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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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THURSDAY, MAY 11, 1995

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, 11565 Rockville Pike, Room T2B3, at 8:22 a.m., Barry A. Siegel, Chairman, presiding.

MEMBERS PRESENT:

BARRY A. SIEGEL, M.D., Chairman

DANIEL S. BERMAN, M.D., Member

DANIEL F. FLYNN, M.D., Member

JOHN GRAHAM, Member

WIL B. NELP, M.D., Member

ROBERT M. QUILLEN, Member

JUDITH ANNE STITT, M.D., Member

DENNIS SWANSON, M.S., BCNP, Member

LOUIS WAGNER, Ph.D, Member

DAVID WOODBURY, M.D., Member

ACMUI STAFF PRESENT:

TORRE TAYLOR

ALSO PRESENT:

LARRY W. CAMPER
JOSEPHINE M. PICCONE
IVAN A. BREZOVICH
JEFF WILLIAMSON
JACK ROE
JANET SCHLUETER
DONNA-BETH HOWE
ROBERT AYRES
DONALD COOL
JIM SMITH
PATRICIA HOLAHAN
MARJORIE ROTHSCHILD
JOHN CORDES
KATHY SEIFERT
MARK ROTMAN
JERRY JOHNSON

AGENDA

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

8:03 a.m.

MR. CAMPER: Good morning, ladies and gentlemen. I am pleased to welcome you to Rockville and to the NRC Headquarters for this public meeting of our Advisory Committee on the Medical Uses of Isotopes.

I'm Larry Camper. I am the Chief of the Medical, Academic and Commercial Use Safety Branch and the designated federal official for this Advisory Committee meeting.

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 19, 1995 and that notice stated that the meeting will begin at 8 a.m. and we're about four minutes late.

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

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

opinions, and we ask you would clearly articulate those dissenting opinions as we discuss the specific agenda items.

The agenda is full and I would request that you make your comments specifically germane to the topic under discussion and make them as succinct as possible so we can conduct as much business as possible.

As part of the preparation for this meeting, I have reviewed the agenda for members' financial and employment interest. I have not identified any conflicts from that review based on the very general nature of the discussion that we're having at this time. I don't see anything that involves any specific institution where there might be a conflict nor am I aware that any of you have raised any of the items that are on the agenda as part of a petition for rule making so, to the best of my knowledge, there are no conflicts.

However, should any member of the Committee during our discussions become aware of a potential conflict of interest with regard to a topic under discussion, you are obligated to inform the Chairman or myself and recuse yourself from discussion of that particular topic as a Committee member.

I would like to take this opportunity to introduce the Committee members with us today. Starting on my left we have Doctor David Woodbury from the FDA. We have Mr. Dennis Swanson, our radio pharmacist representative. We have

Doctor Judith Stitt, a radiation oncologist and therapist. We have Mr. Bob Quillen from the state of Colorado. We have Doctor Josie Piccone who is the section leader for the Medical and Academic Section. Of course, we have our esteemed Chairman, Doctor Barry Siegel. We have Doctor Wil Nelp who is representing our research interest on the committee. We have Mr. John Graham who is a management specialist in health care administration and we have Doctor Daniel Flynn who is a radiation therapy oncologist.

In addition to the members of the Committee, we have with us today two invited guests. We have Doctor Ivan Brezovich who is with the University of Alabama at Birmingham. Doctor Brezovich is behind us. We also have Doctor Jeffrey Williamson with the Maryland -- Institute of Radiology. These gentlemen are invited speakers today. They are practicing therapy physicists and, since our first agenda items deals with brachytherapy issues, we wanted to get the perspective of a practicing therapy physicist not representing any particular organization, not functioning as a Committee member, but giving us their practical, day-to-day observations, and we think that will be of tremendous benefit to us.

I'd also like to take this opportunity to introduce a couple of other members of the NRC staff in the audience and also to announce a couple of changes recently in key management positions within our agency. We recently

underwent a substantial change. Doctor Carl Paperiello, who was previously the Division Director for the Division of Industrial and Medical Nuclear Safety, became the Office Director for Nuclear Material Safety and Safeguards. I don't know if Doctor Paperiello is here.

We have Doctor Donald Cool who's back behind us in the first row. Doctor Cool became the Division Director of IMNS. I assumed responsibility as the Chief for the Medical, Academic and Commercial Use Safety Branch replacing Doctor John Glenn, who is now Branch Chief with the Office of Research, but I assure you that John is here in spirit. He indicated that to me. He hates missing this and all the fun, but he will be with us tomorrow to make one of the major presentations on the rule makings.

And the other significant change involves Doctor Piccone. Josie Piccone assumed responsibility as the Section Leader for the Medical and Academic Section.

So with those introductions, I want to make one or two administrative comments and point out that we do have restrooms nearby. They are just down the hallway. There's also a vending room down the hallway that's available for snacks and the like for any members of the public. We do have some coffee available but that unfortunately is restricted to use by the Committee members. Members of the public can find a cafeteria in the first floor of the adjacent building.

So with those opening comments, what I'd like to do is next ask Doctor Cool to make a few comments. You'll notice on the agenda that we had added a new item and we call it Director's Comments and this was added to afford either the Office Director or the Division Director an opportunity to share with you some philosophical or big picture concerns that they might have from their perspective and sort of set the stage for things that are on their mind that you can bear in your deliberations today.

DR. COOL: Thank you, Larry. Barry, members of the Committee. It's good to be here. This is a slightly different setting from which I am used to addressing this particular committee. I'm not whether it was poetic justice, malice of forethought or exactly what it was that resulted in the Executive Director deciding that the guy who had been responsible for the past six years or so for writing all of the rules should now be put in the position of having to try to implement them. Nevertheless, that's what happened.

I am pleased to be here today. I extend to you a welcome from Doctor Paperiello who is now the Office Director. Larry has already gone through and given you all of the management changes. It was not quite as it might have appeared to be taking all the names, putting them in a basket, shaking it, tossing it up in the air, and seeing who fell out where. There was quite a bit of thought and effort put into

this. I am really pleased with the team that I have with Josie moving over to the Medical Section, Larry moving up to be the Branch Chief in that area.

We are faced with a lot of challenges over the next couple of years and I want to talk just for a few minutes about some of the things that I see, some of the activities that I believe are going to impinge either very directly or at least tangentially on the medical program, on this activities which this division and office need to face over the next couple of years. There are a number of them.

Obviously, we are coming to a point in time where we need to try and do something with all the experience that we've gained with Part 35 since it was revised in 1987. We need to do something with the fact that there are a number of new modalities, a number of things that have changed in the whole approach to health care, the various kinds of new interations, new specialties, new activities and how to deal with those within the regulatory structure.

There are other things external to this agency which includes the review by the National Academy of Sciences that we've all been following with great interest, the efforts on the part of the current administration to streamline government, the National Performance Review and the follow-on activities there which have a significant impact and will have an impact on the way that we do business and our own internal

efforts that we're going to be talking about a little bit later tomorrow to try and re-engineer the whole process of how we go about doing licensing. With the Chairman's permission, I'm going to take just a couple of minutes and outline a little bit of what's going on in each one of those.

When the revision of Part 35 was done in 1987, there wre a lot of requirements that were put in place. It was an effort deliberately aimed at trying to get into the regulation those things which at the time were in various places and various guidance documents, particularly in some of the diagnostic use of some of the areas. I think we've come to understand that there are both gaps in that structure and areas where, in retrospect, we may have been just a little bit overboard with the kinds of requirements that were put in place in order to accomplish a particular purpose.

Since the time of that revision, it has not been a static rule, as you're all sort of acutely aware. Some of the changes have been rather controversial. The Quality Management Rule, the MisAdministration Rule. Some, maybe rightly so, have called those things unnecessary, burdensome, but it's perhaps only with hindsight the actual effect of any regulation can be understood. Over the last few weeks, Doctor Paperiello and I have been taking a look at some of the misadministration data, trying to get ready for discussions with the Chairman, the EDO and various areas.

Misadministrations for a number of years averaged something on the order of 25 to 30. It was relatively steady. Obviously, there's some variation any time you're trying to apply statistics to relatively small numbers of essentially independent events, but for each six month period you'd have 15, 20, something like that. It would vary around a little bit but it was relatively steady over the time that we have some reasonable data on. Very interestingly enough, so far in 1995 through the beginning of May we have exactly two in that six month period coming up with a little over a month left.

Now obviously, it's way too early to put any credence on a particular set of numbers. This might be some sort of statistical variation. On the other hand, it might also be an indication that, lo and behold, all of the things that we attempted to do to try and promote quality, to try and get the active participation of authorized user physicians in at each stage in the process, in fact, had at least some of the effect that we desired for it to have over the course of time and so we look at the programs, as we look at the revisions -- here I hove to preach to myself as much as anyone else -- let's not throw out the baby in the accomplishments along with the bath water of trying to smooth out pieces of regulations.

On the second front is modality such as the high dose rate brachytherapy have virtually no regulatory structure

in the existing regulations. At this point, there's a lot of things in various guidance documents, most of that coming about as the result of the misadministration incident up in Pennsylvania several years ago and the Medical Management Plan was an outgrowth of that, a whole series of guidance activities trying to put together some sort of structure in the interim use for that.

Most of the rest of this morning is going to be devoted to discussions of where we go with that particular arena. How do we go about trying to put together some sort of regulatory structure that can be in the regulation so that it can be a solid program which has a long-term basis and not a program which continually evolves in guidance documents. It's one of the things that I came to really appreciate while I was in the Office of Research, was just how much we as a staff, rightly or wrongly, tend to try to do things by sort of the easiest method because we have this little impingement from this side or this little impingement from the other side and it results in you doing what nearly amounts to a Brownian motion random walk, having to stand back and say, Are we aimed in the right direction? Are we focused on the right sorts of things?

In terms of the Medical Management Plan, by the end of this year we'll probably be 80 percent or better accomplished. All the short-term actions will pretty much be

done. The remaining actions will be the long-term rulemaking guidance actions, some of the things coming specifically out of the brachytherapy area, a number of things related to the revision of Part 35. There are a number of issues that still have to be addressed there one way or another. Training experience has been raised in a number of settings, needs to be looked at.

In my view, I think most of those at this point need to be wrapped into the overall revision of the regulations. Getting back to the same point I made a little bit ago. I think at this time we should really start to focus our efforts on being prepared to address regulation and medical as a whole. Stand back away from the individual impinging pieces and say, What needs to be there? Why? Does it make sense for us to be there?

As you're aware, the NRC contracted with the National Academy of Sciences to take an independent examination of the regulatory approach for medical uses. Each of us is keenly interested in the recommendations. They, of course, have done exactly as they always advocate that they do. They've told us absolutely nothing up to this point, so we all sit and we guess and we worry and we wonder and we try to sort of second guess where they might be going. We'll have that report by the end of this year. That's the time frame that the contract was originally laid out. They're still on

that track as far as we can determine. All of the indications are that we will be there.

Our revision of Part 35 and the time frame for that is, in fact, keyed to the availability of that National Academy study because that will be a key ingredient in going forward with the rule making process. I think that rule making process, once we have that paper, needs to be a very open approach involving all the various folks in the medical community, all the people out in the public.

One of the things that we have tended not to do very well heretofore is identifying and involving people outside of the profession in our rule making process in the medical area. There are other areas of regulation where the Commission has had a wealth of input from those outside of the industry or regulatory process, but not this area very much, and we need to be finding mechanisms to involve them. The Commission pursued what was called an enhanced participatory rule making process in the decommissioning criteria. We may or may not call this particular rule making by that little particular acronym. That acronym, as with all NRC acronyms, has now accumulated its own set of baggage.

Nevertheless, that kind of approach of having workshops based on background documentation I think is going to be a methodology that we'll need to pursue in terms of trying to get to a rule making if that's what we want it to

do. I believe that your recommendations and discussions are also going to be critical to that process.

One of the things I'd like to invite you to try and do, both during today and over the next few months, is to consider what pieces of background information, what kind of documentation, other information, could be best developed in this time frame by the staff, perhaps by some of you folks, in order to facilitate those discussions early next year. One of the things I've found key was that when people began the discussions that they started from a common beginning point, a common level of understanding in terms of what the issues were, what some of the background pieces of information were so the discussion could move forward and a great deal of time wasn't spent trying to get everyone up to speed. I really would hope that you could help us in putting together a good set of background documents on that area.

A totally separate path is the review of the regulations and agency actions as part of the ongoing National Performance Review conducted by the Clinton Administration. NRC, as well as most of the other agencies, are in the process of examining the regulations and activities to determine if there are things that could be done better, if there are things that should be devolved or otherwise states or other organizations, if there are places where requirements can be reduced or streamlined or places where regulations aren't

needed at all.

As I'm sure you're aware, our Chairman, Chairman Selin, has publicly indicated his desire that the NRC reduce or perhaps even eliminate some of its role in the medical areas, at least with regards to some of the protection of the patient issues. If such an approach were taken to its ultimate endpoint, changes would be needed in the Atomic Energy Act in order for some of those sorts of things to be accomplished. There have been a wide variety of other variants that have also been discussed which might get NRC part way out or reduce its role or modify its role in various aspects. That will be a key piece once again as we start to consider what kind of revisions might be appropriate for Part 35.

Jack Roe, who is leading the NRC staff efforts in this area is going to be here later this morning, I believe, on your agenda to discuss the activities of his group and I believe to seek your input on some of the changes or modifications that might be appropriate to recommend to the agency's senior management and on to the Administration.

Inside the agency, last year we began a major effort to try and reexamine the process by which my division and the regions do licensing, do the process of issuing a license, everything from how it's submitted to how it's processed, to how it's sent out and the kind of review and the

kind of documentation that's done. We're going to talk a little bit about that tomorrow. That process basically involves standing back and saying, What is the as-built situation? What kind of things are out there somewhere in industry and other sectors of the federal government and the states where people are doing things which we might be able to incorporate into our process in order to have a significant gain in our efficiency, our ability to do licensing activities? That obviously will directly impact medical licenses. That's one of the very large components of the licenses that we and the states issue.

What we discovered was that what we thought was as nice simple little process, about eight steps of the process, it comes in, the old fee processing takes place by somebody, it gets sent over, you do the review, it gets sent, maybe a deficiency letter is sent out, you send out a license and you send out a renewal notification. The reality is it was an enormously complex process, something like 80+ steps and back and forth and to and fro in the process with nearly 90 days worth of processing time on the average of which only about two days was actually devoted to anything resembling real work associated with the review of the process. We hope to improve that.

Once again, this is an area where I'm in hopes we can gain some ideas from you folks in the private sector in

the way that you conduct business to help us improve our process of doing work. For so long -- it's easy because I'm an outsider and so I can say all sorts of radical things. I'm in this little honeymoon period where no one will hit me too hard. For really too long we have been in a us versus them kind of process. Headquarters versus regions. NRC versus licensees. NRC versus states. You just generate a really nice long list.

I'm in hopes that we can move to a little more of a process which uses the term we where we work together as a team, where we examine the issues and where we try to take the big picture approach to things and come to solutions which are mutually acceptable. I know we will never get to the point where all of us will in fact be in agreement and have perfect consensus. That, I think, is probably asking just a bit too much. But to move in that direction and I look forward to working with you folks.

There are a number of things going on simultaneously these next two days. We'll unfortunately have to be popping in and out of here. We provide the Commissioners this morning with a briefing of our business process for engineering. I'm just going to sort of chunk out most of the rest of this morning but I hope to be back and forth, be available to be part of at least a number of these discussions over the next two days. You've got a whole lot of

things on your agenda that I'm personally interested in as I get into this process, and I look forward to hearing from you.

Barry, depending on your agenda and schedule, I'd be glad to try and answer some general questions for a few minutes and we can get into specifics later.

CHAIRMAN SIEGEL: Does anyone have any questions right now?

Let me just ask one very briefly. Can you amplify a tiny bit on what you meant by getting other members of the general public more involved in the medical rule making process. The sense was that you haven't tried to involve them, and I'm not sure that's true. I just sense that people haven't been terribly interested in coming forward to comment on these issues.

DR. COOL: In fact, I think you're exactly right. My background over the last six years, as most of you are probably aware, is in the rule making area. Some of the rule makings have people just flocking to our doors to provide us their viewpoints, both positive and negative, a lot of it, of course, engendered by policy statements with three other acronyms that everybody loved.

In the medical area, medical regulation has not engendered that kind of interest to date and that's exactly right. There have been some efforts to try and involve some

people. They've not been terribly successful for whatever set of reasons. If that is in fact the way the public wishes it to be, then we'll move forward with those who wish to be involved in the process.

What I would like to try and do though is to make sure that we have taken what steps we have available to us to make sure that if there are people who are interested, people who have some viewpoints, some ideas, things related to patient advocacy, some of the things that are not within the "traditional" -- put that in quotes -- professional societies and various kinds of professions, that we have at least gone through a careful effort to try and identify and involve them in the process.

If they choose not to participate, obviously I'm not going to go out with the handcuffs and drag them to the table. On the other hand, I want to make sure that we have availed ourselves of as many opportunities to get their input as possible because my experience is that the more people who are involved in the front end of the process, the better off the product is when we get to the back end and we actually try to put together a regulation.

CHAIRMAN SIEGEL: Thank you. Look forward to your meeting.

The record should show that Dr. Wagner has joined the committee. Good morning, Lou.

Let me add my welcome to that given by Larry and Don and good morning, everybody. As you see, we've got a fairly busy agenda. We've got a lot to cover and it'll be entertaining to see whether we can get through it in the time that's been allotted. I'd like to reiterate the need for us to try to generate consensus on the issues but welcome the opportunity for minority reports and we'll clearly identify those in the record and in the minutes when they ultimately come out after the meeting.

When people speak, the first time at least, identify yourself so that the transcriptionist gets your voice and we'll be able to follow the program the rest of the day. I think we can probably move on with the agenda after those few brief comments. My goal to try to make this committee operate in a nearly paperless fashion when it's not at the meetings has not worked entirely. I think we need a moment of silence for the trees. This meeting has a lot of background paper and it looks like more is coming.

With that, let's begin this major morning item which is the discussion of brachytherapy and where brachytherapy rule making may be headed. Trish is going to start off the discussion, give us the big picture. Then Doctors Brezovich and Williamson are going to make each brief presentations and will be available to answer questions during the course of the discussion as we wish to call on them and we

will try to work our way through the questions.

