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OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: Nuclear Regulatory Commission

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

Docket No.

LOCATION: Bethesda, Maryland

DATE: Thursday, May 19, 1994 PAGES: 1 - 286

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UNITED STATES

NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON MEDICAL

USES OF ISOTOPES (ACMUI) MEETING

Holdiay Inn

8120 Wisconsin Avenue

Bethesda, Maryland

Thursday, May 19, 1994

ANN RILEY & ASSOCIATES, LTD.
Court Reporters
1612 K Street, N.W., Suite 300
Washington, D.C. 20006
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PROCEEDINGS

DR. GLENN: Ladies and gentlemen, I am pleased to welcome you to Bethesda, Maryland, on behalf of the Advisory Committee on the Medical Use of Isotopes.

My name is John Glenn. I am Chief of the Medical and Academic Safety Branch of the Nuclear Regulatory Commission.

This is an announced meeting of the Advisory Committee and is being held in accordance with the rules and regulations of the General Services Administration and the Nuclear Regulatory Commission.

This meeting was announced in the Federal Register on April 26th, 1994, and that notice stated that the meeting would begin at 8:00 a.m.

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 ccunsel to the Staff but does not determine or direct the actual decision.

The NRC solicits the opinions of counsel and values the opinions of this Committee very much. The Staff requests the Committee to reach a consensus if possible but also values well-stated minority or dissenting opinion.

The agenda is full, and I request that members of the Committee direct their remarks as briefly and succinctly

as possible.

As an administrative matter, I would request also that when you begin your remarks that you state your name so that the Court Reporter can record appropriately who is making the remarks.

I will also note that some background materials have been supplied to Committee members in preparation for the discussion.

Staff is not requesting comment on the background materials themselves but on the issues and the questions contained in the briefing book.

Some of these documents have been provided as a courtesy to members, and the documents themselves have not been approved for use outside of the NRC.

Direct quotes and references through the documents which have not been released are inappropriate, and Committee members should address the issues and not the document.

If members have differing opinions as to direction the NRC policy should take, members should be completely free to state their personal opinion and to offer comments on the draft documents that were submitted by the Staff to the Committee for review.

As a part of the preparation for the meeting, I have reviewed the agenda as well as members' financial and

employment interests.

I've identified that Dr. Siegel appears to have a conflict with respect to the review of the application of a physician to be approved as an authorized user on license of an institution that's affiliated with his home institution.

Dr. Siegel will therefore be asked to recuse himself from being an Advisory Committee member during discussion of that after-application, which will take place during the closed session of the Committee this afternoon.

In addition, there are two subjects on the agenda where a member of the Committee has identified a conflict of interest.

This afternoon there will be status reports on two proposed rulemakings. Dr. Carol Marcus was the author of the two petitions for rulemaking that preceded the Staff's -- Dr. Marcus should therefore recuse herself from any discussions of these rulemakings in her capacity as a Committee member.

She may participate as a member of the audience should the Committee Chairman decide to accept comments from the audience.

Should any other member of the Committee become aware of a potential conflict of interest with regard to a topics of discussion, you are obligated to inform the Chairman and myself and recuse yourself from discussion of

that topic as a Committee member.

I would like now to introduce those members of the Advisory Committee and Staff members and soon-to-be members of the Advisory Committee who are seated at the table in front.

To my left, we have Dr. Dennis Swanson, and then next, Dr. Judith Stitt; next, Robert Quinlin. Lew Wagner has joined us at the table. He has just recently been approved by the Commission to be added as an Advisory Committee member but has not been appointed as yet.

Next we have Larry Camper of the NRC Staff and to my immediate left, Dr. Siegel, who is the Chairman of the Advisory Committee.

To my right, we have Joan McKeown, and to her right, we have Dr. Woodbury, who is our FDA representative. Then we have Melvin Griem, Judith Brown, Daniel Berman and Peter Almond.

And with those comments, I will turn it over to Dr. Siegel.

CHAIRMAN SIEGEL: Thank you, John.

Good morning, everyone.

We do have a moderately full agenda and so I will try my best to keep us on schedule. Before we begin, let me ask the Committee its wishes with respect to the agenda items for tomorrow, and that is the one we'll discuss, the

proposed ACMUI bylaws.

In order for us to be able to get the bylaws tuned up and adopted by the next meeting, we really need to try to finalize the language in them at this meeting.

I have received comments from many of you but not all of you, and that's okay. And yesterday on the airplane I put those comments into a draft and then a variety of editorial changes seemed right to me and seemed right to those of you who commented.

What I would propose that I do sometime today and maybe not until tonight is get a double-spaced copy of the document, write in the proposed changes and either -- it would be ideal to get them to you before the end of the day -- That would be tricky -- but certainly first thing in the morning so that we can have that as a working document as we go through it.

And we'll have to make fewer changes in tomorrow's session. Does that sound like it's that will work or is that wishful thinking on my part?

All right, we'll try it.

And so, Torre and Sally, if I really can get a double-spaced copy or a triple-spaced copy of the document sometime during the day, it would make life a lot easier.

Then we can ideally distribute it to everyone, and I'll spend my lunch fixing up the document and you all can

have it this afternoon.

(Dr. Marcus enters the room.)

CHAIRMAN SIEGEL: Dr. Marcus is joining us.

Okay. So with that, we can move on. I also add my comments to the comments we just had from John that our purpose here is to provide advice and our purpose is to try to do so in a collegial fashion whereby we reach a consensus if we can.

We're not a legislative body, so perhaps correctly our formal votes are less interesting than our consensus.

And the NRC is not bound to listen to us, although we don't understand that. We should make our arguments compelling and therefore our advice will become more interesting.

And with that, let's begin with the first item on the agenda which is the discussion of the NUREG documents entitled, "Management of Radioactive Material Programs at Medical Facilities." And Larry Camper and Jan Schlueter will lead the discussion.

MR. CAMPER: For the record, I'm Larry Camper, the section leader from the Medical and Academic Section.

I'm joined by Janet Schlueter. Janet is a Health Physicist in my section and is the Project Manager for the development of the NUREG document that we're going to discuss today.

You might recall that at our last meeting we provided you with a briefing on the development of this document.

At that time, we gave you an overview, a status report, if you will, as to what we were trying to accomplish and why.

What we'd like to focus upon today is to tell you what has happened since the last time we briefed you on the document, and, more importantly though, is to get substantial input from this Committee.

What we'll do is I'll first go over some of the highlights of what we're trying to accomplish, the purpose of the document, the progress since last time.

After I do that, I will turn it over to Janet, and she will go through and share with you an analysis of the global comments that we have received by the various groups and organizations that have taken a look at this document for us.

We then go through it chapter by chapter, we'll give you -- and again, the large-scale comments that have been provided to us by the various organizations and individuals that have reviewed the document. And we will invite the Committee to provide input on a chapter by chapter basis.

We have a couple of hours to cover this. And I

think we have a lot of things to talk about.

The purpose of this NUREG document, and for those in the audience for whom this term "NUREG" may not be familiar to you, this is not a new regulation. A NUREG is a guidance document in our regulatory policy.

But the purpose is to provide guidance on management issues associated with radiation safety program management and provide guidance on effective tools for programs of varying size rather than focusing upon the specifics of day-to-day operations.

Basically the reason we're doing this document is we felt that there was a lot of people, licensees in the regulated community that, for whatever reason, didn't seem to understand all of the intricacies associated with the management of a radiation safety program.

We've had some deficiencies which we shared with the Committee the last time we gave an overview, some violations that have resulted in significant program breakdown.

And we felt that we want to ultimately do something about the RSO issue in regulatory space, but it would be unreasonable to do that without first collecting guidance and sharing with the community as to what can be done to more effectively manage a program.

So it's a guidance document that really deals with

the management of radiation safety programs.

We want to clarify the roles of each component of the management triangle -- The management triangle is the institutional management, the radiation safety committee, and the radiation safety officer -- and to describe their interrelationships, which is really one of communication.

There are times when any particular point of that triangle, if you will, is in a key role to the radiation safety program.

What is most important is that they understand their duties and responsibilities and that they communicate well with one another.

Again, this document contains no new requirements proposed or inferred. Rather, it is an attempt to clarify existing regulations. It is, more importantly, an attempt to provide management guidance, as I've said, and It's been written in a fashion that's designed to be user friendly.

We have a task force that consists of Janet and myself as well as representatives from each of the five NRC regions that have inspection experience, licensing experience, and two representatives from the Agreement States.

And the idea is to prepare a document that is easy to read, user friendly, and can be used by all licensees.

All right. Since we talked to you in November, we have made presentations at a number of annual meetings of professional societies.

We made a presentation at the American College of Nuclear Physicians, the American College of Radiation Oncologists and the Radiological Society of North America.

We are currently scheduled to make presentations at the annual meetings of the Society of Nuclear Medicine in June and the American College of Medical Physics in June as well.

And, of course, we have continued to draft and edit the document. We're probably at this point on iteration 15 or something. These things require a deal of drafting and editing.

We also sent this document out to nine organizations soliciting their review and comment. We chose number nine -- It wasn't an arbitrary number. It was a number that allows us to operate within OMB guidelines.

OMB allows us to go out and solicit the comments from nine organizations without going through an OMB clearance process.

I mean, we would have preferred obviously to go to as many other organizations or individuals as possible, but in the amount of time that we had, we wanted to get specific input from certain key organizations.

So the organizations that we sent the document out and asked that they review it and comment extensively, the American College of Radiology, the Brookhaven National Laboratory which we also have a contract with to do a peer review of this document, the American College of Medical Physics, the American College of Nuclear Physicians, the American Association of Physicists in Medicine, the National Council of Radiation Protection, the Organization of Agreement States, the Society of Nuclear Medicine. Of course, we're soliciting comments and input from this body.

And we also recently sent the document to the American College of Radiation Oncologists. ACRO, let me say for the record, had requested the document to comment on it.

We ran into this ceiling with OMP clearance, so what we did was we chose to put the document into the public document room, and we provided a copy to ACRO last week.

I spoke to that organization this past Sunday morning. They intend to provide us with extensive comments, and their overall reaction to the document was quite favorable.

We, of course, put the document through an extensive peer review by NRC Staff, and Management in Headquarters and the Region.

The purpose of doing that type of review of getting those types of comments was to try to get as much

input as possible on this document, I think I told the Committee last time.

What we didn't want to do was create a guidance document that there was a feeling by the community that a group of regulators had set in Washington and created this document without going to the regulating community.

So we've gone to these organizations. We've gotten a lot of input. We intend to incorporate to the maximum extent possible the input by those organizations as well as the input by this Committee, and, hopefully, as a result, we'll get a much better document.

There are certain key themes within the NUREG document. First of all, there's this concept of a management triangle, that being the executive management, the Radiation safety committee, and the RSO.

We discussed the management triangle, and, as I said a few minutes ago, there's an emphasis upon the need for each of the legs of the triangle to carry out their duties and responsibilities and functions and above all to communicate so that the program is managed in an effective manner.

We talk a lot about implementation of a radiation safety program with particular emphasis upon having an active radiation safety committee, the conduct of audits that are required in the regulations, and that also serve as

useful management tools.

We talk a great deal about the need for supervision and training of the various technical Staff, physicists and so forth and the role of authorized users and the RSO in providing the supervision and training.

Obviously we talk a great deal about the responsibilities of the radiation safety officers, one of the key chapters in the document as you might expect.

We do also talk about resource implications, Staffing, space, equipment, use of contractors and so forth.

We do not talk about the dollars that are involved. We do not talk about the fact that we have a if you have a broad scope program with X number of laboratories and X number of technical Staff, you should have an RSO, two technical assistants and the like. That would be inappropriate to do that.

What we do talk about, though, is at least the major topics of consideration. We're looking at resources, people, space, equipment, those types of things. And, of course, we provide a lot of management tools and guidance.

All right, What we're going to do now is we're going to have -- Janet's going to go through. As I mentioned, Janet's the project manager for the NUREG.

We're going to go through and share with you then the general comments from the peer reviews to date.

After we do the general comments from the various peer reviews to date, what I'd like to do I think then is offer this Committee an opportunity to make general comments or observations about the NUREG.

After that, then, as I said, Janet will go in and go through each of the major chapters. She will share with you the input provided, the global comments if you will.

Obviously there have been many, many comments. We can't share them all with you, so what we've tried to key is lift the key global type of comments. And then in turn, this Committee can provide comments on each chapter.

CHAIRMAN SIEGEL: What's the operating timetable?

MR. CAMPER: Two hours.

DR. SCHLUETER: Oh, I don't think he means right now. I think he means for publication.

CHAIRMAN SIEGEL: For the document.

MR. CAMPER: It's scheduled to be published in September. September is the date.

CHAIRMAN SIEGEL: So that --

DR. SCHLUETER: That's been our goal. You know, that does depend on continuing review of the peer comments which we have just received about a week and a half ago. Some of them are still coming in.

I received comments from the Organization of Agreement States just yesterday as well as some comments

from other offices within the NRC.

Depending on the magnitude of the changes, our goal is to publish it by September 30th, but we have to allow, of course, some time for the actual publication process, just the electronic processing of the document.

So if the changes are of any magnitude, it could be October, November. At the latest, our goal is the calendar year, but we're honestly shooting for September.

CHAIRMAN SIEGEL: Is it usual for the Committee, if we can't do it at formal meeting, to inspect, to see those revised documents a couple of times so that individual members of the Committee can see what's been proposed and what's --

NUREGs, unlike regulations, don't ever really go to a pre-decisional ---

DR. SCHLUETER: Right.

CHAIRMAN SIEGEL: NUREGS are simply always open for comment.

MR. CAMPER: Barry, I think the answer to that is we will take that into consideration. We haven't scheduled what is one of the key items in the medical management plan. I think what we can do is go back and confer with management to see if that possible.

I would say two things in addition to that. One is I think it's a function of how quickly we can get all the

comments incorporated and make the adjustment so what we have it at the point where we could let you review it again.

And then, secondly, if it means a delay because we can't do that promptly or as quickly as we'd like, then I think our management has to decide whether we want to delay this thing for two or three months to allow it to happen.

But it certainly seems to be a reasonable suggestion.

CHAIRMAN SIEGEL: Well, I would again, given the fact that the guidelines and NUREGS fall more in the class of meddleings, I'm essentially looking for comment at all times.

I'm encouraging, if either of you don't have any mention of responding to comments from members of this Committee that you get a document into our hands as a way that -- it's kind of an insurance policy for you.

It's a way of you knowing that the Committee doesn't feel it's been sandbagged so that at a future meeting, we don't all sit here and say, You know, we told you we would like this, you went ahead and published it anyway, and you are irresponsible.

This gives you kind of an insurance.

Now, we may all say we hate it even if you'd shown us the changes, but at least you were open about that and we were open about it, so I think, even if you ignore what we

say, it is probably in your best interest to get us a copy of something that has been edited at some time up the road.

MR. CAMPER: I agree. What I'd like to do is proceed with the idea that we would, to the maximum extent possible, not ignore what you say.

CHAIRMAN SIEGEL: I understand.

MR. CAMPER: That may in turn cause a delay and that will be the decision to be made.

CHAIRMAN SIEGEL: We like that idea.

DR. SCHLUETER: Okay.

In the comment section that we're going to discuss, there's about six slides or so where we'll step through some general comments which were presented by the professional organizations during the peer review, the Organization of Agreement States.

And then we have specific comments that we've summarized for each chapter. And after the specific comments for each chapter, we also have separate slides to summarize what the Organization of Agreement States said about each chapter.

We wanted to do that so that we could emphasize the role that the Agreement States played in this project, the fact that we did have two Agreement State representatives on our task force which continue to work with us. And 13 states did respond to the request from the

Organization of Agreement States for comment.

Under the general comments for the professional organizations, which obviously included different fragments of the medical community, there were radiation oncologists, nuclear medicine types, radiologists, physicists, health physicists, medical physicists, and so forth.

As you might imagine, they had a variety of comments and they focused on different portions of the document, and obviously they're coming from different perspectives as to what issues in the radiation safety program they believe are important. And their comments reflect that perspective.

Some organizations offered only general comments, philosophical comments. Some organizations offered policy comment or philosophical comments as well as major editorial types of comments.

I'm not going to bore the group with the editorial types of changes. That's unnecessary. I also won't go through changes which sort of fall in the middle ground which are changes which suggested that we changed organization of a particular, paragraph, section, chapter.

Perhaps something was felt to be repetitive in too many locations, and so forth.

So I've lifted only the major comments from each organization. And I have to say from these various groups,

the majority of those comments were very favorable.

We had very positive adjectives used in their letters back to us. And as you can from the screen, it was believed to be well-written, comprehensive, very useful, also interesting, insightful.

It was oftentimes mentioned that there wasn't anything quite like this. Now, you could take that one way or another, I'm sure, but --

(Laughter.)

DR. SCHLUETER: -- it was believed to helpful in that no one could quite pinpoint a document that was quite so comprehensive in various aspects of the radiation safety program.

And, as Larry mentioned earlier, it was an effort to not focus on the details of day-to-day operations. It's really an effort to focus on what's wrong with the management structure in radiation safety. So as you reviewed the document, I'm sure you noticed there was not a lot of detail when it came to day-to-day, hands-on or procedures and policies of implementing the radiation safety program.

All of those comments were very supportive, although we can't overlook the negative ones. And there are some naturally. And we knew that, and we knew that when we put it out.

We knew it was draft. We considered it to be pretty draft in the sense that it did need a lot of editorial polishing.

We had nine different authors, which was very difficult to change writing styles, make it uniform. Vocabulary is different obviously from different authors.

It was a very difficult and it will continue to be so in order to make it a document that flows a little easier and reads better. It still needs help obviously.

The criticism most often was it's too long. Some people believe that it will go to a shelf and sit there.

And we were afraid of that when we started writing and decided that obviously there were a lot of sections to cover.

So what we did was we tried to make each chapter somewhat stand alone. And this is where the second comment comes from: It's repetitive.

Yes, it is repetitive, and it was meant to be repetitive. And that can be a positive. That can be a negative. Obviously you can get bored reading it.

But what we're afraid will happen is that individuals who have different interests in the radiation safety program like the manager types, the physicians, the technologists, the physicists, will look to certain chapters out of there and may not read the whole thing.

I hope the radiation safety officer and a few key other people do, but we run that risk that they will not. So we did repeat information throughout. That can be boring.

Obviously sometimes the presentation of ideas is not fully developed. Maybe we reader hanging in certain spots. Obviously we could go back and clear those kinds of things up.

And, as I mentioned, there were specific editorial comments that some organizations offered. Obviously some people went through it line by line.

And, yes, I was testing to see if you were awake while you were reading it, because, no, there is no such thing as the R-A-Z-E program, RAZE.

(Laughter.)

DR. SCHLUETER: Operator error, the wrong key on a spell-check. RAZE does not exist. It was supposed to be Radiation Safety.

I had abbreviated it originally as RS. People didn't like RS. I went back through. I tried to catch all of the RSs, got a few RAZEs thrown in.

But it's kind of funny to read the comments because a lot of people have mentioned it. "What is a RAZE?" they asked.

(Laughter.)

DR. SCHLUETER: It's nothing.

Moving along here, okay.

Those were the majority of the comments and the consensus of the comments, but I do have a slide here to point out a differing comment from the American College of Nuclear Physicians and the Society of Nuclear Medicine.

And we have two main comments, the first of which, obviously you can read, is that there is a serious concern regarding the volume of extraneous information that goes beyond current requirements.

Specific examples were provided in their letter for several chapters, and the document does little to clarify existing regulations.

There is extraneous information. It's not requirements. It is information that we felt on a day-to-day basis was operational type of information, would help licensee management get a handle on the magnitude of their particular radiation safety program, help them to try to decide who might get the role of radiation safety officer at their facility.

It is not tuned or focused in on specific regulatory requirements. Yes, there are regulatory requirements for a radiation safety officer, radiation safety committee, all through Part 35. Obviously Part 20 applies to medical licensees.

But this was not our focus. Our focus was much more general than that. It was to give this broad perspective on how you might assess the resources needed for your program and so forth. How do the elements of the management triangle function?

And as Larry mentioned, because of this, there are no regulations even cited. I'll take that back. There may be some.

There's some in the appendices. We decided to get specific citations therefore, some of where our reporting requirements come from and so forth. Barry's checking on that one.

But we took it out of the text because we believed it was a little distracting and also there was the effort to make it more universal to Agreement State licensees, so we removed that.

CHAIRMAN SIEGEL: Janet?

DR. SCHLUETER: Yes.

CHAIRMAN SIEGEL: Do you understand why this concern arises, this issue of introducing too much extraneous information?

I think that there is a concern that guidelines have a way of becoming standards and functionally becoming the equivalent of regulations, particularly when a document is prepared by the United States Government and/or by an

organization that has -- premature, like the NCRP, for example.

Those official publications tend to be the citable standards that are adopted by other bodies. And it's not at all hard to imagine someone looking through a NUREG and saying, Well, this must be the way to do it.

And, JCAHO, for example, could turn to this and say, Gee, it's written in stone here, when, in fact, there may be no legal basis in fact for the information that's in there.

So I, although I may or may not agree with SMN comment about too much extraneous information, I think it's important to understand the genesis of the comment.

There is ample precedent to indicate that racheting occurs and it occurs through the complex interaction of many different regulatory agencies and many different other organizations.

And that focus needs to be kept in mind as you keep an idea about what really needs to be there and what doesn't need to be there.

MR. CAMPER: That's a legitimate concern, Barry, and to the maximum extent possible, we're going to make sure that we clarify it in the early parts of this document, a disclaimer, the scope of the document and what its purpose is and that it doesn't create any requirements certainly.

I mean, that, in the final analysis, may not stop certain entities from doing that, from using it that way, but we need to make that very clear. Certainly we're going to make it clear to our own Staff, our own licensees, our inspectors the purpose of this document.

But, you know, on the other hand, we have to weigh that against what we feel is the need to get this guidance out in some way.

DR. SCHLUETER: Well, Larry said exactly what I was going to say.

And that brings up the fact that currently now there's not a what we'd like to call a scope of purpose in the beginning of the document. We are going to create one. That's one area that I think this particular can be addressed and more fully explained.

The background and disclaimer will probably go away as two separate pieces but will be combined into one after our scope of purpose.

This particular draft that went out, if you know NUREGS, isn't it a NUREG format at all either. It was an effort to get something out in chapter form. It won't be chapters anymore.

And when I say "NUREG format," there will be a disclaimer also, which is a standard disclaimer on the front cover, which basically says this is NRC requirements, it was

simply guidance, you know, on and on and on. So there a couple of fixes for your concern.

Again, we currently don't have a scope of purpose, but we're going to add one to help clarify some of the issues plus some of the ideas that are in the background, a disclaimer.

Some words make reading the text difficult. I agree. That's obvious. There were word choices by some authors which perhaps weren't optimal, so we're going to continue fine-tuning and editing and making it a little bit more consistent in its word choice.

A list of acronyms, that definitely needs to happen. There's not that many that are used really. There's quality management program, radiation safety officer, radiation safety committee.

There's a few, but there's enough obviously that, if you do pull certain segments out of the document, you may have missed what they stand for. So a list of acronyms will be added.

The summaries were -- the summaries were kind of interesting. The summaries were sort of a last-minute idea in the sense that we first thought putting in an executive summary in the beginning.

Once again, we were afraid that management would lift that and go no further, so we decided that perhaps we

should place a summary at the end of each chapter. And we did so. And they need more thought.

They should not introduce new ideas obviously. They should be more recapturing what was stressed in each chapter, so each summary will have to be redone in order to focus on the major points of each chapter. Okay.

Now we have specific comments on Chapter 1. But I'll tell you what, let's just open the floor up to general comments that you'd like to give us on the document as a whole because we'll go into each chapter.

And I want to be able to just exchange this information. So if you'd like to pass to us general comments now, we'll be happy to take those.

CHAIRMAN SIEGEL: Dennis?

MR. SWANSON: Dennis Swanson.

My major comment is I would agree. I think that the current version is perhaps too detailed, too specific, and too directive.

In addition to the comments that have already been made, I think some of the problems associated with being too specific and too detailed is you lose a loss of your focus, which is to provide guidance on management issues related to radiation safety programs. And it's somewhere -- it gets lost with all the detail.

Some other risks, I think the most important one

is that executive management is not going to read it if they get this long document.

Our rule of thumb is you give one-page letters to executive management because that's all they read, for example.

You risk errors of omissions. From my perspective, my area of practice, nuclear pharmacy, for example, there's no discussion of nuclear pharmacists as supervised individuals.

There's no discussing -- discussion of out-sourcing of nuclear pharmacy services under consultants or outside service.

And you risk errors of fact. And again in the document there, for example, there are some errors with regard to the FDA regulation of radiopharmaceuticals permitting the practice of medicine, the practice of pharmacy, so on and so forth.

So I think my general comment is again too detailed, too specific and too directive.

CHAIRMAN SIEGEL: Bill?

DR. GRIEM: Since Indiana, Pennsylvania, at least I've been quite busy looking at misadministrations. And as I see them and then read this over, I wonder if there's been any integration of the material we've been sending in on these medical reviews in an attempt to prevent some of those

misadministrations. I haven't seen any.

DR. GLENN: Well, maybe not creative. We're looking at the management and supervision aspects, basically where there's evidence of lessons learned in terms of management and supervision.

DR. GRIEM: Yes. And it seems to me that we've been working, at least I have, diligently --

DR. GLENN: Well, certainly the number one finding of the incident investigation team had to do with RSOs and their involvement and their communication. We've tried to address that.

If you could maybe give us a little more specific --

DR. GRIEM: Well, I think that, you know, the way you've got it set up here is you haven't included the medical physicists really on the therapy side of the equation.

And if you've got to say, Where's the big radiation? and if isn't it in the technetium language, then I am propositioned, but if it's in the high dose rate materials or device numbers, all kinds of important things that I'd hope would be in there.

DR. GLENN: Okay. So what you're saying in terms of listing executive management, we haven't said there are certain programs that you have at a medical institution that

carry much higher risks?

DR. GRIEM: Right.

DR. GLENN: Okay.

DR. GRIEM: And I don't see that in this thing. And I think this is going after the wrong thing. That's my sort of general editorial comment.

MR. CAMPER: That's excellent.

CHAIRMAN SIEGEL: But that's as distinct from including operational.

DR. GRIEM: Well, it's a document, but I don't think, given the direction of things happening, at least in radiation oncology, whether this is -- and where you people fit into it, this really isn't addressing the problem.

DR. SCHLUETER: That's true.

DR. GRIEM: That's my swan song.

DR. SCHLUETER: That was easy.

DR. MARCUS: I think my comments will certainly be a continuation of some of the things you all have said.

I don't think the NRC has a scientifically valid comprehension of the radiation safety issues involved in nuclear medicine.

There are virtually no radiation safety issues in nuclear medicine. The biggest danger in nuclear medicine tend to be poorly done studies, missing diagnoses, not being creative enough with the tools at hand or being hit by a

lead pig.

But the radiation in itself is a negligible concept in nuclear medicine. And there is a complete lack of quantitative physics, quantitative health physics, radiation biology, internal dosimetry, anything indicating the fact that the health physics considerations in nuclear medicine is, generally speaking, is a no, never mind.

The way our drugs are made today, even the potentially total -- drugs like sodium iodide come very, very well buffered so that we don't have the airborne emission problems with them. And we just don't have radiation problems.

When I read sections, for example, about facilities for handling victims of radiation accents, and I sort of looked at it, I was surprised, because my hospital has such procedures because we're near a Navy base and one of the largest ports in the United States and there have been fires and explosions at the port. And Standard Oil is not too far away.

And so somebody had to do that. And our hospital did it.

Suddenly I realized that what was meant in the document was the human radiation accents from the medical activities within the hospital, and I burst out laughing because obviously there is no correlation between real

health physics and that statement in terms of what goes on in a hospital.

We don't have radiation accident victims needing special facilities for treatment in nuclear medicine and the very rare situations in radiation oncology, community service -- the facilities generally are available in any full service hospital.

I have problems in the fact that NRC does not have any comprehension of really what the practice of medicine is.

There were statements in here that were bizarre about the nuclear medicine physicians having to do physical exams on all the patients to make sure that they really need to have the radiopharmaceuticals administered. Obviously the NRC does not understand the practice of nuclear medicine.

Statements such as obviously, you know, it would be ideal if the nuclear medicine physician were physically present every time a does was administered.

Obviously, as far as I'm concerned, the nuclear medicine physician has a lot more important things to do.

Technologists, well-trained technologists can take care of trivial things like that very, very well.

But there are assumptions of the way medicine is practiced, and that showed to me the NRC doesn't understand

it at all.

And in fact, I don't think they belong in this area at all either. I think the NRC should be concentrating on radiation safety considerations, the workers and members of the public and should at least understand in terms of nuclear medicine that we just do not have significant radiation sickness problems, and that perhaps one of the reasons why management is even -- well, when they come to the radiation section, we usually fall asleep because there's really nothing of importance discussed when it comes to things like radiation safety in nuclear medicine.

I was very concerned about management oversight. The NRC is talking about management oversight in medical institutions and I was concerned with management oversight over this document at the NRC.

I talked to Dr. Paperiello and Mrs. Thompson and just asked them on the 2nd of May -- of May if they had read this document, and at that time, neither of them had.

So the draft had gone out for public comments actually without management review of the sort I would have expected to see.

Now, I don't know about Dr. Griem, I don't know about Mr. Grenaro, but I'm not sure who with a more advanced education in physics actually did review the document, but it was obvious to me that the people who wrote it were not

terribly well-qualified in physics.

This document has been written over about a two-year period, and I just don't see management oversight at the NRC of the type that I think ought to be expected by the country in a document like this.

I think there needs to be more heightened scientific oversight of a document like this.

Kathy Allen, who was one of the Agreement States representatives basically is saying that she did not have an input into the document because she got -- she was factored by the NRC.

The NRC said it was not compatible with the Federal Budget Committee Act and she could be there, but basically not participate in what she considered any meaningful way.

John Shark, who started this, quit, from Texas. I don't think that the claim that this was developed with the Agreement States is a very appropriate one.

I remember last year at the -- at the meeting in May, a lot of Agreement State representatives were pretty annoyed that they were not allowed to see any piece of this document.

I think the time frame given to people to review the document was far too short. I would like to see the NCR become -- were they handed in yet?

DR. SCHLUETER: Yes. I have individual comments from members of the NCRP and then the Brookhaven National Lab.

DR. MARCUS: Okay. I would think it would be good if the Committee had an opportunity to review those.

I think that generally summarizes my comments. I know there was some other feelings expressed by the others.

DR. QUINLIN: I don't want to sound repetitious, but having been a local licensee and a --, I read this document trying to wear both hats, and the document is just too long for management to use effectively.

Our theory, as Dennis Swanson said, upper management wants something that's concise and to the point, and probably no more than one page.

CHAIRMAN SIEGEL: Any other comments before you go on?

Janet, go ahead.

DR. SCHLUETER: I just wanted -- as the project manager, I feel compelled to respond to a couple of Carol's comments, one of which is the participation of Kathy Allen and John Shark.

And John Shark did retire. Kathy Allen did work with us and continues to work with us. We did run into a snag with FACA guidelines, having a task force.

That was mainly because we had, in the very

beginning, developed a charter. The charter threw us into a FACA situation.

We explored the FACA issue with our Office of General Counsel. We also discussed it with the State of Illinois from which Kathy Allen comes from, and we developed guidelines for the exchange of information from Kathy Allen throughout these meetings.

Basically, Kathy Allen was allowed to provide input on a continual basis to the NRC for comments.

She authored more than one chapter. She was at every meeting. She participated in exchanging information via disks, Federal Express, every which way we could get information back and forth. She was very much involved.

Also, just because Dr. Paperiello as of the early May had not read it doesn't mean that we in the task force haven't met with our management including Dr. Glenn and Dr. Paperiello and so forth to discuss philosophical ideas, themes of the document, main points, the approach, our time frame, the overall project.

They were fully aware of where we were at any given time and felt confident that the document was on the right track.

They didn't need to sit down and pore through 170 pages every time I felt like I had a working draft. They have read it at this point in time.

MR. CAMPER: I have one or two comments. Dr. Marcus covered a lot of ground.

CHAIRMAN SIEGEL: Can you hear him?

MR. CAMPER: I was saying Dr. Marcus covered a lot of comments in her general comments, and I don't really want to debate them. I would point out one or two things, though.

The document is written in a fashion, as I indicated earlier, to be user friendly, to try to capture as much of the audience in the regulated community as possible.

It's not meant to be a textbook of health physics or radiation biology. The group that composed this document, I would submit, does, in fact, have ample background, academically and materially in health physics, radiation safety, radiation biology and the like.

But the document wasn't written to be a textbook, if you will. It's written to be a user friendly management guidance document.

Now, your comments about the lack of scientific validity, I sense two things. On one hand, I sense that you may, in fact, have some concerns about the regulations that exist, whether or not the proper level of concerns exist in those in regulations for the risks associated with materials used in medicine.

Now, that's a regulatory issue. And we are going

to revise part of 35 in the future, a major revision. And we do plan to go out with an announced, a rulemaking announcement, and I think that we're going to have an opportunity in the near future to take a look at the regulations.

And it's a good opportunity to raise some of these scientific validity questions or risks involved, but that's a different forum, a different vehicle for doing that.

But the other thing is I am very concerned, and I would clearly welcome specific comments from you, Dr. Marcus, about the practice of medicine.

If there are items in this document that you believe incorrectly state the role of the nuclear medicine physician as it relates to radiation safety or if we have misstated something that really and truly is the practice of medicine, I mean I would certainly clearly welcome those comments, because we definitely do not want to misstate anything about the practice of medicine.

DR. MARCUS: Anything about physical examination of patients and reviewing his history, who writes a report, things like that are none of the NRC's business in my point of view from the point of view of public health and safety.

These are medical practice issues that are not to be dictated by people at NRC who really are not professionally part of the group that determines this.

CHAIRMAN SIEGEL: Well, let's propose we deal with that when we get to that because I also have some concerns with those points in terms of those statements simply just not reflecting the real world and then that becomes my concern as to these things have a way of becoming codified when, in fact, that was not your intent.

MR. CAMPER: Right.

CHAIRMAN SIEGEL: So we need to give us some information about that.

Let me ask, does anybody else have any other general comments at this point?

