to be a problem.

I think you could choose either strategy and it works for me.

The reason you got rid of general licensing is

because it was withering. People weren't doing blood volumes in their offices anymore, and they weren't doing Schillings tests.

It was hard for people to maintain the equipment. There were very few people involved.

The only argument for reconsidering that is that this may open the door to a substantial number of other C-14 breath tests that have kind of languished: bile salt breath tests, fat absorption breath tests, that have been in regulatory, and consequently, clinical development limbo because nobody really knew how they were going to find their way in the market place, and there may be a reason to choose considering general licensure if you think that there is some safety need to maintain controls.

Otherwise, I would frankly argue for exemption. What do the rest of you think?

MEMBER NELP: I agree. I think it could be very nicely handled under exemption.

CHAIRMAN SIEGEL: And let the record show that the nuclear medicine physicians are not trying to claim any specific turf here by saying that we are the only ones who can do this test.

MEMBER NELP: I think the gastroenterologists -- that's right, as long as they are board certified.

MEMBER WAGNER: But you don't care by what board.

Right?

CHAIRMAN SIEGEL: If my memory serves me correctly, I think the physician who discovered that iliohypogastric pilary was responsible for ulcer disease just won the Nobel Prize for that or was it a Lasker prize?

MR. COMBS: He just won the Lasker award.

CHAIRMAN SIEGEL: And so the clinical importance of this observation is pretty clear. This has revolutionized the therapy of peptic ulcer disease.

MEMBER STITT: Unfortunately, because the record should reflect that being from Wisconsin, we liked it when ulcer disease was treated with lots of milk.

This is to our disadvantage.

CHAIRMAN SIEGEL: Everybody has got a turf issue to on the floor.

MEMBER STITT: I had to get that in there.

CHAIRMAN SIEGEL: I think we have made our recommendation. Any other comments? We could go either way.

I think whichever you guys think works better -- clearly from a clearly paper trail point of view, and in terms of minimizing the regulation, an exemption --

MEMBER NELP: Which is easier for the manufacturer or corporation? Do you know, Larry? Which would -- both ways would be supportive?

MR. CAMPER: I think either way would be of

minimal burden. General license really wouldn't impose any burden upon -- it would impose a little more of a burden upon the one who wanted to use the lab because then they would have to go through the old process we used to go through where you would get a registration certificate on record, and then a general license is issued.

Whereas, as compared under the exempt distribution process it is exempt, and once it is exempt --

MEMBER NELP: I think the simplest should be the preferred, if they are equal or comparable.

CHAIRMAN SIEGEL: But under the new system, I am just going to open up that NRC's web page -- and I am going to fill out my application for general license under the Internet, click on the submit button, and I will have my license in an hour.

Isn't that correct?

MR. CAMPER: That's right. Yes. You will. Let the record show that you will.

CHAIRMAN SIEGEL: The address is H2TP://WWW.

MEMBER NELP: How long will it take you to get the web page?

MR. CAMPER: It will be five minutes in your case.

CHAIRMAN SIEGEL: Bob, do you have any feelings about this from an agreement standpoint here?

MEMBER QUILLIN: The only thing I have been thinking about during this entire process is that we have suffered from several cases of generating license exempt materials that were never envisioned as accumulating in any one spot in any large quantity, but eventually did, and I couldn't think of any way that this would happen here, but I would certainly encourage that as a consideration that this potential problem be addressed.

MR. CAMPER: Let me comment on that, just real quick. I agree with you, in this particular case I couldn't see some of the problems that I could see in some other things, but there are some things going on today in the distribution process that are a little disconcerting to us, and it is not clear that things are going like they were originally intended to go.

We do intend to take a look at what is going in new distribution. Like, for example, watches that were distributed initially under the exempt distribution process end up today being collected by the same company for the purposes of repairing and fixing these watches, and now suddenly you have a lot of these watches at one site, that were originally distributed under exempt distribution, and that raises questions about was that the original intent of part 32, but that really, I don't think, has much bearing upon this.

We have had the same kind of observations that you have had in Colorado.

MEMBER STITT: Do these capsules have a shelf life having to do with just the capsule? That is, do they dry out or gum up or is there some sort of --

MR. COMBS: The anticipated shelf life is two years, and that is based on --

MEMBER STITT: You could use them to stick your smoke detectors together.

CHAIRMAN SIEGEL: And once they expired they would simply be disposed of?

MR. COMBS: That is --

CHAIRMAN SIEGEL: Oh, we used the BRC word here.

MEMBER STITT: I understand that when you make an exempt decision you lose control of disposal.

CHAIRMAN SIEGEL: Right.

MR. COMBS: I believe we would say that they would be returned to the manufacturer for replacement.

MEMBER QUILLIN: I would encourage that option rather than the direct disposal option because many local government entities have banned the disposal of radioactive materials in their landfills, directly.

That doesn't mean that it doesn't get disposed of, but they have banned it.

MEMBER BROWN: So you would provide a financial

incentive for them to return it to the manufacturer by giving them replacements?

MEMBER NELP: I would just put it down in the sewer because there is more carbon-14 being formed than that in your own backyard.

MEMBER BROWN: Other people might not like that.

MR. CAMPER: Torre was pointing out --

CHAIRMAN SIEGEL: We can't have two conversations at once. Dr. Wagner? Dr. Wagner, cool it.

MR. CAMPER: I was just pointing out, as Torre was pointing out to me, that if it goes exempt, once it is exempt, it is exempt.

Whatever arrangements the manufacturer has with its clients for the return of it is fine, and your point is well made, but from a regulatory standpoint once it is exempt, it is exempt.

MEMBER BROWN: So what they are saying is just their intention. There is nobody who is going to make them do that?

MR. CAMPER: There is no basis for making them do it.

MEMBER BROWN: Right. So they could be saying that now, and then later say, well -- is it a concern that these things will be disposed of in toilets and stuff?

MEMBER NELP: No. It is done all of the time. I

mean we put thousands and thousands times greater activity down the sewers on an almost weekly basis from human excreta.

MR. CAMPER: The sewer part of it is the easy part. The part that Bob Quillin is getting at is even though in regulatory parlance we call it exempt, there is a detectable amount of radioactivity there, and many of the landfills today, by virtue of the permits granted to them by the local municipalities have zero tolerance for radioactivity.

CHAIRMAN SIEGEL: They only have gamma detectors. Is that right? Have you ever noticed?

MR. CAMPER: That's true.

CHAIRMAN SIEGEL: Here is -- I really propose that this committee has made an important judgment for you that we don't think the person using this test has to be an authorized user under part 35.