Let me just make one other comment. I'm not aware of any members of the general public who asked to address this Advisory Committee at this meeting yet, and consequently we don't have to, but as has been our desire in the past, if there are members of the general public who feel the need to contribute something to the meeting and if our agenda allows, the Chair will reserve the right to recognize those individuals.

Trish, go for it.

DR. HOLAHAN: Good morning. I'm Patricia Holahan and I'm in the Medical and Academic Section and I'm speaking to you today as the Project Manager for the brachytherapy issues. I believe everybody received a copy of a draft issues paper that we prepared in preparation for this meeting basically to give some background of some of the issues that we wish to cover. This area was discussed at the last two ACMUI meetings and what we've done is we've tried to put everything now into one place with some questions. As I mentioned, it is a draft paper and we look to making any changes that have been identified at this meeting.

As we've mentioned previously, NRC is currently in the process of reviewing the medical use of byproduct material for brachytherapy with regards to the adequacy of the existing regulations, standards and procedures to include the

guidance documents that are currently out in the public. As part of this in the last meeting, the ACMUI had recommended that NRC proceed with an expedited rule making to address some of these issues. However, with the National Academy of Science study being due at the end of this year, we have decided to hold off until that study comes in, look at that study and possibly incorporate the rule making into the major revision of Part 35.

However, in the mean time we are still going out and seeking comments on many of these issues to try and get some of the issues clarified and identified. We're coming here obviously to the ACMUI and then we'll be going to some of the professional societies over the next several months. Jim Smith has been working with me. He's also in the Medical and Academic Section and will also be doing a considerable amount of the work over the next few months.

Some of the background, too, is the NRC had recently issued a policy statement, proposed agency-wide policy statement on the use of risk assessment. As part of that, medical devices is included in that policy statement and if the policy statement becomes final, we'll be using much more of the risk analysis in terms of future rule makings and so there's been a workshop conducted last summer looking at, for example, the HDR and the gamma knife. And so that is also being considered in some of these efforts that are currently

ongoing.

What I'd like to do at this point is perhaps pause and let Doctors Brezovich and Williamson make some introductory comments. As Larry mentioned earlier, we have invited, because there are very many issues in here that are heavily physics-oriented, we invited the participation of two additional medical physicists, so we've asked them if they could make a few opening comments and then I'd like to walk through all the issues.

Doctor Brezovich, would you like to start? Do you need a projector or anything?

DR. BREZOVICH: No. The podium.

First of all, I would like to thank you very much for inviting me to this most important meeting. I recognize it's going to be a great responsibility and certainly a pleasure and honor. I will therefore try to do my best to give you an unfiltered view as seen through the eyes of a medical physicist who has been working for the last 20 years in the trenches of day-to-day patient care. I will only address radiation therapy. Because of the limitations, obviously I can only talk about the major issues. I have responded in writing and I will give you a copy of that.

My greatest concern as the current regulations of the NRC are written is that they are not recognizing the role of the medical physicist and the role it is playing and the

quality of delivery to the patient. Specifically, as the rules are written now, the physicist lacks the authority to do his job because individual jobs are not assigned to him through the regulatory process.

#2, NRC regulations do not put any specific quality requirements on the education and training of the medical physicist as they do on authorized use and on the radiation safety officer. As a result, you have unqualified people doing some very sensitive work, including, literally speaking, brain surgery if it's done with radiation.

As an example of what can happen if you don't have the authority to do your job, I want to point to the accident at Riverside Memorial Hospital which happened a number of years ago. The root cause of the incident was that a medical physicist, the work of a medical physicist was interfered with by the authorized user. Specifically, if you look at the report, the authorized user requested the medical physicist use linear paper to graph the output of the exponentially decaying cobalt source. The confusion which arose due to this unorthodox way of determining the output resulted in an ever increasing overdose to patients which resulted in up to 40 percent of over-exposure.

NRC's response to that was to put a patch on the problem, namely to require that the output of radiation units be periodically checked. That may have solved this one

problem, but it did not eliminate the root of the problem. It eliminated the symptoms but not the root. Even now medical physicists have difficulty practicing their profession because they do not have specific authorization for certain procedures. Two examples come to my mind.

One of them was at night. A medical physicist was called by the nursing staff to a hospital because it seemed that the radium ribbons had shifted. The physicist came to the hospital, verified that this was the case. She notified the authorized user who felt that they probably didn't shift and did not come to the hospital and the next morning it was verified that they had shifted. So the medical physicist, strictly speaking, would have had to violate current rules in order to prevent this misadministration from happening.

Another case which comes to mind is a medical physicist working out the procedures for brain treatments with iodine sources found that it would be very desirable to do a dry run before you implant the implants into the patient. By dry run, I mean treat a plastic phantom head. The brain surgeon objected to that, feeling that it was unnecessary waste of time. The medical physicist insisted on it but it put him in an awkward position. He felt that he was maybe even endangering his job by insisting on it, again because NRC procedures do not authorize him to make any specific request.

During the dry run, three of the four implants would have missed the tumor completely because the physicist tracked it down to there were two different types of frames being used.

So again, what the NRC regulations needs to do is be specific on what the medical physicist can do and should do so that he can do his job right.

The other issue is qualifications. Right now as the rules are written, it appears as if the physicist's work was a black and white issue. The physicist does his work. Right. Everything comes out okay. Or if the physicist does a poor job, there's a misadministration, time for more rules or some fines. This is not how medical physics is practiced. The outcome of radiation treatment depends in a graduated way on the performance of the medical physicist.

For example, in the brain treatment with radioactive sources, it is the medical physicist's ability to come up with an implant configuration which does not require an undue number of bore burr holes which the brain surgeon doesn't want to do and the ability of the physicist to come with the configuration which encloses the tumor with the proper isodose curve. If he doesn't do it, either part of the tumor sticks out of the radiation field and doesn't get treated or undesirable structures do get treated.

When you look at isodose curves of an isodose plan which has been prepared by the physicist and you see that

the 5,000 rads curves, just as an example, nicely includes a tumor, most of us are satisfied. In reality, you are kidding yourself. The treatment plan in computers use algorithms which are just not that accurate. We are not that sophisticated yet. So right there you have an ingrained inaccuracy of several percent.

By the time the medical physicist has prepared or in order to prepare that 5,000 does line, there were at least a dozen steps starting with measuring the output of the radiation unit, measuring beam profiles, depth dose curves, entering those data into the treatment plan and computer. So if in each one of those many, many steps there's an inaccuracy of only one percent which certainly wouldn't cause any major concern, the cumulative error can be such that you are more then 10 percent off. So unless you have superb medical physics services you may end up having a misadministration in each and every one of your treatments without knowing it.

So, therefore, the misadministration which is so often quoted in NRC regulations loses totally its meaning unless you have a physicist who has the ability of measuring the radiation and computing it with this kind of accuracy. To do that requires superb performance.

Therefore, I would highly recommend that NRC recognizes the importance of the physicist and make specific requirements for their training equivalent to those of the

authorized user that is available. Medical physicists now have the ability of getting qualified with board certification by the same specialty board which qualifies the authorized user, so why not do it? I'm not asking you for anything special to do this because the American Board of Medical Specialists lists physicists who are qualified by ABR certification as medical specialists. They are listed in the same book in which neurosurgeon, urologists and radiation oncologist are being recognized. I'm not asking for anything special.

Then finally I want to point out why is it so important to address this issue right? With the increasing use of HMOs, you can expect many radiology oncology departments to be reorganized. It happens all the time. It was exactly the reorganization of a medical physics procedure at Riverside which led to the death or injury of 400 people, so unless NRC intervenes and makes specific duties for physicists' specific qualifications, they're going to set the stage for similar incidents to happen many, many times as the reorganization continues.

Thank you.

CHAIRMAN SIEGEL: Any questions for Doctor Brezovich before he leaves right now? If not, we'll catch you with questions during the discussion.

MEMBER NELP: I have a question. Of the people

working in the field of medical physics, medical physicists as you describe, what fraction of them are qualified by the standards you quoted and what fraction would not be qualified?

DR. BREZOVICH: I would say that right now there's enough qualified physicists available to cover all the nation, what needs to be done. I would say that probably two thirds of them, the ones who are in direct practice. That would be my guess.

MEMBER NELP: Most of them are board certified?

DR. BREZOVICH: I would say.

DR. WILLIAMSON: Jeff Williamson. I think the market penetration of either American Board of Radiology certification or American Board of Medical Physics -- there are two boards in radiation oncology physics -- I say it's somewhere between half and two thirds.

DR. BREZOVICH: Okay.

MR. CAMPER: One of the things we're going to be exploring, Doctor Brezovich, this morning is this question of the training and experience and qualifications of the physicist. We have particular concerns about HDR use and in our regulations, as you know, we currently have qualifications for teletherapy physicists and we've made some adjustments in guidance space as it relates to physicists involved with HDR. So when we talk about that, your perceptions of what is the appropriate level of training and the types of training

specifically.

One thing I would ask you to bear in mind is that in our regulations we do not and can not limit qualifications to only board certifications. There has to be an or pathway, and that's because of some constraint of trade considerations. So it's very important to us. The board certifications, of course, for us carry a specter of success and accomplishment and achievement obviously. By the same token, there are other qualified individuals, well-trained individuals who don't, for whatever reason, achieve board certification.

And so knowing in particular, are the boards currently addressing the right kinds of things in terms of HDR? Do you feel that board certification today in the realm of HDR is an adequate level of training and experience and documentation of such? And for the or pathway, what types of things might we specifically focus upon? So when Trish Holahan goes through that part of the talk, your perceptions on that would be extremely useful to us.

DR. BREZOVICH: Okay. First of all, I want to point out that the ABR is not the only one. American Board of Medical Physics would be another one. Also we would certainly be in favor of recognizing the equivalent Canadian boards. That is not different at all from what NRC is right now doing for the authorized user. The authorized user specifically lists the number but I would certainly be all in favor of

doing that for the physicists.

As far as HDR is concerned, usually my experience has been when a really qualified person has been in work for many, many years. When we get the job like I had, okay, we are going to do HDR half a year from now. Most of us know it is a big involvement, a big step. The first thing, as soon as I knew what would happen, I spent days on the phone trying to talk to my peers and qualify myself. I evaluated individual units. I went to places. So basically a person who knows the responsibility you have. I know that every one of those patients' life depends on what I do, so I think if you have a person with this -- and most of them, I would say, do it. They will on their own do whatever it takes to do the job right. I would certainly not object that NRC put specific requirements like that you get shipped to the company where you start to look at how they are doing it and try to understand. I would be very much in favor of it and I think it would help because again, with the HMOs money may be a problem and if it's required that you get training from the factory, I think it would be great.

CHAIRMAN SIEGEL: Jeff.

DR. WILLIAMSON: Well, I would like to thank the people here at NRC for inviting me here to address you about the very important issues that have been put before us. As you can see, I am going to make some critical comments about

current NRC regulatory and enforcement practices. I don't wish this to be construed to imply that I'm opposed to the involvement of NRC in directing the improvement, in motivating improvements of quality care in our field. I'm really not at all. As Doctor Brezovich has very eloquently described, the whole focus of our profession as medical physicists is to, with the resources at hand, maximize the quality and efficacy of the treatment.

Well, what I'd like to do is share what are some widely perceived problems with the current appraoch that NRC has taken and then present some positive suggestions. So I'm going to be a little more general.

I think one concern that a lot of people is that NRC rule making attempts, rule making understood very generally to include the licensing criteria and the whole schmear, seems to be catastrophe-drive. That is, possible error pathways come to the attention of the rule makers through basically a series of low probability, random events, occurrences which I believe themselves are defined according to relatively arbitrary criteria so you're not getting sort of a balanced view of what the endpoints of true quality assurance programs are if that's all you look at.

Then relatively rigid and inflexible rules are made by individuals who, by education and lack of clinical experience, are really not qualified to do. So, as a result,

we have -- I'll show on the next slide -- sort of no balance, no sort of consideration for the relative probability of these events, their relative importance compared to other things we have to be concerned with in order to guarantee adequate treatment to the patient.

Finally, this is coupled with an adversarial and punitive enforcement policy that basically focuses again on isolated deficiencies and errors, more often than not paperwork and documentation errors that have really, in a sense, nothing to do with the adequacy of treatment or the program. There doesn't seem to be much emphasis on the overall quality of the institution's program for guaranteeing good quality therapy.

So I guess the question is, is this helping the quality of treatment or is it hurting it? I would submit that it is in some ways doing a fair amount of harm by basically distorting the whole process. I think we're in a situation now where most institutions under NRC rule have to have two quality assurance programs.

First of all, there's the real quality assurance program that's developed by the professionals involved in order to guarantee not only protection of the patient from catastrophic errors but overall quality of treatment, and it's looked at as a much broader perspective. It's a coherent system in the ideal situation that's thought out

perspectively, looking not only at the errors that have happened, i.e., the horses that have escaped from the barn already, but sort of reviewing the whole system of treatment planning and delivery in an effort to identify the critical decision points and build in checks to guarantee or optimize success at least.

So we look at things, for example, the adequacy of the treatment. Have we used the best applicator of those available to realize the clinician's intent. In addition to making sure the prescribed dwell positions in HDR are accurately delivered, we asked the question, gee, are those dwell positions in the right place? Are they consistent with all available imaging information you have in order to identify the location of the tumor? So this is how we work.

The for show system that NRC has developed through, I think, what is a random, rather haphazard way of looking at the process seems to be motivated by exaggerated concerns like the one out of 100,000 chance that the tipica source is going to detach and stay in the patient, that someone in the middle of the night is going to come and steal the remote afterloader, that some thoughtless technician or therapist is going to treat the patient simultaneously with the LINAC and the high dose rate. Certainly we don't want these things to happen but they really detract from our attention and focus on the things that are important. It's

simply unbalanced.

I'll point out some other things. One very important issue that seems to be neglected is the staffing and the credentialing of that staff. Now just is there a physicist there but given overall the duties of that physicist in the institution, is there enough physicist FTE to take care of technologically sophisticated modalities such as HDR?

What are some positive things that could be done? I'm very pleased to hear that you're looking at the whole process with an attempt to try and come up with something that's more realistic. Well, as Doctor Brezovich has talked about, recognizing, I think, the role of the radiation oncology physicist is a very good start. He very eloquently explained what our role is.

I'd like to point out one other area that we're actively involved in as a national community or professional community and that is development of professional standards of technical practice through groups such as the AAPM, ACR, American Brachytherapy Society, ASTRO and NCRP even has some relationship. These are groups of experts who have both the technical background and enough involvement with the sort of clinical problems that I think we're in a very good position to try and define a coherent, broad-based system that looks at all of the endpoints necessary to assure quality, not simply the sort of arbitrarily defined catastrophic ones NRC has

traditionally looked at.

I'll mention one other thing. I think probably the single most helpful thing you could do to improve radiation oncology technical quality of practice would be to look into the issue of staffing guidelines. Number of physicists related to patient load, number of treatment units in the institution, and their sophistication. I think compared to other developed countries in the world this is an area where implementation of standards is highly variable and in some cases so bad that it wouldn't even be tolerated in many third world countries the way, in the worst cases, therapy has been practiced in the last 10 years.

I just show you some of the practice standards that AAPM has recently issued, other ones that we're involved with which the last two I'll bring to your attention. Brachytherapy code of practice and HDR safety are going to basically generate very detailed QA protocol recommendations. So I'd like to issue, just not only personally but in behalf of my profession, an invitation for NRC to participate in the development of these standards with the community instead of going it alone and sort of using the catastrophe-driven appraoch that seems to have characterized past behavior.

I'd also suggest reviewing enforcement strategies. As I say, right now I think institutions with well-functioning quality assurance programs and high volume of

patients that detect the errors are basically singled out for punishment for these isolated failures despite having an overall good quality assurance program. I don't think I have time to go into examples.

I'd suggest rethinking this strategy, not punishing isolated compliance failures, but rating the licensee on overall program quality, staffing levels and qualification, whether they have in place procedures to implement the standards of practice as developed by groups such as AAPM and ACR and then an overall score to sort of rate the compliance of the institution in implementing these programs. I think also a little flexibility in accepting practices that may appear different but lead to basically the same end would be well-advised.

Finally, I'd suggest looking at the reporting criteria that you use for defining catastrophes which is the input of the current rule making system. I'd say with regard to administration there are a couple of approaches that could be taken. I would recommend that you change the meaning of the concept from serious technical error that may have some potential negative consequences to the patient to a serious technical error which has a well-defined non-zero probability of having negative consequences to the patient in terms of increased cost of treatment, complications or increased recurrence rate.

I think certainly the misadministrations that have been alleged in our institution, none of them has resulted in any kind of patient injury or even epidemiological risk really. So I'd suggest if you're going to have a criterion that involves some implications for the physician-patient relationship, define it more realistically.

A second thing you could do if you are interested in technical errors for their sake as indicators of possible inadequacies of the program, then make a criterion which is purely technical to identify those errors that you'd like to see without interfering or having implications for the clinical management of the patient. So I'd suggest really taking a good look at that.

In fact, a detailed proposal has been submitted to you, which I was involved in drafting, by the Radiation Committee of the AAPM and a similar proposal, I believe, through ASTRO and ACR.

I'd like to thank you for giving me an opportunity to give some input into the process.

CHAIRMAN SIEGEL: Thanks, Jeff.

Larry, do you have a question?

MR. CAMPER: Thank you, Doctor Williamson. You made a lot of very interesting comments and we thank you for those. Amongst the things you said, although many of them were important, I was struck by one and if I were in the

regulating community, I would be concerned about this as well. It's this question of the qualifications of individuals who create the regulations that you have to live with on a day-to-day basis. I guess what I really want to do is take a moment or two to address that, not so much to defend the NRC but more to elevate your level of comfort because again, I think it's a genuine concern that those who regulate us have some idea of what they're doing.

On our staff we do have a number of individuals, graduate level physicists who, in their careers, have practiced in the therapy arena, but we do recognize, of course, that the world of regulation on a day-to-day basis is not the same as being in the hospital clinical environment dealing with patients, so it's important, it's crucial that we get out and get the kind of interaction that you're talking about.

What I want you to be aware of -- I don't know if you are or not -- in addition to this committee, we hove several meetings, participations in upcoming professional society meetings which we intend to take the very things we're going to discuss with the Committee today and solicit input from the practitioners and I'm very happy to say that recently we were invited by the AAPN to participate in a task group that's been created to develop standards, industry standards, particularly with regard to HDR. I think that's a perfect

example of the kind of thing that you're getting at.