DR. SCHLUETER: Only one, and that is that the task force first met in April of '93 and began writing -- had the first outlines of the document in July of '93, so we've been working less than one year and not two.

CHAIRMAN SIEGEL: Let me ask the Committee to try to reach a general consensus at this point if we can.

When we heard a comment from Carol that would tend to point in the direction that this document should simply be thrown away, tend to point in that direction --

DR. MARCUS: Pointed in it.

CHAIRMAN SIEGEL: She was more than specific than that.

And I haven't heard any other specific comments to that precise -- is it the general consensus that this

document in its overall purpose and scope fills an information gap and therefore at least conceptually such a document is -- we would endorse its need for being on the street?

Is there a consensus on that point or do members of the Committee think the document --

(Dr. Marcus raises her hand.)

CHAIRMAN SIEGEL: You will have your chance to dissent, Carol. Wait a second.

-- or is there a sense that this document is just worthless and we should recommend that you guys stop doing it now.

Joan?

DR. McKEOWN: I think that it is a very necessary thing to have as a management document, but I think you also have to be very careful not to overstate risks or understate responsibility.

I think the document is necessary. I disagree with a lot of what Dr. Marcus said, but I agree with a lot of what she said.

You've got to state the correct problem and make it as short as possible and then have the rest of these --

But I don't know of any hospital management, executive management person who's going to read more than four pages. Trust me on that.

DR. ALMOND: Essentially the same comment. I think it fills a need, but in its present form, it isn't going to be read so it is useless.

And it isn't going to be read by management who you particularly want to read it. The RSO might read it and maybe the chairman of the radiation safety committee, but hospital management will not sit down and read this document in its present form.

CHAIRMAN SIEGEL: So that leads me to a second comment before we answer -- or a second question before we answer the first one I posed.

Is there anyone on the Committee who thinks this document is too short?

(Laughter.)

CHAIRMAN SIEGEL: Hearing no objection to that question, I think the repetitiousness and the length of the document really is something you all need to work out.

The notion that each chapter will be free-standing may be the document's undoing in a way. And so I would urge you to really carefully consider that.

I personally urge you, and we can hear from the others, to reconsider the concept of an executive summary because that is indeed all of it may be read by a CEO-level administrator who ultimately would be the one who is the person you correspond with when you write license notices

and violations.

On the other hand, I'm not entirely in agreement that a lower-level manager who may be the operational manager responsible or the hospital vice-president responsible for the radiation safety committee or the university facilities officer responsible for the radiation safety committee, you might get a little bit more into the document.

I think you all are -- maybe -- and less enlightened administrators than I do. I think administrators are starting to pay attention to some of the regulations these days because they recognize the potential adverse impact on our institutions if they don't have a clue about what's going on.

So you may get some people to read it, but I clearly think that it's except in summary, for the person who's only read four to six pages, it will serve you well if you can write it with great clarity and use it to point to the appropriate places in the more comprehensive document.

Overall, the document is too long and will even be a tough a read for the average radiation safety officer.

I was struck by the adjective that the document was interesting, as you said. It took me the better part of four nights about 45 minutes to a hour a night to get through this thing because I didn't find it that

interesting.

(Laughter.)

CHAIRMAN SIEGEL: It was not one of those novels I couldn't put down.

(Laughter.)

CHAIRMAN SIEGEL: Okay. So I think -- is there a consensus on that general comment about length, the need for an executive summary, if you all would take that under consideration, and possibly, and certainly with Carol as an exception, consensus that such a document fills an important need?

Carol, you'll get a chance to dissent openly in a moment.

Does anyone else want to dissent on that last point?

(No response.)

CHAIRMAN SIEGEL: All right. Carol, if you want to say more, please do.

DR. MARCUS: Okay.

I think that this document is so misleading in terms of suggestion of radiation hazard that does not, in fact, exist and the suggestion of resource allocation that is, in my opinion, misspent, that it is not helpful, and I would rather see it not exist than come out with a spin on it that I think is not useful for medical institutions.

CHAIRMAN SIEGEL: Peter?

DR. ALMOND: I think it's a useful document, but there are parts in here which I think definitely have to be changed.

I mean, as a concept I think it's all right, but there are chapters in there which I think have to be drastically changed before it goes out, so I'm sort halfway between the document should be published and halfway with Carol that maybe it shouldn't be.

I will be if certain changes are made in there, but, if not, in the present form, there are things in here which I think -- and I guess as we come to those chapters, we'll discuss them.

CHAIRMAN SIEGEL: I think you have to have a sense of where we're coming from.

Carol, just to respond to you, and I've already said this, but I think I see you disagreeing more with the regulatory philosophy than what's in the document there.

I may well agree with your regulatory philosophy, but I think the right place for your objections to be stated will be when we as a Committee have an opportunity to talk to the National Academy of Sciences and the panel that's evaluating the overall regulatory approach to the use of radiation in medicine.

This document more or less accurately reflects

what is needed to comply with NRC requirements and Agreement State requirements as they are currently on the street.

You may well disagree that those requirements are completely lopsided with respect to the risk issues associated with the practices.

And there was a wonderful editorial in yesterday's Wall Street Journal about Government agencies coming to recognize that some of what they're afraid -- were afraid about in terms of risks, and I don't disagree with that philosophically.

But given current regulations, given current NRC approaches to the way they interpret their regulations, the guidance in this document will help licensees at least understand how to run the gauntlet.

DR. MARCUS: Let me just comment.

First of all, there are things in this document that are not in the requirements at all.

CHAIRMAN SIEGEL: And we'll come to that.

DR. MARCUS: So I think that they don't belong.

Number two, you are probably quite correct that the root cause problem are existing regulations that don't make scientific sense, but maybe what you ought to do is not put the cart before the horse.

If your basic problem, and I see that definitely it is a basic problem, are requirements that don't make good

scientific sense and fix them before you waste a lot of your user fee money writing a document like this that's going to have to be thrown out and redone when you finally fix the root cause problems.

CHAIRMAN SIEGEL: Bill?

DR. GRIEM: Griem.

This is going to administer a certain financial burden, and I would really like to see the cost/benefit ratio.

How many errors is this going to prevent as a result of the document? If it's not going to be read, it's not going to be helpful at all. It's going to --

And I really think the Committee would like to know what's the benefit of this and what's the cost.

Finally, I think at least as we move into managed care and so forth, this is going to be an additional burden that must be borne before the money finally gets to the people who do the work.

And right now, of your dollar that is spent, one quarter goes to administration. That's in the -- journals, average.

MR. CAMPER: I appreciate your comments about the limitations, if you will, of the document, but again, let me just emphasize that it is not a regulation. It is not even a regulatory document.

It is written to provide guidance on one might handle a regulation and consequently is not subject to cost/benefit analyses other than to --

It is a guidance document. And I think Dr. Siegel has eloquently, as he so often does, captures things.

I mean, it's an attempt by the Staff to share with the regulated community the kinds of things that are useful today to the existing NRC state and community regulations.

You can't -- while I certainly agree and sensitize that the document is very long in its length and we'll do what we can to shorten it because the point's well made, but on the other hand, I know of no way to put into a one-page executive summary all the intricacies involved in managing a radiation safety program in institutions of various sizes and various broad scope facilities. That can't be done.

What we can do is try to find a way -- and it may well be that the executive summary is the way to go. It's crisp and succinct and can be useful. And we'll certainly consider that.

But let me just emphasize that it's a guidance document. It is not a regulation or a regulatory guide.

DR. SCHLUETER: The specific comments on each chapter, two slides on each chapter, the consensus of the organizations, the professional organizations on the first slide followed by comments by the Organization of Agreement

States.

Chapter 1 is the role of executive management. This is where we introduce the concept of the management triangle which, I believe, needs more explanation, more build-up.

It's not explained enough. It's talked about later. We need to build up the management triangle again.

This is the first component; the executive management, with the RSO, the radiation safety committee being the -- would be item two.

Again, the term "executive management" may not always be clear to the reader exactly who we're referring to.

We need to make it clear that it is the CEO level, administrator level, president level, presidents high. It's top management. It's not the radiology department manager. It is not department managers.

It is management, executive management for the facility which has authority to allocate resources to the radiation safety program.

Also, an outside inspection of the program may be helpful to assess the performance, but it is not required.

The idea there was simply a discussion to recognize that executive management is not going to be familiar with the intricacies of a radiation safety program,

the resources needed to run it effectively, the roles of all these parties necessarily, so it may be helpful for management to at least consider to get someone in from the outside to evaluate the effectiveness of their program, the contents of the program, implementation and so forth.

It was a light suggestion. It was not in any way meant to be a strong recommendation. It was an idea. It was a concept. It was something we threw in that we thought they may consider if they need help.

MR. CAMPER: That's just for Chapter 1 and 2.

DR. SCHLUETER: Yeah, you're right.

MR. CAMPER: Any --

DR. SCHLUETER: Yes, because OAR had very little on both of those so I combined them.

MR. CAMPER: We're going to cover Chapter 1 and 2.

DR. SCHLUETER: The specific comments on Chapter 2, which is the "Role of the Radiation safety committee," we tried to explain their part in the management triangle, their interrelationship with the management, the radiation safety officer.

We described their function, of who should be on the Committee, how you decide who is represented on the Committee and their function as far as evaluating the RSO, meetings, and so forth.

Executive management should not be a radiation

Committee member. This primarily stemmed from the idea, this comment stemmed from the idea that management should not have voting power.

They should be an ex officio or de facto member whereby they could not make a difference on a vote when it pertains to radiation safety matters.

The RSO should not be RSC chair. That was a very popular comment. These two individuals should not be the same.

One comment that's already been mentioned that we should add a third element there. An authorized user should not be an RSO who is the RSC chair. You don't want three units as the same. And that was a single comment.

Also one commentor suggested that we discuss possible problems with the large user, meaning someone who's using a great deal of material at their facility, someone in a great deal of power or clout shall we say, as RSC chair who may be in conflict with the RSO.

And the management rep should be the RSC chair. So as you can see, that's rather contradictory from the first statement, which is they shouldn't even be a member at all. It's very different.

The Organization of Agreement States commented on Chapter 1 and 2. Obviously various states had different reactions on the idea of an exchange program of other

licensees.

They said that this was resource intense, they hardly to do their own job. They couldn't see going out and evaluating someone else's program when they were barely keeping their own alive.

Clarify whether all components of the management triangle had equal importance. Apparently in one portion of the document, we tended to stress that the radiation safety officer was perhaps the most key element whereas we're also simultaneously describing that each component of a management triangle is equal.

So obviously there needs to be come clarification on that issue, and also broad scope licensees' authority to approve authorized users.

-e is a statement in there. I went back to try to capture this yesterday, and I believe it simply is just not clearly written.

It almost infers that the NRC would approve those authorized users under a broad scope, and that's simply not true. I think it's just a matter of semantics and it can be cleared up easily.

Now, we'll open it up to comments on Chapters 1 and 2 before we move on to Chapter 3. Remember that's the role of the radiation safety officer and the Committee -- or, excuse me, "Role of Executive Management" and the

radiation safety committee.

DR. GRIEM: On page 13, paragraph 3, "User group representatives , such as research, pathology, radiation safety and nuclear medicine," well, the big dose users are radiation oncologists or his medical physicists.

And I mean, given Indiana, Pennsylvania, and things since then, I think that feedback has to begin there and you have to put the person who has not millicuries or microcuries but curies of stuff needs to be on this Committee or his representative.

CHAIRMAN SIEGEL: I'm sorry? Now where are you?

DR. GRIEM: The third paragraph, "User group representatives, such as research, pathology..." the last sentence in this document here that you sent me, 130 pages.

CHAIRMAN SIEGEL: Well, in fact, you are addressing an issue that's addressed in the regulations.

DR. SCHLUETER: Right.

CHAIRMAN SIEGEL: The regulations already require that each category of authorized user must be represented on the radiation safety committee.

And, in fact, the comment that you got about who should or should not be a voting member or not a voting member is irrelevant as the regulations currently say who has to be on the Committee.

And the management representative has to be a

voting member the way the regulations are currently configured.

MR. CAMPER: I think I can -- this is sort of involved in your comment earlier. I think what I'm really hearing here is that we need to make sure that we're capturing larger activity areas, therapy areas, and I'm also hearing the great consequences --

CHAIRMAN SIEGEL: Right.

MR. CAMPER: That's a good point.

CHAIRMAN SIEGEL: Now, Bob.

DR. QUINLIN: I don't know what edition we're looking at here, but the very first sentence on Chapter 1, where you use the term "radioactive materials safety program" where in the disclaimer, you said you were never going to use that term.

You said you were going to use the term "radiation safety program" rather than "radioactive materials safety program."

MR. CAMPER: We'll have to double-check it. As we mentioned last time, it is about radiation safety management and it obviously doesn't cover all radiation safety materials.

Those are things that we don't regulate, diagnostic x-rays and accelerators and the like, so we'll make sure we capture that concept.

DR. QUNILIN: On page 5, the last paragraph, you have a sentence, "The root cause of weak radiation safety programs where inspectors identify significant violations is frequently a breakdown in this communication triangle."

That stands alone and sort of leaves me cold. I don't know exactly what you're trying to say here. If you would just try to be more specific, it would helpful so I understood what the real problem is that you're trying to address there.

MR. CAMPER: Well, I think what we're trying to say is that one of the things worth looking at where there are incidents, violations and the like, is what is the root cause?

And sometimes that root cause, even when it's identified or partially identified, is not being communicated back to the radiation safety committee or the executive management, and therefore the problem is not ultimately resolved.

But we perhaps should say it better.

DR. QUINLIN: Right.

On page 8, at the top, you say, "All RSO must perform their duties in the somewhat nebulous area that exists between firm enforcement of regulations and extremely casual and passive atmosphere."

Again, I think that's a rather broad statement,

and you set up two extremes here. And one extreme happens to be firm enforcement.

Well, I thought you liked firm enforcement, but that seems to be an extreme the way the sentence is written.

MR. CAMPER: I agree. I've already -- in that sentence in my review. I think, first of all, it has a very negative connotation, too much so.

I also think it's too touchy/feely or something. It's an adjustment to guilt.

DR. QUINLIN: At the bottom, the last paragraph starts, "In the concept of the management triangle, the executive management must be committed to resolving all egregious cases reviewed by the Radiation safety committee."

And again you've used a term here which I think needs definition, "egregious cases."

In Chapter 2, on page 16, it says, "Additionally, regulatory agencies will also utilize the consultant's report to assess the licensee's response to the findings identified in the report and may cite the licensee for possible violations identified in the consultant report."

Colorado's legisLAture has just passed a statute which gives the privilege to such consultant's reports, unless it's specifically required by law or regulation, so a consultant's reports in just a general review of the status of a program is a privileged document. We can have access

to that document. We cannot cite to that document.

And that kind of privilege may be another state's regulation, so we don't have that option.

CHAIRMAN SIEGEL: I think that raises a very important generic concern when we come to the use of consultants.

You suggest use of consultants as a valuable management tool, but -- and I agree that they may well be but it's kind of double jeopardy here for institutions for using consultants.

I mean, a consultant can turn out to be a jerk that could provide you with advice that is worthless, and now you're in a position of having to defend yourself against the NRC or an Agreement State regulatory agency or you go bad advice.

MR. CAMPER: We thought we had countered that but perhaps we didn't do it. I agree that we should.

DR. SCHLUETER: I think what happened is we tried to stay neutral in that we recognized they're used a lot and perhaps used more and more.

But in recognizing them and acknowledging that they do perform certain services and sometimes it's good and sometimes it's bad, and if you've got one, you need a contract with them, we may infer that we are suggesting to them that they consider this or we need to get back on the

tightrope. Maybe we fell off.

MR. CAMPER: Yeah. We don't want to endorse the use of consultants.

DR. SCHLUETER: No.

MR. CAMPER: We want to condemn the use of consultants.

DR. SCHLUETER: Well, recognize that it happens.

MR. CAMPER: That if you're going to use them, as Janet said, there are pros and cons to be aware of and ultimately, and your point is very well made, is that ultimately the licensee that has the responsibility here.

And, frankly, you're right. Some consultants to a great job, and some do a terrible job. We hope we captured that but if --

CHAIRMAN SIEGEL: Janet, one last comment.

DR. QUINLIN: When we briefed the American College of Radiology Commission on Medical Physics back in I guess it was November, the issue was raised about the fact that at some hospitals, the radiation safety committee is the medical Committee and only physicians can vote in certain states on medical Committee matters.

In other words, you can have the administration representative not having a vote, the nursing representative not having a vote, and the radiation safety officer not having a vote on such a Committee.

And I don't see that concern being addressed in this document.

CHAIRMAN SIEGEL: Is that by regulations of certain states?

DR. QUINLIN: Under state law.

CHAIRMAN SIEGEL: Apparently it's not consistent with NRC regulations.

DR. QUINLIN: I'm saying that they brought -- some of the physicists brought this up that they can't vote on the radiation safety committee because they're not a radiation safety officer because it's a medical Committee and only physicians can vote on a medical Committees.

DR. SCHLUETER: Was this at the AAPM last August?

DR. QUINLIN: No, it's the RCM.

DR. SCHLUETER: Oh, RCM.

DR. ALMOND: You've addressed in a couple of the chairmanship of the RSC, and you list on page 13 peoples who might be chairman of that Committee in the first paragraph.

You should in there medical physicists. I know of some very large programs where the medical physicists, separate from the RSO, is chairman of the RSC and, in fact, that may be because they are involved in all the different departments.

DR. MARCUS: I wouldn't put too much emphasis on voting or nonvoting members. In my 34 years of experience

in this business, I don't remember very contested issues in radiation safety committee meetings where, you know, it was a 5 to a 4 vote or something like that.

If there are real concerns about radiation safety, if there are real concerns about ethics, anybody raising a real concern usually, almost invariably, you have unanimous decisions.

It's very, very rare that you have a bitterly contested thing, and when you do, it's not about radiation safety. It's some other detail.

So I don't think it's terribly important.

CHAIRMAN SIEGEL: Judith.

DR. BROWN: If everyone's finished with the content, I wanted to get back to the format a little bit, just because I've been thinking about it and because I have absolutely nothing to input in for the contents section.

I want to say something here. What I'm thinking, if you really want to make it user friendly, it should be friendly. It's deadly now.

I don't think there's any reason that something this technical or going to a, you know, a technical audience has to be deadly. I mean, we're all people.

And I think -- I'm thinking brochures here. And I know that's radical, but I think it would be great.

I can see some kind of envelope that inside has an

executive summary in this kind of format, and then brochures because the chapters really do stand alone.

I think then that repetition would be tolerated in the brochures. And your fear of it being codified in time is less likely if something is lifted out of a little brochure as opposed to this kind of material.

So, yeah, get us thinking.

CHAIRMAN SIEGEL: Well, Pete brought up --

(Laughter.)

CHAIRMAN SIEGEL: Actually, if we do it like that, then we can assure the fate of the document.

(Laughter.)

DR. BROWN: If you're going to do it at all and invest the time, this Staff time, et cetera, it's important that it be read.

And I think, even though it's going to take more printing dollars, it's worthless just to put something out there that nobody's going to read, so you can save your money.

DR. SCHLUETER: We actually considered a brochure or a pamphlet. I don't have --

DR. BROWN: I mean, like a lot of brochures.

DR. SCHLUETER: Well, that's exactly right. We could never do it one. And that's why we pulled out that idea. We realized we covered too much ground for something

that could be a pocket-size book, let's say.

If we broke it down and did separate, maybe we need a management one. Maybe we need a radiation safety officer one, radiation safety committee one, whatever, supervised individuals.

There may be ways to break it down. And it is something that we considered in the past, and maybe it's worth looking at again.

CHAIRMAN SIEGEL: Okay, let's move on.

DR. SCHLUETER: Okay. Chapter 3. This is selecting the RSO. This is not one of the more lengthy chapters, but it did solicit some comments obviously from different fragments of the medical community on who might be suited to fill the roles of the RSO at a particular institution.

Obviously as you know, we talked about physicians, dosimetrists, technologists, health physicists and medical physicists.

The RSO should be independent of clinical use of radioactive material. Deputy RSOs should be allowed. This was offered by the Organization of Agreement States as well, I believe, and some of the peer or the professional organizations.

Technologist as RSO is not ideal. I got that comment in about three different communications. I got not

a lot of support for the technologist as RSO.

Recommend that NRC reference all regulations including guidance on T and E criteria for RSOs in broad scope programs.

This comment is based on the fact that there is discussion about training and experience criteria for broad scopes which obviously exceeds that. That's currently described in Part 35, since Part 35 is for the specific licensees. What it really discusses is guidance that's in a current draft regulatory guide that is not in the regulations.

And the commentor merely suggested that we make the leader aware of that fact in our discussion.

The role of the RSO and IRBs or institutional review boards and radioactive research Committees needs to be clarified.

The Organization of Agreement States comments on Chapter 3, we need to emphasize good communication as a powerful tool or a skill which someone must possess in order to fill the shoes of the RSO.

Emphasis the advantages of the health and medical physicists more. There, the OAR letter indicated that we did not fully describe the advantages of this individual being an RSO.

And additional guidance on adequate time

commitment by consultant RSO. They wanted more information as to what appeared to be adequate.

That's very difficult to do when addressing different programs of various scope. And that's something that generally the NRC does on a case-by-case basis.

Any comments on Chapter 3, the role of the RSO? This is probably one that received maybe a little less comment than some of the others.

MR. CAMPER: Well, let me just say is what we will do due to the time constraints, what we'll do is get your comments. We're not going to respond. We're going to get your comments on the record.

DR. ALMOND: Two comments. First of all, I would suggest Chapter 4 comes first because they're describing the role of the RSO and then you can say, you know, who fixed this role.

It's a little strange you have the selection before you describe the job description, but that's just a point.

I found this chapter very negative. I mean, I read through it, and it has to do with what the OAR said, especially about the medical physicists, health physicists.

If I were management reading and trying to decide who should be the RSO, I'd read all of these descriptions, and you give one line why should have them and about three

why you shouldn't have them.

I think this chapter needs to be much more positive.

I really quite upset about the healthy physics, medical physics section here because we really do do that, and they point this out.

For every sample that you can give me where a physicist didn't do his job well because he was somewhere else in the hospital or, heaven forbid, consulting for extra somewhere and he couldn't do the RSO -- you know, leave that out of there.

I can tell you 50 physicists, health physicists who do excellent jobs as an RSO, and I really things this really gives them the wrong slant upon it.

But I got through with this chapter, and, as I said, I felt it was terribly negative, and you really need to be more positive about why these people can be RSOs than why they shouldn't be RSOs.

CHAIRMAN SIEGEL: Carol.

DR. MARCUS: On the top of page 21, there's an interesting sentence in there. "The RSO should be authorized by executive management to terminate an unsafe activity immediately without being challenged..." et cetera.

I can't imagine a physician wanting to, you know, continue some activity for its own sake. What I see is a

radiation safety officer so attached to regulations that he might forget the fact that the purpose of hospital is not to use regulators but to take care of sick people.

And, you know, the one situation I ever ran into where I had to override an RSO to take care of some people who were in danger of dying, I just think that this is not a good sentence, because it's more important to protect someone from dying than worrying about a very trivially unimportant regulatory or licensing requirement that it's not threatening someone's life.

So I think you ought to take that stuff out. I mean, you've got to take care of sick people.

DR. ALMOND: I don't agree with Carol, just for the record. I think it should in there. We can discuss that Friday.

CHAIRMAN SIEGEL: Right. I also agree that the radiation safety officer has to have the authority to address imminent dangers to the public health and safety within an institution without fear of being challenged by a powerful medical authorized user.

There's clearly room for disagreement in individual instances, but ultimate authority has got to be somewhere.

And in circumstances where a negotiated compromise cannot be reached in 10 minutes, someone ultimately has to

be responsible.

DR. McKEOWN: May I say something?

CHAIRMAN SIEGEL: Please, Joan.

DR. McKEOWN: It's very important that the RSO has the final decision because -- so that the critical part of it management, knowing what to look for. But I think that in that sense --

CHAIRMAN SIEGEL: Dennis.

DR. SWANSON: On page 23, there's a sentence that says, "The RDRC and IRB are required by the Food and Drug Administration when licensees propose to use non-FDA approved radiopharmaceuticals on humans."

Again, this does not recognize the use of well-established radiopharmaceuticals under the practice of medicine and the practice of pharmacy, and that sentence is technically incorrect.

CHAIRMAN SIEGEL: It's more than technically incorrect. It's incorrect.

DR. SWANSON: Yes.

I would disagree with Dr. Almond. You need to be particularly sensitive to statements that may be veiwed as offensive by some individuals, especially if this is supposed to be a user friendly document.

There are statements in here, for example, "Physicians were simply not interested in performing these

duties and only agreed to perform them thinking that the position should be filled by a physician."

If I was a physician, I would find that very offensive. And although that may be true, you need to be very sensitive to those type of statements.

DR. QUINLIN: I agree with what both Dennis and Peter said. The paragraph that starts at bottom of page 28 and top of page 29 doesn't talk about the negative aspect of hiring a consultant, an outside consultant.

And going back in my history of observation of major breakdowns in radiation safety programs that I've seen and hiring consultants with ill-defined responsibilities and limiting access as being one of the major events.

DR. BROWN: If we are ready to go on, I just wanted to add something.

I wanted to add something to my suggestion. I was just showing the brochure, NRC's effort before, and I was afraid it was going to look too technical, and the drawings -- It's kind of revolting. It has pictures of clouds and foods, sandwiches and things here. It's like someone has confused the idea of a brochure with the Japanese --

My suggestion was just to kind lift the material and put it in a readable format, so instead of Larry -- I mean Barry spending four nights, he could take one one night and another another night instead of trying to find where

you left off in this awful document.

(Laughter.)

DR. BROWN: The wording was also changed here, it is very clear to me. Like at the end it says, "NRC, a final thought."

That is so strange.

(Laughter.)

DR. BROWN: Anyway, point taken, but NRC should have a different consultant than whoever consulted --

(Laughter.)

CHAIRMAN SIEGEL: We don't want to talk about --

(Laughter.)

CHAIRMAN SIEGEL: Continue.

DR. SCHLUETER: "Role of the RSO." Perhaps this needs to go as Chapter 3 as Dr. Almond mentioned. The one reason we stuck "selecting" in between RSC and RSO was that obviously you don't have an RSO until the management of RSC selects that individual.

And we thought that perhaps once those two people knew what they were supposed to do, they could turn to how they want to select them.

More emphasis is needed for facilities on iodination and preparation of large dosages, less on the more insignificant quantities.

Historically there is no clear delineation of

authority for contracted physician RSOs to supervise or be responsible for facility employees.

The Organization of Agreement States, "Expand the discussion on delegation of responsibilities during the absence of the RSO."

Obviously there needs to be more information on how one goes about this. Some states do recognize alternate or assistant RSOs, and some states strongly disagree with NRC's failure to do that.

Any comments on Chapter 4, "Role of the RSO"?

DR. QUINLIN: On page 41 there is a section on medical devices. And most of the sophisticated medical devices I am familiar with are basically monitored by the medical physicist rather than the RSO.

An RSO has to monitor the safety aspects, but a physicist has more day-to-day hands-on experience and that responsibility doesn't really come through.

On page 42 I also had a comment on the -- RSO division. I'll just give you an example. We had a major facility in a state where the RSO just had surgery and was going to be out for two months. There is no RSO in there, so they needed somebody to back that RSO up under the program.

DR. SWANSON: I agree with that comment. On page 42, we address the issue of who is to be the RSO in the

absence of the RSO, but you don't give any advice or direction.

And I think that would be particularly useful in this document as, you know, what do you do when the RSO is absent? So you kind of leave people hanging.

DR. STITT: Again, page 41, just to reiterate, the specificity regarding the RSO, particularly the thought that they be involved in high dose rate remote afterloader devices and stereotactic gamma surgery devices, is that the question you had in mind or is it more radiation detectors, et cetera, et cetera, because as a rule the RSOs wouldn't have the foggiest idea how to handle these other types of devices.

CHAIRMAN SIEGEL: Nonetheless, he is responsible for oversight in terms of --

DR. STITT: Right, but I couldn't tell from way it read how it was directed. If we're talking about -- it could have been interpreted as calibration and a variety of other things that are very, very specific.

CHAIRMAN SIEGEL: Let's continue.

MS. SCHLUETER: Chapter 5, which is the "Role of Authorized Users and Supervised Individuals." We need greater delineation of responsibilities of the medical physicists and dosimetrists.

I had a few comments on making sure that we do

clearly distinguish their different roles and responsibilities and also that between health physicist and medical physicists as well.

The training of authorized users should be discussed, the need for adequate training, including training on the requirements, the licensed program, how to supervise individuals, how to ensure that they follow your instructions and so forth, and the authorized user must be responsive to the concerns of the Committee and the RSO.

The Organization of Agreement States comments on Chapter 5, "Additional discussion on state and NRC regulatory concerns regarding an authorized user's ability to safely handle radioactive material," meaning that the states believe that we needed to at least discuss the fact that regulatory agencies are concerned about the radiation safety aspects of administrations to patients.

CHAIRMAN SIEGEL: Carol.

DR. MARCUS: One of the big omissions in Chapter 5 in the discussion on nuclear pharmacists --

DR. ALMOND: I assume your comments about the medical physicists was for those with AAPM. If not, I have the AAPM comments.

DR. SCHLUETER: I have them all here. I have everybody's.

DR. ALMOND: You have them. Okay.

DR. SCHLUETER: I'd have to look, to tell you the truth.

DR. ALMOND: Well, you can let me know later if the AAPM sent these comments they were sending to you, which were very specific to this. I am not going to repeat them, but you need to break out medical physicist and medical dosimetrist --

DR. SCHLUETER: Yes, I was doing a little cut and paste yesterday, so they are right here.

Yes, it was.

CHAIRMAN SIEGEL: Thank you, Jan.

Bob.

DR. QUINLIN: I have a comment at the bottom page 50, where it talks about "part-time, cross-trained technologists," cetera, et cetera.

I just would like to reiterate this is a -- could be a really substantial problem. We recently had a part-time technologist come to us.

And that technologist told us that, I think, 10 or 11 different positions that she had worked in, she had never been briefed by the hospital as to their radiation safety policies, and only in one hospital had they ever given her a dosimeter.

And, you know, this issue of rent-a-techs in nuclear power industry I think is now in full force in the

medical field.

And the temporary service that provided this individual to do film bags is not regulated by us because they are not a licensee, so we can not require a temporary service to provide us a copy of the worker's exposure.

It is a specific problem and just sort of peripherally addressed here, and it's not --

CHAIRMAN SIEGEL: I want to reiterate something that Jan said earlier with respect to Chapter 5, because I am also very troubled by it.

In a way you are using the NUREG to break new regulatory ground, no pun intended. But section of authorized physician users beginning on page 47 and extending t. ough page 49 contains, as Carol pointed out quite correctly, some statements that do not reflect the reality of at least nuclear medicine practice in the vast majority of medical institutions.

Here is the reality of most hospitals. In most hospitals a referring physician requests a nuclear medicine examination.

Upon receipt of that requested nuclear medicine, technologists follow the procedure manual, perform the procedure, and it is interpreted by a radiologist or a nuclear medicine physician.

The nuclear medicine physician in most hospitals

does not first authorize the procedure may in fact be done, does not tailor the procedure to the specific needs of a particular patient, does not necessarily even review the results of the procedure before the patient --

That is the truth in most hospitals. And what you are setting up here is some conditions that, although I personally don't think that I like the way nuclear medicine is practiced in all institutions in the United States, There is no regulatory basis in fact for saying this is what really should be going on. So you need to soften this substantially. That is number one.

Number two, I observed in some NRC correspondence over the course of the last five years a change in NRC thinking about who can interpret a study.

And although I may be pleased from a turf point of view about your current position, I am not sure there is any regulatory basis for it.

Page 48 in the second paragraph, you have the statement about who has to be responsible for examining patients and medical records to determine which radiation procedure is indicated and who ultimately has to issue the official interpretation.

There is nothing in either the Atomic Energy Act as amended or in Part 35 that says who can interpret the medical study.

And I think there has been this recent conversion from the statements that I think I've seen in letters from Dr. Glenn in the past that say anybody can interpret a study of the authorized user's responsible for the radiation safety aspects of the application of the byproduct material in the medical center to a recent letter from Dr. Glenn that says the authorized user is ultimately responsible for making the official interpretation. I don't know where that is coming from.

MR. CAMPER: Well, I also want to comment, just to make a clarification. That comes from Item 7 of Regulatory Guide 10.8 that lists what we consider to be more responsibilities of an authorized user. The fourth one is to provide the interpretation.

MS. SCHLUETER: I think the distinction in those two correspondences is simply that the NRC wants to know that the authorized user is in that loop regardless of how many other physicians have those scans made available to them to make an interpretation.

MR. GLENN: Certainly if I've sent out a letter recently that said that there is an official interpretation, I may want to revisit that. I don't that's consistent with what I have been trying to say, which is anyone can interpret the scan; however, the authorized user is responsible for reviewing scans to make sure that in fact

the scans are producing the information that they should. The authorized user is responsible for the quality of the scanning process. That is what I am trying to say.

CHAIRMAN SIEGEL: But that is not real, John, it doesn't happen that way. I mean, in a setting where there are practices where there may be only one or two authorized users in the group, and those are the individuals who in theory are the only ones who can alter a procedure, can change the administered dose of the radiopharmaceutical in a nuclear medicine procedure, there may be another half-dozen people in the group who actually are interpreting the images.

And obviously there have been some real turf concerns about what is right or not. And I am not aware of anything that is clearly stated in the regulations that would say who can interpret and render an official medical interpretation of a piece of data. And I don't think the NRC has the authority to make that decision.

DR. GLENN: And my letters have not been intended to say who can actually make the interpretation.

CHAIRMAN SIEGEL: What you just said, said that the authorized user would in some way be ordering those interpretations.

DR. GLENN: Not the interpretations, but the scans and to determine that they were adequate to make the

interpretation.

CHAIRMAN SIEGEL: Well, but that doesn't happen either. If you've got someone reading the scan, I mean you can wish it but it isn't true.

MR. CAMPER: The other point I would make for clarification is the letters that Dr. Glenn sent out represent -- these come to us from a specific organization or a specific question.

The question that often gets asked, of course, is not the right question. The question on here is, do you have to be an authorized user to interpret this?. Well, the answer is not simply yes or no.