Whether you all choose to do this under an exemption or under a general license, based on whatever BRC fringe environmental concerns you might have about this is up to you.

You must recognize that the amount of total paper work load that you will have if you do it under a general license is going to be substantial.

You will get a lot of applications because this is a common medical problem and a lot of people are going to

want to offer this clinically important test.

MS. TROTTIER: Okay. All right. Thank you.

CHAIRMAN SIEGEL: Thank you. Cool. We actually finished something.

MS. TROTTIER: Done.

CHAIRMAN SIEGEL: Can we go home? Okay. We have finished lunch. It is now 1:00. Actually it is 2:00. We are exactly one hour behind schedule, and next is a discussion of role of medical consultant, inspection manual 1360, and Dennis Serig, you are going to speak to us.

MR. SERIG: We have among us a number of medical consultants. I think six of you sit at the table here as ACMUI members, and then we have five of our non-ACMUI medical consultants sitting as part of the audience.

CHAIRMAN SIEGEL: Can I invite doctors Almond, Griem, who else?

MR. SERIG: Mrs. Watson, Dr. Whittington.

CHAIRMAN SIEGEL: Yes. I mean, there are at least two chairs open on this side and there are two other chairs there that can be pulled up.

So if you guys want to join us at the table, we would love to have you for this discussion. If it is legal. Is it?

MR. CAMPER: That's fine.

CHAIRMAN SIEGEL: Thank you.

MR. CAMPER: It is illegal, but that is fine. We have to remind Peter, of course, that he can't vote. He is in the habit voting historically, having been a member.

CHAIRMAN SIEGEL: And Dr. Marcus will have to sit on the other side of the room.

MR. SERIG: Although these pieces of paper that you have in front of your or you are seeing on the screen have a lot of writing on them, I think that the concern is a fairly simple one.

We have two pieces of -- or two documents which direct that we use the services of medical consultants under certain conditions.

The slide here in essence says that when we have a misadministration reported to us that involves an over-exposure to the patient, then we are to use a medical consultant, read physician, in this case.

We may also, upon review of the event, choose to use a scientific consultant, read medical physicist. In short, we have a requirement to use a physician consultant and we may also choose to use a medical physicist as a consultant.

The next page is an excerpt from another document which helps to implement the management directive, again, a lot of words, but basically there are a number of other conditions under which we feel obligated to use the services of medical consultants.

Go one more page. Now we will get down to the crux of it. Even though we have some guidance to the staff that says, "You will, in fact, use a medical consultant under certain conditions."

When we call or the regions call the medical consultant, you are free for any number of reasons to refuse to provide that consultancy.

One of the reasons you might refuse is that you feel this is not a case which really warrants the services of a medical consultant, and that is the crux of the matter.

In our current mode of operation what we then are required to do is ask you to give a brief note that explains your basis and we then transmit that to the director of the division of industrial medical nuclear safety and he makes the call as to whether or not we will use a medical consultant.

What we would like to do, go to the final slide, is ask you for your comments about ways we might improve this.

I think some of the aspects are pointed out here. Even though you are refusing to give us your services by stating that they are not necessary, you actually do provide some service.

You provide us a note that explains why not. We would like to alleviate the need for the director to make a decision which may be more appropriately made by medical personnel.

We would also like to expedite this process. We have the regions and the headquarters staff going back and forth for a day or two trying to do something which is very simple.

So if we could get your comments on those things, and there is another issue that I think you can help us with, and maybe this is related to that.

It is the -- how soon we get medical consultant reports. We are required -- the documents require that we get a report within 30 days and sometimes we do, but quite often we do not.

If we can facilitate the process by screening events, somehow we would appreciate your input about that type of situation as well.

CHAIRMAN SIEGEL: The typical contractor letter that comes from the region to a medical consultant says, "Please provide us with your report within 30 days of completion of your analysis."

It doesn't say within 30 days of the phone call that brought you into the loop, and sometimes the analysis has involved getting additional medical information that has taken a couple of months to get.

Now as I think I have said before, it is easy to generate a first report and reserve the right to create an amendment in follow up at a later time, and then you have

solved that problem.

Let me ask, to focus, this simple following question. How often has the director of INMS gotten notification that the medical consultant declined to participate for the following reasons, feeling that a medical consultant was not necessary, and has overruled that opinion?

MR. SERIG: Never. Never has he overruled it to my knowledge.

CHAIRMAN SIEGEL: You have answered your own question. The process is currently complex because you are requiring it to be complex, and I think that if a medical consultant simply says first and follows with the written documentation that this case does not need a medical consultant because and articulates the reasons, that person has made a professional judgment.

He or she puts his or her own credibility on line by so doing, and why do you choose to second guess? Go for it and let the regions go for it.

I would go a step further. I wish you would take E-mail and not require a written letter. I was actually a little surprised, I think it was last week, to find that a three paragraph E-mail response that articulated my reasons for not consulting needed to be translated into a letter.

MEMBER NELP: I have another question in terms of numbers. How often do you use medical consultants during the

course of the year, and how often do they deny to provide service because they think it is of minor importance?

MR. SERIG: Over the last three years there have been on the order of 25 to 30 misadministrations that were finally judged to be misadministrations, of those, probably 10 to 15 required the use of a medical consultant, of those probably 4 to 5 maximum were situations in which a medical consultant was contacted and said, "This is not a case where I need to be involved or a medical consultant needs to be involved," and to get more specific, usually those are small doses of iodine in a nuclear medicine situation.

MEMBER NELP: So once or twice a year the situation comes up.

MR. SERIG: Correct.

MEMBER NELP: Those consultants apparently have been given enough information to render an opinion that their services are not necessary. So all you want to do is get that in writing.

MR. SERIG: Correct.

MEMBER STITT: Is that what they always are? Almost always?

CHAIRMAN SIEGEL: I am wondering if any of them went to the wrong treatment site on brachytherapy sources, you know, the thigh getting two rounds as opposed to --

MR. SERIG: We believe that they could be, that

that could be the situation, but that has not been the situation.

Very often we end up sending anything having to do with wrong treatment site and brachytherapy to OGC for a decision.

MEMBER STITT: Wrong treatment site usually is also coupled with the intended treatment site didn't get the right dose. So I don't think that would fall into that category. Those are usually being viewed.

CHAIRMAN SIEGEL: Yes. I am talking about the one where the source was being retracted intentionally and then got stuck, hit between the thighs for 10 minutes instead of going through in the expected 30 seconds, and it ends up being called an unintended dose to the thigh, which is less than the dose that would have occurred had the treatment been conducted normally. At any rate --

MEMBER NELP: That is not in this domain. We are not talking about that. It seems to me that you have solved your problem.