I said before on record and I would only reiterate again that the best that can happen from our perspective is that industry would develop standards. We could work with you to do that and then embrace those standards in our regulation. That is the best way to go. We don't want to do it on our own. We certainly don't want to do it in the absence of participation by you, the practitioners. So I hope that, in sharing these comments with you, it elevates your comfort level a bit but we are sensitive to your concern.

DR. WILLIAMSON: Well, I certainly didn't mean to impute the educational credentials of the professional NRC staff. I'm well aware that, more than most federal agencies, graduate degrees in health physics, reactor engineering and all kinds of very complicated technical specialties are well-represented.

I do want to point out though that there is a sort of a critical additional potential that a medical physicist has and that is basically clinical experience. It's sort of like expecting sort of a general practitioner or neurosurgeon to be able to write detailed practice standards for radiation oncology clinical practice without having gone through a residency. It's sort of hard to know what all the issues are. Someone can tell you what all the issues are but

it's sort of difficult to get across. What is sort of the balance and relative importance of the different issues? How in a really model program from our perspective, maybe not yours, do we balance the concerns for non-catastrophic maintenance of patient quality versus focusing on catastrophic? These are sort of big questions because there aren't infinite resources to staff all of these things. We can't focus everything on avoidance of low probability catastrophic events. It's that kind of a perspective that clinical practice can give you.

CHAIRMAN SIEGEL: Dan.

MEMBER FLYNN: I had a brief question, since you have that slide up. Since you've highlighted it in yellow, misadministration might be redefined as greater than 20 percent of the total dose or a total being emphasized. With cobalt telepathy going by the wayside-- by the year 2000, there'll probably be fewer than 100 machines. We're closer to 2,500 machines or more of linear accelerators that the NRC doesn't regulate. I want to understand your intent. Do you intend to say that the NRC should be taking into account errors generated from linear accelerators which they do not regulate when a misadministration is reported for brachytherapy when a patient is being treated by combined external beam with a linear accelerator and brachytherapy? Is that what your intent is?

DR. WILLIAMSON: Well, I think so. I mean you've identified a lot of possible implications. The idea here developed in the ASTRO Physics Committee and in the AAPM is to try and come up with a criterion that captures more closely errors in dose delivery that have a significant chance of really having some implications for outcome, clinical outcome in terms of the treatment.

The way we proceed is one has to look at the entire course of therapy and that a 20 percent or 30 percent error in a single fraction, provided it's caught in time and adjusted or compensated for by adjusting the prescription for subsequent treatments, be they other brachytherapy procedures or LINAC-based external beam therapy, there may not be a patient injury, so it was an attempt to come up with sort of a more realistic definition that would try and capture those events where there is sort of a serious interest or need to involve the patient and perhaps have regulatory agencies oversee that that has been done.

So yes, that was the intent was to sort of include all relevant therapy in the determination of whether the event is a misadministration.

CHAIRMAN SIEGEL: Just in addition to that, I think as we work through this later this morning, we should continue to try to focus on the issue of what events the NRC needs to be aware of because they wish to evaluate systematic

problems out there in the world as technical problems and try to figure out ways to help the community do a better job versus what events the NRC needs to deal with in its perceived responsibility to make sure patients are being adequately protected and then result in the sort of criminal outcome events that sometimes are associated with misadministrations. We've talked before about the disconnect between that need to know, and which we all completely agree with, and the fact that sometimes there's punitive outcomes that simply don't make any sense given the fact that there's been no injury involved. So we should keep that in mind.

Another sort of general comment because I'm hearing something both from Jeff and from Doctor Brezovich that I want us as a committee to keep in mind as we talk specifics. One is to what extent we want to go along with recommending that the role of the medical physicist as part of the team be codified. Do we want to protect medical physicists' jobs per se by way of NRC regulations? That may be good. It may not be. But I think in general this committee, at least over the last several years, has been urging the NRC to back off from protecting the roles of certain medical specialists by way of regulations and letting the market place do a better job of filtering that out by itself and letting professional standards work out it. I think we want to keep that in mind as we talk about the

medical physicist role.

I was even a little bit more troubled by the staffing issue and I was curious to know. If you push staffing as part of a federal regulation, there's two things that can happen. One is you can get the staff. The other is you can just drop the brachytherapy program as you look at it and say, Gee, in order to do this it's going to cost too much. Let's just forget it and we won't offer the service.

So medicine is re-engineering right now far later than occurred in most of the rest of corporate America. If we get too much federal regulation while re-engineering is going on, we may find ourselves out of work and not necessarily better staffed.

Doctor Wagner.

MEMBER WAGNER: I just wanted to commend Ivan and Jeff for some excellent comments this morning and I'd like to request Jeff, could you possibly get at least me a copy of your slides, please?

CHAIRMAN SIEGEL: Did you bring paper copy with you?

DR. WILLIAMSON: Yes, I brought a paper copy.

CHAIRMAN SIEGEL: Maybe we can get those xeroxed. If you give them to Torre, we can get copies made sometime later for distribution.

Judy, do you have a comment?

MEMBER STITT: Yes, I did. This is Judith Stitt. It's a response to the last comment that you made. Doctor Williamson and I are both part of Task Force 56, the brachytherapy code of practice and, in fact, the introduction to 56 has a large section that deals with staffing and sort of the pluses and the minuses. I don't think this needs to be something that's regulated through the federal governments. The hospitals, their administration and the clinical practice groups are making some very straightforward comments about what you need to consider if you're trying to develop and maintain a program.

CHAIRMAN SIEGEL: And that's fine. Once it becomes part of a federal regulation though, then you've got something that constrains you because the federal regulations can not evolve as rapidly as we re-engineer and figure out more clever ways to solve the problem with fewer resources.

MEMBER STITT: That's what I was trying to say.

CHAIRMAN SIEGEL: Good.

John, you want to comment on that?

MEMBER GRAHAM: One brief comment. Back to some of the earlier remarks that even alluded to HMO development and re-engineering and health care and the potential negative impact that that has. There's simply in all of the management literature and most of the overall tracking of quality of care and mortality and morbidity data is not an indication that as

we become more efficient, as we identify ways to maximize the use of those trained staff, that patient care is being damaged. If anything, it would appear to be a corollary that the quality of care goes up as the cost comes down and as we work together in a team to identify that best patient care.

So the whole concept of trying to regulate at a federal level staffing requirements in a field that is changing as rapidly as this one just doesn't seem to be consistent with the way that medicine in the United States has developed and in a system where I think the rest of the world still recognizes that it is the best in the world.

CHAIRMAN SIEGEL: Good.

Doctor Brezovich, you had a comment?

DR. BREZOVICH: Yes. I just wanted to comment on your comments and concern maybe that the physicists are trying to protect their turf. Well, there's always this possibility when you request certain standards but I do want to point out that NRC at the present time is requiring the authorized user to meet certain standards. So you could say we already are protecting the turf, namely the radiation oncologist.

In that regard, I want to point out the chain is as strong as its weakest link. So what good does it do to have the most accurate dose prescription if we can't deliver, if the patient won't benefit from it? If you consider the possibility of somewhat lowering the standards, at least

easing up on them, for financial reasons which I totally agree, then I think we should use the material which we have to make the chain, to make each link of equal strength. So if you lower the standards on the physicist, maybe we should also not be quite as stringent on the radiation oncologist and thereby get the best possible outcome for the given amount of money.

In that regard, I want to point out that I think in Sweden -- I have not yet fully researched it-- the gamma knife in Sweden I think is used by neurosurgeon without the benefit of radiation oncology, so that would be down your line.

CHAIRMAN SIEGEL: Jeff.

DR. WILLIAMSON: I would like to make a comment, too, about the suggestion that there's an issue of self interest. Of course there is, but I would like to point out, we did not invite NRC to come in and regulate quality of radiation therapy delivery. That's their sort of announced goal. I simply want to support what Doctor Brezovich says. You can't make a sailboat without a sail. Technologically sophisticated therapy involving stereotactic radiation and HDR therapy simply goes beyond the level of technical expertise shared by radiation therapists and technologists and radiation oncologist in this kind of therapy. If it is either going to be done safely, basically, it's sort of a critical and

essential role of the medical physicist, so you can't have quality therapy, I think, at least in this domain, without some involvement of the physicist.

CHAIRMAN SIEGEL: Jeff, you don't have to convince me. I completely agree with you and I'm only reflecting on my own experience related to the way credentialing is done for physicians and the notion that simply codifying it in the federal regulations is just a nice comfortable way to do it and it'll protect the jobs and it'll make sure everything is okay isn't necessarily the only way to get where you want to be.

I think if the radiation oncologist and the medical physicists of the world agreed that this simply had to be a team effort and that that was the right way to do it -- and I suspect the people around the table pretty much agree with that -- then there may not be a need for it to be rigidly defined in federal regulations that this is the only way to skin the cat and I just want us to keep that in mind as we work through the questions.

Trish.

DR. HOLAHAN: Well, I'm going to try and talk while I'm flipping slides. Jim Smith -- I don't know if you all know him -- is going to be helping me, as well.

A couple of comments that I would like to follow up on based on comments that both Doctors Brezovich and

Williamson made is that the use of industry standards is something that we're very interested in and we addressed this at the last meeting is that we are trying to determine the availability of industry standards that do exist. I know the AAPM, ACR and ASTRO all do have a number of different documents out currently.

Some of the other issues include the role of the medical physicist and things like that. We're going to sort of walk through some of these.

One other point I would like to make is that in the issues paper and as I'm talking there may be some discussion of the policy and guidance directive for licensing of remote afterload loaders as having requirements in it. They are not requirements as regulations but through the licensing process there are things that license applicants are being asked to commit to and so when I use the term requirements, I don't mean in terms of a regulation and I just wanted to make sure I clarified that in case I did use that term. But it's more a recommendation and licensees can propose an alternative to what's in the guidance.

The way that I've outlined this is I've broken the paper down into three different topics. One that applies to all brachytherapy, then the next topic is remote afterloading brachytherapy specifically and the third topic is manual brachytherapy. Now the only issue that I have

specifically under manual brachytherapy is prostate implants and I think Doctor Flynn will address that more and I'll hold those questions back until perhaps his discussion. I've already talked with him about that.

(Slide change)

DR. HOLAHAN: Because of the number of issues, we're going to try and do this with two projectors. I hope that I don't get too confusing.

The first issue, and we discussed this briefly again last November, is the use of sources for brachytherapy. Currently there is very specific listings in 35-400 for specific isotopes for how they may be used and the form in which they may be used. What NRC has proposed doing is deleting the specific listing and making it a more general requirement because, in addition to having these requirements in the regulation, all sources must have a sealed source and device review and, therefore, the particular use is listed in the source certification sheet.

So NRC is considering removing the listing and adding basically a general requirement that states either there must be a certificate of registration issued by NRC or an agrement state and be manufactured and distributed pursuant to Part 32 regulations for manufacture and distribution of sources. The question is -- again, I recognize this was discussed earlier at the last meeting

-- is should NRC pursue this appraoch in terms of the listing of sources for brachytherapy uses?

CHAIRMAN SIEGEL: Can I ask a question, something that struck me as I was reading the document. When a certificate of registration is issued, does that certificate indicate the specific use of the source?

MEMBER STITT: Yes, it does. It indicates interstitial, intraluminal. It does specify the specific use. That's basically what the testing is done for.

CHAIRMAN SIEGEL: So the restriction to use a particular source for a particular application would be by way of its labeling rather than by way of Part 35.

MEMBER STITT: Correct. It would be whatever is listed in the source certification. Currently now if a manufacturer goes in and requests a change to their source certification sheet for an additional use, a licensee would then have to come in and ask for an exemption to 35-400 if it's not stated in that or it would require a change in the regulations.

CHAIRMAN SIEGEL: Okay. So the process would become more efficient by doing that. A manufacturer can change the package label, if you will, the package insert for a source -- I'm thinking in FDA terminology right now -- without you having to change the language in Part 35 to allow licensees to be able to do that. They wouldn't need

licensing amendments and you wouldn't have to change Part 35. But the restriction to not use a source for an off-label indication would still be there. Is that correct?

MEMBER STITT: Yes. They could not use it for a use that is not specified.

CHAIRMAN SIEGEL: Since I don't practice brachytherapy, I just want to make sure. Judy and Dan, is that the way it ought to be?

MEMBER FLYNN: I believe so. I don't think you should use a strontium applicator for skin cancer as was done in Pennsylvania. I think that's reasonable.

MEMBER STITT: I think it makes the clinician's life easier. I think it makes your life easier and, as an institution who would be reviewing the sources and their uses, you would try to make it as broad as -- you might be using something for interstitial and might later want to be using it for intraluminal and as long as that's a reasonable indication, it's how you'd prepare the paperwork for you. I think it makes a lot of sense. It simplifies many things. So my answer to one and two was yes and yes.

CHAIRMAN SIEGEL: But if the source is only certified for interstitial and you want to use it for intraluminal, then you still won't be able to do it unless you do a license amendment or unless the manufacturer does the paperwork for you. What I'm concerned about is the potential

for an orphan application of a source that you want to do in a relative hurry because you've got a patient and you see a perceived need. You don't have time to file a license amendment and you can't recruit a manufacturer to get the source recertified for that purpose for you. It doesn't make any difference what I do for a living whether or not you have the same flexibility with sources that I have with drugs, and that you have with drugs, but I'm just wondering whether the practice warrants, practice needs warrant that level of flexibility.

MEMBER STITT: Let me ask Jeff. Is that a highly unlikely circumstance? Our sources are a little different than yours are obviously.

DR. WILLIAMSON: Yes. I think our categories of use are very general. I mean interstitial covers a vast range of procedures. I guess I would like to ask. Under the current procedure, if we contemplate a use, for example, that's not listed in the original device registration -- say, for example, some cesium tube the vendor forgot to say, you can do quality assurance with it or you can do animal experiments with it -- and we wanted to do that. Could we do that under the current process and would the new process make it any easier if we can't?

DR. HOLAHAN: Well, first of all, you're at a broad scope facility and so you have a certain amount more

flexibility than a specific licensee. Now, in terms of the Part 35, that's only for human use. So if you're looking for non-human use --

MR. CAMPER: Let me add to that. Currently, a licensee or a manufacturer can seek approval of a source for some purpose other than which it is currently registered. There's criteria in Part 32 that has to be met. If the licensee can satisfy that criteria, they can pursue the approval process currently. Interestingly enough, the reason why we want to change the language is there is a perception that the NRC is the entity that's being restricted in terms of denying the capacity to use these devices for other purposes than, say, for example, interstitial or what have you for a particular source. In fact, as Barry has pointed out, it's what the source cert says.

So we believe it's more clear to the industry from our perspective as regulators, you may use the device for whatever purpose has been approved and it's irrespective of whether it was obtained by a manufacturer or by a licensee who submitted the appropriate material to satisfy the requirements of Part 32. Interestingly enough, over the past few years, we've had a few requests that have come in from licensees to use certain things and in almost every case in our deliberations with them, we found that they were unable to get the manufacturer to pursue the adjustment. I don't know if

that's just purely cost consideration, volume or what have you, and it poses a problem for them. But yes, a channel does exist.

DR. WILLIAMSON: I think this is reducing a two step process, revision of the device registration, plus a license amendment on the part of the user to a one step process, mainly the revision of the device registration, and that's not changing.

CHAIRMAN SIEGEL: And I'm still asking one more time, I just want to make sure we're clear. Does this committee think it should be a no step process, namely that an unapproved use of a registered device should be something that authorized users and medical physicists should be able to do on their own recognizance? I'm not saying that I want that. I'm just wanting to make sure we've addressed the question. Dan and Judy.

MEMBER FLYNN: I think you can keep it broad. Interstitial in some sources could be interstitial and intraluminal.

CHAIRMAN SIEGEL: Right, they could be but they only will be if the manufacturer took the time to register them that way. Registering, I presume you would require some data for registering a source for a purpose. You just don't do it because you write the words down. And that means that the manufacturer has to spend the money to register the source

and there's always the risk that there would be some orphan application for a source that a manufacturer will say, the market is too small for me to expend the effort to get that documentation into the NRC, therefore, I'm simply going to leave it out of the label and that means that you won't be able to use that source for that purpose unless you gather the data and you file a license amendment. And it's okay if it's a non-issue or if it's not going to come up.

I can tell you, if that were the way drugs were handled, it would be a disaster and the FDA, at least until very recently, has quite clearly recognized that the package insert does not limit the physician's ability to use a drug for a purpose that isn't in that insert. And the only question I'm asking is whether that's appropriate in this practice, whether sources should be limited to interstitial, intercavitary, intraluminal, pick your term, or whether you want it broader than that.

MEMBER NELP: Do you practice that way? Do you sort of have impromptu revisions of treatment plans where you think, in this case, I would use this source for this because it might be more beneficial in this particular case?

MEMBER STITT: The run of the mill brachytherapy is really quite straightforward as to which source you're using and what application and it has a lot do with how the sources are made, whether they're small and thin, can be used

for interstitial, or bigger and bulkier and have to be used for intercavitary.

The physicists are over there jumping up and down and I can see them.

MEMBER NELP: We in the nuclear medicine end, like Barry said, we can take a drug that we do tumor imaging with, it's not approved for that but it may be useful for that. We found that out and we just go ahead and use it, but apparently it doesn't seem to be a problem in your practice domain.

MEMBER STITT: Certainly for the bulk, probably 90 something percent or even more of what clinicians would want to do, there's a pretty well recognized use of a particular source. As I said, it has a lot to do with its energy, how it decays and the physical form that you can get it in. Our practice for isotope work is different than nuclear medicine.

MEMBER FLYNN: I think the drug work is another good example because we're talking about a very small number of radioactive isotopes that we're using for a very small number of uses with a number of manufacturers you could probably count on one hand. I mean I don't think the manufacturer is going to neglect to put that information. You're talking about a very few suppliers of these isotopes.

CHAIRMAN SIEGEL: It's no skin off my back.

Ivan.

DR. BREZOVICH: I certainly agree with Doctor Siegel's concerns, namely, you could have a need for an orphan application. By the time you get through any kind of a regulatory process, the patient has no longer benefitted from the treatment. Maybe we should make an exception which says in individual cases any source can be used for any use, maybe after consultation with a physicist. The reason why I think the physicist may come in, I know it may sound again as turf protection, but I think there's a legitimate concern if you have, for example, an iodine source and those are encapsulated in very fragile capsules so if that is being interstitial in a way that it bursts open and the iodine is a thyroid seeker, you could really have major damage. But I still that an individual case should be allowed to do it. Maybe after you've done it, you should simply report to the NRC what you have done and if you want to do it routinely, you should then get the amendment.