And his letters tried to convey on one hand you -- physicians may interpret it just in the course of practice of medicine, but on the other hand, there is this concept called authorized user that we believe has to be involved in the process.

Now, what is always -- what I found interesting in one of these letters if the materials being used by authorized users, the scans being created by technologists under the supervision of an authorized user, and another physician is going to come in at the 11th hour and interpret the image, the process by which that happens, we would be very interested to know how that happens.

In some institutions, in fact, the authorized user

may say that this other physician may interpret it with my blessing. In some cases I suspect the institutional management has something to do with who interprets the image.

We try not to get into that. What we are trying to do, though, to answer that question, on one hand say, yes, in the course of practice of medicine a physician may interpret, but on the other hand there is a role for the authorized user, and it centers about Dr. Glenn has said.

So it is a tough question. And obviously remember the context in which the question is asked.

CHAIRMAN SIEGEL: I guess the only thing I would caution you is, you almost seem like you are breaking new ground in this NUREG that, if that is really the current operational requirement, it may need to be disseminated in a more definitive format by licensees, not by rule change.

I mean, we have been dancing around training and experience criteria for the last five years for fear that someday we might have to address it. I am hoping that my tenure on the Committee will be over before it has to be dealt with, though I suspect it is coming up soon.

(Laughter.)

CHAIRMAN SIEGEL: But I am concerned here that you are addressing something that is not clearly delineated in Part 35. And even though it is stated in Regulatory Guide

10.8, it may not be being implemented the way you think it is.

Mel.

DR. GRIEM: Now, given a recent case that I am currently reviewing, it involves brachytherapy, and the physicist didn't want to watch the procedure, so he walked out so the sources got put in backwards or something like that, I understand when I reviewed the case.

But it seems to me you have a team effort here and that with high-dose effects and so forth that this type of thing, just how this is done -- and I think Dr. Stitt is going to have an interesting task on her hands when the neurosurgeon is putting the source in the brain and the radiotherapist or physicist may say, Well, that is not quite where we want to know, and all that sort of stuff.

So I am saying I think it's going to be an interesting area, and this really doesn't get into it.

It may all be the practice of medicine. And this is something that, as far as the health and safety of the general population, it -- but it seems to me it is an interesting can of worms that is coming along, especially with high-dose rate afterloads.

DR. CAMPER: What I would like to do, Dr. Siegel, is ask you about a couple of options. We have several chapters to go yet, including a couple of the interesting

ones.

We can do a couple of things. We can, at this point, go to the four key big picture questions we have for Committee, there's four of those, and then come back and explore individual chapters as time permits, if we make up time on the agenda.

Or we can focus upon a couple more chapters, a couple of the more difficult chapters and avoid the general questions and come back to them later perhaps.

Regardless, we certainly would ask that if Committee members have any comments on the chapters to provide them to us. We certainly would like to see them and invite them, if they want to do that.

How would like to proceed?

CHAIRMAN SIEGEL: The coffee has caught up with me. Why not take a break for ten minutes?

I have just spoken with Dr. James and Kitty Dragonette who tell me that the Institute of Medicine discussion they don't believe will take an entire hour.

What I would like to do is take a ten-minute break, ten maximum. I will start talking again at 10:08, whether you are at the table or not.

(Laughter.)

CHAIRMAN SIEGEL: We will then try to get through the rest of these chapters and try to address the questions

and then get back on with the rest of your chapters. Is that okay.

(Brief recess.)

CHAIRMAN SIEGEL: It is 10:08. My watch is correct by definition.

(Laughter.)

CHAIRMAN SIEGEL: Janet, continue.

Before you do, let me make an announcement. I have been discussing the issue with John. This obviously is a very long and complex document. There are in fact issues of fact that members of the Committee are concerned with. It is very important that we be discussing it in a public forum; however, I would ask all members of the Committee to take their copies, either mark them up or try and put their comments into a letter.

If you mark them up or mark specific pages up, put a cover letter with it and send the document to Janet with the comments.

And if you do it within a week, you will be assured that your specific comments will find their way into the PER for viewing as part of the official record of commentary on this document.

We can do that. We can reach consensus statements as a Committee, but we also can provide our individual viewpoint as Committee members officially as part of the

process. Okay?

DR. SCHLUETER: And just for your convenience, NMSS did move about two weeks ago, so we do have a new mailing address that would be applicable to all of us here, including Carl.

After our names and then in my case Medical and Academic Section, the next line you would put the letters "M" as in mother, "S" as in Sam for mail-stop, "TWFN" for Two White Flint North, 8 "F" as in Fred 5. That will get -- Washington, D.C., 20555.

That will get the document to me. And then my phone number is area code 301-415-7894. And I have a fax that I can tell you about it if you call. I don't know the number at the moment.

DR. GRIEM: Would you repeat after the TWFN?

MS. SCHLUETER: 8F5.

CHAIRMAN SIEGEL: What about your voice mail address, as long as we are at it?

MS. SCHLUETER: JRS-1. You have to put that "1" there --

CHAIRMAN SIEGEL: Sometime during the meeting, I want to address the issue of how many of us have E-mail.

DR. STITT: Could I ask you to put that on a transparency and flash it up there. We are lost on this side of the table.

DR. CAMPER: Do what to it?

DR. STITT: Any old addresses or fax numbers or anything, could you put them on a transparency and put them up there?

DR. CAMPER: Yes, we can.

CHAIRMAN SIEGEL: Or we will pass it. Janet will write it down when we're done and we will just pass it around the table.

DR. STITT: Thank you.

DR. CAMPER: All right.

CHAIRMAN SIEGEL: Continue.

DR. SCHLUETERR: Chapter 6, "Resources for the Radiation Safety Program." This met with comments from one extreme to the other.

One extreme is, "Throw it out. You have no business talking about resources. How can you estimate adequate resources," to, "Give us hard numbers." Very extreme ends of the comments.

"Commenting on salary seems outside NRC's role. Reduce or eliminate this section. Much stronger emphasis on proper resource allocation as is needed. Salary comparisons between medical and university facilities is difficult."

The Organization of Agreement States, "We need hard numbers for adequate resources. Mention resource needs for training material for in-service."

In other words, for RSOs that are videotaping, making brochures and pamphlets, conducting in-services, they need money to do this. Mention that de-commissioning and de-contamination may be needed for remodel or relocated nuclear medicine departments.

Any comments on Chapter 6?

CHAIRMAN SIEGEL: I think you would need to have this chapter in. That's my personal opinion. The documents I've seen -- and they think this is not important, and they are not going to spend any money on it whatsoever. I agree that putting hard numbers would be difficult. If you had access to real data that in the form of ranges based on what exists out there, it might be helpful for guidance, but I suspect those would be very difficult numbers to get.

What people spend now and what people will be willing to spend in an captivated environment under health care reform will prove to be interesting questions. Be sure to send of this chapter to the Health Care Finance Administration and to the Task Force on Health Care Reform. That's President at White House.

(Laughter.)

CHAIRMAN SIEGEL: Remember what I said about E-Mail.

Other comments?

(No response.)

CHAIRMAN SIEGEL: Which, by the way, no one reads as far as I can tell. They certainly don't respond.

DR. MARCUS: I would think that all mention of -- and accelerators should be removed -- the NRC is not ready for this.

DR. GLENN: I wonder if other Committee members could comment on that last comment because the Agreement States, if they want us to include the references since their radiation safety programs cover those activities.

DR. SCHLUETERR: Yeah, this is a generic issues that we wrestled with for quite a while. Since it was an NRC document, do we limit our comments to only byproduct material?

Well, we tried to do that. We started working that way. We realized that we needed to make it applicable more to states, so we found ourselves in a situation where we do discuss, in certain situations, other radioactive materials.

MR. CAMPER: And add to that just one thing, that in fact this chapter was authored by one of the two Agreement State representatives, and I think that was one of the key reasons why it was included in here.

DR. ALMOND: But if you open it up to areas that concern you regulatory consumer, then this has to be drastically changed because you know radiation safety

officers and radiation safety committees deal with a whole wide range of things that you haven't even dealt with here.

And if you open it up a little bit, you have to open it up all the way.

DR. STITT: I strongly agree. And again, it takes it into the realm that if it's in this format, then it starts to appear as a reg even though it's not a reg. I think nuclear accelerators should not be included.

DR. ALMOND: Or diagnostic radiology or all the other things.

DR. STITT: Right.

DR. GRIEM: In Indiana, UV is regulated ever since there's been a couple of people who died after some suntan parlor propositions.

And I just want to say that you can get into the UV -- we can cover everything.

DR. QUINLIN: There's a question I have on the bottom of page 59 in the nature of contracting for services, for maintenance services, how that had to do with a radiation safety program.

DR. SCHLUETER: Larry, can you flip open the text?

MR. CAMPER: I thought we weren't going to comment.

DR. SCHLUETER: Okay.

CHAIRMAN SIEGEL: Let me just respond to the issue

about including things like that in -- I understand the concern, but I think it would be naive to write a document that is meant to be an information document and not a regulatory document on how to run a radiation safety program without indicating that the program involves more than the things that are produced in nuclear reactors or the radiations therefrom.

And the key to, and especially in a chapter on resources where you're talking about what the scope of the program has to be, the key will lie in the disclaimers indicating that the situation will vary from state to state, depending on how the state regulates, whether or not its an Agreement State, but ultimately these radiation sources are regulated and ultimately these radiation sources have institutional oversight usually in the form of a radiation safety committee that wears many hats, so that's -- accelerators, and it looks at NRC-licensed activities.

I think you can't leave it out, but I think you need to have a disclaimer so I demure a little bit from Carol and Judy's comments.

Dennis.

DR. SWANSON: I would agree with Barry. I think that realistically radiation safety programs aren't broken into byproduct material and accelerated material.

And I would view this chapter on resources as

something that aids the radiation safety officer and the radiation safety committee in going to executive management and pointing out the types of resources that are needed to conduct the total radiation safety program, and therefore I feel that they need to be addressed, clearly with the disclaimer of the regulatory authority of the NRC somewhere in the document.

DR. ALMOND: Well, we clearly disagree, and we don't have time to discuss now. I think if you open the door, you get into all kinds of trouble.

And you cannot put part of it in and leave part of it out. The disclaimers -- that would just be a mess. I think you have to be clear cut about it.

What the NRC does and what they regulate, you can put in here. If they don't, I don't think you can have it in there even with disclaimers, because you cannot have all of the things that the RSO does that is not regulated by the NRC.

MR. CAMPER: What I want to try to do again for the purpose of time, you all respond to all comments, okay. What I'll do is comment if there is a need for clarification.

And in that vein, I'll just point out that what we tried to do here was to address the materials uses, materials uses, across the board, for Agreement States and

the NRC states.

References to other modalities, if they are in there, were included for purposes of making the point that there are other elements to radiation safety, management that need to be considered, that management needs to be aware of in addition to or as well as the materials problem.

Now, if you have specific issues where you think we've gone too far in that vein with regards to looking at accelerators or something else for that matter, again, please, specific comments would be helpful to us.

DR. GRIEM: Well, it seems to me that when we get into the modality of sites and commonly-produced isotopes, you, the NRC, need some expertise up front.

When you get in OJ emitters and short-life oxygen and so forth, the Committee that supervises this really has the tasks, and having served on the Committee for a long time, realized that we were looking for answers and we got none from our state, which is an Agreement State.

CHAIRMAN SIEGEL: Continue.

DR. SCHLUETER: Chapter 7, "Use of Consultants or Service Contractors."

Consultants provide independent verification that the radiation safety program was properly implemented. The Chapter should be removed because NRC regs do not mention consultants and therefore it is inappropriate.

The Organization of Agreement States had just to comments. They strongly agree that ultimate responsibility for compliance rests with the license and not the consultant, and some states do not authorize a consultant as RSO.

Any comments on 7?

CHAIRMAN SIEGEL: Dennis.

DR. SWANSON: This chapter consultants and service companies related to the radiation safety aspects. I question whether the chapter should also extend into the responsibilities of management with regard to service organizations that provide services related to the use of radionuclides that is not related to a radiation safety program.

For example, out-sourcing of nuclear pharmacy services would be an example. What is the responsible of the institution with regard to the utilization of those types of services.

And that is not addressed in here.

CHAIRMAN SIEGEL: Bob.

DR. QUINLIN: On page 74, "Consultant as RSO," and there's a sentence that says, "...the consultant commits to being physically present at the facility for a specified minimum amount of time in order to perform satisfactorily the duties of the RSO."

That's a vague statement. What is that minimum amount of time?

CHAIRMAN SIEGEL: Excellent.

MR. CAMPER: No, there is an announcement in the room that they're testing the alarms today.

(Brief discussion off the record.)

CHAIRMAN SIEGEL: All right. Who was next before the bell?

Bob, do you have anything else?

DR. QUINLIN: I'm finished.

CHAIRMAN SIEGEL: Okay, let's continue.

SCHLUETER: Chapter 8, "Conduct of Audits."

The first paragraph on the slide is the comment and then, secondly, is the little explanation there.

"NRC regulations do not specifically address a major audit; therefore, the discussion should be removed."

CHAIRMAN SIEGEL: A management audit.

DR. SCHLUETER: Pardon me?

CHAIRMAN SIEGEL: A management audit.

DR. SCHLUETER: What did I say?

CHAIRMAN SIEGEL: You said "major audit."

DR. SCHLUETER: Oh, did I say "major"?

"-- address a management audit, therefore the discussion should be removed."

Audits are discussed in a couple of different

places in the regs. In 35.22, which is our responsibilities for the radiation safety committee.

With the assistance of the RSO, the radiation safety committee does have responsibility to conduct an audit.

Obviously, the radiation safety committee as one of its members has a management representative, so, in fact, ideally the manager would be involved in an audit conducted by the RSC.

Also, in 10 CFR Part 20 --

(Brief interruption.)

MR. CAMPER: It's my understanding that there may be one more of those.

DR. SCHLUETER: Okay.

DR. SCHLUETER: Continue.

DR. SCHLUETER: -- 20.1101, it does require the licensee to at least annual evaluate the program for content and implementation, and how best do you do this besides conducting an audit of the program where management is involved.

Also in Appendix G at 10.8, it does specifically require that management conduct an audit. This is obviously in 10.8, it's a guidance document, so only if you've committed that model procedure would a management audit be in order.

So there are requirements in Part 35 for an audit where a manager would be involved if you commit to 10.8 --

(Brief interruption.)

DR. SCHLUETER: It does identify a management audit, which, in fact, could be part of your comprehensive, annual safety program review done by the radiation safety committee.

The Organization of Agreement States comments on Chapter 8,"Discuss how audits are to be documented and presented," the findings, that is, "and information regarding follow-up to findings" so that the issue is brought full circle.

There's probably not enough information there to complete the loop and they want more discussion on that.

Any comments on Chapter 8, "The Conduct of Audits"?

DR. SCHLUETER: Bob.

DR. QUINLIN: I just have one comment, and that's use the word "audit" prior to this chapter, so when you used that word, I immediately went back to the glossary to see what you meant by that, and there's no definition in the glossary.

DR. SCHLUETER: Are you going to discuss the appendices?

DR. SCHLUETER: We had a couple of comments, but

not much.

CHAIRMAN SIEGEL: The only comment I had about the audit section is the list of audits in Appendix K was truly daunting.

DR. SCHLUETER: Is what?

CHAIRMAN SIEGEL: Daunting.

DR. SCHLUETER: Chapter 9, "Incident Response."

"Reference the FDA is mandatory, reporting requirements applicable to medical devices called MedWatch."

And OAS, "The RSO should be afforded the opportunity to confer with a patient subject to a misadministration when indicated."

I think the language says "when absolutely necessary." It's a little -- slightly different.

Ambulance services and emergency medical technologists should be addressed in the discussion on handling of accident victims as far as individuals that need training on their vehicles and how to handle those individuals, the accident victims, that is.

CHAIRMAN SIEGEL: Let me -- Carol addressed this one.

Emergency response radiation accidents, is that related to NRC license other than things that might occur within the institution itself.

I mean, you all don't license whether or not a

hospital can oversee someone who showed up from a road accident where plutonium got spilled all over the highway.

MR. CAMPER: The chapter is written in such a fashion to make people aware of various kinds of incidents that you may need to respond to to cover certain things that typically in a medical setting, a spill, that type of thing, but also discusses an awareness, if you will, things for you should be concerned about if you are in a position where you may be receiving a radiation accident victim, an option some institutions --

(Brief interruption.)

MR. CAMPER: Some of have the possibility and some do not. So we tried to cover the complete spectrum of possible incidents to respond to.

CHAIRMAN SIEGEL: I guess insofar as radiation accidents are not specifically related to the radioactive materials program, this may indeed be extraneous information that is very well covered in a variety of other documents.

JCAHO obviously has a requirement that all hospitals have a radiation accident plan. It's part of hospital licensure.

(Brief interruption.)

CHAIRMAN SIEGEL: And it may not be necessary here, because it really is not terribly related to the nuclear medicine activities that go on in those hospitals

and not very often will it enter radiation oncology things that go on in hospitals, so I suggest -- is it extraneous in this setting? Is that the consensus, that that may not belong?

Joan.

DR. McKEOWN: The radiation safety officer we do require the radiation safety to respond, being the radiation safety officer, if we have a radiation accident.

And I think they need for training is duplicated in here is essentially --

But that's from a victim's perspective, not from nuclear medicine -- emergency response from the hospital. You need the responding personnel to have hospital training --

CHAIRMAN SIEGEL: But it's not related to your NRC license?

DR. McKEOWN: No, but it's related to the duties of the RSO.

CHAIRMAN SIEGEL: We've got this problem of balance that we're wrestling with here, and I understand what you said. Okay.

DR. SCHLUETER: Okay, Chapter --

CHAIRMAN SIEGEL: Oh, I'm sorry, Bob and Mel both, so Bob first.

DR. QUINLIN: One suggestion on the bottom of page

94, you've got a statement that the "NRC does require that licensees report any event where unplanned medical treatment at a medical facility is provided to an individual with spreadable radioactive contamination on their clothing or body."

A reference on that would be helpful.

CHAIRMAN SIEGEL: Because that certainly doesn't include --

(Brief interruption.)

CHAIRMAN SIEGEL: Mel.

DR. GRIEM: I would like to suggest that you look at your past experience for five years on accidents and so forth and say where we have to put the band-aids to prevent further trouble with this.

And if I understand it, one of the Big Ten universities, they walked the isotope all over their campus. Now, how do you prevent that? What went wrong?

And I would think that somehow as you handle all of these incidents, you would finally attempt to bring some of this to us and then work this into this document rather than just --

(Brief interruption.)

CHAIRMAN SIEGEL: Did you get that?

COURT REPORTER: Not once the bell rang.

DR. GRIEM: My concern is that there is no use of

the collective data of accidents over the past five years and how this finding feeds back into helping us in the future in the use of radioactive material in the broad sense.

CHAIRMAN SIEGEL: Carol.

DR. MARCUS: I'd like a comment on page 91 under "Contamination." There doesn't seem be a citation here where the interpretation by the Office of the General Counsel on what is reportable in terms of notification of accidents under Part 20 in the situation where the licensee may reasonably expect some type of contamination, a patient vomiting or being incontinent or something like this, and already has proceeded to take care of that.

There is a letter that was generated when Mr. Cunningham was here that basically says these are not reportable --

(Brief interruption.)

DR. MARCUS: -- as incidents or accidents because they are expected some reasonable portion of the time people are prepared to deal with them.

I think that interpretation really belongs in here. It took us a little while to get that interpretation and this kind of leaves it out.

CHAIRMAN SIEGEL: Doesn't it say that already, Carol, on page 92 that says "...contamination resulting from

nausea" in fact was in error and should be --

(Brief interruption.)

CHAIRMAN SIEGEL: -- or incontinence would be associated with the standard procedures and would not usually be reported; the second paragraph on page 92.

MR. CAMPER: Just for clarification, what Carol is getting at is there is information that came out some years ago, and it's 30.50, and what we would like to do is to further clarify that point.

Also, something you're not aware of at this point in time, we do intend to add an appendix to this document that would provide a listing for all information that has been prepared over the last five years, and that would help.

But I think at this point, all the words are there, but we could probably add to that to make that point much clearer.

DR. MARCUS: "Usually would not be required," that's what it says. Would not usually be required, true.

CHAIRMAN SIEGEL: Or it might be required if the accident resulted in overexposure of occupational personnel, then a report might be required, even though you have procedures in place.

DR. SCHLUETER: "Interactions with Regulatory Agencies." After doing it, it may more preferably called "Interactions with NRC," because we do limit our discussion

to NRC.

Regulatory inspections should be done on short notice rather than unannounced. Discussion should be more critical of the regulatory agencies and less neutral.

OAS: Differing opinions regarding whether to include this chapter because the existing guides may be sufficient.

Strengthen discussion of radiation surveys by the inspector, meaning ambient and contamination wipes. Add discussion on interviewing allegers.

Chapter 10, "Interactions with Regulatory Agencies," wasn't something that we initially thought about writing, but as we got into it, we thought that it was important to provide some readers that didn't know a lot about the NRC with some overall information of the general process, meaning how do we license, how do we inspect and a little bit on enforcement.

We placed it at the end because we didn't want it to -- we didn't want to distract the reader with having it up front where we had first placed it.

Any comments on 10?

DR. BROWN: Is that a different word from alleged with a D in it or is that the same, allegers?

CHAIRMAN SIEGEL: A-l-l-e-g-e-r-s. Allegers as in someone makes allegations.

DR. BROWN: Oh, okay.

CHAIRMAN SIEGEL: I believe the correct term is "alligator."

(Laughter.)

CHAIRMAN SIEGEL: Any other comments on Chapter 10.

DR. SCHLUETER: Okay, that is the last chapter, but we do have a couple slides quickly just on the appendices.

I got basically very few comments on any other portion of the document other than a couple on the appendices and one on each, the disclaimer and the background.

The comments on the appendices, most people believed that they were sort of the meat of the document. They provided a lot of useful, specific information, practical information.

We simply need to add an item to Appendix J, which is a "Sample List of Equipment" that we had provided.

As I mentioned, the Organization of Agreement States -- I think we have a slide on that too, Larry -- yes.

Delete the list of Agreement States because it won't be timely. It's something that will be outdated quickly.

Add the use of a survey equipment to training

subject list. Delete the sample licenses. They're not helpful to Agreement States license fees or Agreement States who may license very differently than we do.

Delete description of NRC's enforcement policy. It should be described in another document.

As I mentioned, we got comments on the appendices. I got one comment on the disclaimer, which was simply a clarification on private physician offices, and one comment by ACMSM that again, as I mentioned earlier, we would place just a statement in the background section regarding their serious concern about the development of this document.

Other than that, all the comments were on chapters, so does anyone have any comments about the appendices in general or any other sections of documents?

CHAIRMAN SIEGEL: Bob.

DR. QUINLIN: In Appendix D, you said, "The NRC is in the process of revising its regulations to recognize the following certifications, and it's (G) the American Board of Medical Physics in radiation oncology physics, but there was no specific listing for the American Board of Radiology.

In other words, you have criteria for the American Board of Medical Physics but you didn't have any specific criteria for the American Board of Radiology.

And in Appendix E, you only listed in items F, G, and H, Medical Nuclear Physics, Nuclear Medicine and Medical

Health Physics as criteria, so it didn't seem to be consistent criteria that you're using in the physics area.

CHAIRMAN SIEGEL: Carol, any comment?

DR. MARCUS: Appendix L, "Catastrophic Incidents." I object to the word "catastrophe" and "catastrophic." We don't have them. We have contamination, but this makes it sound like Chernopyl is happening all over the country, "catastrophe."

Appendix O, at the very bottom, you talk about "Notices of Deviation that address violations of non-legally binding commitments, such as an industry good practice or standard."

I just have a big question mark on what in the world is this?

CHAIRMAN SIEGEL: Where?

DR. MARCUS: Appendix O.

I don't think you have to give notice of anything that's non-legally binding. And besides whether we're going to accept somebody's idea of good practice or standard.

You know, there are lots of organizations that could have standards. That doesn't meant that we have to agree with those standards.

And if they're not legally binding, I don't see why the NRC is going to start giving notices of violations. And I was just very confused about this whole thing. I

don't understand what it means.

CHAIRMAN SIEGEL: Larry.

MR. CAMPER: I know we said that we wouldn't respond, but I think this one needs a clarification.

A notice of deviation is a long-standing enforcement practice of the NRC. It is not a notice of violation. It is not a legally binding requirement.

What we do is when an observation is made that a particular activity is unsafe and it violates an existing standard, we will notify the licensee of that fact and ask them to respond in terms of what the commitments they are making with regard to that deviation.

However, they aren't cited. They're not subject to penalties. It may be that on the basis of their response we would order them to modify their procedures and make it legally binding.

CHAIRMAN SIEGEL: Mel.

DR. GRIEM: Given that reading, what you're really attempting to do ultimately is to prevent an accident.

It seems to me that the growing body of material that's on electronic media and -- and all the rest of that should be included here under Appendix P rather than printed out available in a kind of a news format onto electronic medium.

When you consider the amount of data transmitted

this way and you wish to get the information out, there's no reason why the NRC shouldn't have some sort of news bulletin with all this document in what I would consider the 21st century.

And I think you might show some leadership to some of the other agencies.

CHAIRMAN SIEGEL: Please continue.

DR. SCHLUETER: We have four general questions that are in your briefing book that we'd like to get a consensus on.

The first is, "Is each element of the management triangle adequately discussed in relation to each other?"

CHAIRMAN SIEGEL: What page are you on?

DR. SCHLUETER: I'm on page 2. Sorry.

CHAIRMAN SIEGEL: That's fine.

DR. SCHLUETER: We'll do this.

CHAIRMAN SIEGEL: That's fine.

DR. SCHLUETER: "Is the guidance applicable to most medical programs using byproduct material?"

CHAIRMAN SIEGEL: Yes.

Dan.

DR. BERMAN: Dan Berman.

I just -- "daunting" is a good word for the overall document. It's extremely long and I think it's somewhat frightening to the kind of facility that might be

getting involved in use of radioactive materials.

It would seem that there is a sub-group of users that are from the diagnostic field, they don't do anything, just diagnostic nuclear medicine, no therapy nuclear medicine, and that perhaps some kind of indication someplace in this document that the amount of paperwork and the amount of requirements for that kind of reduced facility might be considered less, that would be appropriate.

DR. SCHLUETER: The answer is yes?

CHAIRMAN SIEGEL: The answer is yes. I answered for the Committee --

DR. STITT: I just have a comment. And I'm sitting here pondering Judith Brown's comments.

One of the possible difficulties with the whole undertaking is that it's hard to cross line, going from brachytherapy to bone scan to catastrophes.

And we've heard about all of these things in this. And we can't be all those things to all people, and we're trying to pull out things that aren't applicable.

If you had some sort of a format where you do only diagnostic in this brochure format, I think it would be very, very usable and much more user friendly and certainly much less like a regulation.

So when I fax you or send you my comments, I'm going to reaffirm that. It also might help us organize this

thing so people actually do use it.

CHAIRMAN SIEGEL: Okay.

David.

DR. WOODBURY: It's always treacherous when you're trying to help a sister organization with -- soapbox that I am on with the FDA is try not to put physicians on liability, legal liability.

But I read the section on physician must examine or should examine and so on and so on. You're creating a legal -- that leaves the physician unprotected. We at the FDA are quite against that.

And I hope it doesn't happen here. I hope the guidelines -- to put in the physician out of business as he or she tries to practice medicine.

MR. CAMPER: I think the second bullet we've pretty much got the picture. We've covered that.

CHAIRMAN SIEGEL: The main thing, fewer topics rather than additional topics.

MR. CAMPER: Right.

DR. ALMOND: Let me respond to the second question again. I want to go on record one more time as saying that I believe this document contains -- while there's a lot of helpful, useful information here, I believe it goes way beyond what is needed in a document entitled "Management of Radioactive Materials and Safety Programs," put out by the

NRC.

In some cases it goes beyond the scope of the NRC. And I think that, you know, for reasons we've expressed or you have in comments, but I want that to go on the record.

CHAIRMAN SIEGEL: Okay.

DR. SCHLUETER: "Is each element of the management triangle adequately discussed in relation to each other?"

CHAIRMAN SIEGEL: Yes.

Joan.

DR. McKEOWN: I think that Dr. -- I think -- executive officer with regards to we don't want technologists to be RSOs. Say what you want and let it go at that, not tiptoe around it.

CHAIRMAN SIEGEL: Okay. Let's continue.

DR. SCHLUETER: "Are the appendices helpful and comprehensive."

CHAIRMAN SIEGEL: We've already discussed that.

DR. SCHLUETER: I think we had said yes.

Anything else because that wraps us up?

CHAIRMAN SIEGEL: All right. We're only 45 minutes behind schedule, but that's okay. We know how to play catch-up.

Let's move on to the presentation of the National Academy of Sciences with Patricia Rathbun and Kate-Louise Gottfried.

Sorry to keep you listening to this discussion while you were waiting to get on the agenda.

DR. RATHBUN: I'm pleased to be here today to report to you on the progress on the National Academy of Science study of the NRC's medical use regulatory program.

To place this briefing in context, you recall that the Commission directed the Staff to obtain a detailed review and evaluation of the adequacy of the medical use regulatory program. And they directed us to go to an outside group to have them conduct this study.

There were three areas that they asked us to take a look at. Number one was the examination of the overall risks associated with the use of ionizing radiation in medicine.

Second was an examination of the broad policy issues that underlie the regulation of the medical use of radioisotopes.

And third, they asked for a critical assessment of the current framework for the regulation of the medical use of byproduct material.

In addition, the Commission asked us, directed us to apprise the Committee of the progress of this work, and this briefing today responds to that Commission directive action.

On January 2nd of this year, we were able to award

the contract to the National Academy and they are off and running and have had their first Committee meeting.

We have invited today to speak to you Dr. Kate-Louise Gottfried, who is the study director for the National Academy of Science.

And at this point, I would like to turn it over to Dr. Gottfried.

DR. GOTTFRIED: Just to clarify before we get started, I am a doctor but a Doctor of Law, not in medicine so don't ask me any difficult medical questions.

I want to thank Dr. Bathecee, M.U.Y, for allowing me on behalf of the Institute of Medicine of the National Academy of Sciences to talk with you today briefly about this study that's underway.

Pat Rathbun actually already summarized in brief what we are doing, and, in fact, I just wanted to give you a little bit of an idea of the genesis of the project as I understand it, too, which was there was the incident in Indiana, Pennsylvania, which precipitated some publicity.

The NRC concomitantly was in the midst of reviewing, as they often do, a self-examination, internal programs.

November of '92 is when the episode occurred, and subsequent publicity which led up to various interests in this whole project or medical use program.

And the NAS was approached by the NRC to provide an independent objective, as Pat stated, objective analysis of the medical program of the Nuclear Regulatory Commission.

The Institute of Medicine seemed to be the best facet of the NAS to undertake this study. And about a -- I suppose it was almost over a year ago that the discussions were underway, and as of technically January -- I myself came on in February of this year -- we started this study.

The brochure I distributed is designed to be user friendly and is actually a duplication of the charge that we received from the NRC.

The emphasis of our study really has to do with three areas, risk, policy and regulation. What is the overall risk of ionizing radiation in medical procedures, both diagnostic and therapeutic; looking at the frequency of errors and the consequences of reactor generated byproduct material in comparison to other modalities of treatment; what are areas with respect to the error rate, mortality, morbidity, the function of patients subsequent to radiation treatments.

What -- misadministration is a big issues. I don't want to get off on that to any great extent, but at this point to say that it's certainly a facet of the study that will be examined and addressed, we hope with

comprehension. Or comprehensively, I should say.

The area with respect to policy that we are reviewing is the adequacy of the 1979 policy that is a short three paragraphs. Many of you I'm sure are very familiar with that.

The extent of the USNRC involvement with respect to patient follow-up and notification regarding misadministrations and overall policy with respect to the use of medical consultants in the program as well as the whole notion of promoting improvement of quality care designed towards satisfying the in effect quote, customer, or the patient.

The quality management rule is clearly an important facet of the current medical use program and we will be reviewing and examining that in terms of its adequacy. That's a subset of what we will be looking at.

The regulatory piece is also, I think, very fascinating from own perspective, a piece of the program. Looking at the federal and state regulation, regulatory authority; its adequacy; whether or not in fact it appropriately addresses the medical use program, whether it needs to be -- this regulatory scheme needs to redesigned.

If so, how would that be, what would our recommendation be; the various agencies that are involved, the FDA, the NRC; to some extent the whole state issue of

agreement versus non-agreement states.

That's the overview for our charge. The committee itself has had one meeting. We plan five more meetings. The next meeting will be in July. These meetings are an opportunity for the committee to convene, review what we've been distributing for to bring them up to speed.

At this point I would say we were in the field stage of a nine-month process. The committee is a sixteen-member panel committee. If you look in the back of the brochure it lists the people on the committee.

It says that we're a twenty-four month study when reality is we're on much shorter time frame when you think about the whole publication process, so virtually a year from now we will have a draft, a working draft for the committee to really hone in on and make some determination as to how the final report will look because of the process that's required for the National Research Counsel process with respect to review.

Review there is a very extensive and kind of scrutinized process. And it takes anywhere from eight to fourteen weeks for a review of a final report produced by the National Academy of Sciences.

Subsequent to that there's another three-month procedure for publication and report. So we're really looking at a final report as of a year from now, or in June

at the latest. June, early July.

The staff on the list with the committee members is also a list of the staff who happen to be here today, Dr. James May and you know Eric Caplan as a research associate and Jeanette Howard is the project assistant. We are the core of this study at the Institute of Medicine.

Obviously our report will reflect the committee's assessment of the problems or issues involved, and will be a reflection of the committee's recommendations.

We, in conjunction with the Committee, will coordinate the formal report. But the report is by no means our interpretation of what the -- a reflection of the committee.

At this point I would only add that as you can see on the brochure we do list the other kinds of activities we'll be involved in. We have some subcommittees that are looking at a variety of issues, education and training, management, data risk issues.

At the same time we are starting what we call a specialty panel. That panel is a panel that is approaching the various societies, associations and agencies that are interested in this particular area. We've sent out a letter inviting them to nominate, in a sense, a representative from their organization to provide us with input with respect to all the medical use program and all of its various

presentations.