If you call me up and ask me to consult on a problem and I said, "Well, from what you say it really doesn't need my services, but I will be happy to document that in writing. Send me the data and I will send you back a reason why I think it is not necessary." Is that what you are asking me to do?

MR. SERIG: Yes. That is the current situation, and one of the concerns is that it is a little back handed or gauche.

Your refusal is actually a consultation. You provide information, and maybe one thought that you could help us with is whether maybe this could be thought of as a positive consultation.

Your consultation is that there is not a very high likelihood of harm. You will write the note to that effect, and you will charge us for a half hour's services.

MEMBER NELP: I might charge you for an hour, that's my minimum charge.

MR. SERIG: Okay. I think that is the minimum you can charge us, anyway.

CHAIRMAN SIEGEL: Actually, that's not true, but that is okay. I think that is a wonderful suggestion. Basically, if I think about every one of these that I have asked not to participate in formally, then my response has been, "Based on the nature of this event further services of a medical consultant are not required."

I will give a couple of reasons, and I will usually enclose a final paragraph which says, "If you later discover that you wish me to review the licensee's response to the incident or the information provided by the licensee to the patient, holler, and let me know, and I will do it."

I think it is pretty easy.

MR. SERIG: Okay.

CHAIRMAN SIEGEL: Anybody else have a problem here? Evelyn.

MS. WATSON: No problem, just a question. I think what has been addressed so far has been the physician's position, rather than strictly a medical consultant, and so what is the policy as to the scientific consultant, for example, the dosimetrist, the person who reviews the dosimetry or the data concerning the incident and then comes up with the radiation dose.

Is that an automatic thing to be done in instances like this?

MR. SERIG: No. It is not.

MS. WATSON: Do you go to the physician first and then decide whether to --

MR. SERIG: It has happened both ways.

MS. WATSON: Okay.

MR. SERIG: There have been occasions when the region was concerned about whether or not something was of misadministration because they were concerned about the dose assessment, and went to the medical physicist first, and the medical physicist, having decided that yes, there was a difference in the prescribed dose from the actual dose sufficient to make a misadministration, then they went to a

medical consultant.

There have also been cases where a medical consultant has said, "I think I need help from a scientific consultant." So it has gone both ways.

MS. WATSON: That doesn't present a problem, really.

MR. SERIG: No.

MS. WATSON: Okay.

CHAIRMAN SIEGEL: So, I guess, if I am hearing the group is acknowledging, what we are agreeing on, is that we would say that if a medical consultant tells you that he or she sees no need for further evaluation beyond review of the information provided in the preliminary notification and/or the conversation with the person in the region who made the contact that you all should accept that as the basis for moving forward.

MR. SERIG: Without the additional step of bringing the director into --

CHAIRMAN SIEGEL: Given that you have not overruled, it seems like it is not adding much in the way of a great safety net for you.

I think that if something looked strange in a given event, that you all would be discussing it enough between headquarters, the region, OGC, and all of the other people who tend to get in the loops on these things, that if

Larry or Dr. Cool felt that the medical consultant said he didn't need to be involved here, but this doesn't sound right, then pick up the phone and call him again or her again, and say, "We would like you to reconsider, and we would like you to take a look."

MR. ALMOND: Or couldn't they get a second opinion from another consultant?

MR. CAMPER: They could.

CHAIRMAN SIEGEL: Right, but in general I think we are making this more complicated than it really is.

MR. SERIG: I think that is really what we are trying to do here, is simplify this, and yet not leave out anything that needs to be done, and toward the point of simplification, E-mail of a response seems reasonable to me if we can make that work within the frame work.

MR. CAMPER: Well, that is the point I was going to raise. The second bullet there, the idea of some pre-established vehicle that could be used, one of the problems we have with the E-mail is the idea of a record for posterity.

CHAIRMAN SIEGEL: Print it.

MR. CAMPER: Well, we could print it out. That is true. We could just print it out. That is a good point.

Is there any value to a standard letter that could be used for documenting the declination?

MR. SERIG: I think the question is probably one

that has to do with the specifics of what you would write, and maybe there is such variety that you couldn't do that, and maybe -- I don't know.

CHAIRMAN SIEGEL: The only thing I can think of is if you or OGC thought there was some need for some boilerplate in such a letter to make it fulfill your internal needs, then you could put it in the letter, but it certainly isn't going to facilitate what we tell you.

DR. GRIEM: On one occasion someone contacted me on a well logging source that had been an industrial situation that messed up and a number of people were exposed, and I would presume that you do it the same way as the medical situation?

MR. SERIG: Yes.

CHAIRMAN SIEGEL: I would think so.

MR. CAMPER: Yes. That is true.

CHAIRMAN SIEGEL: All right. Have we reached closure on this? So I think our consensus is that giving you the consultation that telling you that no further evaluation is necessary constitutes a consultation, and that it need not be reviewed further per our recommendation, by the director of IMNS, and we leave it up to you whether you need a form letter of some sort to fulfill some legal requirement.

MR. CAMPER: That's fine. I want to thank the consultants who came in to participate in the deliberation,

and also, I want to thank you now for the help you have provided in the past or thank you in advance for any help you might provide in the future.

Let's hope there is little of that, but seriously, you do provide a very valuable service to us.

When we are dealing with these events you provide a level of expertise and attention that we can't provide, and ultimately your report is a significant component in the final analysis of the event, and we thank you for that, very much.

MR. SERIG: And you also put up with a great deal, and have over the last month in providing paper work to get yourselves reappointed, and we appreciate that.

MEMBER STITT: Larry, just a chatty point here. Your associate next to you is so enamored with E-mail, as you know, and I do enough medical consultings that I have put the NRC form on my computer, and so when I am writing a report it is on my computer and I make a hard copy for myself.

I have sent my report by E-mail as an attached document because whenever I have a region that calls in or a state that calls in I get their fax number.

We are doing business by fax, hard copy is easy to generate on either end, and they are able to look at something as I have it completed, and then I usually print one out for myself and one to send them.

I use the form for format, and I don't end up

typing stuff on that piece of paper that I get sent because I do a fair number of them, and it is easier to do it this way.

This is just commentary. I don't know if you have a response back to the electronic version of things. There is as much security in that as there is in the U.S. mail.

CHAIRMAN SIEGEL: You could have the region do a telephone notarization of the E-mail message. You know, subscribed and sworn to this day with three people on the phone. I think E-mail ought to do the job.

Okay. Next. The manual chapter on follow up. Who is going to present this?