CHAIRMAN SIEGEL: Larry.

MR. CAMPER: Let me point out that the Part 32 criteria -- I don't have a copy of Part 32 in front of me unfortunately, but it focuses upon, not so much what the clinician wants to use the source for, that's almost secondary, if you will. It does more to do with the design of the source. For example, if the source is on some type of rod

that will be bent to place the source, it has to do with the tensile strength of that particular applicator. It has to do with the dosimetry of the source in a specific body part or a specific mechanism such as interstitial. But clinical utility is almost secondary in that process. It's really about the source itself.

CHAIRMAN SIEGEL: Jeff.

DR. WILLIAMSON: I just would like to give you an example of where our institution got in trouble with the existing regulation or had a problem. We were forced to trash $60,000 worth of cesium 137 after loading Heyman capsules because the vendor wrote in the device registration that they could only be used in the Microselectron LDR Remote Afterloading System. There was no technical or safety reason why those sources couldn't have been used for manual afterloading after we abandoned the use of those devices. They were unwilling to cooperate in changing that device registration.

CHAIRMAN SIEGEL: Jeff, could you have gotten a license amendment to allow you to use those sources for another purpose? Did we explore that?

DR. WILLIAMSON: We were granted authority to use them only as an emergency measure if the remote afterloader broke and we needed them to complete the treatment of the patient, but my understanding was that we were kind of barking

up the wrong tree with the amendment process. We needed the device registration revised.

CHAIRMAN SIEGEL: Bob and Dennis.

MEMBER QUILLEN: Bob Quillen. I'd just like to agree with what Larry said about the device registration. It's about the safety of the device, manufacturing of the device. It's not really about the use of the device.

MR. CAMPER: Yes. If you look just for a moment, bear with me. I know regulations can be boring to listen to as well as to read, but maybe it's some value to us all. 32.210 is the part and it basically, for example, says "The request for review of a sealed source or a device must include sufficient information about the design, manufacturer, prototype testing, quality control program, labeling, proposed uses and leak testing and for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards to provide reasonable assurance that the radiation safety properties of the device are adequate of protect public health and safety."

MEMBER NELP: It does say proposed use.

MEMBER QUILLEN: Yes, but that's really secondary to the review of these sources. We've done those kinds of reviews and the use is just sort of a secondary issue.

CHAIRMAN SIEGEL: What role does FDA have in this

process? Do they evaluate clinical uses of the sources?

DR. HOLAHAN: I don't know. Larry, can you answer that?

MR. CAMPER: It's going to undergo a device approval by the FDA but there again, the FDA focus is not so much about clinical use as it is about the device and how it is manufactured.

CHAIRMAN SIEGEL: Dennis.

MEMBER SWANSON: I guess the arguments I'm hearing would seem to support the concept of not limiting it to the registration provided -- I'm getting some mixed messages. Does the NRC look at uses? You're saying they don't but is there the risk that they will limit it to the specific uses in the registration? Then I think you're losing the flexibility to practice medicine again.

MR. CAMPER: Well, currently that's what happens for these specific sources for these specific purposes and there's a historical basis because those are the sources that have been approved for those uses, of course.

MEMBER SWANSON: I understand that.

MR. CAMPER: What we would do is we would have language, as Trish is pointing out, that you may use a device for which a registration certificate has been filed for the purposes authorized by that registration. It would not allow use of that source or device for something that had not

undergone review and approval.

CHAIRMAN SIEGEL: but I'm hearing a different consensus than you are from the radiation oncologists at the table who are saying they can live with this language. And I'm concerned that it might be going abridged too far to make it wide open. So, we need closure on this one.

MEMBER SWANSON: The point, I guess, I was trying to make, I just heard that you lost $60,000 odd because basically you couldn't use this device because of restrictions in the product registration. Am I correct? And that's not a concern to anybody else? I would think it would be a concern.

CHAIRMAN SIEGEL: Dan, Judy, Bob?

MEMBER QUILLEN: One of the issues here is what the manufacturer wants this source to be used and how it wants the source to be used. And in some cases they want to limit their liability for the use of the source.

MEMBER STITT: Yes, I mean I'm sort of caught here because I'm thinking of generic cesium, generic radium tubes, generic iridium, and then you've given a very good example of what you got caught in, and I think what you caught in is just exactly what you're referring to, Bob.

So, if you have cesium tubes and it states that you can use these cesium tubes for intercavitary or interlumina work, the way I understand what we're discussing here is that the NRC can't tell me which lumina or which

cavity those are restricted to. And so as we're discussing this I don't have a problem, yet your specific is a very good example of how you could get caught. But I think that comes back to the manufacturer and their protection of themselves.

DR. WILLIAMSON: Yes, I just wanted to point out that sometimes the restrictions on use are more restrictive than just these very general categories of implant.

CHAIRMAN SIEGEL: But then I guess rather than mess with this approach, it's better to have professional societies talk to the manufacturers and say, "Try to make your language a little bit less restrictive insofar as liability issues allow you to do so."

Okay.

MEMBER FLYNN: There should be a way to remove the manufacturer's liability if you're going to use the device. They used this radioactive source outside the manufacturer's device in another device or in another instance where they may not be the same.

CHAIRMAN SIEGEL: We have major changes in tort law necessary before we can remove liability just as easily as that. And Congress is working on it, but they're not there yet.

Okay. So I think the answer is, a consensus is yes, which is where we started. But I wanted to make sure we at least explored that issue and had aired it.

Continue.

DR. HOLAHAN: Okay. Well, that was the simple issue

MEMBER STITT: Yes, that's what worries me.

DR. HOLAHAN: The next issue under this first topic is training and experience. And first of all, and we've sort of heard some very elegant introductions over here, in terms of currently the only requirements for physicist's training within NRC regulations and Part 35 is for a teletherapy physicist. And these training and experience requirements basically did come in as following the Riverside incident. They were incorporated into the regulations. And there are two pathways is the -- currently it's the American Board of Radiology's certification. I do appreciate what was said earlier about the American Board of Medical Physics. But what is in the current regulations is ABR certification, but there is also an alternate pathway which includes clinical experience as a teletherapy physicist.

Now, in the policy and guidance directive for licensing of remote after loaders, there is indications in there that the licensing must provide the name of an authorized medical physicist using the same qualifications or referring to the qualifications in 35.961, which does not have any specific training in remote, after load or brachytherapy.

So, the question I guess to be posed is, first of

all, should NRC create a separate category of brachytherapy physicists or should NRC consider deleting the teletherapy physicists and making a general medical physicist category, and then have specific training and experience requirements under a broader category of medical physicists? So, if we deal with that question first and --

CHAIRMAN SIEGEL: Yes, let me just address one part of that and wonder whether you would at least for a transition period under all the teletherapy units have gone away want to do something like you've done with radionuclide therapy where you have 35.930 that's all encompassing, but then you also have cancer of thyroid carcinoma alone and hyperthyroidism alone. And I'm wondering whether you might want to aim towards a broad medical physicists category but still allow a teletherapy or a brachytherapy only while people have more restricted practices at the present time?

DR. HOLAHAN: Now, would that come in to say more in terms of the actual criteria under the or category as to what would be acceptable alternate criteria to board certification.

CHAIRMAN SIEGEL: I think so.

DR. HOLAHAN: And I'm assuming here that board certification would encompass teletherapy and brachytherapy.

CHAIRMAN SIEGEL: Right. Just as it does with--

DR. HOLAHAN: Correct me if I'm wrong, please.

CHAIRMAN SIEGEL: Just as it does with 35.930 and 32 and 34 ABNM certification captures the whole thing, but you drop to the or category if you want to do just Graves disease or you want to do just thyroid carcinoma. So, I mean, I think I would recommend that you not drop out the subcategories yet is my sense, but I'm also willing to hear what other people vote or think, obviously.

Judy?

MEMBER NELP: Does this describe a brachytherapy physicist as well as a teletherapy physicist if you just change the title?

DR. HOLAHAN: Well, except here in the alternate criteria it requires specific clinical experience with teletherapy physics.

MEMBER NELP: It could be teletherapy and/or -- change a few words if that's close to what the physics people perceive themselves to be. Just add teletherapy and/or brachytherapy and continue with that definition.

MEMBER STITT: Well, I've got some biased opinions on this matter. I thought it was a very simple issue. I just had a single word as far as my response.

The NRC created the teletherapy physicist and the question is should they create a brachytherapy physicist? There is no such thing as a teletherapy physicist. You're a medical physicist or you're not and so my answer is no, they

should not create a specific category.

There is a broad category of medical physicist. There's no such thing as a teletherapy radiation oncologist except possibly -- well, actually that doesn't even exist in regulatory language.

So, I'm just saying that we have professional credentials or standards, they're very specific, and I won't speak for the AAAPM, but I know that there's some heated discussion by the physics community in this regard.

DR. HOLAHAN: I guess I just wanted to address that if I could quickly. I think the broader question is, is rather than creating a category of medical physicists should NRC have training and experience criteria for a medical physicist? I think rather than trying to talk about creating a new section --

MEMBER STITT: Well, and that's why I brought them up as separate because it does talk about a teletherapy physicist, and that's an NRC phonomania, that is not a -- that's where that phrase has come from. So training and experience is one issue, and I think we have to be very careful about making up these artificial sort of categories that don't exist for physicists or for radiation oncologists or diagnostic equivalents.

MEMBER FLYNN: In most of the small programs, not the big programs like Mallinckrodt, but in the small programs

the physicist has teletherapy duties and brachytherapy duties. So, I agree. I mean, I don't see how you can break it out separately.

Maybe I'm bias in thinking of that person as a radiation oncology physicist as distinct from, let's say, someone from nuclear -- whose trained in nuclear medicine physicists and has a lot of training and experience in nuclear medicine physics and maybe thrown or cast into the role of being a radiation oncology physicist for whatever reason and not having the experience in brachytherapy physics and teletherapy physics, and that's my only concern. I think of it in terms of a radiation oncology physicist. Would you agree with that or not?

CHAIRMAN SIEGEL: Let's see, Jeff?

DR. WILLIAMSON: Yes, I would agree with the concept of a radiation oncology physicist as opposed to specialized teletherapy and brachytherapy physicist. I mean, I just would -- I'd like to underscore a point of Dr. Brezovich's, and that's that we're not like factory workers that are trained to do one task repetitively. One of our major roles in the clinical practice is to be able to respond to the novel and the unexpected, and as a result we have, you know, graduate level education and credentialing process very similar to that of physicians in order to sort of build up that base of scientific expertise and judgment to do that.

So, I think that no more than you require an authorized user to have specific clinical training in HDR, I would suggest that you not impose additional requirements on the physicist beyond board certification, specifically in radiation oncology physics as Dr. Flynn has suggested.

CHAIRMAN SIEGEL: But board certification alone won't do the job from a regulatory point of view because not everybody chooses to become board certified and the Federal Government cannot require that that's the only way you can get these credentials, because otherwise it's restraint of trade.

MEMBER NELP: Well, that's you do what you've done there.

CHAIRMAN SIEGEL: No, but Jeff seemed to imply that was the only route.

DR. WILLIAMSON: Can I clarify. No, I'm not opposing that you have a Part B. I think it's sort of reasonable, just as you do for physicians, radiation authorized users and you now do for teletherapy physicists to basically reiterate some alternative credentials which are very similar, I should think, to the eligibility criteria for sitting for the boards. It's basically very similar to that. It says you should have a master's degree or Ph.D. in an appropriate area and X number of years of experience working under such-and-so depending upon the level of your degree.

CHAIRMAN SIEGEL: Okay.

Ivan?

DR. BREZOVICH: I do want to bring out some concerns about Part B, namely there are now programs where you can get a master's program in physics very easily because that's the way to attract students. I mean, physics programs are badly hurting for students and therefore what they do is they lower the standards to whatever it takes to get their classes full. There's no generally recognized credentials for somebody to be called a master's. If three physicists get together or two, they can start a master's program with students, and they'll go down, down, down until you get the students.

So, while in the medical doctor, the requirement of a medical doctor there's at least some kind of a general consensus that a medical school has to meet certain criteria.

So Part B now, it might be regulatory not possible to eliminate it totally, but maybe we can add that it must happen at an accredited schools, otherwise it becomes meaningless.

CHAIRMAN SIEGEL: That probably also is restraint of trade, too, my guess. You can use those kinds of approaches to get deemed status and thereby bypass some of the regulatory requirements, but it's not clear that you can exclude people who don't meet those various tests from participating in the process.

You can go to medical school in Grenada and you can jump through some hoops and get to practice in the United States even though you went to an accredited medical school. So there are ways to achieve these things.

I'm not sure that it would be easy for the NRC to do that.

DR. HOLAHAN: The other point in the alternate is that it does also require a full year of full time training in the specific field and also under supervision.

CHAIRMAN SIEGEL: Right.

DR. HOLAHAN: So there is some aspect that you do have to have some experience in the --

CHAIRMAN SIEGEL: Bob and then John.

MEMBER QUILLEN: My comment falls under your comment you just made about training in the specific field. And I don't see this in the alternative, and I'll give you an example. In our state we have no teletherapy units left, but we do have HDR and we have gamma knife. And if you wanted to be a gamma knife physicist, you could become a gamma knife physicist under this criteria without ever have seen one because you were in an institution where they didn't have one, you got all the other kinds of training, let's say, but you had no experience in that.

So one of my concerns is that you're talking about this alternative approach here, you need to clearly say

that you have applicable training.

DR. HOLAHAN: Well, that ties into my second question that says what is an acceptable alternate criteria to the board certification process?

MEMBER NELP: Well, what's wrong with what you have up there now if you just changed the title training for radiation oncology physicist and whenever you say teletherapy, just change it to that and you'd have a very complete definition?

CHAIRMAN SIEGEL: Well, the problem is what Bob just point out.

MEMBER NELP: You'd have the or.

CHAIRMAN SIEGEL: In the case of A the assumption is is that the American Board of Radiology will have made assurances to the NRC that it's training programs include training in teletherapy, in this case which will be linear accelerators rather than with cobalt units, brachytherapy, gamma knife and all the other things that come into play. The problem with B, though, is that if you just change B to radiation oncology physicist it's conceivable that someone could have been trained only in the use of the gamma knife during a year and have had no training whatsoever in brachytherapy.

MEMBER NELP: That doesn't depict the integrity of the field of medicine. You're not going to hire someone or

you're not going -- this person also has to have training and experience. I mean, the NRC can't expect to cover every considerable or every conceivable situation in a broad sweeping term. I mean, the integrity of the field is, you know, is responsible for what goes on, not the NRC.

DR. HOLAHAN: We do get requests, though, from people that do not have experience in the field that they wanted, either for example gamma knife or for teletherapy or even for brachytherapy that have had no brachytherapy experience. So we do see that already.

CHAIRMAN SIEGEL: We see that also.

MEMBER NELP: You say they must have brachytherapy experience. If you'd change teletherapy, you'd have that in section B, as I see. That's all I'm saying.

DR. HOLAHAN: So you're agreeing that it should be the applicable therapy experience for -- okay.

MR. CAMPER: Well, perhaps you could continue that modification slightly by putting in some additional qualifying language where it says a year of full time working experience under the supervision of a radiation oncology physicist at a medical institution including the modalities requested for approval, or something that affect.

CHAIRMAN SIEGEL: That's fine. And that would do it.

MEMBER NELP: Now isn't there more than one board

that certifies physicists and you're only referring to one board here. You should put the other board in, I think.

MR. CAMPER: Well, there's a process, though, for that. I don't recall exactly, because the American College of Medical Physicists came to us recently and sought approval, I think, for teletherapy physicists and perhaps radiation safety officer. And we had discussed that with the committee previously and the committee, in fact, is the ones who ultimately approved the request by the board. And then that certifying body will be added to when we revise the language in the part. But the process is that if a board for either physicians or physicists chooses to be added to our regulations for recognition, then they go through a process of submitting a request to us for that; we review it, we see if it appears to meet the criteria which has been established previously in our reviews in extensive interactions over the years with the American Board of Radiology. And then we ultimately bring it to this committee and ask that you endorse it or not. Then, of course, it becomes added to the regulations.

So, if there are others that haven't gone through that process yet, they could do so.

CHAIRMAN SIEGEL: Dennis?

MEMBER SWANSON: One quick question, how does the Part B training experience requirements correlate with the

training experience requirements of the authorized user physician? Does it parallel it? It probably should. It can't be more?

MR. CAMPER: Well, it is certainly similar to the therapy categories. Obviously, it's substantially more than the diagnostic categories. But, yes, I would say that for the therapy uses in 35.600, for example, it's very similar.

I think that the physicians have a little bit longer. I think it's three years for theirs, but it's very close.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: I'd like to just ask the other physicists, the therapy physicists over there a question regarding this. In brachytherapy physics it seems to me that the physicist would have to have specialized training in brachytherapy physics. Obviously at some of the larger institutions there's a responsibility that any physicist would know that if they don't have training, they have to go get the training. That's quite clear.

I think some of the concern is that at some of the smaller places, private practices or other areas that might be doing some kinds of therapy would hire physicists who might not have the training and the physicists might not get the adequate training. And I think that is what the concern is, and that's the potential. What are your thoughts on those

areas if you get outside the larger institutions and university based institutions?

CHAIRMAN SIEGEL: Jeff?

DR. WILLIAMSON: Well, I think maybe the suggestion that the alternative experience requirement includes some exposure to brachytherapy or the modality, might not be a bad one. One has to be sort of careful. I mean, how many institutions in this country could one go to have a two year fellowship in brachytherapy physics? There's probably maybe four or five, and I, you know, there just aren't programs to support a very narrow specialized and extensive training experience like --

MEMBER WAGNER: But if that's the case, if that's the case, is it then appropriate to release physicists that don't have that training into the area without the specified training? Is it adequate in that case or is the fact that we just have so few a restriction we're going to have to live with?

I don't think that you've asked -- you've directed yourself at the point. The point is, is would the physicists be adequately trained without that?

DR. WILLIAMSON: Would the physicists be adequately trained without some direct exposure of some kind to brachytherapy I guess is the question.

MEMBER WAGNER: Right.