In addition to that we are planning site visits to various universities, hospitals, even manufacturers across the country. There will be a public hearing which is scheduled at this point for mid-October. And then we may have some what we call both technical panels, those are panels that will give us input that will be much smaller than the specialty panel which is anywhere from 20 to 30 organizations; some technical panels, these panels will be very specific in nature, probably constitute anywhere from five to eight experts in a particular field. The most likely area would be education and training --

(Brief interruption.)

-- as well as quality management.

One thing that hasn't been affected here is that they still are ringing those bells. And we should let the management know that that really can be disruptive. But I don't know if they'd appreciate our feedback, but that is the approach of TQM, feedback.

And we will certainly be --

(Brief interruption.)

-- extensive feedback from the various competing constituents in this area, the various societies and organizations. There's also a hope to have some -- or not just a hope but an intention -- that we will get

practitioners to talk to us as well as the public. Because the committee --

(Brief interruption.)

-- can see -- or you may be able to detect from the list of committee members, it's a very diverse group, a group constituted of, you know, physicians, lawyers, an ethnicist, an economist, a data person, a nurse, a research person, et cetera. So its a very diverse group. It's not as though you're going to take a special group -- a special group of radiologists to talk to us about this.

It's both in strength I'd say in its weakness, because to get any kind of a consensus is going to be interesting to say the least.

(Brief interruption.)

And with that I think we conclude our time limit.

DR. GRIEM: Yes, in your brochure you list radium 223, I think that's a misprint and you really want radium 226 which is the common radium. I think the radium 223 is not a common radium.

(Brief interruption.)

DR. GOTTFRIED: We'll definitely make sure that's corrected.

CHAIRMAN SIEGEL: That's good to know.

DR. QUINLIN: It starts off with material called radionuclides, and it's actually radium 226 is not a

byproduct material.

DR. GRIEM: Yeah, that's true, but I mean if they're going to deal with radium then the common one that people think about is 226.

CHAIRMAN SIEGEL: Lest we get diverted at this, we have the organization to tell us how we should be regulating radiation. We had few mistakes in the front end in terms of semantics, that's not a --

DR. GOTTFRIED: Well, it's not just semantics, though, in that we do need to -- we understand that the charge has to do with reactor generated byproduct material. And yet we cannot restrict ourselves exclusively to that.

CHAIRMAN SIEGEL: Actually it's not clear that that's your charge. I mean I think there is a charge --

(Brief interruption.)

-- from the overall framework for radiation use in the United States, and you can't advise the NRC with respect to whether what it is doing is sensible or not sensible without looking at all radiation that's regulated and without looking at the way all medical practice is regulated as you're comparing benchmarks

DR. GOTTFRIED: Agreed. It's just that the scope of that -- I mean we have to be realistic, too, in terms of what our committee in five, six committee meetings can accomplish. And I think that's something that we have to

really be clear about.

We certainly want to undertake as much as we can. But in terms of the NRC's current regulatory authority, it's clear that's that what they're -- that their regulatory authority is such that --

(Brief interruption.)

-- we're getting into byproduct material.

Now, we have to look at the other areas, but overall ionizing radiation is a really broad --

CHAIRMAN SIEGEL: Let me ask you another question. Given that your -- if you had to choose between the following two things in your report, which would you place at the higher importance. Choice one would be a specific set of recommendations about how the NRC should adjust its own regulatory program based on its current legislation and legislative authority; and choice two would be a model statute for someone to submit to congress that would completely do away with the way radiation is regulated and controlled in the United States. Which would your committee currently think is --

DR. GOTTFRIED: I mean it's an excellent question, and I don't know the answer in terms of the committee's interest. I think the committee wants to both address --

(Brief interruption.)

-- the charge as well as provide useful

information to the NRC. We certainly don't want to just parrot the existing program and say, here's a synthesis of X, Y and Z, and this is what's being done and, you know, great, it's a great job. That's not what we're commissioned to do and we don't plan to do that.

But realistically there's going to be quite a great deal, I think, of -- and I can see from the first meeting -- in terms of the focus. There is a need for the committee to coalesce, and that's a process that's underway at this point in terms of what they're focus ought to be.

I certainly think that that could be a recommendation, though.

DR. JAMES: You might want to tell Dr. Siegel that it ought to be certain people invited to our next meeting to just discuss that particular issue. And I think we all understand you can't do this without understanding the problem and to understand the problem you have to at least look at --

(Brief interruption.)

-- this is a very diverse committee, and not only for nuclear medicine, this is the most diverse one that we have ever had. So we will have people in just to discuss these issues, but like I say, it was comments that are really well taken, because that's one of the major thrusts of our reasoning process.

CHAIRMAN SIEGEL: That's Dr. James for your information. He needs no introduction to most people though you may not know him.

DR. CAMPER: A couple of questions or comments. Given that you're conducting detailed interview, there are three areas of exploration. You can openly provide recommendations. I have two questions. One is, the panel meetings that you're going to hold, will those be recorded and transcribed?

DR. GOTTFRIED: Are you talking about the committee itself or --

DR. CAMPER: Any meetings or panel meetings or -- will there be records of those?

DR. GOTTFRIED: They're not public documents. We do have -- the committee meetings undoubtedly will be recorded and transcribed.

DR. CAMPER: With regard to providing a recommendation, will you prepare a background as to the logic that you reached and the rationale which you make your recommendations?

DR. GOTTFRIED: Certainly hope to. We usually have a problem with excess as opposed to -- we have 400-page reports instead of user-friendly 200 page reports.

CHAIRMAN SIEGEL: Would you get into the broad topic of mammography?

DR. GOTTFRIED: That's a good question. I -- to some -- I would guess to a limited extent.

CHAIRMAN SIEGEL: Dennis?

DR. SWANSON: With the health care reform, those of us who are involved in the provision of medical care are being required to make cost effective decisions. I get rather concerned that the same requirement is not being put on those people who regulate us. And I would certainly -- it does not appear as part of the charge. But I think in review of the regulations and the regulatory authority cost effectiveness of the regulations and dual regulatory authority must be a charge to this committee.

DR. GOTTFRIED: Well, I appreciate that comment, and in fact one area I omitted to discuss was that we are also commissioning papers, and those are papers that -- it's a form that -- or a style that the NAS/IOM often uses, which is to commission papers from experts in the various fields to talk to us or write to us about some esoteric topics that we don't have the time to really delve into.

And in fact one of those areas that will undoubtedly be commissioned is a paper looking at the cost of the regulatory process.

CHAIRMAN SIEGEL: Dr. Berman, questions?

DR. BERMAN: Just to further something that Barry brought up. At least even if you don't go all the way to X-

ray and the dichotomy between byproduct -- I mean reactor produced products and cyclotron products, it seems to not take into account the realities of products where so much of it is related to cyclotrons.

DR. GOTTFRIED: Right, I absolutely agree. I don't think we can avoid cyclotron accelerators, et cetera. I think that we will discuss that, the historical evolution as to why the NRC regulates only reactor generated byproducts and explain that we think that perhaps that is not appropriate, not the best approach to dealing with this field.

DR. BERMAN: And another question. This relates to the first examination of the overall risk associated with the use of ionizing radiation in medicine. I guess the question is, if you find that the risk is indeed small for diagnostic kinds of procedures would you then be going and looking further into the kinds of regulatory requirements with respect to who can perform and interpret these kinds of studies that you're speaking of?

DR. GOTTFRIED: I don't know the answer to that. I mean I think that we will probably find that the risk associated with the diagnostic procedures is negligible. And how much further we'll go with that at this point I can't speak for the committee.

CHAIRMAN SIEGEL: Will you be able to do all this

in nine months?

DR. GOTTFRIED: Well, that -- that's why I said to you let's be realistic. I mean we talk 24 months but the time frame is actually a lot shorter.

CHAIRMAN SIEGEL: It sounds like with all the panels and subgroups and getting people's travel schedules together to arrange for interviews and site visits is going to be quite an undertaking.

DR. GOTTFRIED: Well, what I've done already actually during the very first few weeks that I was on board is to set up the six committee meetings, and that's already scheduled and on everyone's calendar. So we're very pleased with that.

With respect to the site visits, we're hoping to conduct those over a four month period in the fall. And as well as the public hearing in the fall. And then the technical panels will be convening to meet intermittently.

So you know, it's a tall task. And we don't want to bite off much more than we can chew. What we want to do is realistic and I hope we come up with a useful report.

CHAIRMAN SIEGEL: To what extent does your committee want to hear from this committee, and by way of an answer?

DR. GOTTFRIED: I think at this point what they have voiced is an interest in having someone be present at

the second meeting in July to give them sort of more perspective on what the issues are.

CHAIRMAN SIEGEL: Is it likely that there would ever be a face to face with the two groups or a joint meeting; is that in your --

DR. GOTTFRIED: It's certainly a possibility. I don't -- that hasn't been something that we've been, you know, approached about or considered at this point. But I think that certainly would be discussed at the next meeting.

CHAIRMAN SIEGEL: Are you going to have that meeting at the immunology branch of --

DR. GOTTFRIED: It's certainly possible. Are there people in particular that you're thinking of, and if so we could --

CHAIRMAN SIEGEL: Yeah, John Boyce.

DR. GOTTFRIED: The only thing I would say about -- just to go back to the conjoint meeting -- would be if we could organize it if it's of mutual interest and we could orchestrate it so that it was at the time of our committee meeting so that we aren't duplicating the travel. That would work well.

CHAIRMAN SIEGEL: Well, certainly a conjoint meeting might be very, very helpful to orchestrate.

Any other questions?

DR. GOTTFRIED: Thank you.

CHAIRMAN SIEGEL: Thank you.

DR. GLENN: I decided not to put it on my tie like I did at the last time. I understand I entertained the Committee with my heartbeat during the presentation.

CHAIRMAN SIEGEL: And we noticed an arrythmia.

(Laughter.)

DR. GLENN: As Dr. Griem has mentioned a couple of times this morning, we are seeing events in radiation therapy that in some ways I think are significant.

We do try to look at the reports that we get, the investigations that we do, and see if there are trends that develop.

And we're coming to you this time believing we have seen some trends. And we're looking for some input from the Committee in terms of what the right approach for us to take with respect to these trends is.

We'll be proposing, are the standards already there; is there a need for standards to be developed; what should be the role of the NRC in terms of trying to correct what we believe are some problems.

The first slide I have shows the history for the most recent complete four years with respect to this administration reporting. It's a little hard to draw a clean-cut conclusion from the data because as most of you are aware we changed the reporting requirements in 1992. So

some things that were not this administration's before 1992 became for this administration reportable. Some things that were reportable were eliminated.

So we have a little bit of apples and oranges phenomenon here, but the changes were not too great in the categories that I've listed here.

There is a lot of bouncing up and down on teletherapy but on the average it doesn't seem like we're seeing anything too different today than we were seeing four years ago.

The same thing with radiopharmaceuticals, and mainly that is iodine administrations, either that were diagnostic and got into the therapeutic range by mistake or the wrong patient receiving the iodine.

However, where we have seen trends -- and that's what we're coming to the Committee today with -- is with respect to brachytherapy. In 1990 we had eight total misadministrations reported. And it has gone up ever since then, and in 1993 we jumped into nearly -- well, between 20 and 30 reported misadministrations.

So clearly brachytherapy is where the new sensitivity generated by the quality management rule and the new reporting requirements which I think sharpened the definitions and made it a little easier to determine what is or is not a misadministration, although that is still an

area of some controversy.

But anyway, we're getting more reports. And there are some issues that we believe are coming out of the kinds of misadministrations that we're seeing.

Next slide.

DR. ALMOND: Can I -- just a matter of clarification on the brachytherapy.

Nearly all brachytherapy isn't that afterloaded. Do you mean manual afterloading or remote afterloading?

DR. GLENN: We mean remote afterloading, yes.

Okay, an issue that came to our attention relatively recently, and in fact we amended the agenda in order to bring this issue up -- we had a couple of reported events in the recent months where there was a significant error in terms of the delivery of a fraction of a brachytherapy dose as opposed to the total brachytherapy dose being off.

Although we had been aware of fractionated brachytherapy we really had not focused on it, and at the time that we developed the quality management rule and the revised misadministration reporting requirements we did not factor that in at all.

We put in a definition for teletherapy, for what constituted misadministration with respect to errors of fractions. But we did nothing similar in terms of

brachytherapy.

So what we would like the Committee to help us with is to understand the significance of an error in a fraction dose.

We realize that if the whole dose is delivered too quickly that there could be very significant effects. But we don't know if it's a significance that it would be in teletherapy, and we're looking for some input from the Committee.

The next slide poses a question. And that is in view of the types of fractionated errors that we cite in the preliminary notifications, what harm or risk if any does the Committee believe is associated with the levels of errors that we've seen. And that would be where maybe you have a 70 to a 100 percent excess in one dose out of say two. Is that a real problem. But we'd like to get the Committee's input.

CHAIRMAN SIEGEL: Judith, Peter.

DR. ALMOND: I'll let my medical colleagues here go first, and then I'll comment.

DR. STITT: No, you go first, I'm still looking for the graph. I've had it in front of me --

DR. ALMOND: Well, it seems to be in terms of fractionated brachytherapy that each case is probably going to be quite different.

There would be some general sort of broad categories, but I don't think it's going to be possible to say that 10, 20, 30 percent over is as serious as maybe 10, 20 or 30 percent over in other cases.

And I think you're almost going to have to look at it on a case-by-case basis.

(Brief interruption.)

DR. GRIEM: I think each tissue is different. What you can get away with, and that is when the attorney finally gives it back to you, is different for each tissue.

When it comes to central nervous systems, if you bend it a little bit it's okay, but if you hit it a little too hard you're in big trouble, and the attorney is looking for that, particularly when it causes paraplegia.

And that's unacceptable to society, whereas in skin or some of the other areas you may be able to get away with a little bit more.

So to fix a number like 20 percent or 30 percent, tell me the tissue and I'll tell you what you can get away with, okay.

And I suppose that's not really the answer you want. That's the real --

DP. GLENN: Well, to some degree it may be. I think you're telling us there are cases where it could be quite significant And that we may need to know about them so

that we can make a judgment with the aid of our medical consultants on a case-by-case basis.

DR. GRIEM: I wrote a chapter on light tissue effects for a symposium particularly in CMS so there are areas of the brain that are more sensitive than other areas.

When you get around the sella turcica you're in much more trouble than you are in some of the other areas, at least based on the data.

And I think the juvenile brain is different than the adult brain. So I think you have to -- and finally, if one is giving chemotherapy concomitant to this, then you add another unknown factor.

So I think the question is not a simple one. And I think to answer it today with certainty is not possible.

DR. STITT: I've got some strong feelings, because I do lots and lots of --

(Brief interruption.)

DR. STITT: Which reminds me, you need to get yourself one of those so when you're tired of listening to us just ramble on you just ring that.

(Laughter.)

DR. STITT: Let me ask you a question about when we're talking about the fractionated numbers, it's my feeling that we're really most likely referring to those that come from the fractionated high dose rate, rate of

therapy. Is that your sense also?

DR. GLENN: Well, I would invite your comments on that. It's certainly the Staff's view, was that that's where there could be a problem.

DR. STITT: Right, and it's my view too, because of the rate of therapy -- we're talking about a course of treatment. And to do this little tweakings or soft touches from one day to the next, but -- and I'm coming to it from two some times conflicting views.

One is as a clinician that does a lot of clinical work, and as I said, Jan Schlueter knows a lot of national lecture circuit regarding high dose rate brachytherapy.

And then the other problem that I'm having with this is that of the medical consultancy, because I am way behind and I've got stacks of stuff with me today doing medical consultations for what are particularly high dose rate administrations.

And I see these people trying to squirm out of what are clearly in my mind as a clinician misadministrations, by saying yeah, looking at the overall picture, this really isn't a misadministration.

So to get down to some of the things that are more concrete, when you look at high dose rate brachytherapy from biologic viewpoints, these fractions really take on the biology of a fraction given in the teletherapy sense, that

is the linear accelerator dose, dose per fraction, time that dose is given.

And I think that we do need to address this question --

(Brief interruption.)

DR. STITT: I'm not done yet -- and come up with something as concrete as we can, because I think in the high dose rate brachytherapy this is a real issue. We are commonly getting 900 to 1,000 centigrade of a fraction. That has to have a biologic affect.

And there's no question in my mind that we as clinicians, we as NRC are going to be seeing a lot more high dose rate brachytherapy misadministrations.

There are some fascinating ways to do misadministration with high dose rate brachytherapy. Ways that we never envisioned. Every time I get a call from somebody from a regional office I think oh, what is it this time.

So I think we need to try it if it has to be done.

DR. GLENN: Okay, I wonder if I could propose a corollary to this question. And that is, do you think it's important enough for the NRC to be getting reports about these events?

We've essentially had a couple of events reported to us where you could argue that there was no reporting

requirement that required them to do it.

Do you think it's urgent enough that we need to do something to make sure we get these reports until such time as we can get a rule-making through?

CHAIRMAN SIEGEL: What manner is it that you could do that?

DR. GLENN: Well, we could do it by orders. We could try for a fast rule-making. My experience with fast rule-makings is that they end up being more troublesome than they accomplish.

DR. ALMOND: Can you restate the question?

DR. GLENN: The corollary is, is the issue of a significant error in a single fraction of a brachytherapy dose, at high dose rate I think is what we're saying, what would be the problem.

Is that a sufficient concern that the NRC should be doing something in the very near term to make sure it's getting those reports?

DR. ALMOND: It's my impression you are getting those reports. I mean the numbers that you gave us show that reports are coming in. You've said that you've got some which may or may not be misadministration, and I think generally the community is aware of this misadministration rule.

And generally when there's a question, they are

leaning towards reporting it rather than not reporting it. I would be surprised if you're missing many such occurrences.

DR. GLENN: Well, our definition for the written directive for brachytherapy only requires that the total dose, the number of sources, the time, those things be listed.

So if in fact the total dose given over the treatment is correct, there probably is not a clear-cut reporting requirement in our regulations.

CHAIRMAN SIEGEL: The issue really relates more fundamentally to the regulations regarding written directives for fractionated brachytherapy.

DR. GLENN: Right.

CHAIRMAN SIEGEL: And HDR, specifically, which we agreed in a previous meeting, was in sort of a regulatory gap.

DR. GLENN: It would also go to the definition of a misadministration, also, where we'd have to define it.

CHAIRMAN SIEGEL: Right now the definition of a -- the dose definition of a misadministration for brachytherapy is calculated "administered dose differs by more than 20 percent"" so if you're supposed to get two 600 centigrade or REM fractions, depending on what you like, and if you gave a 1,000 and 200, you're still okay, even though

the 1,000 fraction may be a lot more than you wanted to do. You're still okay by the NRC definition of a misadministration.

So what am I hearing? Is the consensus that there ought to be reporting of these events?

DR. STITT: Well, I think they ought to. And I get questions from regional offices saying an institution called us, they're trying to figure if it's a misadministration or not, and they're asking my opinion. And it just -- it falls between the cracks. It's not stated. But in order to try to make an assessment I think we have to know how often and to what degree we're seeing this.

I don't know how to speak to that. That's my opinion, and Peter may have a different one.

DR. ALMOND: Well, I think we've stated it. To come up with the numbers to give you as guidelines is very difficult to do, because I think, you know, if you do G-Y-N fractionated high dose rate, that's a completely different situation than if say you're using two high dose rates in another area as opposed -- which is upon the next -- after external beam treatment.

And in order to give, you know, 20 percent or 50 percent over on one and adjust it on the other really is not a serious problem. I mean, it depends upon each case.

CHAIRMAN SIEGEL: There are really two issues here. In fact there are two issues -- there are two fundamental issues on the table whenever we talk about misadministration reporting.

There is the societal issue of if there's something wrong with the system by getting the data we can figure out how to fix the system.

And then there's the individual patient's right issue. If patients are being injured as a result of these events, the NRC perceives that it has a responsibility to make sure that the patient's rights are being protected as a result of these errors.

There may be some disagreement in a later discussion about how far the NRC ought to get into that loop. But those are the two fundamental reasons that underlie misadministration reporting, that underlie the revised quality management rule and the whole bit.

And I think that even if we're not sure exactly where the threshold should be set for harm, then setting the threshold is a way of trying to uncover in some temporary fashion by order or whatever, what the systematic errors are to make sense.

And I'll just throw a number out on the table without any biological reason for so doing. Pick the 20 percent number. And that number would be -- but if a

particular fraction differs by more than the 20 percent, calculated or planned, that that may be an event this is worthy of a systematic evaluation.

Carol?

DR. MARCUS: I've been hearing individuals talking about how terrible this is and you might consider a system where the authorized user physician, when he writes his order, puts down the range that he will accept.

I do that with my radionuclide therapies and that determines the variability in that situation that I think is acceptable.

As soon as you put a number on it, you're defining sin. And that may not be -- whether NRC defines it as sin or the Cleveland Plain Dealer defines it as --

(Brief interruption.)

DR. MARCUS: We end up being sin, and I think it's dangerous to just put a number on it without a biological need.

CHAIRMAN SIEGEL: That's the risk we've always got with all misadministration is that it has the potential to be criminalized.

Nonetheless, there is important value in gathering data about what's going on with new technology as it's being applied in practice and without a way to gather the data, you can't analyze what the problems are.

Mel.

DR. GRIEM: Several meetings ago Dr. Flynn and I debated this issue. I lost and Flynn won. It was set at 10 percent.

And I agreed with your number and probably Dr. Stitt would agree that 20 percent is probably a better threshold or number to work through, partly because brachytherapy has the problems of geometric placement that make the 10 percent level almost impossible to achieve.

DR. STITT: It's written as 10, so it probably doesn't matter --

CHAIRMAN SIEGEL: Where are you? Where is written as 10? That's a recordable -- recordable rather than a misadministration.

When you write a brachytherapy prescription you don't write it as plus or minus 20 percent.

DR. STITT: No, it has to be specific to the decimal, you know, first decimal point.

CHAIRMAN SIEGEL: You mean for the dose to be 4,000 centigrade, not anywhere between 3,000 and 5,000. So consequently that's about the reporting threshold.

DR. GLENN: Question. Does the misadministration quality management rule need to be changed at all -- you said earlier that it says total dose, when in fact it simply says for recordable event, calculated dose differs by

greater than 10 percent. For misadministration, calculated administered dose differs by greater than 20 percent.

And does simply a notice have to go out that this applies to both the fractionated dose and the total dose.

CHAIRMAN SIEGEL: As Larry pointed out to me just a few minutes ago, the real issue is what the written direct requires. And he said that the written directive for the brachytherapy prescription does not currently require a statement of specific fractions. It requires a statement of total dose.

So what you would have to change then is both the requirements for the written directive as the recordable form.

DR. MARCUS: You aren't going to -- certainly what we're seeing is a very specific --

(Brief interruption.)

-- a very specific statement about how many fractions, exactly where the fraction site is -- where it's to be given. That is how the clinicians are carrying that out. Which is a little more specific than how they --

(Brief interruption.)

DR. STITT: Carol, are you saying you accually write directives that way or are you saying that you're doing that as a suggestion for a way to get around the reporting requirement?

DR. MARCUS: When I prescribe a dose I use a range over which I will accept the final -- because I recognize that the calculations that I do are so fraught with enormous error that it makes very little difference within certain ranges. And so I put down what the acceptable range may be.

I also have problems in my department where a patient is supposed to come in, you know, Monday morning at eight o'clock and shows up Tuesday afternoon at four o'clock, and the dose has been sitting there decaying somewhat.

And I am perfectly happy to use that dose, and rather than write a separate directive -- actually I don't have to write anything -- but I just put down a range so that I don't have to be bothered worrying about it, because all I'm going to do is write down an order for what it is. So why even bother to do it a second time.

CHAIRMAN SIEGEL: Do you use capsules or liquid?

DR. MARCUS: No, I use liquid, it's cheaper than the capsules.

CHAIRMAN SIEGEL: Well, I guess -- you run have to run out a radio pharmacy?

DR. MARCUS: No, we don't get more liquid. We have the usual --

CHAIRMAN SIEGEL: So actually what she's saying is a practical and common practice in nuclear medicine. In a

way it really is tied to when it is you want to write the prescription, immediately before the administration, at which point you know how much has already been shipped and it's in your hands, or whether you write it before the order for the radioactive material is placed.

If you write it before the order for the radioactive material is placed then you have to allow for dispensing error by the -- not dispensing error, but for the noise in the dispensing provided by the radiopharmacy and then by potential delay in the treatment.

And biologically what she's doing is absolutely quite sensible. It's less -- it's more of a problem when you're talking about a 1,000 rad differences for --

DR. MARCUS: Yeah, and it's just the difference between the -- it's the same thing we talked about earlier.

(Brief interruption.)

Not the same sort of things. That makes sense to the radiopharmacy and in therapeutic high dose rate therapy you can be very specific. These are computer calculations and not isotopes. And at least my sense is that what John is talking about are problems that we're having with remote afterloading high dose rate brachytherapy, and if we need to be specific. And I think we do.

(Brief interruption.)

CHAIRMAN SIEGEL: So what I'm hearing is that the

radiation and the business of therapy, this is something the Committee will need, that some reporting is appropriate.

DR. GLENN: That's the 20 percent --

CHAIRMAN SIEGEL: The 20 percent of the prescribed fraction --

DR. STITT: The prescribed fraction. But how can we communicate that? Can we simply send a note, do we have to make other --

DR. GLENN: I'll have to explore that, what mechanisms we can use. Whether we can do something short of rule-making or -- in order to accomplish that.

Okay, the next general trend we have seen in terms of reported brachytherapy in this administration -- and this is both high dose rate afterloading and --

(Brief interruption.)

-- low dose rate and manual afterloading.

A SPOKESPERSON: The fire department is here, they're testing the fire alarm system. There are some problems with the alarm system, there is not a fire, however. I'm sorry.

DR. GLENN: The phenomenon we have seen is that we have a very large number of these reported misadministrations that involve some misplacement of the source. This can be for various reasons. It can be trouble with the mechanism that the source doesn't go out a certain

distance that it's supposed to and the wrong area is treated for that reason.

It could be that the applicator itself is put into the wrong area of the body. I think there was a -- I mentioned before, sometimes modesty causes something not to be checked, and we've had several misadministrations where that appears to have played a role.

So we have equipment that --

DR. BROWN: Modesty? Do you want to elaborate on that, I didn't catch the nuance there. You mean where it's placed --

DR. GLENN: Where it's placed. It was placed in the wrong part of the body.

So we have equipment malfunctions that cause it to be in the wrong place. We have implantation procedures where for some reason it's not placed properly. And finally we have during the treatment itself that the source becomes dislodged. And this can be due to physical factors or it can be patient intervention. And so we have a spectrum of source placement issues that come before us.

The next slide I pose the first question, and that is, what is the standard of care with respect to the proper placement and operation of other implanted devices in the medical profession, and how often are devices checked to insure that they operate or that where something was put is

still in the right place.

DR. STITT: On high dose rate or low dose rate?

DR. GLENN: Maybe for both.

DR. STITT: They're different. I think they're clearly different, because I think there are a lot of ways to check where you think you are on a high dose rate and if you do start playing with a low dose rate those things can be anywhere. Anywhere from the -- or the cesium bank. And the system of checking that is much more difficult to pin down.

DR. ALMOND: I'd have to agree that high dose rate afterload is, I think, different than the low dose rate manual afterloading situations. For the high dose rate equipment there is very detailed quality assurance checks that you go through fairly regularly to make sure that the sources do locate in the right position and that your equipment is working correctly. There you're relying upon a mechanical device to take the source out of the safe and put it at a specific point within a capital of the body, and there are obviously quality assurance methods for checking this.

And those are written down by various groups. We have those, I don't think they're in the regulations, but the professional organizations have those.

The manual afterloading, again there are I think

certainly in our institution, we have procedure manuals which state very specifically what quality assurance you go through to make sure that the source in fact is put into the applicator or the catheter or whatever and that it is there.

Now, I think we have to distinguish between the fact of the sources is grossly misplaced within the applicator, that is it doesn't seat correctly in the applicator or falls out of the applicator or is halfway between the safe and the applicator, that's one problem which I think you are addressing.

The fact that the applicator might wiggle about in the body is something none of us can do anything about, and clinical experience takes that into account.

So I think you're looking here at the fact that the source is not located within the applicator or catheter in the right position. And again, most procedures within the problems have that quality assurance. At least to make sure that in most cases -- occasionally it does slip through. I mean it slips out in the middle of the night, and you know it's difficult to write any quality assurance manual that's going to catch that when it occurs.

It may be a couple of hours later that someone comes in and realizes it. But other than having someone sitting by the patient all night long with a geiger counter or some mechanism to make sure it's slipped out, I don't

know -- there are some things you just can't do.

CHAIRMAN SIEGEL: How often our source or applicator positions are checked in brachytherapy for certain --

DR. STITT: Well, with low dose rate, the low dose rate gynecological implant when you make rounds twice a day, there's certain ways you can tell if the thing is in the patient and if it's in the right place. However, that doesn't tell you if the physicist and the physician put sources in the correct place in the applicator.

I had one concentration I did this year where they did -- it was just human error. So that would fit into that circumstance. In the high dose rate implants it's pretty variable from one place to another, but we do visual checks, we do fluoroscopy checks, we do a last check for placement of the applicator just before the source goes in.

It is easier to document the high dose rate remote afterloading if the placement of the applicator and the source is correct. And in the misadministration problems that I've been involved in were the result because of poor QA procedures. And I think those are things that you can set up, yet there's some basic human error that -- again, this totally amazes me that folks must sit home and kind of think about these things, as to how they --

(Brief interruption.)

My time is up.

DR. GLENN: Well, I guess one specific question that came up within the NRC -- and that was whether we had an obligation to inform people that there should be a visual check of the placement of a manually implanted source. And it seemed like to us in the Staff that that's something that did not need to be said. That a visual check would be required.

One aspect of this question, is that in fact the standard of care. I mean is it expected that you would do a visual check?

DR. STITT: It's quite variable. It is at one place and it's not at another. And it, you know, some institutions elaborate treatment planning is put on and in other institutions you look at them on a chart. And how much can you regulate?

CHAIRMAN SIEGEL: Mel?

DR. GRIEM: Well, two of the situations, the source didn't make it into the applicator and the patient sat on the source for a period of time. So I mean there are problems with even the manual afterloading systems were in the right --

(Brief interruption.)

-- and I think the whole problem -- I think the problems in brachytherapy are going to grow, and partly

because of, you know, down here, CPT's encourage some of this as an economic issue. And that many more people are getting into brachytherapy and we need to be more rigorous in all the things we can do in the training process.

DR. STITT: I have a comment to make in that regard. I think it is going to grow, there's no question in my mind. And I think one of the reasons is -- this will be -- this is strictly my opinion, but I've been a clinician for a long time now -- I am convinced that the low dose rate -- there are a lot of things that I might have known that went on that I sort of kept to myself, or one can keep to one's self.

When you get involved in the high dose rate system, because it's every second is on a computer printout, I think there's a lot of verification that is done with high dose systems as far as the treatment and the treatment planning.

A lot of this sort of clinical -- it will all come together at some point in time -- now becomes very hard copy. And I think that that's probably what all of the offices are seeing, that a --

(Brief interruption.)

-- a lot of documentation that we now have that we never had the opportunity to have before. And I think in general that's probably good, because again, as I travel

around the country, one of my favorite stories is a physicist who called me saying my doctor's just got a high dose rate unit and it is plugged in, we're going to use it tomorrow, they told me to call you to find out what we should give.

And that physicist left that place and said it was good advice. So we have a lot more to be --

(Brief interruption.)

-- know and are able to document, and I think that means more and more and more reporting in this administration, and I think the offices are going to be swamped.

CHAIRMAN SIEGEL: Does anybody have a pistol? I want to shoot that --

DR. GLENN: Well, maybe we should flip to the next slide. We've had some discussion on this I think already.

I posed a very specific question, do the physicist or the oncologists, either group, have any existing standards that NRC could refer to for guidance in this area?

DR. STITT: Peter, do you want to talk? I keep talking, I mean --

DR. ALMOND: No, after you.

DR. STITT: Standards for -- I'll just stick to high dose rate, because I think that's really going to be the issues that will keep becoming more and more of a

problem for all of us. There are standards for placement regarding the common gynecologic applications, of cervical cancer, individual cancer, the post-operative vaginal radiation, in the sense that there are a number of articles in the literature that are accepted and describe placement.

Is that the sort of thing you're looking for?

DR. GLENN: Well, you're saying that there's literature but I guess that there has not been a voluntary statement that's been adopted by any society.

DR. STITT: There is one document from the American Brachytherapy Society that actually addresses all sides of the body including the joint applications, relates to high dose rate. And I can get you that if you'd like it.

DR. ALMOND: The AAPM has just published the last issue of Medical Physics, a comprehensive quality management program of radiation oncology. It's a very long document, but it does have a section on brachytherapy.

I must admit I do know what they say about high dose rate afterloading, but it certainly is at the level of the accuracy of positioning and that type of thing. And I suspect that you will find that in there. That is a very good document, though, and I think if you haven't got it -- it also relates to other areas of quality management.

DR. GLENN: Next slide. Sort of a bottom line question. Do you think the existing standards are adequate.

And I guess essentially we've been referred to read them. I don't know whether the Committee's prepared to make any sort of judgment at this point.

CHAIRMAN SIEGEL: I think it's whether this particular set of questions might need the work of a subCommittee. Two or three people who might come in and --

DR. GLENN: Then report to the Committee at the next --

CHAIRMAN SIEGEL: Or Staff. At White Flint and sit down and talk through some of these issues and then come back and report to the Committee and help you all come up with a regulatory framework. And I mean to the extent that people like Mel and Judy and Dan have been serving as medical consultants on these kinds of events, they've got a lot of experience, as much as the Staff does, in trying to understand the way things need to be.

I sense that there are some problems here that need to be addressed either by practice standards, ideally, or by regulation if practice standards won't do the job. But it's clear that this group at the moment doesn't have a collective expertise to say do this.

And so I throw that out for a suggestion.

DR. STITT: I would strongly endorse that. I think that even the highest rate brachytherapy is a small component of general medicine. I think it -- I get -- one

of my colleagues loves to call it high risk brachytherapy, and so she and I are kind of on the national panels, but I agree with her. And I end up calling it that myself even though that's a component of it. And if there's any calamity that should be in the making it's certainly with high dose rate brachytherapy.