MR. CAMPER: Cathy Haney.

CHAIRMAN SIEGEL: Cathy. We have lost her. Okay. We are done.

MR. CAMPER: The next issue is discussion of NUREGs. Isn't it?

CHAIRMAN SIEGEL: Dennis just walked out the door. Well, I have got the wrong version of the agenda, then. Torre. You have an old version of the agenda.

MR. CAMPER: That figures.

MS. TAYLOR: That had to be switched to accommodate Cathy Haney.

CHAIRMAN SIEGEL: The manual chapter on patient follow up is the correct version. NUREGs is on for tomorrow.

MR. CAMPER: Well, your highness, you seem to have the correct agenda.

MEMBER BROWN: Esteem highness.

MR. CAMPER: Your esteemed highness, your regalness. It shows you who ranks around here. Right.

CHAIRMAN SIEGEL: How about we go off the record.

(Whereupon, the proceedings were briefly taken off the record at 2:23 p.m.)

MR. CAMPER: Did everyone meet Dr. Ramirez today? Dr. Ramirez. Does everyone know her? She is visiting us from Spain. She is a physician, and she is involved with the regulatory program in Spain.

She is spending six months with us to learn more about the licensing and the inspection process and the regulatory process at large.

So make it a point to say hello and chat with her.

CHAIRMAN SIEGEL: Okay. We are back on the record and Cathy, you are on.

MS. HANEY: Okay. Thank you. What I would like to do today is just give you an overview of where we are on patient follow up.

I guess it was November, 1994, was the last time we spoke with you about patient follow up, and just as a status report.

What I have up on the screen, and what you have on an overhead is the NRC's current policy on patient follow up.

This comes out of management directive 8.10, which is the NRC management directive for dealing with follow up on medical events, and it is used by the regions when they are following up on misadministrations.

It basically says that in the case of where there is an indication by the medical consultant that there could be long term effects, the director of NMSS in conjunction with our executive director for operations, will make a decision whether a long term medical consultant should be -- or long term follow up should be done on a patient.

In the November, 1994, meeting the issue of patient follow up was discussed at some length. This is a quote that I took out of the minutes of that meeting.

There were two possible goals that came out of that meeting, but there were caveats that were associated with both of them.

Basically, what we want to let you know is that we heard what came out of the November, 1994, meeting, and in conjunction with the next slide, which is our experience to date with patient follow up, where we are going.

We have followed one patient for a year. This would be the end of the year, this October. We have received

monthly reports on the patient's status.

The reports have been reviewed by the regional and headquarters staff. Once they have been reviewed by that staff they have been reviewed by upper management at NMSS on a monthly basis at our monthly operational events briefings.

So we have been following the reports that we have gotten from the licensee.

CHAIRMAN SIEGEL: This has been a single case?

MS. HANEY: One case. Right.

CHAIRMAN SIEGEL: Can you give us a little information about the nature of the exposure without revealing any proprietary information?

MS. HANEY: I would leave that to Larry or Josie to do. I don't know how much information can be released.

MS. PICCONE: This was the case of the prostate therapy where the seeds ordered were 10 times --

CHAIRMAN SIEGEL: Okay. Right. So we are aware of this case, and we have discussed this previously.

MR. CAMPER: Order of magnitude error in the seeds.

MS. HANEY: Okay. So where we went from there is based on these two items a draft guidance document was prepared, and it basically reiterated the guidance that was in 8.10.

We received some comments on it, but again, based

on what we kept -- the recurring theme from the ACMUI in the November meeting, as far as what we learned from this patient that we have followed, we have decided to put the finalization of that chapter on hold, and it probably will not be revisited again until after we receive the NAS study.

That is where we are right now on patient release.

CHAIRMAN SIEGEL: Patient follow up.

MS. HANEY: I mean patient follow up. I have patient release left in my head.

CHAIRMAN SIEGEL: I wish we were in this good shape on patient release. Okay. Comments? Do you have specific questions?

MS. HANEY: No. I have no specific questions. This was just intended to be a status report.

CHAIRMAN SIEGEL: It was scheduled for an hour. That is the only problem.

MS. HANEY: We are trying to catch up on schedule.

CHAIRMAN SIEGEL: We are now ahead of schedule.

MS. HANEY: I ran upstairs, cut my schedule to get my presentation down.

MR. CAMPER: I think that Cathy's last point -- when the agenda was put together we had originally intended to talk with you about some specifics in the guidance on the

patient follow up issue, but subsequent to that we have decided to table that and talk about it when we talk about the program at large after the NAS report.

So that changed it quite a bit.

CHAIRMAN SIEGEL: Okay. Thanks, Cathy. Any other comments or thoughts on that?

So really, the bottom line is that patient follow up is not something that is needed very often, nor did we expect that it would be.

Are you learning from these monthly follow ups information that you think is useful to the NRC?

MR. CAMPER: No. Not really. The patient's condition is progressing as you might have anticipated. There has been nothing striking or alarming.

Occasionally there will be events that arguably warrant following, but they are rare.

CHAIRMAN SIEGEL: Okay. We are like way ahead of schedule all of a sudden, after being way behind schedule.

Pat Rathbun is not going to be available until around 4:15, I am told because she was up in Gaithersburg. I was speaking with Cathy earlier and the option was whether she would come tomorrow morning, because it would only take a few minutes, versus coming later, and she is coming later.

I think to do the modules we need Trish, who is not here.

MR. CAMPER: She is apparently in a meeting right now.

MS. TAYLOR: She won't be here until 3:30.

CHAIRMAN SIEGEL: She won't be here until 3:30. That means we have an hour. We can open up the whole discussion of training for cardiologists.

MEMBER BERMAN: That's a good idea.

CHAIRMAN SIEGEL: Not a chance, Dr. Berman. There is no background material for me to look at. I won't know what to say.

MEMBER BERMAN: That is a good idea. We can talk about what concurrent means.

MS. TAYLOR: Since we have a closed session tomorrow at 8:30, we could possibly go ahead and do that now.

MR. CAMPER: Which one?

MS. TAYLOR: We have a closed session tomorrow at 8:30.

CHAIRMAN SIEGEL: How many members of the general public, non-NRC staff are in the audience who would have to thrown out for a short period of time if we had a closed session?

MR. CAMPER: Four.

CHAIRMAN SIEGEL: Okay. You have got your hands raised. Now put your hands down. How many of you care if we throw you out for a short period of time?

No one raised their hands.

MEMBER OF THE AUDIENCE: Are you buying the coffee, Barry?

CHAIRMAN SIEGEL: Only if I have to. We could do that. Who is going to present that?