DR. WILLIAMSON: Well, I think it would be kind of difficult to get through the board certification process unless you had some exposure to the clinical practice. I'd put it that way. It would be very difficult. I think one could maybe learn it on one's one.

CHAIRMAN SIEGEL: We're agreeing with you.

So the consensus as I hear it here in answer to the first question is that what NRC ought to do is not create a category called brachytherapy physicist and should in fact delete the category called teletherapy physicist and call it radiation oncology physicist, if that's the language we like.

MEMBER STITT: I think that's artificial, too. I think medical physicist is the correct term both from board certification and from training. There are certain subdivisions within that, but then you've got some very specific things in Part B. And I think that the teletherapy ought to be deleted, brachytherapy shouldn't be instituted, but you can very specific in both Parts A and Parts B and that should cover both the institutions where you've got folks that do nothing but brachytherapy physics and institutions where they're doing diagnostic as well as therapy physics.

MEMBER WAGNER: The only problem I have with medical physicist is that also includes diagnostic physicists.

MEMBER STITT: That's right. And that's a common practice in the community hospitals across the country.

CHAIRMAN SIEGEL: But there's nothing -- you can be a medical physicist who does diagnostic physics and still meet the NRC requirements to be something more specific. And, I mean, it doesn't make any difference what's in a name. And does there --

MEMBER NELP: You have to have that list of--

CHAIRMAN SIEGEL: Is there a strong feeling about whether the NRC regulations ought to say medical physicist or diagnostic -- I mean radiation oncology physicist?

MEMBER NELP: You say medical physicist and he has to have those criteria, that's fine.

CHAIRMAN SIEGEL: Whose the one who suggested the term? Was Da the one who suggested?

MEMBER FLYNN: I suggested it originally and Jeff endorsed it.

MEMBER NELP: And I endorsed it. I'm taking back my endorsement.

MEMBER FLYNN: I withdraw my suggestion then.

CHAIRMAN SIEGEL: All right. So call it medical physicist and then the alternate criteria should include sufficient language to make it clear that you've got to have applicable experience for what you propose you want to do.

Continue.

DR. HOLAHAN: Okay. So on the training and experience issue is currently in section 35.410 there are

special requirements for radiation safety instructions to personnel carrying for patients undergoing implant therapy, which includes size and appearance of sources, safe handling and shielding, procedures for notification of RSO and emergency. In addition to these requirements is policy and guidance directive on licensing of remote after loads; specifies training for ancillary nursing personnel carrying for patients undergoing LDR therapy in patient rooms.

And, again, this is something that is done through licensing guidance. Now, the issue of training of nurses and things has come up in the past and we have had several incidents involving in which the nurses have not received sufficient training to be able to respond in the case of a source becoming dislodged, you know, how to handle either the source or the patient.

And so I guess the question is, first of all, are the current requirements adequate to ensure that all personnel carrying for patients have received the sufficient training to minimize personnel exposures both public and occupational.

CHAIRMAN SIEGEL: I have no opinion.

MEMBER FLYNN: I have a couple of comments, since this is an area that I've been interested in for like three years.

In the big institutions it doesn't seem to be a problem with the nursing personnel because the nursing

personnel in a big institution see the procedure commonly performed, become accustom to it and are dealing with physicians and physicists who are well trained who also doing it very frequently.

The problem seems to me to be in the very small institution when this low dose rate implant patient is by themself with the nursing personnel at night, nights and weekends, and things happen. And so I'm concerned that at least in the smaller institutions that one hour of training per year, or whatever the program is requiring of their nursing personnel for nurses who are on a brachytherapy floor, is not sufficient. And I've nurses in small hospitals when I've gone there to give a talk, you know, what would you do if the patient had -- a brachytherapy patient on a Saturday night had severe chest pain, had trouble breathing, a whole series of problems. And there was a great deal of hesitancy as to what to do.

For example, I mean, if I was to interpret what you say there, procedures for notification of the RSO in an emergency, that's actually part of Part 35 now. It should be procedures for notification of the authorized user physician and the RSO because there have been instances where a problem has occurred and the nurse has called the radiation safety officer for a medical condition. And waiting for the radiation safety officer to return a phone call when she

should have called the physician I think is a problem. And I think if that gets into the training of nurses, that they don't call the physician for a medical emergency or a medical problem and they call the RSO first and then the physician, I have a big problem with that. So I think that there needs to be more training for the nursing personnel. It doesn't appear to be necessary in the big institutions, but certainly in the smaller ones where there have been problems it -- the nurses are left by themselves and I think it's not fair to the nursing personnel who have many, many other duties to just have one hour of training. They could be on vacation during the time of the year that one hour of training was given. So I think a lot more has to be done for nursing personnel.

CHAIRMAN SIEGEL: But, Dan, but you're missing the question, I think. You're addressing the question of whether the training has been provided adequately as opposed to the question is are the requirements for training sufficient. The rule says you've got to train people in these things, it doesn't give you the option to not train them. So what Trish is really asking is do there need to be more things in the list of training. And you've suggested one, and you've suggested it before and we're on record as agreeing with you. But that's more of an implementation issue than it is a requirement issue.

What the content of the training should be. So

do you think the content of the training is currently adequately as specified in the regulations?

MEMBER FLYNN: No.

CHAIRMAN SIEGEL: Aside from what you just said, what else do you want in that list of things?

MEMBER FLYNN: For one thing, what the radiation safety instruction should involve personnel exposures. We have many instances of nurses who are afraid to go into a room and patients have problems. So for the nurses to understand the exposure, exposure rate and other things --

CHAIRMAN SIEGEL: That's addressed elsewhere in the regulations.

DR. HOLAHAN: That's also addressed in these Part 19 training that they have to provide them.

MEMBER FLYNN: And should the nursing personnel be trained in the procedures they would follow in terms of what if a patient has a medical emergency while being a brachytherapy patient in the hospital?

MEMBER NELP: I think that latter is the practice of medicine between the nursing staff for credentials and her physicians. And I don't think the NRC wants to get into that domain at all. I think if you notified instead of the RSO up there, notified the licensee, that would be the physician in charge of the case that's ultimately responsible.

MEMBER FLYNN: I think the NRC should judge what

specific training, but if they could require that there be policies and procedures developed by the licensee with the nursing staff as to addressing a range of medical emergencies that occur in brachytherapy patients.

CHAIRMAN SIEGEL: Let's see, I think Judy was first and then Lou.

MEMBER STITT: You know, I think that the requirements are adequate and, you know, they look very sufficient. I think what Dan has brought up as an example is not the requirements per se, the frequency or the clinical utility or actually just how often do you go through these procedures. And he's right, the places that do a lot of this, they're very adept at it. IF you do one or two a year, and you had an hour of training a while ago, it doesn't count for much. But when you just look at the material that's listed, I think those requirements are adequate. It's how it may be carried out from one place to the other that may be the issue here.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: Yes, I think I'd like to have a little more definition of the issues. In all the cases that you cite here for examples where there's a place deficient in its instruction of the nurses or did they just not have the instruction at all or was there a violation in terms of their not instructing their nurses?

DR. HOLAHAN: There were both cases. And there were some cases that there was sort of insufficient training, although they had gone through and shown them. For example, in one case they had shown them what a ribbon looked like, but they didn't really explain that the seeds were in the ribbon because they had a dummy ribbon up on the door, and they had just -- they taped the ribbon to the patient's abdomen when it came out of the implant site.

There are other cases where there have been temporary nurses brought in from other areas that have not received the training. So there are both issues.

MEMBER WAGNER: So we got a problem here in that number one, we don't have to solve the problem because the institutions didn't abide by the rules in the first place, that's part of the issue. But now the second issue that you're pointing out is that although the content of the instruction appears to be adequate, the effectiveness of the instruction is inadequate.

DR. HOLAHAN: Correct.

MEMBER WAGNER: So the issue isn't whether or not we have to expand on the content, the issue is how do you expand on the effectiveness of the content?

MEMBER NELP: Well, that's done by inspecting the facility, isn't it, and getting assurance at the time that they have a program that's appropriate?

I mean, someone either at the state level or NRC goes in, "Okay, let me see your program for training your nurses. Does it fulfill these criteria?" They have then the opportunity to make a judgment that you do or don't have an adequate training program. And that's about it.

MEMBER WAGNER: I usually find that to be relatively inadequate itself.

MEMBER NELP: Well, it may be, but --

CHAIRMAN SIEGEL: But that's actually not the right way to inspect it. Increasingly that's not what you all are doing. What you're doing is you're going and talking to the nurses and saying, "Tell me what you do when the following happens?"

MEMBER NELP: Well, yes, that's part of the inspection.

CHAIRMAN SIEGEL: You don't look at the paper program, because you can write anything in a paper program.

MEMBER NELP: OF course.

CHAIRMAN SIEGEL: I think the program effectiveness is being inspected, so I'm still confused here.

We heard that Dan wants to include notify authorized user in the event of an emergency in addition to RSO. I'm still not clear I'm hearing the answer to what you think should be in there about procedures for dealing with emergencies other than notification, whether that should be

part of the training or not.

DR. HOLAHAN: I guess maybe the other question is, is does there need to be something in in terms of what are the actual procedures for training the nurses and how is that information relayed, as I know there's generally specifics for a specific patient; that often rather than the radiation safety officer coming back in, is it's just relayed from the head nurse on one shift to the next head nurse, you know, as the patient goes through.

And what are the actual procedures in terms of the actual training, and maybe that's another question do we need something in terms of written policies and procedures?

MEMBER FLYNN: Well, I've got specific phone calls about -- and these are specific instances that weren't reported to NRC because they didn't feel it was a problem. But a patient has chest pain, severe chest pain with a heart history, significant chest pain. They don't call the EKG technician, they don't draw the blood until waiting for one hour until the authorized user/physician comes in and takes the sources out.

Now, many of these patients are elderly and they have other medical problems. I think you can't be too prescriptive, I agree, but I think there should written policies and procedures on how medical emergencies are addressed for brachytherapy patients to allow for the safety

of the patient while minimizing the exposure to the staff and personnel. And I think we're going to have a misadministration in the next year or two, we're going to have a patient who either dies or -- for a medical reason, not because the radiation.

MEMBER STITT: But that's fine, Dan, as long as that's not a misadministration. They can die of a heart attack and we're happy. It's better than dying of a radiation isotope --

MEMBER NELP: You're inferring that the nursing staff is frightened or hesitant to go into the patient's room because the patient is radioactive?

MEMBER FLYNN: That's correct, and also the EKG -- once you get the EKG technicians involved and the blood drawers involved, this was an actual case, by the way. And it wasn't report, but then you get other people involved and the nursing personnel don't have enough training to let them know that, you know, that this is allowable in an emergency situation. So what they do is they wait until the sources are removed from that patient.

CHAIRMAN SIEGEL: So wouldn't it be sufficient to change bullet number four up there to be something like procedures for handling both medical and radiation safety emergencies, including procedures for notification of the authorized user and the radiation safety officer? Doesn't

that capture the whole thing.

MEMBER FLYNN: Yes, I don't want to be too prescriptive, I just want to be able to make sure it's covered, that's all.

MEMBER WAGNER: Maybe the additional thing there is what you're trying to point out is the procedures for the immediate care of a patient in the event of a medical emergency?

MEMBER FLYNN: Yes.

MEMBER WAGNER: Because it's the immediate care of the patient that you're concerned about.

MEMBER FLYNN: That's right.

MEMBER GRAHAM: Well, it's the clarification I think of the source because I'll bet in every one of those hospitals there were nursing policies and procedures that clearly delineate the responsibility of a nurse to contact the attending physician in a medical emergency.

MEMBER NELP: Period.

MEMBER GRAHAM: Period. So I don't think we can regulate what is a basic element of running a hospital and the interaction between that medical staff and the nursing staff.

CHAIRMAN SIEGEL: Right. And really in this case remember what this is addressing. This is radiation safety instruction and it's designed to teach the people who are involved what they need to do to protect themselves and

visitors in order to do their job. And so that's the focus that has to be there. But I think this expansion into the area of how to deal with a medical emergency is a reasonable thing to incorporate in this. Do you agree?

MEMBER FLYNN: You know, in the case that I talked about the nursing staff called the physician, the physician ordered an EKG and blood work and the nursing staff would not let the blood drawer nor the EKG technician enter the room because they weren't controlling personnel.

CHAIRMAN SIEGEL: So we agree? Judy, you agree? Judith, you agree?

MEMBER STITT: I have no idea.

CHAIRMAN SIEGEL: Okay.

CHAIRMAN SIEGEL: Folks, we're way behind schedule here based on the way this looks. And we need to buggy here or we're in deep trouble.

MEMBER STITT: My comment would be that I think the requirements are properly written. If you want to modify, I agree with you, they're there for safety of patient, visitors, public, etcetera. It sounds like the hospitals are having a problem with their implementation of their own program. And you're right, every hospital has something about interaction of patients, nursing and the medical staff. So I think we have to e careful not to try to regulate how institutions are practicing medicine.

Yes, I agree with whatever it was you said.

MEMBER NELP: I agree with what you agreed with.

CHAIRMAN SIEGEL: So we think we've reached a consensus.

MEMBER STITT: There's a question over here, and it relates to something that's happening tomorrow.

MEMBER SWANSON: One quick comment. If you go back to the brachytherapy module, for example, it includes training for nursing staff that, in fact, there are 27 items there and part of those items are exactly the things you're discussing.

CHAIRMAN SIEGEL: Okay.

MEMBER SWANSON: That's a reg guide.

DR. HOLAHAN: Yes, that's guidance.

MR. CAMPER: Guidance, right.

CHAIRMAN SIEGEL: Part of the issue here, just to make sure that all of the committee understand this, is that there are things now that get written into licenses as part of the licensing process that are not clearly spelled out in Part 35. In general the goal of putting new Part 35 out eight years ago or nine years ago was to get all that licensing stuff into the regulations and make it uniform, and that's part of what this discussion is largely about.

Okay. Why don't we continue with these questions and then we'll try to take our coffee break.

MS. TAYLOR: Excuse me. Can you me a consensus of the committee?

CHAIRMAN SIEGEL: The consensus is that the requirements in 35.410 are in fact adequate with the modifications needed, the language needs to address medical emergencies and it needs to address the need to notify the authorized user as well as the RSO in the event of an emergency. I think that's what we said.

Okay. Next?

DR. HOLAHAN: The next question I think is sort of fairly straightforward is -- maybe I shouldn't say that. Sorry.

CHAIRMAN SIEGEL: Indeed.

DR. HOLAHAN: Are the current requirements in 35.410, are they sufficient also then to address low dose rate remote after loading or do we also need to include perhaps the use of a survey meter in there, which is what's currently in the licensing guidance?

CHAIRMAN SIEGEL: Lost me. Where is that question?

DR. HOLAHAN: Middle question. Should the licensing requirements for training of ancillary nursing personnel in the policy and guidance, which is --

CHAIRMAN SIEGEL: Oh, I see.

DR. HOLAHAN: I apologize. Does there need to be

anything additional added for nursing personnel handling patients with remote after loaders? It's maybe a more basic question.

CHAIRMAN SIEGEL: Dan, Judy, Lou, Jeff, Ivan?

MEMBER STITT: Ask Jeff.

CHAIRMAN SIEGEL: Jeff?

DR. WILLIAMSON: I think basically the requirements that you have written up there could be slightly generalized. Size and appearance of the sources, you know, and associated treatment delivery devices, which I think the implication would be they're taught how to do those operations they're supposed to do.

Regarding a survey instrument, I would disagree that for most remote after loading institutions, that's necessary at all because the handling of emergency procedures and finding lost sources and so on is not the responsibility of the nurses, I think, in most institutions. There are on call personnel, usually the radiation oncology physicist who does that and the time scale I think is viewed in the community as, you know, a half hour to an hour response time is adequate. So I wouldn't want to put more restrictive in there.

Pulse dose rate would maybe be the only exception where one would have to have more rigorous technical requirements or qualifications.

DR. HOLAHAN: Okay. And we're going to address that pulse dose rate separately later.

CHAIRMAN SIEGEL: Maybe.

DR. HOLAHAN: I hope. Maybe I'll jump -- I may move through some of these.

CHAIRMAN SIEGEL: So I'm still not sure I've got the clear answer to this.

MEMBER NELP: Why would we change it?

MEMBER STITT: I think no is the answer.

CHAIRMAN SIEGEL: Okay. No. All right. All right.

DR. HOLAHAN: Okay. And then the last question on this issue was whether or not NRC needed to consider adopting specific training and experience requirements for dosimetrists and technologists, which are not currently in the regulations. And I know you address it very briefly at the beginning, but we've discussed it in the past.

CHAIRMAN SIEGEL: Well, that's a big issue, right? I mean, that's not a ten second issue.

DR. HOLAHAN: Yes. Currently the regulations do not, and it's always being placed in the responsibility of the authorized user to ensure that people working under their supervision have received adequate training and experience. I think the question has come as brachytherapy becomes more evolved, the dosimetrists have a larger role obviously working

with the physicist.

MEMBER NELP: What's the difference between the dosimetrist and the physicist that we were talking about? Don't the physicists do the dosimetry?

DR. BREZOVICH: I would say the relation between the physicist and the dosimetrists is similar to that of a physician and a nurse. I mean, the physicist basically trains the dosimetrist and tells him in terms of telling them the basics of physics, tells him how to use a computer to do those sophisticated calculations. If there's any problem with the computer or if they don't know how to do it, they come back to the physicist.

MEMBER NELP: Does the dosimetrist operate under the supervision of the physicist?

DR. BREZOVICH: That's correct. Absolutely.

MEMBER NELP: And so the physicist is his boss, so to speak.

DR. BREZOVICH: Absolutely.

MEMBER NELP: And assumes the responsibility for his actions?

DR. BREZOVICH: Yes.

CHAIRMAN SIEGEL: Yes, I think that it's very much similar to the way nuclear medicine technologists would act under the supervision of a nuclear medicine physician. I think that we would be wise to say that for right now we're

not prepared to answer this question until the time we're ready to discuss major paradigm shifts in how you evaluate training and experience both for professionals and ancillary personnel involved in all medical practice.

I think to take this big a jump with a very short discussion would be a mistake. Does the committee agree?

MEMBER NELP: I agree, yes.

CHAIRMAN SIEGEL: Okay. And therefore we're going to take a big jump to the little boys and little girls room and take a break.

(Whereupon, a recess at 10:16 a.m. until 10:27 a.m.)

CHAIRMAN SIEGEL: We need to try to reconvene folks. Can you all take your seats? Okay, we are back on the record. Are you ready for us at that end of the room? Good. We need to cruise.