The case in Pennsylvania is an excellent case in point. I think a subCommittee is an excellent idea. And I think that the existing standards and procedures are not adequate. And I think that we do have the capacity to move to something that is very specific. And to me this is the ideal circumstance for this group to be addressing, because I think for public safety, patient safety, this is something we can have an affect on and I think we should.

DR. GRIEM: Given the greater biologic community in the world, who has more data on large animals and high dose rate brachytherapy -- and in England it's very high administrative stuff -- but I'm trying to think, who can I assign as either lung or vessels or hearts or CMS where this has been tested and the data about so many animals, and this in fact is for X number of animals in the population --

DR. STITT: Yeah, I don't think there's much of that available. We can look at actually the IRT, although it's not brachytherapy, it's the fraction size. And there's a lot of known tissue from the people on the FCI. But most

of the data that's available is theoretic in its calculation and it would be by Fowler and Orton who approach it from some different sides.

DR. GRIEM: Because for IRT there is new data from Germanic and others -- I think you should get someone who's done a lot of IRT to bring that expertise which relates to this whole question.

CHAIRMAN SIEGEL: We have a comment from the floor we shall be happy to take, Dr. Rogers. Please introduce yourself for the --

DR. ROGERS: Yes, I'm Jim Rogers, a clinical physicist, also representing the American Association of Physicists in Medicine. I have just one comment I want to make about the type of standards, recommendations on how practice should be done, but in the case of low dose complications there is usually adequate time to radiographically verify the placement of the applicator. And this is not common -- well, I'd say uniform practice. And this might be an area where the NRC would make some recommendations.

And I think that would alleviate or go a long way to alleviating this problem of misplacing the applicator. High dose rate, there's a different issue there that I think is sufficiently done and -- but the low dose rate, I see no reason why radiographic verification be done.

DR. SWANSON: If I could ask a question -- a lot of these problems could have been addressed through perhaps better patient education and nursing education. I'm just curious how much emphasis has been in providing this.

DR. STITT: I think that here particularly we're talking about the low dose rate types of incidents. And again, I've been a consultant on several of those and I've read the other reports and I -- on clinical experience as a physician in brachytherapy is that the nursing Staffs were very quality, they understand the nature of radiation safety, they couldn't identify the source of this.

If they picked it up which they did in some of those reports -- and when we discussed at our last meeting -- and the post proponents are going to train nurses and RGTs -- hopefully they'll have more success that most hospitals will.

I agree with you completely in that education and training is an important part of this. Many institutions don't do many low dose rate insertions, and trying to train the Staff to a high level of confidence for an occasional insertion is certainly good for that.

CHAIRMAN SIEGEL: I would just note that following the discussion we had last time on false dose rates that we did explore with that institution, actually instituting the program. And the decided they could not in fact carry

through with that program.

It is very hard to train nurses to the level of performance that we were expecting.

DR. STITT: Yeah, I had somebody come up to me recently and say gee, after talking with you and reading this material we decided we were not going to get into the false dose business.

DR. GRIEM: Just for clarification, John, currently in 35-410 you do have some requirements for safety instruction that get into this issue of newly arising nursing Staff and those in participation as to the safe handling and certain precautions to be aware of when handling the sources.

This Committee of course has discussed a couple of times in previous meetings and agreed to which 35-410 is clear or is enough of a need to convey information. We have in fact put out an information notice not too long ago on it, within the last year that does deal with this attempt to try to make more information available to the nursing community about the process of handling frightened therapy patients.

But it nonetheless remains a concern.

CHAIRMAN SIEGEL: Let me reemphasize too that patient education I think is critical here. Very critical. Not just nursing.

DR. GLENN: The suggestion is that we get a subCommittee to help us answer this particular question. I will also mention that we've already made contacts with some of the therapy societies new in brachytherapy to meet with them and discuss some of these issues with them as well.

I don't know whether -- I think they cannot get on the program for ASTRO this fall.

MR. CAMPER: It's still in the air, actually. We're trying to get on ASTRO and we also it appears at this point will be conducting a two-hour workshop with the American Brachytherapy Society meeting in Florida in December.

CHAIRMAN SIEGEL: The kinds of questions that you've got on the table here sound to me almost as -- certainly they're as important from tne public health and safety -- as the kinds of things you have all those workshops for -- it seems to me that if we appoint a subCommittee that would serve to direct one of those workshops with invited guests from AAPM and ASTRO and ACRO and your own Staff to sit round the table and really work some of these things through, you know, a one day or one and a half day meeting, it may well be the way we want to try to get more public input on this thing.

DR. STITT: Well, let me interject here. Low dose rate brachytherapy has been going on since Madame Curie and

her cohorts, and high dose rate is very, very new, and I think it's hard to legislate some of the low dose rate business in rule-making.

But with high dose rate, now is the time -- and I think this group needs to be at the forefront of that -- because this stuff is risky business.

CHAIRMAN SIEGEL: An accident with a patient, are those -- do those get classified as a misadministration or --

DR. GLENN: That's a case, again, we talked about it before. It's a case by case decision. We look at such things as what would the area have received if the dose had been delivered as intended. How quickly was it picked up, those kinds of things are factors that we look at.

In terms of the -- whether it's a misadministration and what the corrective actions are.

CHAIRMAN SIEGEL: So if the patient physically removes a source in the middle of the night, is that a misadministration? It's way beyond the control of a licensee, isn't it?

DR. GLENN: But we are also asking the question, should there be some standard of checking so that does not go on too long, and how long is too long, if the source is lying in the bed with the patient.

CHAIRMAN SIEGEL: In the high dose rate setting,

if the normal source travel time is that it completes it's course in ten seconds to get from outside the patient to inside the patient, and for one reason it takes 20 seconds, is that a wrong site treatment? Because part of the body - -

DR. GLENN: That's exactly the sort of issue we do on a case by case type system.

CHAIRMAN SIEGEL: I mean I think the real -- there are some real important issues that need to be dealt with about device malfunctions and the way these procedures are conducted. But by the same token I'm concerned that there are some of these wrong site interpretations that get into the whole misadministration reporting scheme that get a little bit silly.

DR. GLENN: Well, I think in terms of -- you said two aspects to what we're doing with misadministration. In terms of our knowing about those incidents, I think we would like to know about all of them.

CHAIRMAN SIEGEL: I agree.

DR. GLENN: Now, the question is, is there fault and corrective action required on the part of the licensee. That may be a different issue.

CHAIRMAN SIEGEL: And as an example, notifying the patient of a misadministration when the wrong site gets one percent of the dose that it would have gotten during the

course of the treatment anyway, because the source was well -- somewhere outside the body for four or five minutes seems like it's a little silly. It's a lot of extra paperwork.

On the other hand, letting the NRC know that that occurred because of an equipment malfunction seems very prudent.

So it's -- there's a loss of balance, I think, here in the misadministration rule.

MR. CAMPER: I would sort of add to what Dr. Glenn pointed out, that is in those cases where it's been clear that it was sheerly patient intervention, and there was an appropriate response by the licensee, I think in almost every case that involves general counsel that the statute has gone on the recommendation that it not be a misadministration. OGC agreed.

However, as Dr. Glenn pointed out, we have had a case not too long ago, in fact, where indeed there was patient intervention but there was a prolonged period of time, I would say on the order of for an hour, I believe, in that time frame, where the licensee did not check on the patient and there was exposure to the patient's leg, I believe.

The other point I would make is that thus far, at least, we get into the wrong site, it has been things that are fairly gross, if you will, in the sense that source fell

out, lay next to a patient's leg or in fact a wrong treatment site was truly mistreated in the sense that it was to have been the left side of the brain and the right side was -- and then there's the case where we have found ourselves having to come to grips with these minimal movement of brachytherapy sources.

We have really tried to characterize those as not being misadministrations, because it's a real tough thing to report.

DR. STITT: Anybody that's got enough money can buy one of these little boxes, that's the source of it. And they are all over the country. It makes me wish I had some stock in it. And I can see the American Academy of Sciences working in here --

CHAIRMAN SIEGEL: I wanted to say that --

(Laughter.)

DR. STITT: I can see the American Academy of Sciences saying that gee, what you folks really need is a whole regulatory system that does nothing but look at high dose rate brachytherapy units, and they sound like the sky is falling kind of a person, but they're extremely dangerous and anybody can buy one, and it's just very frightening to me as a clinician who takes care of patients day in and day out.

And I think that I guess I've said this probably

three times and this is the fourth version, but this is going to be more of a problem because there are more of these being distributed. And I think we have to have some way of putting controls on some of the mindless and senseless use that I have seen with some of these units.

DR. GLENN: Okay, if we could move on to the next slide then, and this gets into a slightly different issue and one that I don't think is quite as much of a crisis, but it has to do with the direction that we take in terms of regulating brachytherapy, especially high dose rate remote afterloading brachytherapy.

Just to remind everyone, that in the area of teletherapy we actually do have a series of quality assurance checks that have to be made. And the next slide shows what some of those are.

We require that dosimetry equipment meet certain standards. We have requirements for full calibration measurements, we say what those full calibration measurements have to entail, how often they're done, those sorts of things.

We then say that on a -- that's on an annual basis. We then require that on a monthly basis there are periodic spot checks where you check certain parameters of the treatment but not the full spectrum that you do during the full calibration measurement.

Then we have safety checks that are done on maybe a daily basis or some sort of periodic basis. Then we have radiation surveys that are made around the equipment to make sure that the source is actually where it is, that the shutters are closing, so forth and so on.

One of the commitments we have to the commissioners themselves is that we come back to them next year and make recommendations about whether further rule-making is needed in the area of quality management and quality assurance. And it seems like this is perhaps an area where our regulations are currently deficient. That we do not have the same level of assurance built into our regulations for brachytherapy that we do for teletherapy.

And so the first question is, do any professional medical organizations have existing standards on calibration of brachytherapy sources.

DR. ALMOND: Yes, and if they're not specific at the present time they're being looked to. Again, I would check with the AAPM and see what they have working and what's in their comprehensive quality management.

I understand with the high dose rate brachytherapy you're now looking at changing sources several times a year so that it will be in essence different from the cobalt which you have a different time period.

So calibration must be done every time the source

is changed. And certainly those procedures are well established. Protection surveys must obviously be done every time the source is changed, et cetera, so there will be some differences certainly because the half-lives are significantly different.

DR. STITT: There are regs that are being developed, and as Peter says, we can get ahold of those. Or not regs, I'm sorry, but there are institutional statements that are being adopted by some of the national groups.

I really feel strongly that the sorts of things we've been doing for teletherapy should be done for high dose rate brachytherapy, because it can be done. Some of the misadministrations or at least the report of events that I reviewed recently had to do with things like changing daylight savings time. It can make a big difference. A source change that was going to be calibrated the next day and then it was used in an emergency in the middle of the night.

One of the things that it will do in trying to make this more safe is that there are some institutions who shouldn't be in the business but because, you know, Mr. So and So who died wanted to leave some money for that unit, therefore they bought one, they're going to have to have the physics Staff and the dosimetry Staff and the physician Staff to go along with that.

And that's the problem. You can buy the unit, but that has nothing to do with the high level of expertise that also is required to go with it. And hopefully it will maybe contain some of these units that are flourishing now.

DR. GRIEM: It seems to me that the NRC has to work closely with the FDA to make sure that computer entry systems and methods of using the computer are properly checked and so forth. And I think I'm being unctuous here, that the physicists have to take a hard look at the computer and that it's not misbehaving.

I'd leave that to the physicists to really set the standards for where the FDA units, set the standards of how often you should check the computer, and I think that could be daylight savings time, how the date is entered, whether you use the European or the American system, and it goes on and on and on.

DR. GLENN: I will mention, we have been meeting with the FDA on some of these computer errors that have resulted in misadministrations. One clear demarcation is though that the FDA regulates design and manufacture. They don't regulate the actual use in the institution. And that's where we may have a role to play.

Okay, the next question is for information, who within the medical institution determines the appropriate schedule for preventive maintenance for devices. Then the

follow-up question is, who normally performs that preventive maintenance. If someone other than the manufacturer, what type of training should be provided.

CHAIRMAN SIEGEL: So again, this is very much akin to your teletherapy type question --

DR. GLENN: Right.

CHAIRMAN SIEGEL: -- so that -- where you only allow teletherapy services to be done by certified individuals.

DR. GLENN: Right.

CHAIRMAN SIEGEL: Again, I think you're pointing in the direction of looking for a subCommittee. And maybe even a model regulation that the subCommittee could start to dig into rather than just focusing on ultimate questions.

I thought, you know, it was very effective the way the pharmacy rule -- to have at least NRC's first prod at what happened and then let the players sort of dig into it and see how it works in reality.

And as long as it's recommended regulations, there's a starting place as you all know. But this seems to be at a place where it may work very effectively.

This is probably done -- and each institution has developed its own scheme for dealing with it as institutions that have a lot of experience and have thought very carefully about their quality assurance program generically

probably are doing it terrifically. And institutions that are just getting into the game and are getting in with less experience are probably not doing it as well.

DR. GLENN: I'll mention that our licensing policy is that -- our default position is that the manufacturer does all of the servicing. But we do face the problem -- people come in and say we want to do our own servicing and then establishing the criteria for them to do that is an issue.

DR. ALMOND: The source exchange has to be done by the manufacturer. This is something that the hospitals properly are not licensed to do, but certainly are qualified to do. And during that source exchange at least minimal maintenance must be done.

I mean -- so I think there's a mechanism here where the manufacturer or the supplier of the source has to come on site several times a year. Which is different again from cobalt, again, when you know you have the regulation that every five years of comprehensive review of a machine is done, and that's generally when the source is changed, and it must be done by a licensed source handler.

You've got a somewhat similar situation here, but done with a much more frequent basis, the cobalt. And let me just say, I think the cobalt regulations have been very good because they have spelled out very clearly what you

want the physicist -- and the institutions know what is required. And I find that most people follow those quite well. And they've certainly I think been very helpful.

A similar set of regulations, I think, will be extremely helpful, and I don't think anybody will think that this is interfering. I mean it will give them very specific guidelines. So I think along the lines of the cobalt regulations will be very good.

DR. GLENN: The last slide, and to some degree Peter has already addressed this, what type of test checks are performed at source exchange, and we may find that that is the appropriate set of checks.

CHAIRMAN SIEGEL: All right, do we have any generic comments or specific comments about this issue?

I think the primary message we left you with is that we agree with you that there's a problem, and there probably is going to be ultimately a regulatory solution. We may have short-term need to do something else about the reporting by different methods, a workshop -- have this Committee help you deal with regulatory structure, language, et cetera.

DR. MARCUS: May I say something?

CHAIRMAN SIEGEL: Yes, dear.

DR. MARCUS: What proportion do you sort of think of physicians who are not board certified --

DR. STITT: What do I think of it?

(Laughter.)

DR. MARCUS: What percentage of physicians doing this are -- 50 percent are, or 20 percent are; I have no idea what the numbers are.

DR. GLENN: My guess is it's 99 percent. They have to -- actually if you're not board certified you actually will have to come in with an exception, and we've -- we don't see those.

DR. GRIEM: I see a turf battle with the neurosurgeon with lots of money who suddenly wants one of these and is convinced that he has enough training in six months or -- I see a turf battle if the economics are --

DR. GRIEM: Well, neurosurgeons are not used to dealing with this level of regulation. The don't enjoy this kind of practice.

CHAIRMAN SIEGEL: All right, let's take a break for lunch. It is now 12:13 -- why don't we resume at 1:10.

(Whereupon, at 12:13 p.m., the meeting was recessed for lunch, to reconvene at 1:10 p.m., this same day.)

A F T E R N O O N S E S S I O N

CHAIRMAN SIEGEL: Okay, we are back on the record. Are you ready?

DR. GLENN: Ready.

CHAIRMAN SIEGEL: We are talking about two things now, inadvertent misadministration to the wrong patient and physician notification issues.

DR. GLENN: Right. Actually for both of these issues, you might recall that we discussed these with the Committee before, I think as recently as last fall. And what we want to do then is tell you what has happened since that time. And I think share with you some fairly important information about where we seem to be headed.

So we're going to be talking about the inadvertent administrations of diagnostic radiopharmaceuticals. And what we really mean, of course, by inadvertent to be more focused and narrow is those cases in which a patient receives a dose from a procedure, nuclear medicine procedure or therapy procedure or diagnostic procedure particularly, where none was intended. None was intended.

Now, this brings to mind then the applicability of the of the provisions of 10 CFR 20.1301, to the administration of a radiopharmaceutical to the wrong patient.

Now, the point there of course is the 20.1301. It

carries with it the 100 millirem limitation to a member of the public. And then the wrong patient, as I said a moment ago, this is someone that receives some radiation that they were not intended to receive from byproduct material or radiation therefrom.

You might recall when we discussed this last fall we pointed out to you there was an enforcement case at that time the Staff was reviewing, and this involved a patient that had undergone an unintended diagnostic nuclear medicine procedure.

Due to a misorder from a medical student under the supervision of the patient's referring physician, this error occurred. In other words the wrong patient, this order was filled cut for in fact the wrong patient contrary to what the referring physician wanted to have happen.

The resulting dose of 800 millirem or eight millisevers was higher than that which is allowed a member of the public under the 20.1301 criteria for 100 millirem, as I said, but below the whole body threshold criteria of 5 REM or 50 millisevers in 10 CFT part 35. That's the misadministration, whole body threshold.

This type of event though, the Staff was aware, it wasn't really that unusual in a sense that in 1989 and 1990 we went back, took a look at the diagnostic misadministration reporting data that we had. You might

recall that there was about 400 or so diagnostic misadministrations per year for the preceding ten years.

We found about 200 reports involved administration of a diagnostic radiopharmaceutical where none was intended.

Well, as a result of this there was -- actually what happened was a technical assistance request came in to the regional office and raised this question of whether or not this was in violation of the 20.1301 criteria. And so we resolved that -- the Office of Enforcement had the lead and we worked with them preparing a commission paper to explore this question from a policy standpoint.

In the commission paper we proposed certain Staff options. First, that part 20 is the controlling regulatory part, because the patient is considered a member of the general public who was not intended for any nuclear medicine procedure.

That particular option had two sub-options associated with it that dealt with if indeed this is to be the case there are certain severity level issues associated with it, what severity level would be assigned.

And or course that would bring this 100 millirem total effect equivalent to this patient issue.

The second option that the Staff proposed in the commission paper was that part 35 is controlling because exposure occurred as the result of an error in administering

to any patient a radiopharmaceutical and while the slide says which is addressed in the misadministration regulation, what we really said in an option was that part 35 when it comes to patient issues is the exclusive province.

This comes as an exclusive province of part 35 and would not be subject to part 20 considerations even if the patient was an unintended patient.

The Staff felt that this was consistent with the quality management rule focus which you might recall elevate the thresholds for diagnostic reporting of misadministrations and put the emphasis upon therapeutic events.

And the third option was that we would issue -- the issue was of such a nature that it requires clarification through rule-making and that the Staff should fullest discretion during interim period until that rule-making was completed.

We also talked about in this clarification issue that we would need to point some emphasis upon either option one or two as we went about the rule-making process.

Well, the commission has reviewed the Staff commission paper and has provided us with a Staff requirements memorandum, dated 10 May, 1994.

In this SRM the Staff approved the following actions: That no violation would be indicated for part 20

in this type of case. The Staff in the commission paper included in the copy of the Staff-prepared notice of violation for this inspection, there were some other violations as well, but in the draft notice of violation the Staff did not include a violation under part 20 for this issue.

And the commission agreed with that, that the notice of violation could be issued as developed by the Staff and that there would be no citation in part 20.

That the Staff should in fact proceed with rule-making to clarify that the medical administration of radioactivity or radioactive materials to a patient which includes a wrong patient is the exclusive province of part 35.

So, if you will, what the commission directed us to do was really a sort of hybrid of our options two and three.

We would of course exercise enforcement discretion until rule-making is complete. And that we would follow part 35 whenever unintended dose is exceeded, from this administration threshold, of course.

And there's no need to notify the patient in the case at hand.

With regards to Staff memorandum, it also goes on to state that we should seek public comment on notification

following errors in administrations where no administration was intended and the threshold of this administration was not exceeded.

It asks the Staff to explore the question of whether or not there are practical ways to apply 10 CFR Part 20 to such inadvertent administrations without defeating the policies behind the definition of misadministration, and for that matter the intent of the quality management rule and the exercise we went through developing those thresholds.

The practical ways to apply 10 CFR Part 20, such inadvertent administrations without defeating the policies behind the definition of misadministrations.

You might recall the management rule was acted upon by the commission, they decided that the diagnostic use of radiopharmaceuticals is in most cases an area of relatively minor radiation risk to patients. And that institutions should devote their resources toward more serious errors, that being therapeutic, of course.

So this is an interesting question that we have to explore, in the draft rule-making, and we would certainly in a few minutes welcome some thoughts from the Committee on it.

They also asked the Staff to take a look at whether or not notification in such cases when unintended patient is to receive exposures would impose record-keeping

and procedural requirements upon licensees beyond those explicitly set forth currently in 10 CFR Part 35.

Remember, bear it in mind if you will, that if you have a second category of wrong patients, if you will, at the 100 millirem level -- let's call it the pink patients or blue patients for sake of simplicity -- well, what happened in terms of implications administratively, record-keeping and the like, if that in fact did exist -- obviously we want to seek some recommendations from physicians identified in the SRM and we need to find out from the Committee what it's recommendations are for definition of a patient and/or a wrong patient, particularly as they apply to those individuals that are not scheduled to receive byproduct material.

This is an interesting issue to discuss with you, because it would seem that either defining the patient -- or for that matter defining wrong patient -- one way or the other would seem to do. You wouldn't seem to have to do both.

Now, we can debate the pros and cons and we'd welcome your input on which is the better way to go. We can define the patient -- of course any time you try to define a well-established word in the English language that's well-known and used and you try to define it for regulatory purposes you run into some problems.

On the other hand, it may be that a more simple approach would be to make it clear what we really mean by wrong patient. So we would -- we need some thoughts on those.

In looking at some of the background information that was associated with the commission paper and looking through some of the OGC positions on the matter over the last few years I did rind an interesting comment that there's been a long-standing policy that all patients are members of the public, and this is associated with the statements of consideration from 1979 and the policy statement.

So it's an interesting issue we have to get through.

With regards to the wrong patient question I'd like to give you some thought. Today, look in the definition in 35.2 under the "wrong" category of misadministrations, you'll find "wrong patient," "wrong radiopharmaceutical," "wrong administration," "wrong mode of treatment," "wrong treatment site," "wrong radio isotope," and I guess the question that I would ask the Committee, is there anything that's not covered by the wrongs that would then make it clear that the wrong patient has to be the inadvertent patient.

And if that is the case, is it simpler to define

wrong patient as such.

So, with that brief overview I'd like to welcome your comments and thoughts. And I think what I would do is to try to just kind of make sure we go through these questions that the commission asked us about, and that first one is are there practical ways to apply 10 CFR Part 20 to such inadvertent administrations without defeating the policies behind the definition of misadministration or the quality management considerations in part 35.

Dr. Marcus?

DR. MARCUS: If you look at that old part 20 you have a definition, because we went through this the last time. The words -- it made it very clear that part 20 was not to apply in a medical situation. In the new part 20 when the wording was streamlined, that mention dropped out.

When I talked to people who have been involved in the streamlining of the language, they said it was their conviction that they didn't mean to change the area of part 20, that patients always were in part 35 and that the change in the opening language of part 20 really should not have resulted in a change of who it was implied to be.

And I think if you go back and look at the original language in the last part 20, not the new one, and incorporate that into the new part 20, you'll get out of this whole problem, because it was discussed completely when

the quality management rule was discussed.

There is no sin in that 100 millirems. That limit has nothing to do with the dangerous level of radiation. It has to do with predictable levels of radiation imparted to members of the public by activities of users of radioactive materials.

And what the NRC seems to be doing is trying to impart danger, hazard and sin to that 100 millirem number, when in fact it has to do with a sensible goal for working level limits of ultimate exposure. A totally separate concept whatsoever.

And I think we should continue to try to separate part 20 from patients in as much as possible.

MR. CAMPER: I think what that translates into, that as the Staff is working on this particular rule-making, what we should do is read -- this is a scope part of part 20.

DR. MARCUS: Yeah, it was the scope part.

MR. CAMPER: Old and new, and determine if it poses rule-making or does it need to adjust certain language within the scope of part 20 to aid in facilitating this objective that we're trying to achieve.

DR. MARCUS: Yeah, the whole discussion is very interesting. For example ICRP in a recent publication specifically exempts members of a household who take care of

a patient who has radioactivity in them as being members of the general public.

One of the things that the NRC keeps discussing, what with the ICRP -- and I think maybe you can address this -- the whole issue as to who the general public is and then we have specific -- workers, patients, people who have a stake in what happens to the patients.

There are other publics here that are different from the general public that might serve in formulating policy.

MR. CAMPER: I wonder if I could pose the question in maybe some clear-cut categories, I won't say that they're exclusive.

But what we're looking at is within the hospital situation if someone is administered byproduct material, when is that person a member of the public, it's up to part 20, and when are they subject to this administration rule.

Let me give three examples of people who may be in a hospital who are not occupational workers. You have a visitor who's come in to visit a relative. You have a patient who has come in for a nuclear medicine procedure. And you can have a patient who came in to have their eyes checked.

I think we all agree if the visitor got an administration, he was a member of the public, part 20 would

apply.

If it was a person who came in for a nuclear medicine procedure, clearly part 35 applies under this administration.

But it's that case of a person who came in for a different procedure completely unrelated to anything involving radiation that this policy is trying to address. And that's really the patient we're talking about.

DR. QUINLIN: How often does that occur?

MR. CAMPER: About a hundred times a year.

DR. QUINLIN: That particular situation of a person --

MR. CAMPER: Well, I won't say that the eye type of thing, but say someone in for diagnostic X-ray gets a nuclear medicine -- that occurs fairly frequently.

CHAIRMAN SIEGEL: A fairly common problem, and I'll give you a perfect example, it may get caught and it may not get caught, that the order be written for one patient and being transcribed by a word clerk who then enters it into the computer system which sends a requisition to the nuclear medicine -- a very common problem is the order is written for a right upper quadrant ultrasound and turns into RVG, which a treatment gram. Then a patient who was supposed to get an ultrasound ends up having a cardiac -- so unless you've got a mechanism in the department to

check and see if you've got the right patient, that's sort of thing happens fairly often.

The other kind of thing that happens is where an outpatient, a doctor's secretary is told by the doctor, order the following study of the patient -- the doctor's secretary misunderstands the precise nature of the study and instead of calling CT calls nuclear medicine and orders a study that's got a similar description but isn't really the one that was intended.

The problem that I have with that, first of all that is a patient, it's just a patient who went for the wrong study, and so it's the wrong patient.

The potential problems with escalating that to the level of member of the public, escalating it to a level of record-keeping and notification, even -- or escalating it to a level of reportable event, is a question of resource application.

Nearly all the time these events will cause no harm to anyone. They may inconvenience the individual, but they don't cause harm as a result of radiation in either a stochasic sense or a deterministic sense.

And we will do exactly -- we will unravel the whole force behind the quality management rule if we impose a new set of requirements here. I think as I pointed out at the last meeting, the reaction as I understand it in this

particular hospital where this event occurred, while we were waiting for a final ruling from the NRC, was that they put out a list that said no patient would have an examination of any sort performed until they absolutely unequivocally signed a document prepared by the referring physician that was in the hands of the authorized user, for the authorized user to approve the study to commence.

And if the referring physician couldn't be found on the day that the patient was supposed to have the study which might be two weeks later, the patient was just sent home, because they couldn't validate it.

Now, that is much ado about nothing. It's inconveniencing patients, it's disrupting medical practices. For radiation exposures they're not really fretting about. And with a denominator that is very, very large.

What fraction of the total number of nuclear medicine procedures do you all predict or NRC regulates, what, there are 13 million, 16 million --

MR. CAMPER: We have roughly a third of those.

CHAIRMAN SIEGEL: We're getting a hundred out of five million and they're all resulting in doses that are in the range of a few hundred millirems effective dose. And we still allow people to live in Denver. As long as we do that we shouldn't be getting excited about this.

This will unravel where you want the attention to

be. Do I think it's appropriate to make these errors, do I want to make these errors? Never.

Before we go on with the question let me just tell you something.

In my original quality management program I included these events. All the things that were not captioned under diagnostic administrations, we created a category called radiopharmaceutical incidents that included things like the wrong patient or doses that would go over the threshold, wrong radiopharmaceutical -- we investigated them, we treated them as if they were reportable events in our internal quality management program.

We have just six weeks ago created a new quality management program in which we have deleted that component of our quality management program, because we don't want to make it a red flag for NRC inspectors, even though I can tell you that I'm personally going to continue to evaluate all of those events from a hospital quality assurance point of view the same way I would if the NRC didn't exist.

I just think that you're just marching down the wrong path on this one. I'm not saying you're marching down any path. But if you go down the path of raising a level of consciousness on these to require reporting, notification, undue record-keeping and certainly if you treat it as members of the general public you're unraveling the quality

management rule and in an area of cost confinement in medicine, it will be just not a very sensible thing to do.

MR. CAMPER: So your comments and your reaction is a resounding yes to the second question up there.

CHAIRMAN SIEGEL: Yes.

MR. CAMPER: And the first portion, thus far we have Dr. Marcus' comment about perhaps the scope of part 20 should be modified to make it clear in regards to medical exposure. I don't recall exactly what the -- I do recall the differences in the previous, the pre-part 20 scope and existing, but don't recall exactly what the words are.

CHAIRMAN SIEGEL: The finding in the intentional administration of radiation or radioactive material or the radiation therefrom to a human being or believing that a human being is a patient and believing that patient to be the correct patient, even though they may later turn out to be the wrong patient, should be considered medical practice and not considered inadvertent exposure to a member of the general public.

And changing the language of part 20 back to the -- something like the old wording which probably was not as inclusive as I think you're interpreting it to be, Carol, but making it more inclusive would solve the problem.

DR. TELFORD: John Telford, NRC, Regulation Development and Rulemaking Section.

I've heard Dr. Marcus say that of part 20 showed -- I'm interpreting here -- says in essence anything that was of physical medical use as defined in part 35 should be the province of part 35 and should not be in part 20.

Let's assume you do that. And there's a couple of definitions there in part 20 that need to be corrected as well. Then I think the question that I want to ask you is, how would you define patient, because I think you just did define patient for us in your last two-minute talk here.

In other words, could you put the slide back up to what the rule-making is really about? Because the rule-making is to make clear that we would like to keep these apart on this kind of inadvertent administration or exposure -- the first step is what Dr. Marcus has suggested, is that make sure part 20 does not apply to patients or anything called a medical user.

But if we add to part 35 the definition of a patient in order to make clear what a patient is, how would you define that patient? I don't want to put words in your mouth, but I thought I heard you -- perhaps the people in the Committee, as to how they would like to define patients.

Do you follow me?

CHAIRMAN SIEGEL: Well, I do. I didn't really define patient, but what I defined was a medical act of administering byproduct material or the radiation therefrom

to a human being based on the presumption that that human being was getting the right thing done to them, and therefore for medical reasons that made that human being not a member of the public, but that's an operational way of defining a patient without saying what a patient is.

I mean in a way, John, your example of a visitor -- I mean a visitor who responds to a request, walks into an injection room and says sure, go ahead an inject me -- I mean that person should be a patient.

(Laughter.)

I mean how can you protect yourself against people who walk into a hospital and their interesting problem is the problem of Munchausen's syndrome. Or we might have people trying to get radioactive material intentionally to -- I don't think that this is a clouded area, but I think the intentional act of performing a medical procedure on someone whom you believe to be a patient defines that individual as a patient.

It may turn out to be the wrong patient, but it is at least a patient. Judy, do you agree with that?

DR. BROWN: I guess so. I have a lot of questions.

CHAIRMAN SIEGEL: Please.

DR. BROWN: Are you saying that the hundred per year now, these are all Munchausen's?

CHAIRMAN SIEGEL: No, I'm saying that most of them are the kind that I just described to you. There are requisition errors, errors that get generated at some stage of the process, and in medical practices which is the standard throughout most of the United States where a requisition showing -- of a patient showing up is all it takes to get a nuclear medicine procedure started.

DR. BROWN: Right. Now, my first question is, what kind of record-keeping did those hundred cases have to present to NRC in order for you to capture them? Was it a lot of work, a little work?

CHAIRMAN SIEGEL: They were previously captured under the old misadministration reporting requirements.

MR. CAMPER: That's correct.

CHAIRMAN SIEGEL: They are no longer being captured. That was there up until the time the rule was changed in '92. And one of the reasons that it was okay, at least from my perspective, to change the rule is that we had ten years' worth of data that told us what the problem was, gave us a feel for what kind of doses we were talking about and --

DR. BROWN: And nobody's concerned that this is going to balloon at some point because of reasons like you keeping your internal records. This is just kind of static in the --

CHAIRMAN SIEGEL: I have no reason to believe otherwise.

DR. BROWN: And what's the standard practice if -- is the patient told, even though they're not required by NRC generally, I mean outside of -- does anybody know?

CHAIRMAN SIEGEL: I don't know, but I would assume patients are told about this sort of thing. It's pretty hard to explain to --

DR. BROWN: It would be a sticking point for me, because I can't imagine having that happen and not having someone required to tell the patient, but the way you document that is --

CHAIRMAN SIEGEL: I guarantee that if you are a patient, an inpatient in a hospital bed and a nurse walked by and gave you a dose of digoxin when you were supposed to get a dose of diltiazem you would not be --

DR. BROWN: But, you know, this is why I like nuclear medicine. Because you are -- this is why -- this is the standard of care I've long aspired to.

CHAIRMAN SIEGEL: The only problem is I can't cure your heart failure if you really got the drugs.

DR. BROWN: But you know, I've told you all, there's a standard for other people to come up to. So that doesn't cut any ice with me.

MR. CAMPER: But one of the points the Staff made

in the commission paper in fact gets at this point, and that was we stated that this idea -- there are those who look at the patient who receives unintended exposure and they would say, wait a minute, these people have no idea of the risk, they have no idea of the consequences of what's going to go on, they simply have no awareness.