MS. TAYLOR: Sally. We just need a few minutes to pass something out.

CHAIRMAN SIEGEL: All right. Why don't we go off the record for a second.

(Whereupon, the proceedings were taken off the record at 2:32 p.m. and resumed in Closed Session.)

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

(4:25 p.m.)

CHAIRMAN SIEGEL: If the members of the committee would please take their seats it would be greatly appreciated. We are out of order, but we're on report on subcommittee review of draft licensing modules. Let me preface this with some background information.

You all will recall that at the last meeting, we spent a fair amount of time talking about a number of issues. The draft licensing modules we really didn't have time to go into in great depth. Consequently, we proposed and the NRC accepted that we have a series of subcommittee meetings to address the specific details in the draft licensing modules. A series of subcommittee meetings were held on September 27, 28 and 29 with kind of a rotating cast of characters.

On the 27th -- I don't have the list in front of me, but on the 27th in the morning, I and Lou Wagner were there along with NRC staff to look at mobile medical services. In the afternoon, I and Dennis Swanson were there to look at radioactive drug therapy.

Then over the next two days, a group that consisted of Bob Quillin, Dr. Stitt, Dr. Flynn. Who did I forget from that group? Looked at a variety of radiation oncology related modules.

When discussing how this was going to be

presented to the committee, I wasn't exactly sure how we were going to handle this. So in discussions with Torre over the last couple weeks, we decided that we would try to put together some summary statements of what the major changes, conclusions, recommendations were made by the subcommittees, that I and Dr. Stitt would try to report what the subcommittees did, in conjunction with the staff person responsible for that particular module.

In addition, Trish has I guess overall responsibility now for all of hte modules in coordinating them. So she has an overall summary of major issues involving hte licensing modules.

Now we can do this in varying degrees of detail, depending on how we see fit. We can make these documents available for the record as part of the minutes of the meeting. I can make the general comment that the subcommittee met. They discussed the issues. We found a number of important points that needed to be clarified that related to just points that seemed ambiguous. I think we made a number of valuable suggestions and recommendations that the NRC I hope appreciates. I think overall, the discussions were useful.

Then why don't we, Trish, oh you're here. Why don't we just briefly, and I mean quite briefly, go over your major issues, summary statement. Let's just present it in a

couple of minutes. Then we can just kind of quickly walk through each of them and hit on what the big issues are. We can scan them simultaneously. If any people who are not at the subcommittee meetings have specific questions, we'll try to address them.

My recollection is, is there anything that came out of the meetings that the conclusion was too controversial, needed to come to the committee for resolution?

MS. HOLAHAN: No. I don't believe so.

CHAIRMAN SIEGEL: Good. Go ahead.

MS. HOLAHAN: Basically what we identified is there were some issues that were across the board in all modules, so we thought rather than going through repeating them for each module, we could just sort of summarize them. First of all, one of hte recommendations was that we should ensure that all the modules should be consistent where possible on such overlapping issues as training. We made several modifications to the training for nurses, training for ancillary staff, and training for physicists and other staff to be consistent amongst modules.

Also there was in general recommendations that previously the authorized user training requirements were only up in the body, but in many cases, there was an indication that for authorized users that were coming under the "or" category, there may be specific training in a modality in

which they were going to be using, and so we should also include a discussion of the authorized user training requirements within each module.

Another recommendation was that there should be comprehensive list of the records and retention requirements for each module, or we may consider actually having one overall list in the body of the front part of the reg guide.

Currently, the only module that includes standard license conditions is the remote after loading brachy therapy module. That was primarily because many of hte issues that are not addressed directly in the regulations. There are standard license conditions that have been developed, so we felt that licensees should be aware of those standard license conditions.

I think following discussions on all the modules, it was felt that we should actually include standard license conditions that would be used for all modules, and in fact, it's under discussion that we may include also a reviewer checklist and a sample license, that that could also be made available to licensees as well as the license reviewers.

Also, and you heard this morning about the final patient release rule. So there will be modifications as a result of the revised patient release roll that will be made to primarily three modules, mobile medical services, radioactive drug therapy, and manual brachy therapy for

permanent implants.

There was some discussion with regard to there was a statement within several of the modules that once a patient is released, the material is no longer -- the licensee no longer has a direct regulatory responsibility for the material. I think that's an issue that we believe, and we have gone on record previously stating that that is the case. Once a patient is released, it is no longer licensed material.

I think there was some question as to whether it was in conflict with part 20. But I don't believe our review is to date that it does not appear to be in conflict.

Also the modules, this is a minor thing, are not consistent. We can make sure that they are all numbered consistently.

There was also a discussion in several of these subcommittee meetings as to whether the appendices should be revised at this point in time. Well, as Dr. Cool mentioned this morning, is much of this is going to be tied in with the overall BPR efforts in the licensing process. I think we will not update the appendices at this point in time but that will be done as part of the BPR manual.

The other issue that we'll review as we go through the finalization of these modules is look again at what is in 10.8. I think some of the modules contain more details that are repeated in the body. We need to make sure

again that it's not confusing between flipping back and forth between the module and the body. So we need to make sure that the appropriate references are in place.

Finally, a question was raised that modules that are affected by the QM rule we should include specific guidance addressing the QM rule. A decision was made that what we will do is make sure that the appropriate references to Reg Guide 8.33 are included in there. Again, any modifications will be included in the BPR process, and then again following a major revision of part 35, we would look at 8.33 again.

CHAIRMAN SIEGEL: Okay, good.

MS. HOLAHAN: So that's pretty much my summary.

CHAIRMAN SIEGEL: Any questions about that, general comments? Big fabric issues? Okay good.

So the first one that was discussed on Wednesday morning was mobile medical services. Torre, do you want to do it? Do you want me to do it? Okay. That's fine.

This was a I thought a very interesting discussion. We got some very interesting items on the table. I think the key thing we recognized is that the scope of mobile medical services is in evolution and it's not clear exactly how things are going to change with time. So part of what is in this regulatory guide needs to be a little bit flexible. I'm sure it will be.

We suggested that as we just heard, that the language be adjusted with respect to patient release rule. There was considerable discussion about including some point in the document, I'm not sure we knew exactly what needed to be in there about reciprocity with state licensing where the mobile medical services crossed state lines, and some guidance needed to be in there about how to address that.

I'm trying to remember what item three was. I expressed the concern that the regulatory criteria did not reflect the current trends. Torre, refresh my memory.

MS. TAYLOR: Yes. That was in line with what you just said about the scope of services changing and the new modalities.

CHAIRMAN SIEGEL: So this is just an observation?