DR. HOLAHAN: Okay, while everybody was out I went through issues 3 through 7, so I hope you all appreciated the discussion on those. I thought what I would do is I would put those aside for now and maybe work on some of the ones that are a little more controversial.

CHAIRMAN SIEGEL: I actually have a sense that some of the time that we've alloted for other things in the meeting will be more ample than we need. And if we later in the meeting have to revisit some of this, then that's what

we'll do.

DR. HOLAHAN: Okay.

CHAIRMAN SIEGEL: Because this is important stuff which is why we're discussing it at the length we're discussing it.

DR. HOLAHAN: Yes, and it has been very helpful, you know, so.

Okay, what I'd like to do is move on to some of the definitions. And I know at the last meeting we had some discussions that there's some concern with some of the definitions that we have as to being either somewhat awkward to use or additional information whether it needs to be in there or not be in there.

This is first of all the definition for written directive. And, Jim, if you can put up the first question. First of all for HDR, basically all that's required is the isotope treatment site and total dose. And the issue of fractionated HDRs has come up before, do we need to have a dose per fraction? What additional information should be in this definition or is it sufficient as it is?

CHAIRMAN SIEGEL: I would defer to the experts.

MEMBER STITT: Dan, you start because I'm still -- this bothered me. I mean I don't have --

MEMBER FLYNN: Well, Judith has done about 20 to 100 times more HDRs than I have, but since she asked me to

start. The one that bothers me is the total dose. Is it easier that we look at a prescription? Now, sometimes a prescription can be for one fraction and sometimes the patient will come back because of an incomplete tumor response to the one fraction to get a subsequent fraction with a second prescription as opposed to a prescription that says (x) dose times five twice a week for two and a half weeks. So I don't know if one always knows that the total dose is going to be.

DR. HOLAHAN: Well, I think in terms of your first response, I think where NRC's perception has been, that would be two written directives.

MEMBER FLYNN: Okay.

DR. HOLAHAN: If you're saying that the patient goes, has one treatment and then comes back at a later time because of their insufficient response. So it would be the total dose in terms of that treatment.

Now, it could also be that you could say five fractions per total dose of.

MEMBER FLYNN: Just so you know that it's my understanding that some of the authorized user radiation calls your physicians writing their prescriptions. Sometimes they write them as a per fraction basis and sometimes they write them as 500 times six, 500 centigray times six. And are you looking at the written directive then as the 500 times six as the total dose for that prescription?

DR. HOLAHAN: Total 3,000.

MEMBER FLYNN: As opposed to -- and you will look at it differently if a physician is writing it fraction by fraction as he decides how far to go or writes it for that one treatment for that day. He writes a prescription for that day only.

CHAIRMAN SIEGEL: But maybe you're getting the cart before the horse. One issue will determine how a misadministration gets defined.

DR. HOLAHAN: Correct.

CHAIRMAN SIEGEL: The other determines what's a practical relevant approach to writing these prescriptions. And maybe if we could, for the moment, put aside the impact on the definition of a misadministration and rather address what's practical, how do you want to write HDR prescriptions. Do you want to write a prescription that says the patient is going to come and be treated three times over the course of the next six weeks, and that's my plan, and have that be really the directions you're giving to the people who work for you? Or do you want to write three written directives and have a treatment plan recorded separately in the patient's medical record, but that it doesn't obligate you to NRC related activities because it was a written directive? That I think is really the question or part of the question.

DR. HOLAHAN: Well, yes. And actually that also

gets into, if you could maybe put the next slide up underneath that one please, Jim, as in terms of a treatment plan is, you know, talking to many members of the community. They've indicated that really they develope the treatment plan and then they go and write a written directive to sort of fit on our C definition, but all the information is on the treatment plan. Can the treatment plan actually be the written directive, if that's signed by the authorized user?

MEMBER STITT: Barry, I don't disagree, but the problem is that many people do practice in the fashion to try to avoid a circumstance that puts them into the definition of a misadministration. And written directive is not a medical term, it's an NRC regulatory term. And we do doses and we give treatments, and we don't do written directives except that when you come back and put something on paper so it looks right to the NRC. This issue has to do with also issue 4 which is fraction of brachytherapy. They're all related.

And in general I try to be a broad spectrum person, and I think that's probably the best way to try to do regulations. But I'm having trouble and I'm a clinician that does lots of this day in and day out, and I have trouble trying to look at it both from a clinical aspect as well as from the regulatory aspect.

For example, if you look at teletherapy, and I was trying to say can we do HDR somewhat like teletherapy

because actually the dose rate for high dose brachytherapy is the similar sort of dose rate for cobalt unit single fractions. But for teletherapy all of the biology that we know about tells you that you should use five to seven fractions a week. In this country we tend to do five fractions Monday through Friday.

But in brachytherapy that same constraint really doesn't hold. You can do one fraction a week, but if you write your prescription to say you're going to do 600 centigray in five fractions and then you do five fractions over five weeks but decide to change that to five fractions over four weeks, in theory that could get you into regulatory problems depending on how you wrote it or didn't write it.

So I'm having trouble justifying what we do clinically and trying to stay out of regulatory problems. So I'm having trouble doing what you're saying that we shouldn't do. There are two separate issues.

CHAIRMAN SIEGEL: Okay.

MEMBER STITT: While in theory they are, but your theory can get you into a lot of trouble fractionation-wise. If you say I'm going to give a total dose of 2,000 centigray, you might like to do it 500 plus 500. And let's say you give 600 one time as long as you, you know, you can still not enter into misadministration realm as long as you have then given your second fraction of 400. So there's a lot of ways to

fudge this and I haven't been able to come up with something.

In fact I don't have any specific answers to the first issues that we looked at, and these, the written directive business and the fractionated brachytherapy leave me with a lot of difficulties. How's that for non statement?

CHAIRMAN SIEGEL: I agree. So what you're saying is that current NRC requirements are potentially or in fact distorting the way you go about creating the records for treating these patients?

MEMBER STITT: Yes, particularly we were really focusing on high dose brachytherapy because for low dose brachytherapy there is so much art to it and then for high dose rate you have a tremendous amount of computerized information available before you do anything, and so you can predetermine to a much greater extent what you're going to be doing with high dose rate than you did with low dose rate.

In one of these sections, you can probably find it Trisha, you talk about how low dose rate is actually done, and that's a good description of how it's done. You have an idea where you want to be heading, and then you get some treatment planning and then you make some modifications and then you actually do it, and then at some point before you finish you have to have that written directive completed, right?

DR. HOLAHAN: Yes.

MEMBER STITT: And that's not the case for high dose rate. So I'm having trouble trying to correlate how we practice in high dose rate and relating it to teletherapy, which might be a good example, and I don't think it's going to work in relating it to what we've done for years which is a low dose rate, and that doesn't work easily either. So anybody got any--

DR. HOLAHAN: The other point you raise about teletherapy, and let me just ask you, you had indicated, you know, if you say that you're going to do it in four weeks as opposed to five weeks, well currently in the definition there is no, unlike teletherapy where you have to specify the overall treatment period --

MEMBER STITT: Right.

DR. HOLAHAN: -- there is nothing like that currently in the definition. So you could just say I'm going to give 2,000 rads and then decide you want to do four. And I mean that's a question is, is should it be specified?

MEMBER STITT: Well, for teletherapy I would say yes. Now, that's the way it's written. For brachytherapy I'm less inclined to say yes because you're commonly combining it with external beam and there's a lot of ways in which you would combine it that if you start putting that particular end point on it, that is the total length of time, you've gotten yourself confined into a narrower space and likely to get into

regulatory problems, not into clinical problems, but into regulatory problems.

MEMBER NELP: Well, how in the day to day practice then what do you consider to be a misadministration or an adverse therapy event? How do you say gosh, we really screwed this one up, we gave too much or we gave too little, or so forth, how do you really define that under the setting that you've been discussing?

MEMBER STITT: Well, how you would define that clinically is different than how you would define that by regulation. We know what the regulation --

MEMBER NELP: Well, the regulation should speak to the real world is what I'm trying to get at.

MEMBER STITT: Well, we go around and around and around about that quite a bit. And Jeff and the physics community suggestion that the misadministration be related to a level of clinical outcome, we've talked about that at other meetings, but I think that's a theoretic discussion, it's not one that we're going to be able to solve at this time. And it doesn't help with issue 8 or with issue 4.

MR. CAMPER: Just a comment on that. You're right, Judy, we did just as recently as during the American brachytherapy Society meeting in December in Florida.

The misadministration concept, you know, the term is -- in the mind to some, and I understand that. But it's

purpose was to, you know, to get at errors in the delivery process between what the physician wanted to be delivered and what in fact was delivered, then have it reported for awareness, possible information dissemination, etcetera, etcetera.

Now, there's no question that the advent of the quality management rule, in some cases when there is programmatic problems with the quality management program that can be identified and a reactive inspection following a misadministration theory in some cases or some enforcement activities. There's no question about that. But this theory was to be a threshold well below harm in which things could be identified, reported and corrections actions taken.

And you're right, we've gone around and around a few times about what that threshold is. Now, the threshold you currently have today, we developed during the quality management rule. We did have extensive interactions with the community including the American College of Radiology, AAPM and so forth and so on. And there was a lot of lively debate as you might expect about whether these thresholds are the right ones. And we still debate that of course. So that was at least the goal behind the threshold for misadministration.

Let me point out something else too with regards to treatment side and the problem that we find. And this treatment side I think we've explored with you before and it

really is problematic. You get into this question of licensees being confused. Now, the idea of a fractionation, if you look today int he regulations unlike teletherapy you'll find that there is a requirement specifically in the written directive for teletherapy that you identify a fractionated dose in the written directive.

In HDR that doesn't, it's not the same. And frankly in all candor the reason for that is in 1990, 1991 when we wrote the quality management rule, we weren't aware that fractionated HDR was emerging as a technology. If we were writing it today we probably would have addressed fractionated HDR.

Now, then you get into the question of what's the right threshold. You might recall that we had a discussion with you a meeting or two ago when we were preparing a generic letter and we were discussing what the right threshold. And it was a lively discussion. And I think generally, if we pursue this fractionated HDR reporting, we're probably settling in around 30 percent, at least in our thinking.

Now, this is a practical problem because for licensees who had a problem or a mistake, an error, whatever you want to call it, in a fractionated HDR, in some cases they're reporting them to us because it's not clear to them whether they should or should not be reporting. So that's an issue from a practical standpoint that we're trying to deal

with.

But treatment plan is interesting in the written directive. And I found Judy's comments, her introduction comments to this, were interesting in a sense that we use a treatment plan and then we go back and we create a written directive to satisfy this Agency's requirements.

Well, from our perspective you don't have to do it that way. I understand why you do do it that way, but here's what the real problem is. In some cases a person, an institution, will have a written directive, let's say for example this says right lung (x) number of rads. If you look at a treatment plan though and you intend to have an HDR source dwell in nine or ten different positions of a specific amount for a specified period of time, and in the course of that procedure the dwell position is determined to have been off. Now, we find ourselves along with our colleagues in the Office of General Counsel having to wrestle with does that constitute a misadministration because the level of specificity detail and a treatment plan is far greater than that which is required in a written directive. And the question is, should it be?

Now, I recognize there is a tendency to want to obviously not put anything more into a written directive than one has to because of the regulatory implications, and I understand that. But it does plant as a practical problem for

us as regulators and for the regulated community.

MEMBER STITT: Well, in response to that, I mean the broader the better. Friday I was treating a patient. My prescription for external beam with a linear accelerator, and it's important to how we practice medicine because this is a small part, a very small part of it, and you don't regulate accelerators. But I wrote a prescription to treat the right lung to a certain dose. And then I do, you know, treatment planning different size and shapes of field, various blocks, but it says right lung. Well, I'm not going to be treating the whole right lung. But, boy, if it's a written directive and if it involves an isotope, if it says right lung, but then under some other sub definitions you've gotten some fraction, you know, of a dwell position here or there, we're saying that if it's too restrictive probably anything that was done could be interpreted as a misadministration.

And I think that we have to look at brachytherapy in the overall practice of radiation oncology because it is a part of a whole and shouldn't be separated out with too many subcategorizations that become so tiny that they don't make sense in a clinical setting.

And that, you know, is why I continue to have problems with how broad should the definitions be for written directive? How do we handle fractionation? How do we handle total time? And I don't have a specific answer, and I'm not

sure that we can come up with it right now. I think there are lot of people who need to be involved. I'd like to hear the physics community report on that.

DR. BREZOVICH: Yes, I think from the physics point of view, the most important thing is before we deliver the treatment we want to make sure that we know what the physician wants to be delivered. And that's all that the written directive should really do for us. So, for example, if the physician at the beginning of a treatment course does not show if he's going to give ten or 12 treatments because that will depend on the reaction of the patient. He may put a wavy line after ten treatments which means after ten treatments ask the physician do you want to continue or not. So that means it's totally unambiguous for the delivery of the treatment that we know what the authorized user wants. And I that's the spirit of the law.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: The biggest trouble I have with all this is that the written directive is apparently written for the NRC in order to be something against which they can judge whether or not there is a misadministration. I don't see that it has a real medical value.

And the difficulty here is that that really is tying the hands of the physicians and the practitioners to try to conform to something and cause anxiety to conform to

something wherein they know that this prescription and treatment not only will be written once, but might be changed in mid course for various clinical reasons.

So I have a lot of difficulty with the idea of this written directive being independent of treatment, but then I don't want the NRC going to the treatment and then defining that in such a restrictive way that that becomes a very difficult burden on the physicians either. The practice of medicine here is what's imperative and the written directive seems to me to be a very difficult issue for regulatory reasons. But I really question its importance in terms of medical practice.

MR. CAMPER: Well, let me clarify something for you. The written directive is a regulatory creation, that's correct. We specifically avoided the term "prescription" when it was developed because prescription itself at that time was undergoing some review by the appropriate organizations, and prescription has a certain meaning throughout the health care industry.

But the written directive was created not for the purposes of identifying misadministration, but rather for the purposes of insuring from a regulatory perspective that in fact a written document did exist that contained certain specified information as a minimal requirement because in some cases we had observed instances and had problems where

literally the amount of prescribed radiation that the therapist wanted administered was not written down.

There was verbal communication going on and/or upon questioning the physician would say yes, I know what I want and that's in my mind. But that's where it was, there was literally no written directive.

So it wasn't for the purposes of trying to identify misadministration, it was really for the purposes of insuring that something is in place prior to the administration signed by the authorized user.

CHAIRMAN SIEGEL: And as I've said before, and I think most of us agreed, all the quality management really needed to be was something that said the instructions of the authorized user should be recorded in writing before the treatment commences, period, end of discussion. Not link it to this misadministration reporting stuff and patient notification and all these other things because that's what's now creating -- we're doing exactly what people do when they're faced with an obstacle, we're figuring work-arounds.

And people are finding ways to write written directives that will minimize their liability for NRC action and not interfere with their ability to practice medicine. And that's a waste of everybody's time. It's not useful for anyone.

So I mean I would really encourage that the

fundamental issue is to reinvestigate the link between a quality management program, the written directive, and misadministration notification, patient notification, etcetera because that's really where the problem is.

We all agree that we think it's appropriate. I think we all agree that we think it's appropriate that when patients are being treated that the physician record what he has in mind in writing as a way of clearly specifying the type of treatment to be performed rather than just accepting emergency circumstances, picking up the phone and saying do what I told you, which is bound to lead to errors because of miscommunication. Written communication seems to work best. And we agree with that. It's this other stuff that's creating the problem.

Dr. Williamson?

DR. WILLIAMSON: Yes, I really agree with what Dr. Siegel has said. I think all the comments illustrate that there's a great deal of variability in clinical practice as to what the term written prescription means, and what things might or might not be included in it. You know, there just simply are a lot of variations in the way people practice radiation oncology.

But the issue seems to be how can this be decided here without sort of visiting the sort of essential regulatory issue which is not what is the written directive, but what are

the consequences of not following it exactly. And so I think, you know, it depends on how misadministration is defined and what sort of the enforcement attitude is towards it. I mean that's sort of the central problem.

MEMBER FLYNN: I agree with you also. But I disagree in one aspect.

DR. WILLIAMSON: Please?

MEMBER FLYNN: For HDR, 9301 bulletin, requires that the physician be physically present at the consult, be within audible voice range. That's why I didn't see a problem. I know Judith disagrees and Jeffrey disagrees. I didn't see a problem whereby the authorized user physician would for each fraction of brachytherapy sign his or her name because he's there supervising the treatment anyway.

My problem is that if one writes 500 times ten HDR treatments, and you go by some threshold like 20 percent or 30 percent of the total dose being different from what was prescribed as being a misadministration, you could give more than 100 percent, you could be more than 100 percent off given double or more of the dose when an error is made. Yet because you're in the context of ten other treatments or nine other treatments, it's not codified as being a problem.

I didn't think it was extra work for the physician since they're physically present at the console to sign their name to that fraction because that problem with the

fraction, that that be reported. Just when low dose rate brachytherapy they treat with two fractions oftentimes, sometimes three, usually two, and the prescription is written for each low dose rate fraction.

I realize there are more HDR fractions, but I didn't think it was imposing more on the physician who has to be physically present there supervising the treatment. Maybe if you were to adopt fractional differences, you have to make it a higher percentage like 30 percent or whatever.

But that's my major problem, is you can give a very high fraction in a complication or a possible complication could be associated with a very high fraction as opposed to the overall number of fractions being less than, and still the overall number of fractions, the dose, could be less than 20 percent different than what was prescribed.

CHAIRMAN SIEGEL: We didn't answer your question, did we? I tell you I really think that it's time to go back and look at some fundamental philosophy again and really evaluate what the goals are. I mean "every defect is a treasure," if I can partially quote Deming. But I think we've created a situation here in which defects are not treasures. Defects are things that haunt you.

And rather than the NRC being able to gather information as part of its appropriate governmental responsibility to be a central clearinghouse for problems and

then have the big picture and try to get the word out to help people avoid those problems in the future, we've created a situation where the problems has such severe consequences, reporting the problems have such severe consequences on the people practicing that they're trying to do a work-around. And that's just the wrong spirit of what you really wanted to have in mind.

So I think it would be a mistake for us to jump and tell you how to change the written directive for any specific type of brachytherapy right now until we look more carefully at fundamental issues. Which I presume, based on Don's comment earlier, that one of the things you look at as part of a big part 35 redo is the fundamental philosophy underlying this.