And the Staff -- certainly from diagnostic procedures -- we don't believe there's a compelling volume of evidence to show that patients who are scheduled to get a nuclear medicine diagnostic procedure have those kinds of consequences and risks and the outcome of the examination explained to them either.

It doesn't happen as a matter of routine diagnostic nuclear medicine, we don't believe.

So therefore the difference between those patients who are in fact supposed to receive and are scheduled to receive and those who in an unintended fashion receive, there really isn't a lot of difference in terms of their awareness.

And that's not to say that there aren't some cases where the diagnostic nuclear medicine procedure scheduled to be done for a patient is explained, some people have more interest in radiation than do others.

But as a general operating premise they do not.

DR. BROWN: But I think the fact that you've

entrusted yourself into a doctor who is of the opinion that you need this diagnostic procedure, and if they do, you know, insurance company's money, you know that's okay. I mean I don't need full disclosure for everything.

But if it turns out that nobody ever ordered this for me, there was no intermediary, I just got the wrong -- somebody else's prescription, then I want to know about it.

MR. CAMPER: Well, that would be an argument in favor of the 100 millirem limitation in 20.1301 or more primarily toward the patient being notified, which is another requirement --

DR. BROWN: I'm only concerned about the patient.

MR. CAMPER: There is a requirement in part 20 that the patient notification occurs if in fact the figure for the 20.1301 is exceeded.

DR. BROWN: Right, but I don't know how to get to the patient being notified as a requirement without having all the extraneous other reporting that has to accompany it. So I don't know how you do that.

MR. CAMPER: Or rule directing in this case --

DR. BROWN: Yeah, and if it is more of a standard of care that somebody who -- the rule says we goofed.

MR. CAMPER: Or more directly in this case is the 100 millirem threshold versus the 5,000 millirem threshold for misadministration. And the trigger of the threshold is

going to cause --

DR. BROWN: For me it's very true. If I'm going to involve a patient for anything in that office --

DR. GLENN: Well, clarify for Judy that if in fact it is a 5,000 millirem occurrence part 35 of the regulations would require notification.

MR. CAMPER: That's what I'm saying. The difference here now is it's a question of whether it's 100 millirem threshold versus the 5,000 millirem --

DR. BROWN: I know it would be the lowest.

CHAIRMAN SIEGEL: Daniel?

DR. BERMAN: I agree that you can lose track of various common denominators, and the gravity of the events needs to be taken into account, 100 out of five million. And it was something that no measurable account -- the amount of extra costs, of extra time -- time and effort and cost this is going to take out of our ever increasingly cost-conscious society shouldn't be lost.

If a person undergoes a barium enema by mistake or a GI series by mistake those are outside the purview of this organization, but there's no official kinds of regulatory process that leads to these kinds of events being notified.

We should be compared with that kind of other modality rather than just to any kind of radiation. I think that the level that's associated with this -- with a true

misadministration as a protective effort is an appropriate one and we should accept his small amount as --

CHAIRMAN SIEGEL: We're suffering from -- it's a point I was just going to make, too. There's kind of a capacity fallacy argument that is built into the Atomic Energy Act. We have the capacity to make you do this sort of thing, therefore we're going to do it. It must be useful because we can do it.

And in fact if your argument, if your argument is correct that whenever something incorrect is done to a patient, the patient has the right to be notified. And that right is a high enough priority for society that it should be by regulation, that it should apply to the entire practice of medicine in all its aspects.

And consequently instead of telling me or John or Larry or John Telford about the problem, you should be up on the Hill telling Congress about the problem and asking them to please make a law.

DR. BROWN: I know that.

CHAIRMAN SIEGEL: But absent that law, absent that law, you shouldn't just do it to the nuclear medicine practitioners because the Atomic Energy Act provides you a convenient modus operandi to achieve the goal.

That is a standard of fairness that I think we must apply to the practice of nuclear medicine by comparison

to the rest of medicine.

DR. BROWN: I don't agree with anything you just said.

CHAIRMAN SIEGEL: I know you don't.

DR. BROWN: First of all --

CHAIRMAN SIEGEL: And you're entitled not to.

DR. BROWN: Thank you. Thank you.

First of all, if anybody gave me a barium enema that I wasn't supposed to get, somebody would pay.

(Laughter.)

DR. BROWN: Secondly, if it's only happening in 100 per how many denominating, millions? What's -- you know, it's like, who cares? I mean, your institution is not going to file too many. It's not that much of a cost, right?

CHAIRMAN SIEGEL: It's not the reporting of a hundred that's a problem.

DR. BROWN: It's just the reporting --

CHAIRMAN SIEGEL: It's the action on the 499,999,900 to prevent it from happening is the problem. It's the cost and the added burden of preventing it because you don't want to go through the rigmarole of reporting it.

DR. BROWN: Right.

CHAIRMAN SIEGEL: That is the major cost to society.

So I'll ask you a question.

DR. BROWN: Well, I have --

CHAIRMAN SIEGEL: If every nuclear medicine procedure was going to cost $50 more because of this requirement, is it worth it to you, every procedure?

DR. BROWN: No, I'm not for adding more burdens here.

I'll tell you a little story. NRC lost me and my support in great measure when they sent me a 20-page form to fill out that I already filled out two years ago when I was appointed to this Committee.

And I said, "You're doing this to the wrong person." They haven't got many friends left. They asked me to fill out the same 20 pages to say that my parents are still dead, and that, you know --

(Laughter.)

DR. BROWN: It just did not make sense to me. So I'm even more sensitive to --

CHAIRMAN SIEGEL: That's the NRC's fault.

DR. BROWN: Well, whoever. Whoever's fault that is, it just -- it was not appreciated.

So I'm even more sensitive to not wanting to add extra paperwork than I was before this happened to me personally.

So I don't want to add extra paperwork. But I

want to know if someone gives a wrong patient who shouldn't have gotten anything in this regard that they're going to be told by someone. I don't know how to get to that without added paperwork.

DR. STITT: Barry, let me make a comment and sort of answer your question.

If these sorts of things occur in hospitals, something as simple as a one-time misadministration, wrong patient, you got digoxin instead of aspirin, an incident or however the hospital calls it, has to be filled out, making that statement, the patient has to be informed. And it's part of the hospital process.

But it seems to me that some of what we're discussing here would be captured within that. I mean, if it does happen --

DR. BROWN: That would be fine with me.

DR. STITT: And people do get a barium enemas instead of a blood test. It happened at our place. I know it sounds peculiar but it does. And that has to be recorded.

There's no radioactivity associated with any of that, but those statements have to made by JCAHO regulations.

DR. BROWN: Well, then, that would capture it for me.

CHAIRMAN SIEGEL: I believe that if there are a hundred of these a year that 80-plus percent of the patients are told. That's just my level. It's just sort of the minimum level of --

DR. BROWN: Why 80 percent?

CHAIRMAN SIEGEL: What?

DR. BROWN: Why?

CHAIRMAN SIEGEL: Because it's just the standard. When you make a mistake, you tell someone you made a mistake.

DR. BROWN: You. You do.

CHAIRMAN SIEGEL: No, doctors do. I know you don't trust doctors, but doctors tell people when they make mistakes.

It's hard to explain why you're just sending the patient back to the floor after the injection. People ask, Well, what's going on here; why didn't I have this test; why did I have this test; why did you do this test to my gall bladder when I'm here for heart disease? People do ask questions and you tell them you made a mistake.

I believe that the level -- the level at which people are being told is 80 percent or greater. I really do believe that.

Now, the question is, assuming you accept that as my thesis, then do we want to put a set of regulations in

place for that other 20 percent of those 100 here.

DR. BROWN: That was my question, was the standard of the practice there.

CHAIRMAN SIEGEL: The standard -- we've been through there. The standard of care is --

DR. BROWN: Great.

CHAIRMAN SIEGEL: -- is truth-telling. That is the standard of care in the practice of medicine. It really is, Judy.

Lew?

DR. WAGNER: I was just going to comment that the point here is that the -- of a patient is a factor that should come under the ethics practice, and it has nothing to do with the radiation that's administered.

We're not going to be telling specifically to the patient that there was so much radiation, there's so much risk involved, et cetera, et cetera, et cetera.

It has nothing to do with the patient. It's simply the fact that the wrong thing was done. And by virtue of the fact it has nothing to do with radiation but it's so low in itself, it shouldn't come within of the NRC to tell us how to practice in that direction.

It's just an ethical question about what went on that has nothing to do with the radiation itself.

DR. BROWN: And do you think patients are being

told out there?

DR. WAGNER: Oh, yes. As a matter of fact, we recently had such an incident at one of my institutions.

And the way we handled it is we went through the referring physician, called him in and told him exactly what happened, why it occurred, et cetera. And we had him inform the patient of the matter.

So it's that simple, but you take care of these things in a reasonable way according to the ethics of practice. It has nothing to do with the radiation.

And that's the point. And that's why it should not come under the NRC rules.

MR. CAMPER: Could we, Mr. Chairman, try to get some consensus on those two questions from the Committee? I think I know where we are.

Are there practical ways to apply Part 20 without compromising on this issue of --

CHAIRMAN SIEGEL: I think we answered the first question by saying you ought to work out Part 20 to more clearly discriminate between a member of the general public and --

MR. CAMPER: That's a Committee? That's your Committee's --

CHAIRMAN SIEGEL: Is that -- do you agree with that?

(Several members nod their heads.)

CHAIRMAN SIEGEL: Okay, it's a consensus.

And the second one is I think is there anyone who doesn't think that some either notification or record-keeping -- would impose an undue burden on your practice?

And it's less the burden on the practice that I'm worried about. I can tell you it's a burden on the patients as well, because what will happen, Judy, is we'll come in for a study and your doctor will not have sent the requisition and he'll be playing golf and you'll get sent home when you have blocked out the whole day for the study, taken off from work, and I just send you home.

Your time's valuable. You've got to give me and my Staff the opportunity to use our best judgment and expect us to get it right. All but a hundred are -- that's not a bad --

DR. BROWN: And then if you don't get it right --

CHAIRMAN SIEGEL: What?

DR. BROWN: If you don't get it right, you'll tell me.

CHAIRMAN SIEGEL: If I don't get it right, I'll tell you.

DR. BROWN: That's the only thing I care about.

CHAIRMAN SIEGEL: Okay.

Continue.

MR. CAMPER: And I assume that it's safe to say that there's a consensus that the commission's direction to the Staff to pursue rulemaking to clarify that the medical ministration of radioactivity or radioactive materials to a patient, which includes even a "wrong patient" is the exclusive province of Part 35? I assume that there's a consensus on that.

CHAIRMAN SIEGEL: I think we agree with that.

MR. CAMPER: Okay. Then can we just finish up then with this issue of "patient," "wrong patient"?

Is there any feeling from the Committee as to whether or not it could be advantageous to attempt to define "patient" or to clarify instead what is meant by "wrong patient"?

And as you ponder that question, I would draw your attention back to that list.

Put the wrongs up there again.

I would like some feeling from the Committee, is there any -- is there anything that goes on that's not being captured by one of the wrongs that would cause us to think that the only "wrong patient" could be the inadvertent patient.

For example, if you give someone the wrong radiopharmaceutical, you know, if Patient A gets Patient B's does, the wrong route of ministration and so forth, is there

anything other than inadvertent patient under "wrong patient" that you're aware of?

CHAIRMAN SIEGEL: I don't think so. Well, getting the doses mixed up, that's the wrong dose.

DR. GLENN: It should be on there.

MR. CAMPER: Camp?

CHAIRMAN SIEGEL: Well, that getting the doses mixed up is the wrong -- actually the wrong dose. Wrong does should be on the list, shouldn't it?

DR. GLENN: It's in the regulations.

CHAIRMAN SIEGEL: So that's what's missing.

MR. CAMPER: Okay, we add wrong dose.

CHAIRMAN SIEGEL: Yes.

If you add wrong does, no, I don't think so.

MR. CAMPER: So does that -- then in turn does that say that we should attempt to define what "wrong patient" is clearly in regulatory language versus defining what "patient" is or is there an advantage to it one way or the other?

CHAIRMAN SIEGEL: I think there's a real advantage to looking at the definition of a patient in reference to the scope of Part 20 and trying to do that in a very broad way in reference to Part 20 rather than getting encumbered with difficult language that people will not agree about.

Yes, Dennis.

MR. SERIG: Dennis Serig, Operations Branch, NSS.

I'd like to point out I'm partly responsible for that figure of 200 in two years. I keep a database or kept a database on nuclear medicine misadministrations for 1989 and 1990.

What I'd like to point out is that over 200 is an evaluative number because "wrong patient" and wrong radiopharmaceutical are quite often confounded.

If a patient who is scheduled for a nuclear medicine study got another nuclear medicine study, that is sometimes reported as a "wrong patient" misadministration.

I did my best, in going through the data, to ensure that what you saw, the 200, were in fact people who were not scheduled for a nuclear medicine procedure at all.

Many were scheduled for some other procedure, a CT scan or some other procedure, an x-ray, for instance.

Some were scheduled for no procedure at all. They simply got the nuclear medicine procedure inadvertently, so there might be some help to distinguishing at least between people that were scheduled to get a radiopharmaceutical dose and those who were not.

CHAIRMAN SIEGEL: Lew?

DR. WAGNER: That's something that I was going to say. If it's not in terms of the risk, then I don't see the advantage because of the fact that it's not in terms of

risk.

It's a matter of it's the wrong patient, and whether or not the patient was scheduled to receive a nuclear medicine study or a CT scan, I don't see the different. It's just the wrong patient.

MR. CAMPER: He's merely clarifying what the numbers were.

CHAIRMAN SIEGEL: What you're not capturing is what about the patient that supposed to have the nuclear medicine procedure and gets sent for a CT scan? Is that an NRC reportable event?

DR. GLENN: No.

CHAIRMAN SIEGEL: I'm sure our friends from OGC would figure out a way to make it reportable.

(Laughter.)

CHAIRMAN SIEGEL: There's some way they can twist the language to make it work.

John.

MR. TELFORD: Yes, John Telford here.

Dr. Siegel, I'd like to see a little clarification to make sure I understand your point, specifically your statement that you would favor defining "patient" in as broad terms as possible.

But let's recall just for a moment that in Part 35, defined medical use means intentional, intentional

misadministration of byproduct material or radiation from byproduct material to a patient or a human research subject under the supervision of an authorized user.

CHAIRMAN SIEGEL: Okay.

MR. TELFORD: The word "patient" is used there. Now, if we were to clarify a "patient," let me give you two alternatives to choose from or you can pick your own.

The patient is an individual who was scheduled for a diagnostic or a therapeutic procedure. That's A.

B, the patient is an individual who has been scheduled for a diagnostic or a therapeutic procedure involving byproduct material. Alternately you could work medical use into that definition.

So would you choose A or would you choose B or would you put in C?

CHAIRMAN SIEGEL: Which one is the answer?

DR. STITT: C is.

MR. TELFORD: C.

CHAIRMAN SIEGEL: But C would be change Part 20 and don't mess with Part 35.

DR. MARCUS: May I just say something?

I am really sincerely sorry that NRC is spending an inordinate amount of user fee money making up problems to solve that are of no health risk consequence at all.

A discussion of a study of what is a patient and a wrong one, I don't -- I think this is way NRC's jurisdiction and it does not have to be done.

And I really feel for people paying that user fee bill when I see NRC making up things to keep themselves busy.

And I think this is an example of something that is of no public health hazard whatsoever. We're wasting a lot of time.

I understand Judy's point of view, and I understand what somebody else said about it. Do you want to go to JCAHO or do you want to change the way medicine is practiced, do something like that, fine.

But NRC's job is radiation retention. And this has nothing to do with radiation retention.

DR. WAGNER: Don't go fiddling around with the definition of "patient." Barry was giving you an operational definition.

He put it right into the reg itself when he said misadministration is the delivery of the wrong pharmaceutical to the wrong patient or to an individual who was intended to be a patient, but he was not prescribed for that dosage.

I mean, he put it right into the reg. You just put it in there. Don't go changing meanings of "patient."

Barry was giving you an operational definition, so I don't believe we should go throw it out.

MR. TELFORD: We currently don't have a definition of "patient" either in Part 35 or in Part 20. You can choose C, which is no definition at all, or you can choose the alternative that you just gave me. I'll change the wording of the definition of misadministration so that it's more clear.

DR. WAGNER: It is quite clear that this is a unique definition applied to that specific rule so that that would be the proper place to put it.

CHAIRMAN SIEGEL: Yeah, but I think the alternative is to change Part 20 to say that the provisions of Part 20 relating to members of the general public do not in fact apply to the intentional exposure of a human being as part of a medical research.

MR. TELFORD: Okay.

CHAIRMAN SIEGEL: Okay. I think does it.

MR. TELFORD: That will work.

CHAIRMAN SIEGEL: That operationally defines that human being as either a patient or a research subject.

MR. TELFORD: All right.

CHAIRMAN SIEGEL: Is that okay?

Lew.

DR. WAGNER: You might run into some difficulty

when you get up into the therapy doses on patients with that kind of --

CHAIRMAN SIEGEL: No, no, then it gets captured as misadministration.

Even if it's a visitor who comes in and gets treatment, that's a misadministration.

DR. STITT: That's happened, too.

MR. CAMPER: All right. We now need to move over to Dr. Holahan who will talk to us about the draft information notice on patient notification.

This is again a follow-up topic from previous discussions. We are preparing or attempting to prepare another information notice, which is round two, if you will, on this subject.

CHAIRMAN SIEGEL: Patricia, before you get into that, I think I'll introduce something.

There are some important legal issues that came to some of the principles that underlay this patient notification discussion.

And I'd like the record to reflect that I made a request to Dr. Paperiello some days ago that one or more of individuals from the Office of General Counsel be here to help us understand the issues from the NRC's point of view.

And we've been told that none of them are coming, are willing to come, or are willing to come and they will

not participate in this discussion.

I would just like to let the record reflect that in the sense of public-spiritedness, I don't find that to be government in the sunshine.

Continue.

DR. HOLAHAN: Okay.

What I'd like to do is first of all tell you how we got to this information notice and sort of give you some of the background.

As many of you may be aware, last year, May 7th, we issued Information Notice 93-36, which was notification records and reporting misadministrations.

And what prompted that information notice was back in January of '93, we had gone to the regions and they had done a survey, data on therapeutic misadministrations over calendar years '90, '91 and '92 and asked licensees how many cases had the referring physician being notified as required under 35-33, what percentage of the cases was the patient actually notified, and, if the patient wasn't notified, was a reason provided for why the patient was not notified, and then finally, in how many cases was written notification provided.

And basically the results of that survey showed that in the majority of the cases the referring physician was notified, 97 percent of the cases.

I think we had 72 misadministrations over that period of time. In 72 percent of those, there was verbal notification of the patient.

Of that, the patients that were not notified, there was a -- in 32 percent cases there was a decision made by the referring physician that it would be in his medical judgment harmful to notify the patient.

In the remaining 68 percent, there were other reasons that included that there were no adverse effects expected, the doses are within an acceptable clinical limits, it was technically not an misadministration.

And then of the patients that had been notified verbally, in 56 percent of the cases, the patient was also provided written notification as is required.

As a result of this, as I say, we issued the information notice, and in addition, we issued a letter to licensees that were not in compliance with the notification requirements.

And following the information notice and the letter, we got several responses back from some licensees, plus there were some issues that had identified internally by NRC that we believed additional clarification was necessary.

The Staff conferred with the Office of the General Counsel on the interpretation of the current

misadministration rule, and, based on the guidance that we received, we prepared the draft information notice that's in your briefing books.

Now, what I'd like to do is just sort of step through the six issues that we highlighted in that information notice.

The first relates to the notification of the patient's responsible relative. In those cases where the referring physician has informed the licensee they notified the patient, there's a medical decision that it would be harmful to notify the patient.

The responsible relative, we discussed in the information notice, "the responsible relative or guardian must be notified even when the patient is a competent adult when there is a medical decision of harm to the patient, the patient is a minor, the patient is unconscious or incapable of comprehending the information, or the patient has died."

And this has been supported by the regulatory history. And I believe that all the members got copies of the proposed and final rules for the misadministration reporting requirements going back to the proposed rule in 1978 where it was expected that the licensee would report to the responsible relative in those instances where they could not report and the patient has a right to know of a misadministration, and that if you cannot inform the

patient, that you should inform the patient's responsible relative.

Well, NRC conferred with the legal counsel at the AMA and discussed the issues of the principles of medical ethics and the duty of confidentiality and the physician/patient relationship and whether this was consistent or the regulation was consistent with these aspects of medical ethics.

The AMA indicated that principles are not laws but standards of conduct. And I'd like to highlight two of the principles.

Principle IV indicates that a physician shall safeguard patient confidences within the constraints of the law, and Principle III states that a physician shall respect the law and the rights of patients.

And the Commission has previously stated that any duty of confidentiality must be reconciled with the patient's right to know of a misadministration. And again, that's within the regulatory history.

Okay. So that's the first issue. Does anybody have any comments at this point, or would you like me to sort of run through the information notice, and then I've got some questions at the end that may be we can address these?

CHAIRMAN SIEGEL: Why don't you go through it?

DR. HOLAHAN: Okay.

Issue 2 related to documentation of a referring physician's decision not to notify the patient, there being some instances where there was an indication that the referring physician had decided not to inform the patient but there was no documentation as to what the rationale was for that decision.

And so what we're trying to clarify here is that if reliance is placed on the referring physician to notify the patient, the licensee should either confirm that the notification has been made or document and evaluate the reason for not informing the patient.

And basically when we're saying evaluate, we're indicating that the licensee should look at that decision and see if it was the referring physician based on medical judgment that informing the patient would be harmful, not for some of the other reasons that I cited earlier.

Also, here that the referring physician may decide not to tell the responsible relative. Well, let's go back a step.

If the referring physician's made a decision that it would be harmful to tell the patient, he or she may also determine not to tell the responsible relative if she or she has knowledge that telling the individual would be harmful.

And there have been some questions that arose as

to whether or not the referring physician, if the responsible relative was under a referring physician's care, how were they to make that judgment.

And it's basically that if they have any knowledge that telling them harmful that we're not looking to go and have the referring physician take that patient under his or her care.

In Issue 3, there was some question, and this was raised more frequently prior to the QM rule being employed, because, as I say, we went back and looked at some misadministrations from '90 through '92, whether or not the licensee was required to provide a written report to the patient if the referring physician had notified the patient.

And the way that the rule language currently is is that the licensee has the responsibility, whether the licensee themselves or the referring physician notifies the patient, to provide that written to the patient within 15 days.

Issue 4, retention of misadministration records. There had been some question as to whether or not there was a requirement to maintain copies of reports after being sent to patients and all records associated with misadministration.

And in a separate part of Part 35, 35.21(b)(2)(xii), which gets into the responsibilities of

the RSO, there's a requirement that the licensee, through the RSO, need establish and implement written procedures for keeping a copy of records and reports required by the Commission.

And since the report to the patient is required by the Commission, then it can be assumed that there is therefore a record, something that must be retained by the licensee.

Issue 5, in many cases there are some incidents that occur that there's a question at the time whether or not it actually meets the definition of a misadministration.

And the way that the rule language for reporting misadministration is written is that the NRC Operation Center must be notified within 24 hours of discovery of a misadministration.

Well, in those cases that there's some question but later on the licensee is informed that, yes, in fact it actually is a misadministration, the licensee is still required at that point in time, upon their discovery that it is a misadministration, to notify the NRC Operations Center.

CHAIRMAN SIEGEL: Just in case anybody doesn't understand that, you get a letter from the NRC that says the event that occurred a year ago has been determined to be a misadministration, when you open that letter, you've got to call the NRC Operations Center and tell them that you've

just discovered we had this misadministration a year ago and we're notifying you of it. It's cool.

MR. CAMPER: Well, the licensee can discover it as well.

DR. HOLAHAN: Yes.

CHAIRMAN SIEGEL: It's always been the licensee. Notification at the time of licensee discovery has always been in the rule. It's just this seems a little bit circular, but it's school. It's in the regulations, and probably isn't worth rewriting the regulations.

It just seems --

DR. HOLAHAN: Well, at this point, we're just trying to clarify this.

And finally, the last issue is there's been some question in the reporting requirement section regarding misadministration or it's referenced to the term "prescribing physician," which is not defined.

And also there has been some question as to who is the referring physician in some cases of misadministrations.

So the Staff conducted a review of the requirements in Part 35 and the associated statements of consideration for the rules, ICRP Publication Number 52, which is protection of the nuclear medicine patient -- I don't believe that's the exact title -- consultation with this Committee, consultation with representatives of the AMA

and AHA, American Hospital Association, and consultation with NRC's Office of the General Counsel.

And based on these views and consultations, I'd just like to clarify that the prescribing physician is in fact the physician authorized user as defined in the definition section in 35.2, who prescribes the radiation dose, the dosage of material for a diagnostic or therapeutic procedure.

And the referring physician is the physician who refers the patient, either to a radiation oncologist, nuclear medicine or other category of authorized user and requests consultation, treatment or diagnostic tests for a patient.

It typically is a specialist, but in some cases, it may be the primary care physician.

CHAIRMAN SIEGEL: We'll come back t this.

DR. HOLAHAN: Okay.

CHAIRMAN SIEGEL: Let's let you finish first.

DR. HOLAHAN: And these are questions that I'd like to --

CHAIRMAN SIEGEL: Let's skip the questions and let's go back to slide one --

DR. HOLAHAN: Issue 1.

CHAIRMAN SIEGEL: Yeah, let's just run through your slides and we'll address the issues from the slides,

and my guess is we'll answer the questions along the way.

DR. HOLAHAN: Okay.

This is Issue 1, and it's notification of the responsible relative in those cases where the patient is a competent, consenting adult and there is misadministration, but it would be medically harmful to inform the patient.

CHAIRMAN SIEGEL: It might -- I actually personally was very, very troubled by this. I was troubled by it at the last minute.

In the process of re-reading all of that material and all the regulatory history, I find myself less troubled about the ambiguity in the rule but more troubled by the fact that the rules seems to be talking out of both sides of its mouth in that there really isn't either/or. In any way, they'll do the rule.

And maybe you just ought to change the rule to say that.

The rule is you are interpreting it, and as you say, the regulatory history shows it, basically says when there's a misadministration, someone has to be notified, either --

DR. HOLAHAN:

CHAIRMAN SIEGEL: No -- well, unless the referring physician is in a position to tell you that not only won't the patient be harmed but the responsible relative would be

harm.

And the questions is, well, surely that responsible relative, possibly him or herself, also have a responsible relative that we could inform, and maybe that person has a guardian.

So why don't you just say what you mean and say you have to tell someone, if that's really what you mean.

Because I think -- because what you're proposing is illogical the way it's currently constructed.

I mean, here if you tell me -- if I tell you I'm the referring physician and I say Mrs. Jones got a 300 millirem or got a dose or misadministration therapy procedure, there's no harm whatsoever, but Mrs. Jones is a very anxious woman, Mrs. Jones is depressed, and we even raise this issue with her, it's going to make her more depressed and upset her, and I don't want to take even that slight risk that that will interfere with the course of her medical care, which I think is going pretty well otherwise; I just can't let it be raised because i think it will harm my patient.

And so the licensee says we agree with you, we've seen Mrs. Jones when she was here for her therapy and she's pretty high-strung and that's a good judgment.

But then the NRC turns around and says I've got to tell Mrs. Jones' husband, who the licensee doesn't know very

well and the referring physician doesn't know very well.

And what does Mr. Jones' husband do as soon as he gets off the phone?

DR. STITT: He tells Mrs. Jones.

CHAIRMAN SIEGEL: He tells Mrs. Jones.

Or you send a letter. In my house, whoever gets home first opens the mail.

(Laughter.)

CHAIRMAN SIEGEL: It doesn't matter whether the letter is addressed to me or the other Dr. Siegel. Whoever is home first opens the mail.

You can't have this rule operate the way you think it's going to operate and really think that you're going to protect the patient.

If you believe that protecting a patient who should be harmed is an appropriate mission for the NRC and its rule, then you've got to change the way this rule is written.

If, on the other hand, you believe that society's purpose is served at all times and in all circumstances by notification, then just say you've got to notify someone.

But right now you're talking out of both sides of your mouth. You can't have it both ways. So that's my position.

DR. HOLAHAN: Let me ask another question then.

CHAIRMAN SIEGEL: Please.

DR. HOLAHAN: I think about a year ago at one of the ACMUI meetings there was a discussion by the ACMUI as to how often the Committee actually believed that it would be harmful to notify the patient.

And I believe at that time the Committee indicated that it was probably very rare.

CHAIRMAN SIEGEL: Quite infrequent, right, so that in a way what we're doing here we're spending again a lot of time and effort about a problem that really doesn't come up very often.

Now, I think that your data show something different, and what your data show is, I think, a misinterpretation of the regulations, but a misinterpretation that is being used by both referring physicians and licensees because they don't necessarily respect the regulation, which is they're translating the words, "would be harmful to the patient," into a different set of words, which is "wouldn't do the patient any good to know because the patient suffered no harm as a result of the event, and therefore why trouble them with it?"

DR. HOLAHAN: Well, that's what I was going to.

CHAIRMAN SIEGEL: And I think many -- if we really analyzed a lot of those events carefully, everything you all have done, that a lot of those non-notifications arose out

of that kind of reasoning rather than the strict of the regulations that said the referring the patient would suffer harm as a result of the notification.

DR. HOLAHAN: But I think we are, even now, still seeing cases that are coming more frequently than you might think that the referring physician the decision that it would be medically harmful for the patient.

CHAIRMAN SIEGEL: And, in fact, going back into regulatory history, if you go back to 1973 and 1978 and documents --

DR. HOLAHAN: The proposed rules.

CHAIRMAN SIEGEL: -- the original proposed rules said you had to notify the patient when there was a likelihood the patient would suffer a clinically defective or adverse effect from the misadministration.

DR. MARCUS: Could cause a demonstrably --

CHAIRMAN SIEGEL: Could cause a misadministration which could cause a demonstrably adverse effect on the patient.

Now, because of difficulty defining that, we went to a much more prescriptive rule saying that whenever there was a misadministration, irrespective of the level of professional harm, there should be notification.

The original approach actually made more sense, but Judy's answer would be it leaves too much discretion to

the physician to decide whether the patient might or might be harmed.

And I understand. I understand that viewpoint as well.

Now, let me tell you another thing that's troubling me, and that is you also have to change the word "relative" or "guardian" to delete the adjective "responsible," because you can't tell me, and I don't care what the lawyers think, you can't tell me that a competent adult has a responsible relative, unless the person is psychotic and is in fact not competent.

My wife doesn't have power of attorney for me. I haven't given it to her. I'm the only one who has power for me, and I really do think that this is a breach of confidentiality.

Now, the rule of law allows you to say we insist on the breach of confidentiality. In that case, get rid of the word "responsible." Make it clear that you mean for someone to be informed under all circumstances.

But then add one more thing to your regulation. Put in a provision that protects the referring -- protects the physician from this breach of confidentiality.

Some laws that require reporting like infectious disease laws and things like that have a provision that protects against the breach in confidentiality.

Maybe it's somewhere else than in the NRC regulations.

DR. HOLAHAN: Well, I think in the discussions with the AMA legal counsel, as I had indicated, that in those cases where there is a breach of confidentiality to notify to comply with the law or regulations is a law, then they are protected on that basis.

CHAIRMAN SIEGEL: It would be even clearer if it was built into the NRC regulations. It provides a much quicker way of dealing with a tort lawyer if you can simply hold an NRC regulation up and say, see, I did it for this reason, because, you know, sometimes there's going to be issues where the patient and the responsible relative are in fact people who hate each other.

They can be separated, estranged, but nonetheless the husband is the responsible relative or the wife is the responsible relative.

And that breach of confidentiality now turns into an actual injury, at least in the patient's mind. And the physician and the licensee need some protection from that if they're compelled to do it.

And it sounds to me like your intent is to compel us to do it.

Tom Greeson from the ACR is at the microphone, but anyone from the Committee first?

(No response.)

CHAIRMAN SIEGEL: Tom. Please identify yourself.

MR. GREESON: My name is Thomas Greeson. I'm General Counsel for the American College of Radiology, and I came to listen to this discussion, not claiming any expertise in the NRC rules.

But at the ACR we have within the legal department of the College, spent an enormous amount of time evaluating the relationships between radiologists and referring physicians and the relationships in their institutions. And it's in that regard that I comment about this proposed notice.

I think Dr. Siegel raised most of the questions that we intended to try to respond to regarding a notice of this type being developed.

One of the concerns that I have is that I just heard you say, Dr. Holahan, that it implied that the American Medical Association had been consulted with respect to this notice and actually had in fact concurred in the recommendations that are going forward.

And I guess that causes us some concerns as to whether or not in fact, the AMA could be construed as having actually recommended that this notice is appropriate, particularly the discussion you just had about the issue of notification, mandatory notification and the issue of

immunity, qualified immunity or whatever and whether the AMA felt that that was adequate protection from potential tort liability for prescribing physicians, licensees that are required to make this kind of notification to the so-called responsible person of a competent patient when the referring physician has determined that it's not in the best medical interest of the patient to be informed.

Dr. Siegel is absolutely correct that in laws that entail reporting that there is normally built into the statute an absolute or qualified immunity protection.

In the area of insurance fraud, most insurance companies are required to report to law enforcement officials, the State Attorney General's Office, or some other law enforcement investigator.

If they have, in the course of their investigation claim, uncovered a criminal act, they are required to report that to the appropriate law enforcement official.

And each of those laws normally contain a very specific provision that says there is absolute immunity from any liability, defamation, slander, whatever of the reporting entity to the law enforcement agency. And that type of legislation is very, very common.

I guess the concern one has is the potential effect this has on the confidentiality of the information when the referring physician has informed the prescribing

physician that it's not in the best interest of the patient to learn.

And, as Dr. Siegel indicated, once a so-called responsible person is told, how does one ensure that confidentiality will be protected?

Also a concern one may have is to what extent can the prescribing physician or the radiologist, the nuclear medicine physician, the radiation oncologist intrude into and actually second-guess the decision-making of the referring physician.

I guess I understood what you were talking about, that there was some additional layer of inquiry of the referring physician as to whether or not they have actually made a legitimate decision.

You have to have some inquiry to their decision-making processes. Once the referring physician says to the radiologist, the diagnostic radiologist, the nuclear medicine physician, it's not in the best interest of this patient -- I'm concerned. It's not in the best interest for the patient or his responsible relative or their responsible person to know about this misadministration.