MS. TAYLOR: Yes. Just an observation. Something that we can do in the guide.

CHAIRMAN SIEGEL: The single most important thing we did during the morning session was we killed the term called medical non-institution, which is not a term, and substituted instead the term non-institutional medical practice. I consider that, frankly, to be a triumph of the English language for bureaucratese. I hope it is accepted.

Considerable discussion about the potential conflicts that could occur between the mobile service contractor and the client, on the one hand, or between the

mobile service provider and the landlord, in those circumstances where mobile services are actually provided out of a residence. The bottom line on that was that the NRC needs to as part of the licensing process, get clearer understanding about the nature of the agreement between the provider, the contractor on the one hand, and the client. Some interesting discussions about scenarios that I think are pretty unlikely, but one has to plan for contingencies.

The document needs a description of the special problems associated with overseeing radiation safety programs in mobile services, since the authorized user in the RSO is not likely to be on site all of hte time. That also goes to the issue of what constitutes adequate supervision of supervised individuals. The guide suggested as often as every 30 days review of individuals work. We questioned whether 30 days was a reasonable frequency. We didn't really come up with a correct answer because it would depend on the nature of the mobile service itself.

We also questioned the current statement that the authorized user or RSO be able to respond to the incident within three hours. Respond in this case means physically present, because there are certain mobile services in rural areas that cover very wide territories where that could be a problem, and where the nature of the potential accidents wouldn't warrant such rapid response. So there's some wiggle

room on that, seemed to be required as well.

Any comments? Torre, you want to add anything?

MS. TAYLOR: No.

CHAIRMAN SIEGEL: Okay. Radioactive drug therapy.

MEMBER STITT: Dr. Siegel, I had a question.

CHAIRMAN SIEGEL: Please.

MEMBER STITT: A clarification. It would never be the case that the mobile HDR units would be looked at as mobile medical service.

CHAIRMAN SIEGEL: Currently a mobile medical service is only authorized for diagnostic imaging. Exemptions could be granted for radioactive drug therapy. You have granted some, is that correct, in the past in mobile services?

MR. CAMPER: Mobile? Yes. We have.

CHAIRMAN SIEGEL: We are told that the State of California either has an application or has licensed mobile HDR.

MR CAMPER: The State of California has licensed. We anticipate receiving an application for a license.

MEMBER STITT: Would that be regarded under the mobile or do we look at that under ---

MR. CAMPER: No. That would be --

MEMBER STITT: It doesn't really fit.

MR. CAMPER: The guidance document here does not

address mobile HDR.

CHAIRMAN SIEGEL: It addresses mobile service as currently defined in part 35, which is limited to 35.100 and 35.200 applications. Correct?

MR. CAMPER: Also if we do end up licensing the mobile HDR, that would require an exception to the regulations because currently it's not addressed in the regulations.

CHAIRMAN SIEGEL: Okay. Radioactive drug therapy. I should point out that at this session, Mark Ratman, per invitation, joined the discussion and made many useful contributions. Key points. Documents are referenced alpha and beta emitters over and over. We basically said that really the key issue was the safety considerations associated with the proposed radioactive drug therapy program and you didn't need to single out alpha and beta emitters. You just need to have the licensee lay out what they plan to do and how they plan to address the safety issues.

There was a point about need to deal with released patients in the module. We basically said that when they are released, they are released, and the licensee no longer has radiation safety responsibility for those patients.

There was a word in there about licensee staff being able to understand isotope burden to the patient. We said that needed to be out. Requirement for including information on staffing levels was recommended it be removed

as not being really something NRC was supposed to be looking into. Rather, it was how the program was laid out.

I'll let you look at five yourself. It is straight forward.

There was a long list of training requirements. There was a list for nurses. There was a list for other people, professional staff involved in the therapy. Then there was a list for ancillary staff, like housekeeping staff. We basically suggested that those first two lists be collapsed into a common list. A training program for staff involved in the administration, monitoring and care of patients undergoing radioactive drug therapy, and that the training for those individuals, depending on their specific nature, should be commensurate with the individual's duties. So that gives licensees room to design their programs as they see fit.

Overlap issue was discussed. Item nine. Oh I see, we just made a redefinition of a term. We decided the dose calibrater and dose measurement were going to be made consistent with the radiopharmacy guide.

Dennis, you want to add anything? Bob, do you want to add anything there in the back there?

Okay. Now this is when I no longer was around. Dr. Stitt became the chairman. Manual brachy therapy. Do you want to do it or you want Dot to do it? Your choice. Manual brachy therapy. Do you want to summarize it? Who did manual

brachy therapy, staff person. Oh Trish, I'm sorry. Well I'm confused.

MEMBER STITT: We were just conferring. I will do it. We were actually conferring on what went between these two, which is --

CHAIRMAN SIEGEL: Was there one for HDR?

MEMBER STITT: Right. That's what we were -- let me start with remote afterloading. You don't have a page for remote afterloading.

CHAIRMAN SIEGEL: Okay.

MEMBER STITT: But HDR falls into -- most of the discussion really revolved around issues that we in this full committee have been discussing now for a year and a half, almost two years. It has been high on all of our agenda on a regular basis. So that there was nothing that was alarming or new or unusual. In fact, we basically verified that a lot of what we have been discussing as a committee will now show up in that format.

I think one of hte issues that Trish and I were just reviewing also had to do with reciprocity, state licensure, and the different vendors of the different HDR units. That was brought up and we put out on the table as an issue much like you were discussing that in radioactive drug therapy or mobile.

I'll stop there on remote, unless there are any

other questions or comments. Trish, would you like to make any additions or better --

MR. AYRES: Bob Ayres with the staff. The reason there's no sheet is I felt as Dr. Stitt said, we have been over this many times and our subcommittee never came up with any major issues that I thought needed to come to the committee. The issue of reciprocity was just going to be a short note to the licensees that maybe they should check on it, because it is the service vendor's responsibility in this case to obtain the reciprocity. It's not the licensee's responsibility, but we thought a little note would maybe help jog people's memory.

I think the general comment, the subcommittee went great. I got a lot of really useful and valuable comments. I think a good part of the valuable contribution is we did a lot of work in that committee meeting in bringing this module into line with many of hte comments from previous subcommittee meetings the day before Trish provided input, in bringing these ancillary personnel, nurses training. In that meeting, we started to standardize the modules.

MEMBER STITT: Professor Quillin gets the Queen's English prize. He read every single word, all the colons and the sub-phrases and clauses, and has this in a very readable form.