MR. CAMPER: Right, that's true, Barry.

CHAIRMAN SIEGEL: If there is a temporary fix that you perceive you need to stay in business now, rather than have this big group try to work through the temporary fix, it might be more prudent to consider having an expert subcommittee come and sit down with you for all of a day to really work through some of these issues, and then maybe at the next meeting the committee as a whole can help sign off on some of the specifics.

MR. CAMPER: Yes, that's a point well made. Let me sort of just quickly tell you where we are here. I mean we

at one point, and I think Trish made this comment in her opening remarks, we're headed toward a separate stand-alone rule making in brachytherapy. We recently revisited that decision and decided to pursue the brachytherapy issue as part of a major revision to part 35 that will follow the NAS report.

Now, unless some compelling reason arises during these deliberations with this committee or over the next few months as we meet with various societies, that's our plan, but what we're really doing now and the reason we decided to keep the brachytherapy issues paper and initiative alive is that clearly, as demonstrated this morning, these issues are extremely complex. So the more that we can learn through these interactions and then ultimately move into subcommittee meetings with the right kinds of organizations, perhaps even a subcommittee of this committee and so forth, we'll do that. But due to the complexity we thought that we would gather all the information that we could along the way.

But you're certainly right, I mean the big picture needs to be looked at in terms of are the thresholds right? Is the concept of a misadministration right? And all those big picture issues.

CHAIRMAN SIEGEL: Okay.

DR. HOLAHAN: Okay, I think that sort of ties in with all the definitions then. So I'm going to move on

through the definitions and go on to topic 2.

The next thing that I know, we've already discussed training and experience, but this gets more into some of the specifics related to primarily high dose rate remote after-loading. And it gets both into physician and physicist training.

Currently 35.940 does not require specific HDR training for a physician authorized user doing HDr. And I guess the bottom line question is, should NRC include any specific requirements of having experience prior to being listed as an authorized user for HDR?

MEMBER STITT: I always talk too much. Go ahead.

MEMBER FLYNN: Well, the major training occurs during residency, after residency in terms of brachytherapy in general. A lot of times the brachytherapy training has to do with knowing when to use it. And putting in catheters is the same whether it's low dose rate or high dose rate in many cases, putting in tubes in cavities.

There are some unique aspects of HDR that come into play. Anyone who is going to get into HDR, that would automatically be part of the learning process. I think understanding fraction size and understanding the biological equivalence of a high dose rate fraction of 500 centigray is not the same as a low dose rate fraction of 500 centigray. But that's very basic and that's incorporated in the residency

training even if the resident doesn't actually do it him or herself.

So I don't have a good -- I think Judith is working in this area, aren't you, in terms of what sorts of training you would recommend?

MEMBER STITT: I'm working with the American brachytherapy Society. We're going to have the first school for -- the School of brachytherapy will have its first session this December, and I'm running the GYN training school. So, if that's what you mean, yes is the answer to that.

Trish, let me answer a question with a question, what other specific requirements for authorized users does the NRC have in its regulations?

DR. HOLAHAN: Okay. Well, we have board certification now, recognizing too some of the older board certifications did not specifically include -- or some of the board certification from some of the --

MEMBER STITT: Is it like what we talked about earlier for the physicist, but it's for the --

DR. HOLAHAN: -- for physicians --

MEMBER STITT: -- right, that's what I had referred to.

DR. HOLAHAN: -- yes, and I don't have part 35 in front of me to look at the or category specifically, I'm sorry.

CHAIRMAN SIEGEL: The or category other than board certification is classroom training, supervised work experience, and supervised work experience includes a variety of things, and then three years of supervised clinical experience that includes one year in a formal training program approved by the RRC for radiology or several other organizations. And that includes examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatments and any limitations or contra indications, and selecting the proper brachytherapy sources and dose and methods of administration, and calculating the dose and post administration follow-up. Those re pretty broad.

MEMBER STITT: Right.

CHAIRMAN SIEGEL: And one could make the argument that since the current licensing approach is literally to require the physician present to be able to intervene in the event of problems during an HDR treatment that the or category should include direct experience with HDR. And I'm assuming that if you're going to continue to allow ABR certification to be the basis for doing HDR, that you're going to want some assurances from the ABR and indirectly from the Residency Review Committee for Radiology that the training programs include this.

MEMBER FLYNN: Well, it's the Residency Committee

for Radiation Oncology which I'm on, and we just adopted the standards. And if a facility has HDR equipment, they're required to provide the resident staff with the didactic lectures and the biology and physics background and the training for that.

CHAIRMAN SIEGEL: The current approach, it seems clear that we're basically saying that people who are proposing to do something ought to be able to demonstrate that they've had some training and experience in it, and therefore are likely to be competent in doing that.

Since HDR is obviously a problem area where some serious problems has occurred, to say otherwise for HDR would be inconsistent with the current approach. And so I would say go for it given that this is what you currently do in the way of training and experience.

If we look at a big paradigm shift at some time in the future, this should be re-examined along with everything else.

Do you concur?

MEMBER STITT: I agree. And I'm on the Standards Committee for the American College of Radiology. That's news. So we sort of have a lot of bases covered here amongst the different groups. And I think that HDR could be more specifically addressed than what we have there, but singled out so that that does allow some very specific questions to be

directed at an individual.

CHAIRMAN SIEGEL: So barring other comments, the answer to the first question is yes.

MEMBER STITT: Okay.

DR. HOLAHAN: All right. The other one is sort of more a follow-up of what we discussed earlier in terms, we talked about the training and experience requirements for a medical physicist. Currently in licensing guidance licensees are required to have a medical physicist if they are doing HDR brachytherapy, but there's nothing in the requirements that says you need to have a physicist.

I guess the question is, should licensees doing HDR have an authorized physicist on staff?

MS. PICCONE: Should that requirement be in the regulations?

DR. HOLAHAN: Yes, yes.

MS. PICCONE: We already require it of licensees through the licencing process.

DR. HOLAHAN: Through licensing process, yes, I apologize. So should we incorporate that into the regulations?

CHAIRMAN SIEGEL: You used the word "on staff," did you mean that word?

DR. HOLAHAN: No, I meant should there be an authorized physicist listed on the license, if the licensee is

doing HDR physics,(i.e. I mean it could be a consultant physicist.) I think, was that your question?

CHAIRMAN SIEGEL: Yes.

DR. HOLAHAN: Okay.

CHAIRMAN SIEGEL: Well, the first way to address this question is, is there consensus that a authorized user physician and a physicist should be present for HDR brachytherapy as is currently required as part of licensing?

If you agree that that's appropriate, that that's the standard of care, then it's appropriate to move it -- isn't that what you're requiring?

DR. HOLAHAN: It requires the authorized user and medical physicist or RSO.

CHAIRMAN SIEGEL: Okay.

DR. HOLAHAN: So the RSO --

CHAIRMAN SIEGEL: So are you proposing a change?

DR. HOLAHAN: -- may not be medical physicist.

CHAIRMAN SIEGEL: Correct. And refresh my memory, how did you resolve from a licensing point of vie the issue where the authorized user and the RSO are the same person?

DR. HOLAHAN: Currently --

CHAIRMAN SIEGEL: And so you would license them to do HDR brachytherapy with only one person present?

DR. HOLAHAN: That's correct.

CHAIRMAN SIEGEL: Okay.

Lou?

MEMBER WAGNER: Would you please explain to me what advantage there is since you're already requiring this of licensees, what advantage is there of doing it differently now by moving it on to regulation?

DR. HOLAHAN: Because we're --

MR. CAMPER: Well, I'll certainly explain it just real quick. The reason for that is following the incident in Indiana, Pennsylvania in 1992, we substantially, significantly I would say, upgraded our requirements and licensing space for HDRs. If one looks today in part 35 you will not find a separate section for HDR. And arguably I think that there should be in view of the complexity of the technology. But it fits under the category of brachytherapy.

Now, when we, if one looks today at the number of conditions and the nature of the conditions, and we'll touch on this a little more later, that we impose upon an HDR licensee, the thing that I'm concerned about and we're concerned about as an agency, if we're challenged as to whether or not we believe there is a public health and safety problem today with our regulation of HDR, the answer is no, because we cover it through licensed conditions.

However, please understand that those licensed conditions have never been subjected to due process. They've

never undergone public scrutiny and comment. In the regulatory arena it would undergo such scrutiny. And our question for you is, should we move from licensing space into the regulations and the sunlight affect that it has upon it?

CHAIRMAN SIEGEL: Bob?

MEMBER QUILLEN: From agreement state point of view, one, a criteria like this is in a regulation, then there is the compatibility status attached to it as to whether the agreement states have to adopt this in their regulations. When it is done through a procedural point of view, the agreement states have an option as to what they want to do. So it becomes a question as to whether this should be a uniform practice throughout the entire licensing community.

MEMBER WAGNER: Now, that's a good reason.

CHAIRMAN SIEGEL: Bob, I can't tell if you're for or against. Because I read that comment either way. Would you be willing to commit yourself?

Well, I mean my personal answer, and we'll see what the rest think, is that I really agree that having this done by the proper administrative procedures is a clearer way to make sure that you've had the broadest input possible. And that you have to do due diligence in terms of regulatory analysis and all that other stuff. And I say, go in that direction. Do you agree?

DR. HOLAHAN: And if we do, are you saying to

have a physicist on the license?

CHAIRMAN SIEGEL: It could be physicist or a radiation safety officer. Now, let's see --

DR. HOLAHAN: A radiation safety officer may not necessarily be therapy.

CHAIRMAN SIEGEL: Well, you're already requiring a physicist to issue a license for HDR, right?

DR. HOLAHAN: Through licensing space, right.

CHAIRMAN SIEGEL: Well, then if you're requiring it through licensing space, you ought to take it to the public and find out whether the public wants it to be done in regulatory space.

DR. HOLAHAN: Okay.

CHAIRMAN SIEGEL: That's what I think.

DR. HOLAHAN: I guess the question was, does the ACMUI agree with --

CHAIRMAN SIEGEL: I do, but I don't do this for a living. I'd just be curious to hear Dr. Williamson's and Dr. Brezovich's comment on this and then we'll make the consensus decision.

DR. WILLIAMSON: Well, I guess I would like to answer the question with a question too. What does it mean to be on the license? I think, you know, maybe a little clearer delineation of the role of the medical physicist in the process of treatment delivery might be helpful, or some

consensus what it's for. I mean you can have someone on a license and they're 2,000 miles away, what good is that?

CHAIRMAN SIEGEL: No, but I think that's going to end up, this recasting of the teletherapy physicist as the medical physicist implies that there is now going to be a more central role for the physicist in the whole process of radiation oncology, and so lots of things are going to get adjusted in the process.

Correct, Trish?

DR. HOLAHAN: Correct. And what it is is, for example with the teletherapy physicist, we don't tell the licensees how much the teletherapy physicist has to be physically present, but there are certain things that the teletherapy physicist must do. And it would be the same type of thing, that there are certain, for example some of the QA checks and controls, you know, would be the physicist.

DR. WILLIAMSON: Okay, I guess that's what I was asking is sort of what things you had in mind.

The other comment I'd like to make is I do not think it's helpful to put the radiation safety officer as either being the person to help solve technical emergencies with the machine or do more technically oriented things with the device such as quality assurance. A radiation safety officer in general, you know, is responsible for health physics in the institution. At least that's as I understand.

They have no technical expertise. I mean how are they going to --

CHAIRMAN SIEGEL: They could.

DR. WILLIAMSON: -- solve a device emergency?

CHAIRMAN SIEGEL: I mean, Jeff, they could. You could be the radiation safety officer at Washington University.

DR. WILLIAMSON: That's correct, but I'm also a radiation oncology physicist. It's by virtue of that role that I have the expertise to manage the emergency, so I would give some thought to -- and that would resolve the problem of, you know, only a physician being available during a technical emergency or other device malfunction.

MEMBER FLYNN: I agree with you a hundred percent. And when I saw the draft of 9203 and 9301, I disagree that RSO be there. It should be a physician and a physicist. The RSO should be even listed on that as being a substitute for the physicist in my opinion.

DR. BREZOVICH: My comment, since you asked me to do so, absolutely agrees with that. And I'm going to be just specific to give you an example why the physicist may really indeed be necessary, and that--

CHAIRMAN SIEGEL: How about if I just say we believe you.

DR. BREZOVICH: Okay.

CHAIRMAN SIEGEL: Because I think that there is general consensus on that point.

Dennis, do you have a comment?

I didn't mean to cut you off, Ivan.

DR. BREZOVICH: No, that's fine. You did what I want, thanks.

CHAIRMAN SIEGEL: You're welcome.

MEMBER SWANSON: I guess I have a question about what are the implications of requiring a physicist on the license. Are you saying that the authorized user physician doesn't possess certain bodies of knowledge that thereby requires the medical physicist to be there? And if so, that's a disconnect from who is responsible for the overall care of the patient, which is the physician, okay, and you can't delegate that responsibility to the medical physicist.

DR. BREZOVICH: May I comment on that?

CHAIRMAN SIEGEL: Sure.

DR. BREZOVICH: Okay, if you have -- now, I can come up with the example that I wanted to come up with in the first place. What can happen is if the patient has a coughing spasm during a bronchial treatment and suddenly the treatment gets interrupted halfway in between. From a radiation safety officer's point of view, the problem is solved and the radiation source is back in the safe container. We are out of the emergency.

From a physicist point of view, now the emergency begins because what you have to now try to find out, how much radiation did the patient at this time obtain, how can I come up with a treatment plan with substitutes for the missed radiation so the patient still at the end of it gets what he wanted to get. And that's why we need the physicist.

MEMBER SWANSON: The point I'm trying to make though is, should not the authorized user physician also have the skills to be able to make those calculations?

DR. BREZOVICH: No. I mean this is not how it's practiced. I mean in order to be a real qualified physicist you need a advanced degree in physics plus board certification. And there's a specific degree for this specification. So there's no way that it would be reasonable to expect the authorized user to go through three years of extra physics training and take board certification in physics just to be able to handle this one situation.

MEMBER NELP: I think there is an advantage to just having one person responsible for the program. Like in my shop I'm responsible for my medical physics and the people who do all the technical work and do a lot of administration. And it's my job to see that they do their job. And I'm the licensee, and I would think

that having a single person being the licensee is -- it's implied that the medical physicist is part of his team and the

medical physicist is responsible to a licensee for his performance.

DR. HOLAHAN: At a medical institution though, the licensee is the management. It is not the authorized user. He is listed on the license, or she.

MEMBER FLYNN: But in answer to Dennis' question, there have been misadministration and problems whereby the physicist being there to address the equipment and the failure of equipment while the physician is addressing the patient that the physicist wasn't there a much more serious incidence would have occurred. And there's a number of incidents I can tell you about, but --

MEMBER SWANSON: I don't have problems about the good practice of having a medical physicist there. What I have problems with is what you're saying by requiring a medical physicist on your license, are you implying that there's a body of knowledge that the authorized user doesn't have?

DR. BREZOVICH: Yes.

MEMBER SWANSON: And then there's a disconnect. Because in reality the medical physicist, although they may make calculations, et cetera, they are not responsible for the patient care. Period. They answer to the physician, in this case, the authorized user. The authorized user is responsible for the patient care.

So, like I said, there's sort of a disconnect from the reality of who's responsible for the patient care ultimately, I think.

MEMBER GRAHAM: Wouldn't the disconnect occur only if it was to exclude the licensed authorized user and leave just the medical physicist? I don't hear that being proposed.

MEMBER SWANSON: Then I don't have a problem with that either but why are you requiring that individual on a license? And I guess I could go back and say the thing about--

MEMBER GRAHAM: There's a unique knowledge they're bringing to the table as part of a team. And I thought we were -- So, we're just sending this up to bear the bright light of day.

CHAIRMAN SIEGEL: Do either of the radiation oncologists at the table think that they would like to practice HDR brachytherapy without benefit of physicists?

MEMBER FLYNN: Not unless I had a good lawyer.

MEMBER STITT: Yes, and have a good physicist and a good lawyer.

MEMBER NELP: May I ask, what, in a medical license when you issue a license for the use, medical use of these materials, do you have a precedent now where you list more than one individual on the license other than the --

DR. HOLAHAN: We list the authorized users for a limited specific license.

MEMBER NELP: The authorized users are usually the -- in fact, it's a medicine or the physicians, right?

DR. HOLAHAN: Currently. That's all that is -- yes, and then we --

MEMBER NELP: But you don't currently list anybody else in the authorized user --

CHAIRMAN SIEGEL: Authorized nuclear pharmacists.

MEMBER SWANSON: But not required by the license? Not required by the license.

CHAIRMAN SIEGEL: That's correct. But that's because the NRC's made a judgment that we've agreed with that the activities that could be performed by an authorized nuclear pharmacist could also be performed directly by the authorized user or by individuals working under the supervision of an authorized user.

In this case, the radiation oncologists are saying that they think a step further is required. And I personally think I agree with them. So --

Lou?

MEMBER WAGNER: I just want to make one comment. That I emphatically endorse the comments of the two physicists, two guest physicists. But also would like to emphasize that the important point that was made is that the

medical physicist is there for the additional patient care and that an RSO, by specifically by its definition, is there for the occupational safety and health of other individuals. But it's not directly related to the patient and that's the difference here for the medical physicist.

MR. CAMPER: We're going to need to stop for now and move to the next topic because Jack Roe is h ere.

CHAIRMAN SIEGEL: We're going to figure out a way to make some time to keep doing some of this stuff. Or at least devise a strategy for helping to deal with these questions. Because it's obvious this is important stuff that we're interested in.

MR. CAMPER: As we're making this change, in answer to Doctor Nelp's question. There are several instances in which we do identify several authorized users by a particular specialty or expertise as is demonstrated through their training and experience. We do designate a teletherapy physicist. And of course in the HDR space, we are now identifying HDR related physicists.

But the whole question, of course, is the one that was put out and the idea of putting it into the regulations, having it undergo due diligence, and so forth.

CHAIRMAN SIEGEL: Mr. Roe, welcome.

DR. ROE: Good morning. I hope my voice is loud enough. If it's not, I'll bring the microphone over.

Good morning. Is that acceptable?

I'd like to take the opportunity today to introduce myself and put my briefing in context. I'm Dr. Jack Roe. I normally work in the Office of Nuclear Reactor Regulation as a director for the projects organization regulating nuclear power plants in Regions 3 and 4 of our country. I'm on a special assignment to the Office of the Executive Director to carry out the direction that we've gotten from the commission and the Administration on the national performance review.