Does the diagnostic radiologist, the nuclear medicine physician, the radiation oncologist, have a duty to go beyond on that and start inquiring as to whether or not that actually was a decision that they made that was

appropriate to that patient and the specific physician -- that second-guessing is an issue of concern.

I guess the primary point that I would like to make and the question I would have for the NRC is, was there a question about whether or not this in fact a new ruling?

This is the kind of thing that strikes me as going right to the heart of the relationship between patients and their referring physicians, and it very much brings into question that relationship.

And, frankly, those relationships are very important to physicians, hospital-based physicians like radiologists and nuclear medicine physicians and radiation oncologists.

They have to nurture those relationships. And to the extent that they are involved with having to provide notification in this fashion, potentially breaching the request of the referring physician had requested of them to maintain the confidentiality of this information is of great concern. That's why I asked.

But, frankly, this strikes me as something that's in the realm of new rule or law, new policy-making that perhaps deserves a more rigorous investigation before a notice is issued and some consideration is given to the former rulemaking in this area.

Thank you.

DR. HOLAHAN: I jsut wanted to clarify one point. First of all, the AMA has not seen and concurred upon this notice.

I mean, I don't want to give any misperceptions that they have reviewed and concurred upon it.

MR. CAMPER: Let me just add one point for clarification. This is an information notice. This is the second information notice on this topic being prepared by the Staff.

The purpose is to provide clarification to the regulated community on issues that have surfaced about this topic overall since we issued the last information notice that Dr. Holahan referred to.

This information notice, this draft information notice that you have has been discussed with you by our Office of General Counsel.

What we will do at this meeting, of course, is go back in the transcript and we will identify these key areas of legal comment that you have raised, and we will again discuss it with the Office of General Counsel as to the legal merits of your points before we issue this information notice.

CHAIRMAN SIEGEL: Carol.

DR. MARCUS: I object to using any guidelines as some sort of law to be interpreted by the Office of General

Counsel of the Nuclear Regulatory Commission.

And I don't think OGC is necessarily qualified to interpret AMA guidelines and AMA guidelines are not legally binding. That's the first thing.

I notice that the representative from the Institute of Medicine is still here. I want to just read a sentence from the Atomic Energy Act to put this in perspective.

This is about issuing licenses for medical therapy. "In issuing such licenses, the Commission is direct to permit the widest amount of effective medical therapy possible for the amount of special nuclear material available for such purposes and to impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect the health and safety of the public."

But I think the real question is whether NRC belongs in this whole arena at all. I do not think it does.

CHAIRMAN SIEGEL: Never missing an opportunity to move to a broader issue.

(Laughter.)

CHAIRMAN SIEGEL: Dennis.

DR. SWANSON: The point raised previously, it brings up an interesting question, I think, and it skips ahead to Issue 2, is the requirement of the licensee to

document the reason why a referring physician did not want the patient told.

Does that present problems with regard to confidentiality between the referring physician and the patient?

In other words, if the patient had a psychiatric illness that was known to the referring physician, is it the right of the licensee to have that information or request that information?

DR. HOLAHAN: When we're indicating document and evaluate -- if I can answer this, basically the way the regulation is is that the referring physician, it's based on medical judgment that in his or her opinion telling the patient would be harmful.

That is pretty much the documentation that we're looking at is the referring decision has made a decision that telling a patient would be harmful not as to the detailed evaluation of exactly what they mean by harm, but what we're saying in terms of evaluation, not that the referring physician has just decided it wasn't in the patient's best interest.

The question is, would it be harmful to tell the patient?

CHAIRMAN SIEGEL: But that's like -- document and evaluate reason.

DR. HOLAMAN: That's right. And any information, in other words, would have --

CHAIRMAN SIEGEL: You mean evaluate relative to the regulations.

DR. HOLAHAN: Regulations.

CHAIRMAN SIEGEL: So if a referring physician writes a letter that says today I spoke with Mrs. Jones or today I have decided not to inform Mrs. Jones and request that you not inform Mrs. Jones because in my medical judgment, it would be harmful to her to do so --

DR. HOLAHAN: That's correct, yes.

CHAIRMAN SIEGEL: -- that is sufficient. All right.

DR. HOLAHAN: And in the draft information notice we have a footnote that says basically just making the decision, looking to see that it's a decision based on medical --

CHAIRMAN SIEGEL: At which point, the licensee is not compelled to write a letter to Mr. Jones, right? Right?

So you've got to change the rule. You've got to just say what you mean. If you want us to tell all the time --

And the other thing is tell me what a responsible relative is. Tell me -- let's say Mrs. Jones has no spouse, has no children, but does indeed have a third cousin in

North Dakota who she hasn't seen in 40 years. Is that her responsible relative.

DR. HOLAHAN: You've got a valid point, and I don't know.

CHAIRMAN SIEGEL: Her only living kin.

I really, I just think you've really got to decide what society's purpose is here and then you've got to say it straight out.

We'll argue with you when you finally do say it, but right now you're talking out of both sides of your mouth.

(Laughter.)

CHAIRMAN SIEGEL: And I don't mean you, Pat. I think the NRC is the --

This seems to me straightforward, and you've already said it was the licensee's responsibility to do that.

Is it -- can the licensee give the written report to the referring physician who gives it to the patient?

DR. HOLAHAN: Yes, yes. It just means -- there was some question that, well, the referring physician told the patient, I didn't so therefore, since they told him, I did not have to send it.

Well, the licensee must ensure that the patient gets a copy of the written report. Maybe that's a better

way to say it.

CHAIRMAN SIEGEL: A question about this one. The retention record for misadministration reports is five years, is that right?

DR. HOLAHAN: Yes.

CHAIRMAN SIEGEL: And what about all the background documents that relate to the misadministration?

In reading through this, I got confused about whether any of those might be captured by this, that whatever documents that the licensee might have gone through, hospital records and other things that led to the report, is that --

MR. CAMPER: My guess is you get on with the point, because even some of our own records have retention times and I think this makes the other records as well. I mean, those are controlled by state statute. They may have been a part of the misadministration investigation. It's a problem area.

DR. GRIEM: What about state regulations? Some of the retention times are different, aren't they?

CHAIRMAN SIEGEL: Well, obviously when they're different retention times, the longest one wins.

(Laughter.)

CHAIRMAN SIEGEL: If the state says destroy it in three years and the NRC says keep it for five, you'd better

keep it for five. This is silly but funny.

(Laughter.)

DR. HOLAHAN: Do you want to go on to the next one?

CHAIRMAN SIEGEL: Yes. Because actually I do have a problem with the next one.

The word "prescribe," and I'll defer to Dennis and/or Carol to help me with it. The act of creating a prescription sounds to me like something very specific, and the physician authorized user may have done nothing more than write the procedure manual that says when you do a bone scan, this is how you do it and this is the dose of radiopharmaceutical.

It's not clear to me that that constitutes a prescription the way you've defined it here. It may. Certainly it's consistent with what authorized users do, but you need to be careful that you're not creating a new box that you didn't mean to create to confine us in.

DR. SWANSON: You could change that to "determines," and it would be more appropriate.

CHAIRMAN SIEGEL: "Determines" would be. I think "determines" would be fine.

DR. GLENN: Let me briefly make a point. In most cases where we have a misadministration, it is going to be one that requires a written directive.

In a case where a written directive is prepared, is there any ambiguity there?

CHAIRMAN SIEGEL: No. When there's a written directive, there is a directive.

(Laughter.)

CHAIRMAN SIEGEL: I chose not to use the word "prescription" because we've had this discussion.

(Laughter.)

CHAIRMAN SIEGEL: Mr. Telford will remember, no doubt, those discussions.

But "determines" would be a neutral word that would capture most every directive and diagnostic misadministration that don't involve directives.

There will occasionally be a patient who gets 500 millicuries of technitia MDB, the entire generator somehow, and it ends up being a misadministration, not too often, we hope.

Oh, and the thing about referring physician, typically is a specialist. Strike that. A, not true, and B, not necessary.

DR. HOLAHAN: Okay.

CHAIRMAN SIEGEL: Do you all agree with? that?

DR. STITT: Absolutely. It's usually the primary care physician --

CHAIRMAN SIEGEL: It's usually the primary care physician.

DR. STITT: -- particularly in the new scheme of things. There won't be any specialists.

DR. MARCUS: It's frequently the same as the prescribing physician. Many people in nuclear medicine follow the patient's thyroid condition or primary thyroid -- and determine when it's time to prepare these, so it's all the same person.

DR. HOLAHAN: We were thinking of cases, for example, radiation oncology, where you may be seeing a specialist.

For example, women may be going to a gynecologist that refers her to the radiation oncology department is where we were.

You believe that that's just unnecessary in this definition?

CHAIRMAN SIEGEL: I'm sorry? What? Say it again.

DR. HOLAHAN: That last sentence. You indicated that it was unnecessary?

CHAIRMAN SIEGEL: Oh, about it's typically a specialist. You don't need that at all. It's irrelevant to the definition, and, in fact, it's not correct, because it's typically a primary physician.

Okay, specific questions on this. Are there

specific aspects of the information notice which the ACMUI -- I think we've gone through those.

DR. HOLAHAN: Yeah, I think -- you've sort of gone through those one at a time.

CHAIRMAN SIEGEL: Does the ACMUI -- 1979 medical policies? Carol says no. Where is that policy statement --

DR. HOLAHAN: Oh, yeah, we do have the -- I'm sorry. Thanks.

The first two items, the policy statement. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the safety of radiation safety workers and the general public, and the NRC will --

MR. CAMPER: The --

DR. HOLAHAN: -- the radiation --

MR. CAMPER: I'm sorry.

DR. HOLAHAN: -- safety of patients, where justified by the risk of patients and where voluntary standards of compliance with standards are adequate.

And the third item on that is the NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be part of the practice of medicine.

CHAIRMAN SIEGEL: It's not real consistent.

(Laughter.)

DR. MARCUS: I think part two and three are not.

DR. HOLAHAN: I was going to say, which aspects?

CHAIRMAN SIEGEL: I mean, the real issue is the NRC actually was closer in the way it should have been would be the original proposal, which is where demonstrable harm - -

DR. HOLAMAN: Clinically adverse effects.

CHAIRMAN SIEGEL: And in this case, it will be where justified by the risks.

I mean, the best example of patient notification are some of these brachytherapy things where parts of the body that normally would have gotten exposed as part of the treatment anyway are getting a little bit more exposure because the source was in this position for a second and there is no overall effectiveness, equivalent change. There is no change in the overall risk from the therapeutic procedure.

Here's a clear example where notifying the patient by compulsion becomes kind of silly. It's not justified by the risk to the patient and it just becomes an irritation.

Is it appropriate for the NRC to have the data about the event because it might be a signal of generic problems with the device, with the procedure, with the way people are quality-controlling things? Absolutely.

Must the patient be notified of those circumstances? Probably not.

And so I think one of the issues that you may want to look at is whether the thresholds are set correctly for all types of misadministrations.

For example, wrong site. Does the wrong site always require reporting or does it have to be wrong site with the radiation dose being some significant fraction higher than a dose for that site would have otherwise been?

DR. HOLAHAN: Yeah, apparently there's no threshold --

CHAIRMAN SIEGEL: Apparently there's no threshold.

DR. HOLAHAN: -- in the regulations.

CHAIRMAN SIEGEL: And in fact, you can extract wrong site to the point of absurdity, which is, as I was pointing out this morning, if a dose to the thigh as a source is moving into an applicator by a remote afterloading system is normally supposed to occur at a certain rate, and for some reason occurs at half the rate, it's slower, then the wrong site got an unnecessary dose.

And you could make that argument infinitesimal, and eventually it really gets very silly.

DR. GRIEM: In about 1974, thanks to Eastman Kodak, we recorded each treatment on Hodgkin's Disease for a year with a special film they had developed.

So we then scored all those films, and there were lots of them. One of my residents, he looked at every one and scored them for patient error, physician error and technician error.

Patient error was that the patient moved during the treatment. He found that as an error about 15 percent of the time.

Physician error was that he didn't know whether it was A or B. And we had one physician out of 6 who was not very good.

And then we had technician error that consistently this one technician -- it was an interesting study.

And it seems to me why you really look at errors or misadministration if you call it that is that they do occur, the patient may move, and when we document it, should we report it? Should we tell the patient you screwed up, it's not our responsibility and turn the machine off?

So there are more errors our there than are being reported if you really look for them. And it seems to me some of this, there's nothing you can do about it.

We couldn't figure a way around some of these errors.

CHAIRMAN SIEGEL: The ones to look for are the ones that happen.

DR. GRIEM: That's right.

CHAIRMAN SIEGEL: The ones that harm people, not the ones that don't.

DR. GRIEM: The interesting outcome was that we looked at these errors and then five years later said, well, did the patient's outcome, was that affected by this? And some of them are.

CHAIRMAN SIEGEL: Okay.

MR. CAMPER: That's it.

DR. HOLAHAN: That's it.

CHAIRMAN SIEGEL: That's it?

DR. HOLAHAN: Yeah, move on.

CHAIRMAN SIEGEL: Any other comments? Interesting discussion here.

I'm going to take a 10-minute break.

(Brief recess.)

CHAIRMAN SIEGEL: Are we ready to resume again?

All right, next, actually I would really like Judy here so we can continue this discussion.

The discussion of the American Osteopathic Board of Radiology certification. Larry.

MR. CAMPER: Okay, just a background before we actually get into the particulars of the American Osteopathic Board of Radiology, for the audience and the record, Part 35 contains certain board certifications that NRC recognizes as being sufficient to meet certain levels of

training and experience that have been deemed to be minimally acceptable to protect all the public safety, and a number of board certifications is listed.

And from time to time ,a certifying body will come to us and ask that their certification or that a new certification be recognized or approved in our regulations. We have such a request from the American Osteopathic Board of Radiology.

What we do in this case is that first Staff will review the board certification process to make a determination if it meets guidelines that have been discussed or established in the past and if it is essentially consistent with or equivalent to other board certifications of the same modality in question.

Once we do that, we then bring it to the advisory committee on the use of isotopes and ask this group for its opinion as to whether or not it should be recognized for some certification for the reasons requested.

So, with regards to this particular request, the American Osteopathic College of Radiology, the AOCR, requested recognition in CFR Part 35, diplomates in the American Osteopath Board of Radiology. The letter is dated May 25, 1990; July 26, 1990, NRC.

An individual certified by AOBR are currently recognized in 10 CFR 35.910, training for uptake, dilution

and extrusion studies, and 10 CFR 35.920, training for imaging and localization studies.

NRC responded that diplomates of AOBR would be recognized in the demonstration of training and experience sufficient to qualify also in 10 CFR Part 35.980, safety officer.

Now, the American Osteopathic College of Radiology, in a letter dated August 4, 1993, requested recognition of diplomates certified by the AOBR, 10 CFR 35.930, training for therapeutic use of radiopharmaceuticals.

AOCR submitted the following documents in support of their request. Number one, basic standard for residency training in radiation oncology; and, two, general information of candidates, Radiation Oncology Certification Examination.

These standards were reviewed against other board standards currently recognized by NRC in 10 CFR Part 35.930.

The Staff requested additional information on March 21, 1994. AOCR submitted additional information. The letter is dated April 22, 1994, and April 26, 1994. And those standards and subsequent letters are contained in your briefing booklets.

The Staff has reviewed this information, and has

determined that it does lead -- it is equivalent to other board certification which has been recogrized to satisfy the criteria required in 35.930.

And, consequently with that piece of background, we ask the question as to whether or not the basic standards of certification by AOBR will meet the minimal training requirements of 10 CFR 35.930 in this Committee's viewpoint.

And, if so, should certification by the AOBR be recognized in NRC document 10 CFR Part 35.930?

CHAIRMAN SIEGEL: Okay, just to clarify now, the AOBR certification in radiation oncology currently has gained status with respect to brachytherapy and teletherapy. I just wanted --

MR. CAMPER: That's correct.

CHAIRMAN SIEGEL: And AOBR certification in diagnostic radiology currently has gained status with respect to uptake, pollution and excretion studies and diagnostic imagining.

MR. CAMPER: That's correct.

CHAIRMAN SIEGEL: And the request here is for the AOBR certification in radiation oncology to have deemed status for therapeutic use of radiopharmaceuticals?

MR. CAMPER: That's correct, under 35.300.

CHAIRMAN SIEGEL: Good.

Carol.

DR. MARCUS: I just have some questions. In Article 4, "Program Requirements," page 5, they say, down the middle of the page, they're talking about general educational requirements.

These are to train the basic radio -- handling techniques under the direction of a qualified radiation physicist, 200 hours.

Then they list four categories and they add up to exactly 200 hours. And is this in addition to the 200 hours of handling techniques, or is this what they're calling them, radiation physicists -- These, the 200 hours, are there 200 hours of handling techniques?

CHAIRMAN SIEGEL: This is an Article 4, Subsection C, Item 2; right?

DR. MARCUS: Okay, so I was just wondering. Those 200 hours of -- it looks more like lecture material. It doesn't really say any --

On the next page, Item 8, where logs are kept for all these therapies, I wondered if anyone had ever checked the logs to see if these radionuclide therapies were in there.

And then on page 7, item E1, they're talking about supervised clinical experience that includes the use of I-131 for diagnosis of thyroid function.

There is a diagnosis too and there's a limited role for I-131 these days in the diagnosis of thyroid function.

CHAIRMAN SIEGEL: No, not prior to the therapy with I-131. I mean, most people do a thyroid uptake before they treat hyperthyroidism.

DR. MARCUS: Oh, yes.

CHAIRMAN SIEGEL: If that's what you're talking about.

DR. MARCUS: Well -- Okay, then, you know, it sounds like if they're going to do any diagnostics things too, and I just wanted to see if that was here.

So, any clarifications on the logs, on the 200 hours --

MR. CAMPER: On the 200 hours, I agree. It's ambiguous. We were trying to find Trish Holahan. I believe it's 35 percent in comparison to the other certifications.

DR. GLENN: Carol, if your question is, "Have we inspected these programs?" the answer is no.

DR. MARCUS: Okay, thanks. A program like this was aimed as your minimum standards is kind of interesting in itself.

MR. CAMPER: Well, it's not that their program is aimed at meeting our minimum standards. Their program is aimed at having their board certification listed as a

recognized certification to meet our requirements.

DR. MARCUS: Yes, but in order to justify why that should be the case what they list as what is given in their diplomates just happens to be your minimum standards.

CHAIRMAN SIEGEL: Well, actually, Carol --

DR. MARCUS: Like --

CHAIRMAN SIEGEL: The 200 --

DR. MARCUS: Right.

CHAIRMAN SIEGEL: The 200 hours though actually exceeds the minimum standards currently in 35.930, which only requires 80 hours of classroom experience.

Let's see. What they are doing is related to but not identical to what's in 35.930, which says the alternative board certification "has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals and supervised clinical experience as follows .."

And that includes the 80 hours of classroom and laboratory training that includes radiation physics and traditionally in connection with the mechanics of radiation biology, and supervise clinical experience under the supervision of the authorized user of a medical institution that includes ten hyperthyroids and three thyroid carcinomas. That's 35.930.

They are incorporating the 80 hours required for source therapy, along with the didactic training that they require as a minimum as part of a residency program.

Now, whether the overall amount of training and experience they're required to take as a residency program is sufficient is a different question, as part of the three-year residency program in radiation oncology. Do you have a clarifying point?

MR. CAMPER: No.

CHAIRMAN SIEGEL: Okay.

Are there comments on this?

DR. SWANSON: I just have a question. What they have is consistent with 35.930.

Are we saying that they're limiting their therapy to I-131s? We may be getting ahead here. I don't know what we're going to do for training requirements with things like Strontium 89, P-32, chlorydal phosphate, et cetera, but that is an item of concern.

CHAIRMAN SIEGEL: At a previous meeting we said that Strontium 89 therapy in safety training and experience required for the Strontium 89 therapy was covered by the training and experience required. That was incorporated in either of the I-131 categories, hyperthyroidism or thyroid carcinoma.

And so we, I think at previous meetings, I think I

recommended to the NRC that no regulatory patch was required at the present time.

We did acknowledge that when it got into the one and half curie therapies with I-13, monochromial antibodies that some additional look at what's going to be required would be necessary.

MR. CAMPER: Yes, but the -- they are granted for recognition of 35.930, the materials listed in 35.300, which is therapy uses. That would include Strontium 89 therapy.

CHAIRMAN SIEGEL: And P-32.

MR. CAMPER: And P-32.

CHAIRMAN SIEGEL: Both intercavitary and -- even though the actual training was only documented with I-131.

I have a different concern from the one Carol raised, although I think she raised a good one.

We have two sets of documents here. We had a document that was signed off by the AOCR in October '92 and by the AOA -- and that's the American Osteopathic Association, alpha omega alpha -- in 1993.

And those standard included the mention of radionuclides therapy in the purpose and the definition of radiation oncology, osteopathic radiation oncology, but they did not include a section, Roman numeral four, subpart E, that says this is the training and experience that's required.

It was after that that the AOCR made its request, and I think it was told by the NRC that they needed to send more information.

So their standards for a training program were modified. And the document, the AOA document approved 4/94 and the AOCR approved 10/93, that's the version that's up front, now includes this section of Roman numeral four, subpart E, that says you got to do this and you have to do ten of these and three of these.

Okay. For those of you who are involved in any way with the activities of the ACGME, a change in the special requirements for a training program is approved by the ACGME. That's the Accreditation Counsel on Graduate Medical Education.

There usually is a minimum one-, often three-year lead time for training programs to become compliant with that change in the special requirements.

So it seems to me that the osteopathic radiology training programs have changed their special requirements in anticipation of a need to fulfill a contractual commitment to the NRC in order to achieve deemed status.

And the question I would ask is what is the evidence that the training program is going to achieve that, that they are in fact currently in compliance? How many programs are there? Are they in compliance? And what

should the real start date of this deemed status -- When should it be? And should any grandfathering whatsoever should be permitted, given the program requirement was only changed sometime in the last month?

MR. CAMPER: You have two points there. First, in regards to, what is the guarantee that in fact these changes have been implemented and are ongoing at this time, it's a problem that we would have across the board with any certification that we would accept.

In other words, we do not inspect the certification program. We review them. We ultimately approve them with input from this body based upon the submitted program.

We do not inspect them as a condition of acceptance nor do we inspect them in an ongoing fashion to see if they are in fact doing what it is they said they would do.

We either accept the certification based upon the submittal, this Committee's review, or we do not.

With regards to grandfathering, we certainly could establish a date from which diplomates concluding this program would be accepted for certification.

DR. MARCUS: Considering your tremendous preoccupation with radionuclide therapy misadminstrations, it would seem to me that the most important decision you

make is who you're going to let do the --

And then, although maybe you're not in the habit of actually inspecting some of these programs to make sure their claims are valid, maybe you ought to because it seems so sloppy on this end and so overpoweringly nitpicky on the other end that some balance is reasonable here.

You're very concerned with them management of medical programs. Many people have said that, Well, as far managed programs, you really don't understand what's involved very well.

And this is the place where you make clear that the educational requirements are for real.

I'll tell you, Larry, if the word got out that you were actually looking at some of these residency programs to make sure people were telling the truth, there would be national consternation in a lot of medical training programs.

MR. CAMPER: Well, the issue of training and experience is something that will be revisited again as we move ahead here with a medical management plan, as we ultimately revise Part 35. That's an issue we can explore as a part of the process.

I think that the reason, in all candor, that we have not inspected these programs in the past and so forth is that I guess, in all honesty, we have believed the

certified organizations.

I'm not sure there is any reasor not to have confidence that what they submitted to us was in fact -- was true, and that they were in fact conducting the programs accordingly, but perhaps that's naivete on our part.

CHAIRMAN SIEGEL: Without getting into the issue of -- with respect to training and experience, we'll do that another time.

I think I would suggest that what we may want to do here is to tell you that on paper these programs are likely to meet your minimum requirements, but that you probably shouldn't accept certification by this board as deemed status until three years from now, because these requirements have not been part of the special requirements of this board certification until April 1994.

DR. BROWN: Aren't you talking about one little item, E?

CHAIRMAN SIEGEL: Yes. That's the item that relates to this medical activity.

DR. BROWN: So you're saying it's a big part of it and everybody agrees with?

CHAIRMAN SIEGEL: No, not at all. Item E is the essence of this particular medical activity. This board already has deemed status for a much larger fraction of what these diplomates will do as far as the practice of

teletherapy and brachytherapy therapy.

MR. CAMPER: With regards to the three years, you're saying that based upon that that's the length of the residency?

CHAIRMAN SIEGEL: Yes, that's the length.

MR. CAMPER: Well, could there not be diplomates currently in a residency program that have accomplished this element?

CHAIRMAN SIEGEL: Only if -- yes, it's possible, but from a deemed status point of view can you document it?

The point is let's say that the way the therapy rotation normally would be accomplished is that it's done in a two-month period in the first year of a training program.

Third-year residents aren't going to get the opportunity now unless programs make special adjustments regarding the program.

And I just can tell you that, I mean, when the Medical Board of Radiology makes a change like this, they announce that they're not going to examine in this change or this changed topic area for four years.

So everybody currently in a program has a chance to remove down the cohort and the first people examined are those who enter the cohort to whom these are requirements apply. I think I said that correctly.

Peter?

DR. ALMOND: Well, there's a couple of points. Historically I think these, you know, you pointed out the two areas where they are competent by reason of their certification.

And, as far as we know, they have always performed well. There's no indication that in the applicable association has done anything but excellent medicine.

And in the past, when we have reviewed specific cases that have come through, I think in general historically they have always met up to the standards. So I don't think there is any reason to doubt what they put this in place that they will be anything but qualified --

CHAIRMAN SIEGEL: Correct.

DR. ALMOND: -- to do the work. And I think we need to say that. I don't think we're doubting.

CHAIRMAN SIEGEL: I agree completely.

DR. ALMOND: And there is a mechanism now, of course, that for them to send in their records to show that they have done certain cases to gain approval by the NRC.

Or, more often, as in our case, it's at a state level where they'll have their preceptor statements and how many cases of this, that and the other they've done. So there is a mechanism in place for that.

But I would very strongly recommend that we accept this after the three-year period. I don't think we

historically have any other reason not to.

DR. BROWN: I again was wondering about the three years. That seems a little extreme. And I don't understand the politics. All I know is a vague "MDs don't like osteopaths."

CHAIRMAN SIEGEL: No, that's not true. This has nothing to do with nuclear medicine versus radiation oncology. You're missing a much bigger turf issue here, MDs versus osteopaths.

(Laughter.)

DR. BROWN: I need to know some background here.

CHAIRMAN SIEGEL: But, forget the background. This has to do with paper trails. And there's an appropriate paper trail that needs to be in place when a training program is going to change, and that paper trail needs to change both in relationship to what people are examined in and what they hold themselves out to be to the general public.

The paper trail also needs to change with respect to the deemed status created by the Federal agency.

If this board is prepared to state that as of this day they are requiring program directors to certify at the time when candidates are admitted to the examination that their candidates are having this training, then you can do it tomorrow.

But I think you need more information from the board as to whether these training requirements are really in place already.

DR. BROWN: But if that candidate were to get the training under E, how long would that take? Would they just add it on? I mean, three years seems --

CHAIRMAN SIEGEL: No, the three years is not to do the training. The three years is based on --

DR. BROWN: No. Right, the candidate couldn't be --

DR. GLENN: I wonder if I could clarify this for you, Judith, and that is that this in no way locks this individual out of being approved as an authorized user.

All it says is the paper trail that has to be presented has to be presented by the candidate rather than simply referring back to his certification.

DR. BROWN: Oh, that clears it up. As long as it you're not locking --

CHAIRMAN SIEGEL: Oh, no, absolutely not.

DR. BROWN: Thank you for clearing that up.

CHAIRMAN SIEGEL: It's just a mechanism. It's just whether you simply present your certificate or whether you have to complete a preceptor statement and have someone sign it that says, yes, you have this training.

DR. BROWN: Okay. Thanks.

CHAIRMAN SIEGEL: The point of deemed status is that it's in lieu of the latter step, because it's assumed that the board and the residency review committee has already taken all those steps for you.

Bob, you had a comment?

DR. QUINLIN: I was just going to say that typically when the American Board of Radiology imposes some new requirement, they give a three-, four-, five-year warning on it.

And that is designed so that you can change your training program so that the residents can get the necessary clinical experience and also to get the necessary training in the lectures and so forth and so in that particular area.

And the clinical experience is very important because it says you dealt with so many patients at a certain condition, and you just can't call in ten patients and say, here are ten patients with this clinical condition. It's when the present themselves to the hospital.

And then the resident has the opportunity to see the patient and see the treatment and pursue this from that. So it's a subject just can't initiate overnight.

CHAIRMAN SIEGEL: Any other comments?

(No response.)

CHAIRMAN SIEGEL: So have we achieved a consensus then that the special requirements for this residency

program as it's currently laid out are consistent with the requirements of Part 35, the issue that's open is when timing of deemed status should granted.

And it is conceivable that if you have further correspondence with this board, they can document to you that they've implemented procedures that would allow you to go ahead immediately or they can make it clear that have not instituted those procedures, when in which case three years might be the soonest you can go ahead.

MR. CAMPER: That's clear.

CHAIRMAN SIEGEL: The next item, status reports. First, Kitty Dragonette is going tell us about patient release criteria.

Dr. Marcus is not able to speak to the next two items as a member of the Committee. If I feel like it, and I may not, I may recognize her as a member of the general public. I'm not going to make her leave the table, however. Okay?

DR. DRAGONETTE: I hope this is going to be quick.

Well, there's good news and I think you could use some, and some with which you can agree.

Since your book was put together, the Commission did act on the pending Commission paper on patient release.

As you recall, you've been briefed on that a

number of times, and the paper that was pending basically took the position that Part 35, not Part 20, governs when you can release a patient from your institution.

And it was proposing modifications to Part -- section 35.75 of Part 20.

The "Staff Requirements" memo was issued May 11th. It approved the whole package that was pending without change.

That package included the proposed the rule text, the regulatory guide and the NUREG with the details of the cost and the decision rationale that we call a regulatory analysis.

All of those documents are in the process of being -- doing our internal things to get them published, and you should see them in just a few weeks.

I've been working this week scrounging with computers as best we could, but it just takes some time to get things through the system to get them published, but there are no issues to resolve.

And what that means as a practical matter is that the Commission endorsed what was in the February information notice that 35.75 governs the release of patients, not Part 20, so that means your 30 millicuries and 5 MR per hour provisions are governing until this rulemaking is concluded.

I've reviewed very quickly what was in the

proposed rule package as it was approved. First of all, Part 35 does prevail, but then the second part of that was proposed modification to 35.75, which would provide that you could release licensees from licensee control if the total effective does to an individual is not likely to exceed 500 millirem in a year.

And that is a prospect, is likely to. It's done based on calculations and estimates.

It also has some associated requirements that if the projected dose would exceed 100 millirems in a year, then you should give instructions to the patient for keeping the doses to members of the public as low as reasonably achievable and keep records associated with that for three years.

It also has a provision to formally amend and codify this in Part 20, 20.1301-A and it would amend both 1301-A1 and A2, so that doses received from members -- doses received from patients that are released from the licensee's control do not have to be considered in complying with the 100 milligrem a year public dose limit or the 2 millirem per hour dose rate.

And there was also a couple of cross-references to this proposed section 35.75 and 35.315 and 35.415.

One new issue that was in the preamble and in the regulatory guide that I don't think you were aware of was

that in evaluating the potential exposures to an individual, the nursing infant should be considered and evaluated.

In other words, that you would need to determine that whether or not the patient was nursing, and then, if so, deal with that so that nursing infant would not be likely to get more than 500 millirem in a year.

And that's to say that's in the preamble to the rule in saying that what we mean by an individual, and it's in the regulatory guide in the same sense.

And the regulatory guide includes three basic components, one of which is a table by radioisotope, giving the radiation level and the quantity for both 500 and 100 levels, so that's your quick-and-easy way to demonstrate compliance. You can look it up in the table. It also includes additional guidance on instructions and guidance on evaluating on a case-by-case that an individual is not likely to get more than 500.

CHAIRMAN SIEGEL: Are those tables all based on the patient who gets a sealed source or any of them --

DR. DRAGONETTE: That is an assumption -- in looking through it, we determined that for those listed isotopes and what's going on today, we felt the internal contribution would be small enough you could ignore it. So those -- the table is the -- the patient --

Now, the case-by-case or, you know, if you exceed

the quantities in the table, monochromials or something, then you'd have to go to the case-by-case evaluation and you might have to consider the potential for internal -- significant internal uptake, but it was found to be small enough to ignore for the purpose of the proposed table.

CHAIRMAN SIEGEL: I assume that the calculated evaluating table for I-131 is not significantly different from the current 131 table?

DR. DRAGONETTE: Right.

CHAIRMAN SIEGEL: Is that true?

DR. DRAGONETTE: Yes.

I think -- it's six instead of five. Well, let's see. For the 500 it's 33 millicuries and 7 millirem. So that's pretty low, actually a little higher.

DR. WAGNER: On that nursing infant, is there any specification regarding external versus internal dose on a nursing infant who has a -- of a mother who has a radiation misadministration, for example?

DR. DRAGONETTE: If you were estimating the 500, you should take into account the proximity during nursing.

DR. WAGNER: But that's external dose. I'm talking about an internal 30 dose to the nursing infant from the mother's milk.

DR. DRAGONETTE: Yes, that's the primary thing you would do to show that you would meet the 500 total effective

dose is that you'd have to discontinue nursing for at least a short time or maybe indefinitely, depending upon the half-life of the isotope.

Part of your determinate -- it would be difficult to release a patient and allow them to nurse and show that the dose to the infant would be less than 500 because of the transfer of the milk.

CHAIRMAN SIEGEL: What this is now doing, if I understand you correctly, is that it's codifying a nursing infant clearly as a member of the general public --

DR. DRAGONETTE: As an individual to whom this 500 millirem dose applies.

CHAIRMAN SIEGEL: Right.

DR. DRAGONETTE: We never said they are a member of the general public.

CHAIRMAN SIEGEL: In fact --

DR. DRAGONETTE: And as a practical matter --

CHAIRMAN SIEGEL: Previously a 100 millirems might have well have applied, depending on how you want to interpret Part 20, right?