MR. CAMPER: One comment I would make about hte

remote afterloading discussion. There was a fair amount of time that was devoted to discussion, the qualifications, training experience for physicists. We discussed at great length what we currently do in our guidance, in policy and guidance directive FC 86-4, which was updated substantially following the incident in Indiana, Pennsylvania.

Now we are looking for turning an experience currently for a physicist associated with high dose rate mode afterloading similar to what is currently specified in our regulations for teletherapy, except of course we are looking to see experience that is specific to the use of HDRs.

Now I think the important thing beyond that point is that it was recognized by the subcommittee that ultimately when we look at a revision part 35, we should be discussing at great length this whole issue about medical physicists. What's the best term to be used, should physicists be expected to have a document experience that is germane to the particular modality, be it teletherapy or HDR or gamma stereotactic radiosurgery and so forth and so on.

But that's not something that the subcommittee needed to take on or that we would take on at this point. But just be aware that at some point again, this physics T&E issue is something we'll have to work our way through. But for the time being, clearly for HDR we are expecting to see physicists, demonstrated experience with HDRs, and an overall

T&E similar to what is going on for teletherapy physicists, because all we define in our regulations currently is a teletherapy physicist.

MEMBER STITT: To move on to the manual brachy therapy module. You also have a handout on that. I don't think we need to read through them necessarily, but Dr. Flynn had a number of comments that he brought up and we discussed at great length, in addition to Dr. Quillin's grammar comments. You can read issues of shielding, record keeping, and survey procedures.

Questions or comments on the manual module? Again, as Trish brought up earlier, everything has been brought into line search. It will be easy to refer from one section to the next. The format will be the same.

Dr. Quillin is going to discuss the gamma knife fertility therapy module.

MEMBER QUILLIN: Well, I wasn't here for the teletherapy module, but I was here for the gamma knife module. There was a comment --

MEMBER BROWN: I thought you were going to say, but I'll discuss it anyway.

MEMBER QUILLIN: There was one comment I had that went throughout the brachy therapy and the gamma knife module. That was the laundry list of subjects that other staff were supposed to be instructed in.

We looked at those other subjects at some length and deleted some. I think in at least one case, added one, and clarified some because the subjects were generic in nature, but were not really clear as to the meaning as far as the presentation was concerned. For example, one of the items that was in the subjects as I remember was radiation signs. I think we made the recommendation that we listed down there as the meaning of radiation signs. That we weren't supposed to be training people in how to put up radiation signs necessarily, but what the signs meant to staff.

In the gamma knife module, I think the items here are reasonably self explanatory. Some of the things that we spent more time on than others were the qualifications for the physician and physicists, what type of qualifications and training, experience would be expected and what were the roles of the physician and physicist during these procedures.

Right now the document as written as presented to us was somewhat vague in that matter. We felt that that should be more explicit, and also should be consistent in form and format with the other documents.

Another issue that we talked about, and I'm not sure it's presented clearly here, is page 226 on the worst case scenario for doing radiation surveys. We didn't recommend that you do a worst case scenario, but basically what I would call a realistic case scenario for the survey.

That was based upon realistic work load criteria use and occupancy. The document was presented to us, assume that you did all of the cases in one day within one hour's time period. In other words, if you were going to be treating five people, you treated them all in one hour time frame, which we didn't feel was a realistic situation.

There was an issue on the intercom. We had some discussions. We felt that the need for an intercom, which was not included in the guide, should be included because of hte need to be able to communicate with the patient during the procedure.

So those were the main things as I remember, from the gamma knife module. Any questions?

MEMBER WAGNER: Can I go back one? I just wanted to ask one question.

CHAIRMAN SIEGEL: On manual brachy therapy?

MEMBER WAGNER: Yes. It's under area survey procedures, consider including a recommendation to post a record of the survey. Is that for someone in particular's information or just a document that the survey had been done.

MEMBER QUILLIN: It was for information purposes so individuals entering the room could see what the results were.

MEMBER WAGNER: And what individuals are you thinking of? Who would understand what that means?

MEMBER QUILLIN: An authorized user, for example.

MEMBER WAGNER: Okay. So it is for hte physicists or other physicists? If you had two or more physicists, maybe one goes up, sees it was done, he could read what the number was.

MEMBER QUILLIN: Or for the authorized user to know what hte numbers were, to be able to use that information if a question arose.

MEMBER WAGNER: Okay.

CHAIRMAN SIEGEL: Okay. Any other questions or comments on the gamma knife stuff? Jim Smith will give us a short presentation about what happened to teletherapy. Part of this rotating musical committee members game, Dan Flynn took over the chair at that point of that subcommittee meeting, but Dan as you know is not here because someone else is in labor. I don't understand that totally, but that's okay.

MEMBER WAGNER: His partner's wife I think is having baby so he had to cover the practice.

MR. SMITH: We didn't have a whole lot of comments on the teletherapy. Basically, the first item is the same as from the gamma knife module basically, because we just covered that under the gamma knife.

Dr. Flynn felt that if we needed an intercom for a gamma knife, we also needed intercom requirement under

teletherapy.

The other was sort of a recommendation that we could recommend to our licensees that they post action levels in the form of normal treatment parameters so that technologists or therapists conducting these treatments for the teletherapy unit would know when something was out of the ordinary. That was about the entire gist of the main items.

CHAIRMAN SIEGEL: Good. Thank you. Questions? Comments?

MEMBER BROWN: There was just a discussion that this guidance document was created or revised last in 1985. So we felt there was a need to update it. However, we recognize that it appears that the use of teletherapy is falling off in the United States. We talked about that a bit, but still felt that updating the guidance at this point in time was important.

MEMBER QUILLIN: I just have one final comment. Several comments were made about my grammar review. I do like subjects and verbs in sentences.

MEMBER STITT: You kept complaining about that. He kept finding all these sentences that had no verbs.

CHAIRMAN SIEGEL: Picky picky picky.

MEMBER BERMAN: I'd just like to comment on your part that on page 192, what you meant when you said that the physician and physicist should be physical during the GSR

treatment.

CHAIRMAN SIEGEL: We said that cardiologists had no sense of humor. Okay thank you. Thanks to everyone for their hard work on this.

Having done now a couple of these types of things with you, I am really convinced that when it comes time to roll up sleeves, look at a document, and think through a process in great careful detail, that a group of three or four people in a room gets a lot further than a group of 13 people, being afraid what they are saying in the microphone. So some of these working sessions really are quite effective, and I encourage you to keep having them as issues arise that need them.

The last item of the day is status report on the National Academy of Sciences study of the medical use program. Pat. She had to leave. I think we actually heard part of this from Dr. Paperiello.

Let's see. So I am going to give Pat's report. The National Academy of Science's report to the NAS peer review process apparently occurred on August 25, 1995. The document is not out yet. When approved by peer review, Carl Paperiello and Pat Rathbun will read it. Ten days later, they will get a confidential copy.

I need to get some clarification, because I actually had a conversation with Kate Gottfried a couple of

months ago and was led to believe that members of the advisory committee might actually be able to see copies sometime in November.

So that sounds like the January date is one date that you all are hearing. She seemed to think this document would be done and on its way to the printer in early November.

MEMBER BROWN: I have never heard that comment.

CHAIRMAN SIEGEL: If I get a copy, I'll give it to you.

MR. CAMPER: Would you please do that, because we'd like to have it.

CHAIRMAN SIEGEL: Not until I have analyzed it very carefully.

MEMBER BROWN: There has been some -- what has caused confusion in all of this, and that is, is that many of you probably are aware that the NAS has a process of how it goes about doing business. It is unusual I think that a copy of their reports are provided to the entity which requested that they develop them before they are actually and formally published and released.

However, in this case, you might recall that there was a briefing by the NAS to the commission, during which then Chairman Selin expressed a great deal of interest in the commission receiving a copy of hte report once it had undergone peer review and was on route to being published.

As a follow up to that, there was apparently some telephone discussion between the Institute of Medicine at NIS and the chairman or the chairman's office. Ultimately, a letter was sent from the chairman to IOM, as sort of a follow-up to that conversation in essence thanking them for making a copy of that available to us.

Now we have had some ongoing discussions amongst ourselves and with the EDO's office, that we try to plan to receive this and process it. There has been some confusion as to just what was going to be.

In my understanding of it within the last day or two, in fact talking to Pat, is that once it is available or it is completed, it's undergone peer review. Carl Paperiello and Pat Rathbun will have the opportunity to read it. That within 10 days, we will receive a confidential copy of it. That is our current working understanding.

Contractually, they are obligated to provide us with a report on or about 5 January of 1996. So at this point in time, I think it is fair to say that we anticipate seeing a copy of it and we'll have a chance to look at it confidentially some time I would assume in November I would think.

CHAIRMAN SIEGEL: One concern I have is that if we are planning on meeting on February 21, 22, and now maybe an additional day even added on for training, experience, and

that meeting is going to include an analysis of the document and the commission briefing by this committee, that --

MR. CAMPER: We have a couple issues there. Let's think that through.

CHAIRMAN SIEGEL: That's going to be quite a challenge.

MR. CAMPER: Our plan is not to provide it to the committee until we have the document and it is available for public dissemination. We have not discussed or given any consideration to, nor I'm sure that we could frankly. If we are provided with a copy at all, and if it's confidential, that we could provide it to the committee.

CHAIRMAN SIEGEL: Right. I understand that.

MR. CAMPER: So our plan has been to get it to the committee as promptly as possible once it is published. The meeting on the 21st and 22nd was a meeting that was designed to discuss the NAS report and the staff's analysis as it exists at that time of hte report. I don't think that we had actually considered, but we certainly could, whether or not that two-day session on the 21st and 22nd of February would also include a briefing of the commission by the committee. You may or may not be prepared to do that at that point.

CHAIRMAN SIEGEL: I am not certain we would be. Do you all not have a commission briefing scheduled for that

time frame?

MR. CAMPER: Well, what we intend -- I was going to go ahead. What our thoughts were was we have hte working session on 21, 22 February. Consistent with our earlier discussion today, possibly we would add a third day onto do the first work on the T&E stuff.

We are currently scheduled to brief the commission the last week of March. That would be our annual briefing to the commission on the medical use program. Of course obviously this year it is going to be all about the staff's reaction to and so forth and so on, to the NAS.

We had planned, Barry, as part of that to dial in the ACMUI to participate in that briefing in a fashion as we have previously. Now that could either be a situation where you would represent the committee or select members of the committee could represent, or even the committee as a whole for that matter. But that is something we have to talk about.

CHAIRMAN SIEGEL: Okay. I misunderstood. That's fine. We'll have plenty to do in February just to talk about hte document. If we take on this training stuff, we could meet for days on end.

MR. CAMPER: Yes. That's my guess. I doubt if the committee really would be prepared to brief. But we certainly have to make sure that that opportunity exists, whether it's with our annual briefing or even a stand-alone

briefing.

CHAIRMAN SIEGEL: All right. We have one remaining order of business for today, unless anybody else has business that I'm not aware of. That is, we have to figure out what time we are starting tomorrow.

The Federal Register notice says the meeting starts at 8:30. The agenda shows a closed session from 8:30 to 9:30. The closed session was not noticed in the Federal Register, therefore we could start at 8:30 or if it's our pleasure, we could start at 9:30. I talked first with Larry and subsequently with Torre. I think the conclusion that Torre and I have reached is that we have wiggle room on that. We could go either way. So what is the committee's pleasure? An extra hour of sleep?

MEMBER QUILLIN: 8:30.

CHAIRMAN SIEGEL: Versus getting out of here sooner.

MEMBER WAGNER: 8:30.

MR. CAMPER: Well, the only concern I have about 8:30, and I understand why --

CHAIRMAN SIEGEL: Is the presenters may not be here.

MR. CAMPER: Well not only that. Well that and if anyone was here today who intends to come tomorrow and they saw the agenda, they would not come at 8:30 because of the

closed session. They would show up at 9:30.

CHAIRMAN SIEGEL: So I'm actually inclined -- I don't think we are going to go over tomorrow's planned agenda. I know it's not going to go too late because I have to give a lecture at the Naval Hospital tomorrow afternoon and I plan to be there. So I think we probably need to opt for 9:30 as a start. Then we'll still plan to get out of here on time or ahead of schedule.

MEMBER QUILLIN: If we say 9:00, we may start at 9:30.

CHAIRMAN SIEGEL: No. We started this morning only a couple minutes late. Do you have an earlier plane you would like to catch? That's okay if you do. I suppose we could start at 9:15 and deal with administrative matters.

MS. TAYLOR: Dr. Siegel, the other option, we could do the industrial issues -- (inaudible) --

MR. CAMPER: I suspect that members of the public would be here by 9:15. So we can go in that window, that 9:15 to 9:30 window.

CHAIRMAN SIEGEL: All right. Let's plan on starting at 9:15 tomorrow. So everybody gets a slightly more relaxed breakfast tomorrow. Then we can start with the regular agenda in all likelihood. We are closed for today.

(Whereupon, at 4:38 p.m. the proceedings went off the record.)

1

2

3

4