DR. DRAGONETTE: Right, so this would allow 500 to the infant rather than a 100 if you want to apply 20.

CHAIRMAN SIEGEL: Have you -- we're coming to the item about pregnancy and nursing, two items out of line. Have you a default now established a reporting criteria

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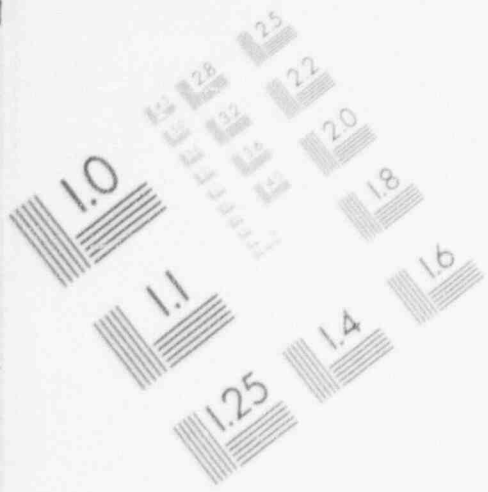

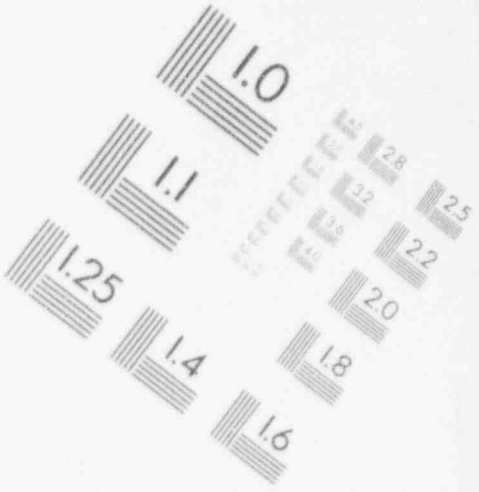

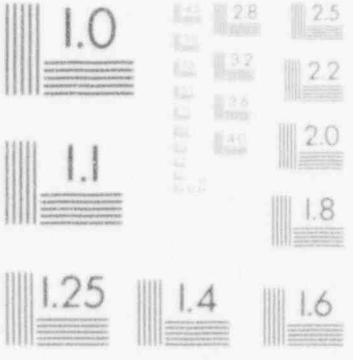

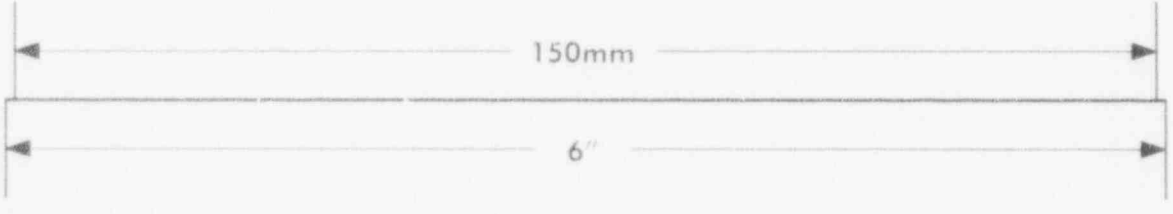

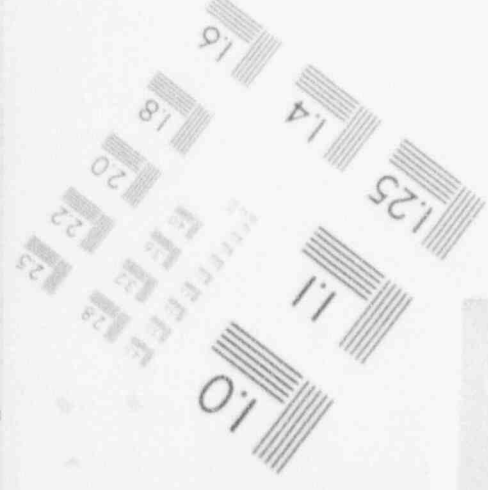

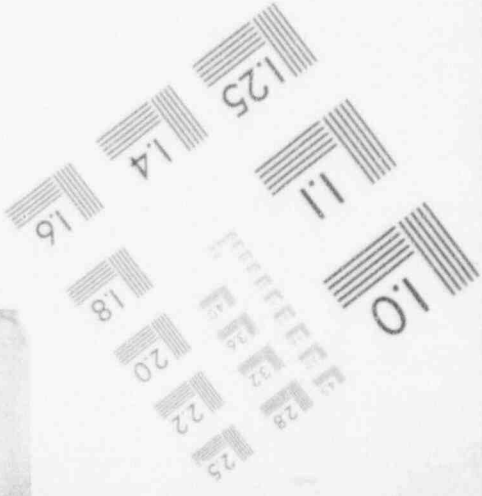

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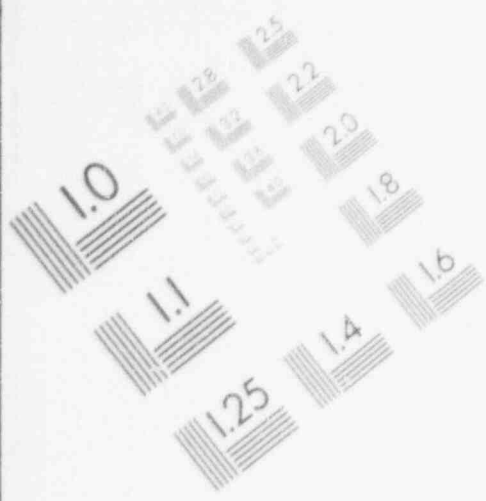

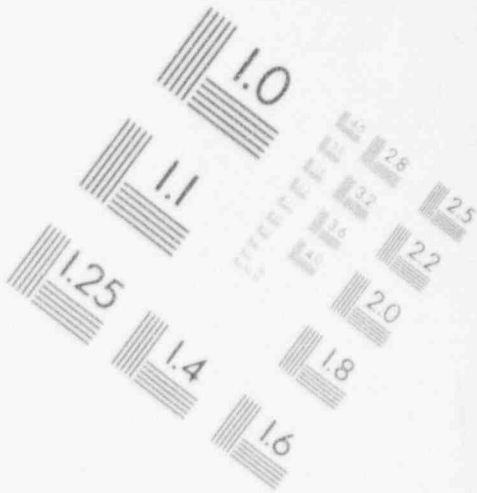

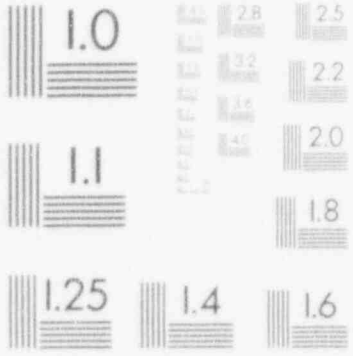

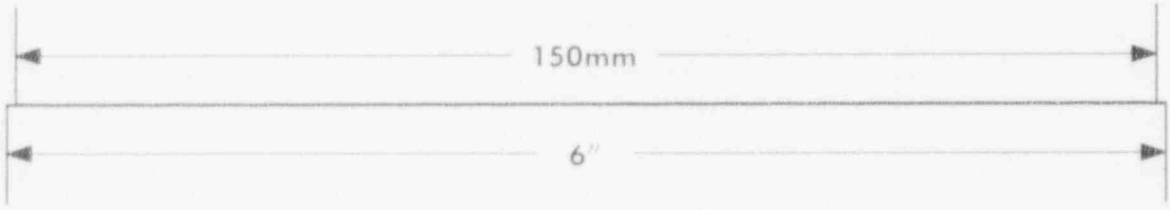

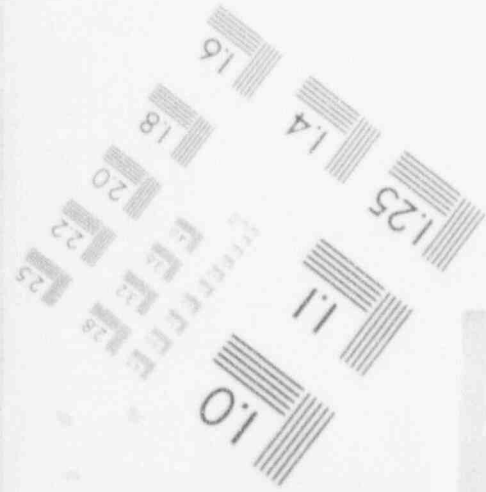

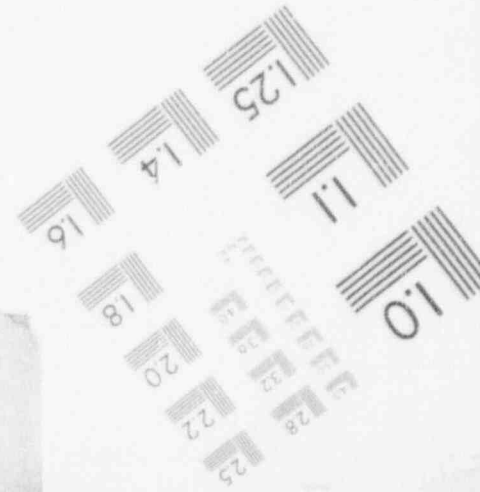

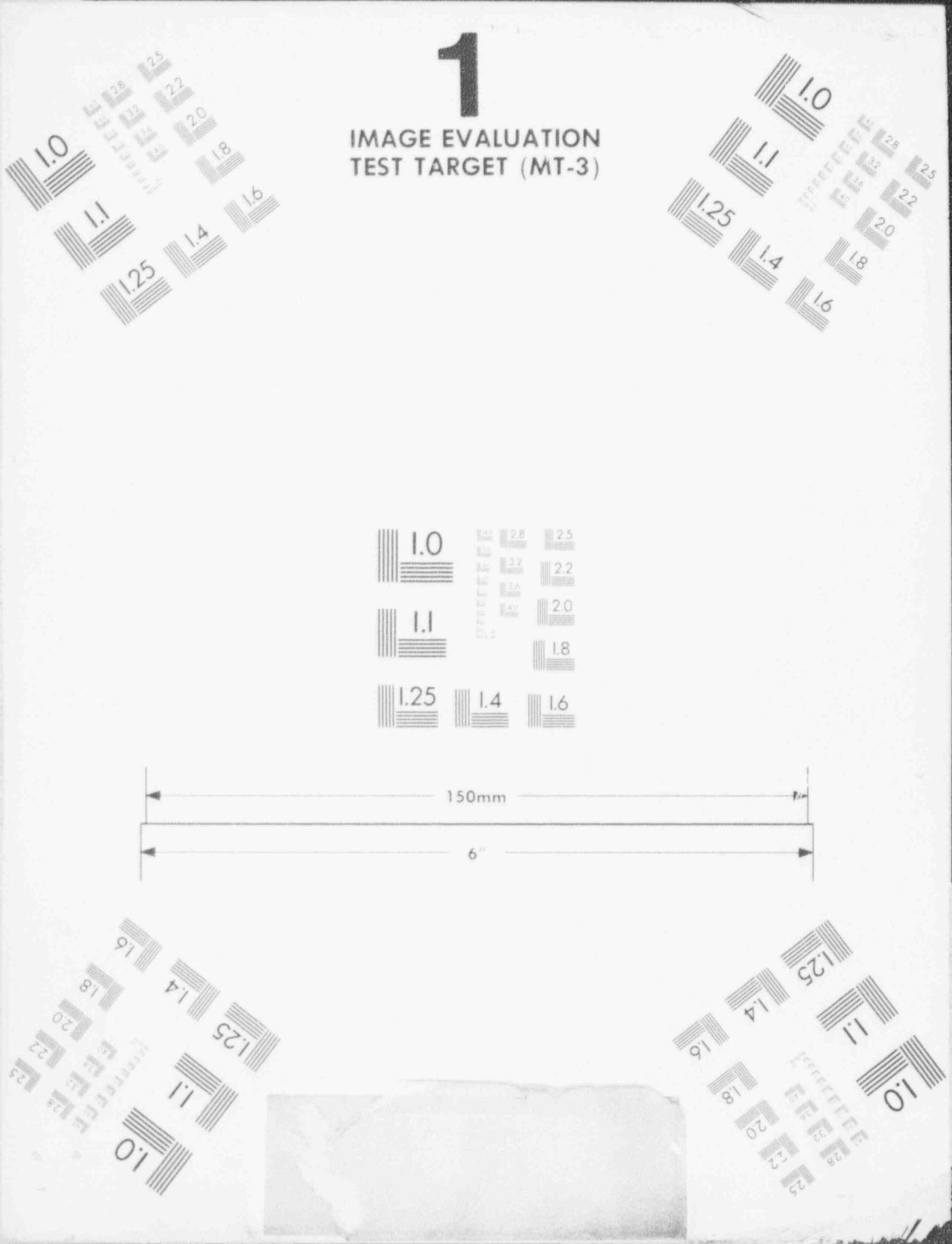
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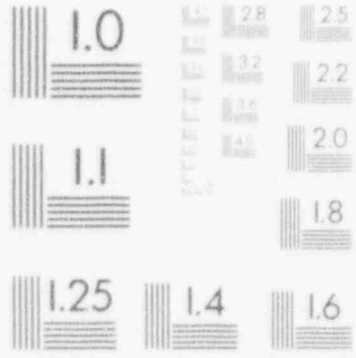

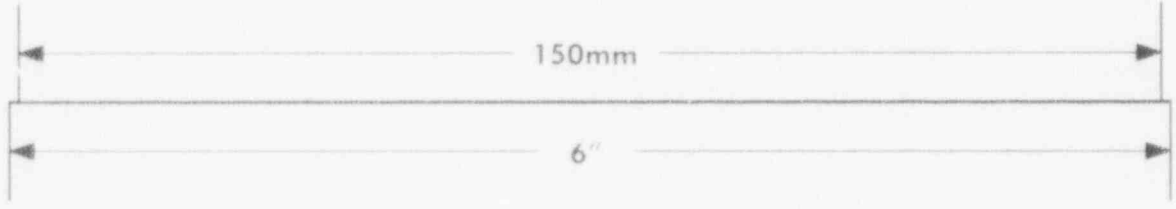

related to the nursing infant that might be different in conducting what was a previous --

DR. DRAGONETTE: Well, actually it was added to the rule in conjunction with the people that were working on the other rule, saying it's very unlikely that you would have in-house nursing, that you ought to be able, you know, if the patient brought their infant in -- the patient release is dealing with the patient and the exposure from patient after they're released from the licensee control. So we thought that would color dealing with the nursing infant.

CHAIRMAN SIEGEL: Okay, we need to work this one through. We need to hear what Sher has got to tell us about the other ruling. These rules may be colliding with each other, if we're not careful.

MR. CAMPER: Yes, in particular pointing out whether or not you sequester the mother from the child so you cannot in fact, so that -- that's another very complicated issue.

CHAIRMAN SIEGEL: Up to now on the pregnancy and nursing issue, we have been addressing inadvertent administrations of pregnant and nursing mothers that were not intended.

It sounds to me like all of a sudden we're getting something that says, "Under no circumstances may the dose to

the infant ever exceed 500 millirems," even if it was medically intended that that be the case.

DR. DRAGONETTE: That the infant get the --

CHAIRMAN SIEGEL: So we're in fact -- and that may be right. I just want to make --

DR. BROWN: How can it be medically intended if the mother is making that determination that she's going to nurse.

Nobody's making a medical determination. The medical intention is for the mother, not for the infant.

Well, let me back track. I know that, Judy, but this really gets very complicated. If you'll go back to our discussions about pregnancy --

DR. BROWN: Pregnancy.

CHAIRMAN SIEGEL: Let's talk about pregnancy first.

DR. BROWN: About unintended.

CHAIRMAN SIEGEL: If the issue with pregnancy was unintended. It is entirely possible for me to be aware that a patient is pregnant and to go ahead with the administration of the radiation anyway because I believe it is essential to the patient's life to do so, irrespective of her pregnancy, okay?

Similarly it is entirely possible that I might have to administer radiation to a breast-feeding mother,

lactating mother, fully aware that the infant potentially could get a dose in excess of 500 millirems, but I was doing that intentionally.

And I think good medical practice would dictate that you wouldn't do that very often.

But our past discussion, I think, did allow for some conditions under which that could conceivably occur. It sounds to me like what the construct has now been made that you can't do that under any circumstances because the infant is being treated as a type of a member of the general public who cannot nave a dose exceeding 500 millirems under any circumstances.

DR. DRAGONETTE: Well, the -- in being prospective, it's saying that -- are you saying there that if you discussed it with the breast-feeding patient and told them the potential risk or harm to the infant and, you know, you recommended that they discontinue nursing that if they said, "No, I won't," then you would still go ahead and give it to them and allow with knowledge?

I mean, is that the issue you are getting into?

CHAIRMAN SIEGEL: No.

DR. DRAGONETTE: Because the intent with -- you will be able to read it in context later. Maybe I'm not explaining it that well.

But what we are trying to do with this rule is

say, in assessing whether you can release the patient from your control, has nothing to do with whether you can administer it to the patient.

If you want to keep the patient in the hospital to control the dose of the nursing infant --

CHAIRMAN SIEGEL: So it's okay for the infant to be there in the patient's room nursing. It's just that the patient hasn't left your control.

DR. DRAGONETTE: Well, hopefully, hopefully you wouldn't allow that.

But what we're trying to do is to say evaluate that potential dose to that infant. You know, what's the most like exposed individual?

The infant, if she's nursing ,is the one that's likely to get the highest exposure. Evaluate that. Instruct her in your judgment, you know.

Instruct her that she shouldn't nurse for either so many hours, days, weeks or stop nursing. Otherwise -- but once you did that and in your judgment she understood, she agreed, and so as far as your determination was concerned, you told her to stop, she agreed to stop, so it was like the dose to the infant was not likely to exceed 500.

Now, if she deliberately goes against her agreement and her instruction and nurses anyway, you, the licensee that released her from her control, would not be

guilty of anything.

You made a good-faith effort to evaluate the likely dose. You talked to her, you know --

CHAIRMAN SIEGEL: You're really creating a new interesting Pandora's box here. I mean, your table is not complete then.

DR. DRAGONETTE: The table excludes --

CHAIRMAN SIEGEL: No, your table has -- your table has now got to be modeled to include a nursing infant for all possible internal sources as well.

DR. DRAGONETTE: Well --

CHAIRMAN SIEGEL: Because in order to be in compliance with what you're saying, if I do a study with 20 millicuries of pertechnetate for a diagnostic study, I have to -- I actually now have to keep the patient in the hospital for 24 hours rather than let the patient go home and not nurse because that's the only way I can control and prevent the patient from delivering a dose in excess of 500 millirems to this particular member of the general public.

I think we're getting into a real funky situation here that needs to be a lot more carefully thought.

DR. MARCUS: There's something else with that. You can't keep a patient in the hospital against their will. That's battery.

You can give -- it has happened to me that I can

give them therapeutic levels of I-131 to patients, who much too early for my taste, have got up, signed out, AMA, and left.

And you can't hold them. You just can't hold them.

CHAIRMAN SIEGEL: Dr. Marcus is speaking as a member of the public right now.

DR. MARCUS: No, I'm not talking about breast-feeding. I'm talking about holding a patient in the hospital.

CHAIRMAN SIEGEL: Yeah, that's right, and you're speaking as a member of the public.

(Laughter.)

CHAIRMAN SIEGEL: You can't talk about that.

DR. DRAGONETTE: This rule is dealing with the licensee, the person who's licensed, what they are allowed to do. And obviously, you know, you can't overrule.

MR. CAMPER: The problem is, reduced to the simplest case, all we're saying is there is 500 limit.

DR. DRAGONETTE: And it applies to the nursing infant.

MR. CAMPER: It surely does, and that's the problem versus what we had discussed before which was unintended exposure.

DR. DRAGONETTE: Right.

MR. CAMPER: There is in fact times when a physician may decide that he or she isn't willing to allow that 500 limit to be exceeded, so that poses a problem.

DR. DRAGONETTE: Under this rule as proposed, it would pose a problem to release that patient --

MR. CAMPER: Right. Being simplistic, that's the problem.

DR. DRAGONETTE: But, you know, it's hard for me to understand when you would want her to nurse and wipe out the baby's thyroid or something.

MR. CAMPER: 500 millirems isn't going to wipe out a thyroid.

DR. DRAGONETTE: No, but if you're saying you want to exceed the 500, you didn't say up to any -- I mean, you can come in for an exception under a rule, but read it in context, make your comments.

I just wanted to highlight that as a new policy that was associated with this proposed rule, but it is limited to at least the patient, not the administration.

DR. BROWN: Excuse me.

How long is the likely period of time that we are talking about that you would be denying a nursing infant --

CHAIRMAN SIEGEL: Okay. I-131, almost any dose, even the diagnostic dose, breast-feeding's over, end of discussion. Galion 67, thallium 201, breast feeding's over.

End of discussion.

Most technetium radiopharmaceuticals, either no need to stop breast-feeding or stop breast-feeding from somewhere from as little as four hours to up to 12 hours.

For doses of technetium pertechnetate in the 20 to 25 millicurie range, you need to stop for about 24 hours to get to the 100 millirem level, which is what the Mountford and Copely calculations are based on.

You really do need to do a table of them.

DR. DRAGONETTE: Well, we -- the table excluded the nursing infant and that pathway. You would have to go -- you would have to either determine if they weren't going to nurse or, you know, you couldn't use the table. And it's labeled that way. It is limited to external doses.

DR. BROWN: The scenarios you're talking about, though, allow the mother plenty of time to express milk which every nursing mother knows all about; correct?

CHAIRMAN SIEGEL: Well, yes and no.

DR. BROWN: Do you have to suspend activity?

CHAIRMAN SIEGEL: Yes and no. Yes, it does. I mean for I-131 it's easy, you must stop breast-feeding. And, in fact, you must stop breast-feeding two weeks ago, because otherwise your breast gets a very high dose, not just the infant. There's reason for the patient to stop a long time ago.

But it's the patient who shows up for a diagnostic examination with a technetium radiopharmaceutical who you don't know they're breast- feeding until they walk in the door who needs not to breast feed for 12 hours and who I now interpret can not be released from confinement --

DR. BROWN: But who ordered the test?

CHAIRMAN SIEGEL: What?

DR. BROWN: Who ordered the test?

CHAIRMAN SIEGEL: No, I have two choices. I can send the patient away and tell them come back when you stop breast-feeding, or I can confine them for 12 hours.

DR. BROWN: Or it seems that if this were more of a generally recognized problem that the referring physician would say, by the way, before you take this test, you can't --

CHAIRMAN SIEGEL: No, let me --

DR. DRAGONETTE: The licensee has to make -- under this proposed rule, the licensee would have to make a determination that no individual would get more than 500, including the nursing infant.

But that evaluation is made as you release the patient or if it's an outpatient, you know, that you could do it. And it could be based on --

CHAIRMAN SIEGEL: It's not based on --

DR. DRAGONETTE: -- that the assurance is that she

will stop or will stop for 12 hours.

And you document that you discussed her with that. And that is part of the assumptions of the dose calculation. That was how we envisioned its working.

DR. BROWN: Maybe.

CHAIRMAN SIEGEL: Maybe. It works some of the time. it may not work all of the time.

I think we'll need to see the language when it hits the street to see how it collides or interacts with the language on pregnancy and breast-feeding generally.

DR. DRAGONETTE: Absolutely, you know, comment on the regulatory guide, on the rule itself.

CHAIRMAN SIEGEL: We're not ready.

DR. DRAGONETTE: I know you're not.

CHAIRMAN SIEGEL: Okay, good.

Sher, can we do your turns out of order? Can we do the pregnancy and breast-feeding first as long as it's at the top of our minds?

DR. BAHADUR: Sure. Okay.

Good afternoon, my name is Sher Bahadur. I'm the Chief of the Regulations Development branch. I see a number of new faces I unfortunately do not know, and, of course, I know some people here.

My branch is responsible for the two rulemakings for which I'm going to give you the status. These are not

new issues as you must have noticed already with the lively discussion that we had on these issues. So I'm going to give you a quick status; however, while giving this status, if you want to discuss some of the underlying parts, perhaps we can talk about that as well.

The unplanned radiation exposures to embryo and fetus of the patient. You must have noticed from the last time when we came, the title has changed somewhat.

Previously it included the breast-fed child as well. It doesn't now. And it doesn't now because of the rule that Kitty Dragonette has now presented to you, a rule which Dr. Siegel thought is on a collision course with the activity that we doing.

Our feeling is if the doctor knows that the patient is nursing and if a conscious decision has been made, that in spite of the nursing status, the byproduct has to be administered, we want to be out of the loop. However, we want to make sure the doctor is in the loop. The licensee is in the loop. The licensee makes the decision whether the patient needs to stop breast-feeding for a while, stop it altogether, postpone administration, whatever. That's not for us to worry about.

However, there is a patient release factor here that Kitty Dragonette just now presented and that presupposes that if radiations to a person other than a

patient exceeds more that 500 millirem, then NRC needs to worry about what the public has to say.

Now, mind you, while doing so we are already making a giant leap from 100 millirem, which is for the general public, to a 500 millirem, which is now to a specialized case provided certain precautions are taken, these precautions being the licensee tells the patient to be careful, make sure the radiations to the other person are as low as reasonably achieved or allowed at this point.

And that goes between the 100 millirem and the 500 millirem. More than 500 millirem, you just put the patient in your control.

The debate is whether that is doable or not. I can't discuss that. That is Kitty Dragonette's rule, and she will let you know what.

What I would like to tell you is the last time that we came, we presented an approach for the unplanned exposure, how to minimize these unplanned exposures.

And our approach was we asked the licensee to develop a procedure manual for diagnosis administrations. And, if there is any breakage in that procedure, then it becomes a recordable event.

You will record more than a certain number per year or per month, and then it becomes -- The Committee commented on that and said this is not right; by doing so we

will be creating a great amount of paperwork; we should think of some sort of threshold, a threshold where which we should not be worried about.

The Committee also suggested that we should contact NCRP on this threshold issue. So we went back, we contacted Brookhaven National Lab through which we contacted the NCRP.

And the NCRP right now is preparing a commentary on this issue. Their commentary is due sometime in June, and as soon as that commentary is published in final, we will be able to finalize our rulemaking.

Our current schedule is to send a paper to the EDO by August of 1994.

Should I move to the next one, or do you have a question?

CHAIRMAN SIEGEL: A question about your slide; the third bullet says that the patient or this rule will result in preventing an unplanned radiation exposure of a breast-fed child.

I read it as preventing any radiation exposure that puts that child in excess of 500 millirems.

DR. BAHADUR: Yes, I think that's a very valid point. We meant to have said it would prevent the unplanned exposure as well.

CHAIRMAN SIEGEL: Okay.

DR. BAHADUR: The second activity is the radiopharmaceutical rule. Before we published the proposal in June of 1993, with a 130-day-comment period, and before the comment period expired in October of 1993, about 284 comment letters were received.

Most letters were supportive of the rule; however, they asked questions. They didn't question the rule itself, but some of these statements that we had made, some of the positions we had done, why they were in the rule.

So that was kind of a good question in the sense that it allowed us to explain everything a little better, add some verifying documents a little better.

So as result, although the final rule remains pretty much the same as the proposal rule was, but we have added certain clarifying statements.

For example, under the provisions of research involving human subjects, our previous requirement was that a licensee would get the -- obtain the informed consent and would also receive a prior approval from the IRBs.

In the final version the requirement remained the same, but we have now added a phrase which states that all this will be done under the compliance of the Federal policy for protection of human subjects.

For the grandfathered provisions, the proposal had the provision for commercial nuclear pharmacies, and now we

have clarified to indicate that this would also apply to all the qualified individuals who are really working for the hospital-based pharmacies.

We are planning on sending this through to the EDO in June of this year. That's next month. But recently the Commission indicated to the EDO they would like to see any rulemaking, along with any associated guidance document with it, rather than to see the rulemaking first and then seeing guidance documents later.

So right now we are in the process of looking at the existing guidance documents, seeing whether promulgation of this rule might cause some sort of either conflict or maybe a void, or maybe a duplication, or whatever.

And once we have gone through this cross-check, then we plan tc send this rulemaking to the Commission, to the EDO in October of 1994.

October is a crucial is time, because as you are very well aware, the current rule is only effective until 31st of December 1994.

So our intent is to promulgate this rulemaking before the current one runs out. So we're trying our best to get it to the EDO by October of 1994.

CHAIRMAN SIEGEL: Questions?

(No response.)

CHAIRMAN SIEGEL: Thank you, Sher.

DR. BAHADUR: Thank you.

CHAIRMAN SIEGEL: It seems likely that the patient release criteria rule and the pregnancy/breast- feeding rules will both still be on the street at the time of this Committee's next meeting.

And I'd would like to suggest that this Committee formally provide comments under both rules before the next meeting.

You actually all have the opportunity to do it as members of the public, but it might be reasonable to get one more status report and to talk about it while you all are in the process of still ingesting public comments, because it sounds like you'll still be there.

Okay? Next, Larry?

MR. CAMPER: The abnormal occurrence criteria, I really don't have much to say other than the fact that you know the status of the Commission paper.

The Commission has reviewed that Commission paper and a Staff memorandum that advises how to proceed is currently under construction, if you will, and will be finalized by this meeting and we could talk about it in more detail, but that's not the case.

So other than the fact that we expect to very shortly receive documents from the Commission as to how to proceed, there's really nothing more to say other than it's

late.

CHAIRMAN SIEGEL: Okay. Any other -- Dr. Almond, you had a comment you wanted to make of the proposal xxx --

DR. ALMOND: Well, it's just as good time to talk about release of patients with radiopharmaceuticals, and it has to do with the recent statement sent to the states concerning patients who have received Strontium 89 and cremation.

And I'm wondering whether we are going to get any further information on that or whether -- you looked surprised.

MR. CAMPER: I'm sorry. Now what is it?

DR. ALMOND: There is -- I thought it came from the NRC to the states, and the states have certainly sent it out to their licensees, that any patients who have received Strontium 89 and who subsequently die shall not be cremated. Now --

I'll be glad to send you this information.

Obviously I think further guidelines needs to be given on this.

MR. CAMPER: Well, we really would like to see what you are talking about. We are currently working on an information notice that deals with issues associated with beta-emitting radiopharamceuticals.

And this ranges from measuring them up to and

including managing the treated patients and some of these issues, cremation and the like, but that is still under -- in draft. It hasn't been --

DR. ALMOND: Well, certainly this study and its interpreters have so informed the licensees -- this is enforceable request, anyhow. These are generally out-patients who come in and go off and you don't where you can inform the patient and the family that they should not be cremated. But whether they will follow that or not, you have no way of interpreting.

CHAIRMAN SIEGEL: The patients will certainly get a kick out of that.

DR. GLENN: We're aware that some guidance has gone out that has been issued by the American Crematorium Association. It may be an industry description rather than a regulatory one.

DR. ALMOND: I'll be glad to send you the information on it.

DR. MARCUS: May I comment?

CHAIRMAN SIEGEL: Yes.

DR. MARCUS: I do know that an inspector in Region 5 so informed the crematorium that if they intended to cremate this patient when they've been given Strontium 89, they were going to have to decontaminate the entire facility.

And when he estimated what it would cost, they decided that they were not going to take the business. That is the only NRC standard that I have seen on it. And I had a patient die with Strontium 89 in her. We talked to her son just to make sure that she was being buried and didn't really go into details with him. But I have seen no data showing how much Strontium 89 is volatile versus what it took in the rule, what sort of program this dose is going to be. There's got to be some science.

DR. ALMOND: I understand, but somehow or other, you know, there's information now that's gotten to lead to the regulatory channel certainly in our state regarding the licensees dealing with patients with Strontium 89. And I will be glad to send you the information.

DR. MARCUS: Would you sent me one, too? I want to see it because we haven't gotten directives like that.

DR. ALMOND: Certainly. If you haven't gotten it, then okay.

CHAIRMAN SIEGEL: Haven't you been measuring their water supply of Strontium to see if that's a problem?

(Laughter.)

DR. GLENN: Well, I will mention that in preparation for the information notice, we have been trying to get information on those parameters and what the exposures would likely be. And the information that we've

gotten so far is that there isn't much danger.

I think the only unanswered question that we had the last time we discussed with the project manager was -- I think the studies were done in England.

They did not include the embalming fluids, so we were trying to find out the dose was in the embalming fluids.

DR. ALMOND: Well, the NCRP has statements about embalming situations of patients with radioactive materials. I have no difficulty with that. It's just that all of a sudden there is -- you can't cremate these patients. And it seem to me after several months it's not going to make any difference anyhow, but not even that subject is addressed.

CHAIRMAN SIEGEL: I'll have to send you the information. That's an interesting problem.

DR. ALMOND: Well, it may be something then that you're going to have to look at if this information is now out, and goodness knows where it, you know, I'll find out where it came from.

CHAIRMAN SIEGEL: It sounds like that's a more likely Meshach's problem.

(Laughter.)

DR. ALMOND: But the state regulation branch sent it to us, so it's --

CHAIRMAN SIEGEL: That sounds more likely to be

likely to be a Meshach's problem?

(Laughter.)

CHAIRMAN SIEGEL: You don't like that, Carol?

DR. MARCUS: No.

CHAIRMAN SIEGEL: Surely you know people gain more than ten millirems per year from the cremations of patients who've been given Strontium 89.

(Laughter.)

CHAIRMAN SIEGEL: Oh, my god, I don't know what led me to choose this specialty --

DR. MARCUS: But when they put it in the same category as iodine, you never know.

CHAIRMAN SIEGEL: Now, what I want to know is what led me to choose this specialty --

DR. MARCUS: Exactly.

CHAIRMAN SIEGEL: -- what possibly led me to do that when I could have been a lawyer instead.

DR. MARCUS: You are a lawyer, that's what's the problem.

CHAIRMAN SIEGEL: We are adjourned officially from the public meeting. We now have a closed session to discuss training and experience requirements. All non-NRC employees may leave the room.

(Whereupon, at 4:20 p.m., the public meeting was adjourned to reconvene in closed session.)

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission
in the matter of:

NAME OF PROCEEDING: ACMUI Meeting

DOCKET NUMBER:

PLACE OF PROCEEDING: Bethesda, MD

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Priscilla Hopchas

Official Reporter
Ann Riley & Associates, Ltd.