In your package you should have the slides that I'm going to generally use as an outline for the briefing. I'm going to try to be short in the brief because I understand that you are pressed for time today.

Overall, in the background of the national performance review, as we well know, is this particular activity is a government-wide activity that has the sponsorship and the leadership of the President and specifically is being carried out day-to-day observation by the Vice President.

In the background, we have received several directives and documents that we have used to guide our review in the activities. And in phase 2 of the national performance review, there are two central focuses. The first one is a focus on the commission's regulations. The second focus is on

the commission's functions. The background there that you will see, there's three entries. Basically those are documents received from the Administration that talked about the general approach. The most specific one was the March 4th memorandum from the President that provided the directive that indicated what he desired to have done by the Administration's agencies and departments, and when he wanted the results.

The next slide will basically talk about current and future NRC activities. When I wrote this in preparation for a meeting, it was a little while ago and some of these were yet to occur. And now they have transpired. The first aspect, first focus that we had wa son regulations review. We wanted a broad range of individuals in the NRC and outside the NRC involved in that particular review. First of all, we wanted to utilize the expertise that was in each and every one of our offices and regions. Those people are closest to the regulations. They understand some of the technical issues better than people that are outside. For example, this particular area, brachytherapy I have learned a great deal in a short period of time because I was never touched by it before in the regulation of reactors.

We involved not only the headquarters offices but we involved our regional people to get what has been called by the Administration the front line regulators to find out, the people who actually do the licensing in the field, if that's

the area that's done, and the inspections give us feedback to the process.

We also used a semi-independent steering group. And I will use the term semi-independent because the steering group was drawn from the offices. As far as a management approach, we tried to take the steering group members and mix them. We tried not to take those people who focused on reactor regulation to be those people who day-to-day work in reactor regulation but a mixture. So that we got a fresh set of eyes looking at the regulations and somewhat of a questioning attitude about some of the regulations. We also did not work those groups so that they were all outside the area so that they did not have the opportunity to get some technical input into the review.

We looked at the regulations from the perspective of are they obsolete? Are they burdensome, prescriptive, and overlapping? Some of those obviously have judgment. The obsolete ones are straight forward and we found some.

We wanted to build on existing initiatives. There are quite a few initiatives that have already gone forth, as you know. And the area of nuclear reactors we have a had a multi-year regulatory reform. And also in materials there is going on now some detail reviews. I think as a matter of a fact, Dr. Paperiello is briefing the commission on the business process re-engineering from the materials program

probably as we speak now.

We requested that input be given to us in the middle of April and we have already briefed the ACRS, the ACNW, and our committee for the review of generic requirements declined to be briefed on this.

Tomorrow our paper is due to the commission. It essentially is approximately a 90 page paper that outlines the activities that we carried out. Has two letters to the President of the United States. One, the first letter to the President, is at his staff's request, a table that indicates what regulations we reviewed, which ones are going to have reinvention. And reinvention is a term they use to mean there will be further action. And a discussion of what time frame that will occur.

We owe that first response to the President the first of June. We owe a second response to the President on June 15th where he has asked for a summary of the regulations. He does not want the multi-page tables but I think he wants basically a numerical approach towards it so that he can take throughout the whole administration and report to the American people what the impact is going to be.

He also wants to have us discuss rewarding results instead of basically a compliance approach and penalizing people. He wants more of a partnership with our licensees.

He also wanted us to address our creation of grassroots partnerships with our clients, in this case the regulated entities. And lastly, he asked to report on how we plan to go about negotiating with the licensees instead of dictating and getting into more negotiated rulemaking sessions.

Somewhat in parallel to those activities because of the due date, we have been directed by the commission in a staff requirements memorandum in the spirit and keeping of the national performance review to carry out a functions review of the NRC. In this functions review we developed a flow chart and also a questionnaire. We took the opportunity to obtain from the very top of the NRC the views about our functions, which functions should be carried out by the federal government and which functions could be carried out by others, more pointedly, by the states.

We carried out these interviews with all the office directors and their senior staffs, and all the regional administrators and their senior staffs. This was conducted by members of the steering committee with various compositions depending upon who we were talking to and at what time. We did this in accordance with the study plan that we provided to the commission.

Our focus was on that federal function and where for the future the NRC could rely upon others. And I think

that well known is that's an approach the federal government is to give to others those functions that are not necessarily to be carried out by the federal government.

We plan to brief the ACRS and ANCW. If it's appropriate, there will probably be some pre-decisional information in there, sensitive information, based on our reviews to date of activities that the commission will have to decide basically on a policy standpoint.

We owe it to the commission, a paper, by the first of July and I think because of the change of the commission, we will probably have that report in the middle of June.

We took a look, then, in this review at efficiencies. We asked ourselves how can what we do most frequently be done with less resources and still get the same product. We wanted to build on the current initiatives we have in place such as the business process re-engineering and materials area and some initiatives we have in the reactor area.

We are identifying activities. We have now come with almost 20 recommendations for future action. Those recommendations have been reviewed and briefed to the executive director and now have been discussed with the relevant office directors and regional administrators. That particular discussions are ongoing.

CHAIRMAN SIEGEL: Do any of those involved the medical program?

MR. ROE: Yes, they do. Specifically, there are two aspects of our functional review that address the medical program. Our view is that we should look broadly at expanding the agreement state program and that we should carefully evaluate the regulations of Part 35 with respect to the use of medicine.

We, at the beginning of this issued a press release and invited comments from various parties, and have briefed various parties. With respect to our functions, we have asked people what should be retained, what should be eliminated, what should be modified, specifically what should be given to others.

Again, we've asked the question of those functions which overlap with other regulatory bodies, is the overlap useful? Surprisingly enough in a few circumstances, we were told yes. Not in every circumstance would you think that that question would be yes. In a few circumstances, we were told not only is the overlap useful, but they want the NRC to retain their regulations because they find them more stable. We're a little bit surprised but we will take that one. We asked if they should be eliminated and also who should have the lead.

The second focus is on the regulations. We've

asked outside parties if they're overly burdensome, out of date, of marginal value to safety, too prescriptive, overlapping with other agencies, basically the whole gamut of questions. And we asked how should they be changed and what are the top priorities for change. We received two distinctive responses. First, from the reactor community the response was, the regulations are in fairly good shape and those that we find of concern to us the NRC has under review and has processes to lessen the burden. And I think that response is because we have been working with that community for several years on regulatory reform.

The second focus was basically from the group similar to your expertise is in the medical area. Of eight letters we received, one-quarter of them were associated with Part 35, one regulation. And we received letters from the American College of Medical Physics signed by Dr. Feller and Dr. Rogers, and one from the American College of Radiology signed by Gary Price.

Basically that concludes the overview of my brief. I'd be glad to answer any questions that you have about our national performance review.

CHAIRMAN SIEGEL: What preliminary conclusions have you come to with sort of which federal agency from your perspective should have primary, the lead, responsibility for radiation standard setting? Have you focused on that issue?

MR. ROE: We focused on the relationship with environmental protection agency and the NRC. In conformance with the direction from the national performance review, those agencies that statutorily have the lead are to look at the overlap. So we have had -- I've had some discussions with the EPA. Our focus right now is to see if the -- if it's useful to seek any legislation or whether it's more appropriate to continue to work out the issues between us. And right now our view is that probably the most useful thing for the NRC to do is to work out with the EPA those issues. And that seeking legislation may be a utilization of resources that is not as productive as working currently with the EPA.

But, the EPA will also report to the President and they will have the responsibility to address it.

MEMBER QUILLEN: When will your reviews or documents be made public?

MR. ROE: They'll be made public on May the 24th. We're going to brief the commission about our report to the President both on the first and the 15th. That information basically will be presented. The reports themselves are normally considered government entity to government entity reports and I think are at the discretion of the commission whether or not in consultation with OMB that they release the actual documents, the reports to the President.

But a great deal of the information, I would say

all the substance, will be presented to the commission on the 24th with respect to those two letters. The first letter is really the one of most focus. Originally the President asked for all the information on the first of June. We did not see from the NRC's perspective a difficulty but large agencies such as the Department of Defense, the Department of Treasury, who have a multitude of agencies, a multitude of areas, found that that was very difficult to put together in the short period of time that they were given. So the President gave two more weeks for the other areas that talked about the areas outside regulation. But he does want the tables on the first of June.

CHAIRMAN SIEGEL: So there will a shorter briefing document for that May 24th meeting independent of the report to the President?

MR. ROE: Yes sir.

CHAIRMAN SIEGEL: And that will be distributed at that open commission briefing?

MR. ROE: Yes, it will.

CHAIRMAN SIEGEL: Can I ask that the members of the committee be sent that document?

MR. ROE: Dr. Siegel, what I should said that if you have not received copies of the two letters I reference, I will give them to the staff so they can provide them to you.

CHAIRMAN SIEGEL: Well, we hadn't. So all we've

gotten are the copies of the slides that you just walked us through. So we'd love to have as well --

MEMBER NELP: Did you examine overlap of interest in regulations between the FDA and the NRC?

MR. ROE: Not specifically, no. We did not -- in our interviews we did not see an issue. In discussions with others that did not seem to be a primary issue. If it is an issue, it would be appropriate that we know about. But it did not come up. And we sought the interviews from, I said, the top of the agency, discuss people. I had a meeting with Larry Camper specifically in preparation for meeting with you to understand what the role of this particular committee was. And also asked the people in the field about that. And this did not come up as an issue that they believe was necessary to be pursued.

CHAIRMAN SIEGEL: John, did you have a question?

Dennis?

MEMBER SWANSON: Did you address at all the issue of the NRC's regulation of limitation to by-product material versus states regulating accelerator produced material?

MR. ROE: Yes, we did. Specifically if you take a look at our approach toward a desire for the commission to address an expansion of the agreement state program, we see that there's a logical follow through for the states to regulate all types of radioactive materials regardless of

where they came from. The risk to the public is the same and is not relevant from a risk perspective of where they came from. So, that's our perspective, is that if the states are carrying out a radiation protection program for other than atomic energy type materials and the states are satisfied with the protection of the people, they should be able to expand that over to those that are by-product material and have the same satisfaction of the people in the state.

CHAIRMAN SIEGEL: Larry and then Bob.

MR. CAMPER: On that point, Jack. Did you get into at all how that might be facilitated given that participation as an agreement state is a voluntary action on behalf of the agreement state?

MR. ROE: Yes, we did. We specifically have in the recommendation which will go forward to the commission, the commission will make their decision is what we consider some approaches, some initiatives, some incentives, some procedures, some approaches that would make it, I would say, more attractive financially for the NRC in the long run. The short run may not be. But the long run it would be, especially if we are interested in devolving to the states that responsibility and authority.

We also put in a few novel approaches to precipitate a little thinking.

CHAIRMAN SIEGEL: Bob.

MEMBER QUILLEN: I just want to comment that the Office of State Programs has sent out a letter to the agreement states notifying them that effective October 1st, 1996, they will be reducing the support to agreement states. The paradox here is you have one program which is encouraging agreement states and another program at the same time is discouraging agreement states. And I've seen already one letter from an existing agreement state saying if this comes to pass, that they will likely give their agreement state status back.

MR. ROE: We understand that and that was a specific point that we briefed the executive director about, is that it appears that the recent commission decisions are in a direction that may be counter to what the national performance review has. And he clearly and sincerely acknowledges that point and I know it's very high on his priority to address that particular paradox.

CHAIRMAN SIEGEL: Aren't you stuck, though, by the requirement that you raise your working capital from user fees?

MR. ROE: Yes, we are stuck and that is one of four legislative proposals we're going to go forward with. We feel that that is hampering us in several areas. I have found that of complaints with respect to regulations is it really is number one. It is -- And I understand why it's number one.

We specifically have a long section in our report to the President about that particular issue. I have found out from talking to different people, if you talk to reactors, they feel it's unequitable. If you talk to materials licensees, inequitable. It's one of those areas where we have been able to cause concern with all of our constituents.

CHAIRMAN SIEGEL: And it is clear that it will have a big impact on this push to agreement state status in the materials programs.

MR. ROE: Yes. Absolutely.

CHAIRMAN SIEGEL: It really will be a major impediment.

MR. ROE: One of the things that I should remark about is that what we have done is given people recommendations for further evaluation. And about a year from now, in July of '96 is what we have to do is basically deliver the plans. Some of them have earlier time schedules that we have put in there. The one with respect to agreement states we have an earlier time schedule because we think that it is a much more important issue that has to be dealt with. And it is more of a policy issue to begin with to make a decision that will give a long term efficiency to the NRC. So we didn't think we should wait until next year at this time to receive those particular issues. We thought it should be brought forward much earlier so that our new commission can

address that. Both commissions, basically, can address that issue.

MEMBER SWANSON: One other question. From the flip side, have you looked at all at international harmonization?

MR. ROE: No, we have not looked at that. Basically we looked at only domestic and see if there was any difficulty there. We did discuss briefly about the relationship of Part 22, international standards. But that-- when we discussed that, there didn't seem to be an issue so we did not pursue it. But it would be unfair to tell you that we did much review of it. We asked questions and they said it was -- that was people were satisfied with it and therefore we took and factored off into other areas where people were not satisfied.

MEMBER SWANSON: The only reason why I bring that up is CORAR which is an organization of radiopharmaceutical manufacturers actually have addressed international harmonization of radiation regulations as one of their major concerns at this point in time. So, there does appear to be some concerns in that area.

CHAIRMAN SIEGEL: All right. Thank you very much. Appreciate it. And we'll look forward to seeing that report.

Dr. Flynn.

And Dan, ideally if -- well, we'll see how the time goes. Depending on how long this takes, maybe we can loop back to try to address some of Trish's other questions or we can stop a little sooner for lunch and we'll figure it out.

MEMBER FLYNN: This will take shorter than a half an hour.

CHAIRMAN SIEGEL: Good.

MEMBER FLYNN: I have copies of the slides being passed out. There's only about 10 or 11 slides. But I wanted to talk about this because we started doing prostate implants ourselves last fall. I did one this week. But also as an NRC consultant, certain misadministration that came to my attention and also outside the NRC certain problems came to my attention. And talking with the experts who have done over a thousand of these in Seattle, they're also getting phone calls in that procedure now to treat localized prostate cancer is becoming popular extremely rapidly. And because as a -- when you have a procedure whereby only a few major institutions are doing the procedure, you may not see the problems, especially when the volumes are low. But as soon as the community picks up on a procedure and you have the number of cases going up very rapidly, you may start to see problems.

In the United States now the diagnosis of prostate cancer is going up extremely rapidly, more than any other cancer. And the reason why is because of the screening

PSA blood test. Perhaps of 1,200,000 new cancers this year, 200,000 or more will be males with prostate cancer. Most of these cancers will be early cancers because it's being picked up in a screening test.

The number of brachytherapy cases I estimated and I estimated incorrectly. I thought after talking to some people that five years ago there were only about 200 cases a year. And I estimated that it's gone up to more than 3,000 in five years and growing rapidly. But actually the next slide -- two more slides -- shows that-- I just got this a couple of days ago. That the total number of procedures using iodine and palladium, at least for 1994, is 4,000 cases. Going up very rapidly.

The number of cases potentially suitable, and this is a guesstimate, is possible half of all the cases which would be 100,000 cases. That would be sort of like the upper limit of normal, upper limit theoretically possible. That's assume the procedure still gets good results and that it's picked up as rapidly by the remaining urologist and radiation oncologist who might do the procedure.

Realistically though, I estimate in five years that probably between 10,000 and 20,000 cases a year. If you realize what brachytherapy numbers are like in the United States, perhaps NRC estimates 30,000, 50,000, cases a year, prostate implants in a few years could be the most -- if not

this year, could be the most common brachytherapy procedure.

So, the typically doses would be for brachytherapy alone 16,000 rad to the prostate and a small margin around the prostate in some cases. With palladium, it's a lower dose. The dose rate with palladium is a little higher, shorter half life so you're giving the dose a little faster. In general, the iodine is used for the slower growing, "slower growing more well differentiated" tumors and the palladium for the "more rapid growing higher differentiated" tumors.

MEMBER NELP: What are the physical characteristics of palladium?

MEMBER FLYNN: I'm going to defer to the physicist because I don't have that. The half life of palladium is about 17 days and of iodine, 60 days.

MR. WILLIAMSON: Yes, that's right. Iodine has an energy, average energy, 28 keV, and palladium a little lower, 22 keV. So they're both --

MEMBER NELP: Is palladium better or --

MR. WILLIAMSON: They're essentially X-ray emitters. It's mostly the photons are from a cascade of characteristic X-rays arising from electron capture.

CHAIRMAN SIEGEL: Dan, are you going to talk about not misadministration but complications of therapy?

MEMBER FLYNN: Misadministration.

CHAIRMAN SIEGEL: Let me then ask you a question. The complication rate or adverse effect rate of prostate brachytherapy compared to prostate teletherapy --

MEMBER FLYNN: Is lower.

CHAIRMAN SIEGEL: -- compared to surgery?

MEMBER FLYNN: Is lower.

CHAIRMAN SIEGEL: Is lower.

MEMBER FLYNN: That's why -- that's one of the reasons -- I'm going to get into that right now. One of the reasons why it's getting such popularity so rapidly, being so rapidly accepted by many urologists and some radiation oncologists is that the reports that the complication rate is lower than with either radical prostatectomy or external beam radiation treatment which are the two primary means of treatment now. And also that reports out of Seattle and some other areas that the PSA blood test, which is a monitor as to how effective the cancer treatment is, whether you accept that or not, but many do. That the PSA is showing better responses to the prostate implant in most -- in many published reports than it is to external beam treatment. Now, that's if you agree that the PSA is going to translate to 10 and 20 year survival.

Now, the data -- the large number of patients is only out five years now. So the critique of that would be the data is only out to five year survivals. The five year

survivals with this technique look good from published reports. The PSA and rebiopsy data looks excellent. Will the data hold up? But it's --

CHAIRMAN SIEGEL: Yes, then that's the back end question. The front end question is what fraction of these patients being found by PSA need to be treated at all. And I know that's a very controversial issue that we probably don't want to talk about here.

MEMBER FLYNN: But these patients who are being screened with elevated PSAs an then biopsied and find they have prostate cancer are being treated with radical prostatectomy external radiation. Most cases the patient does not want to be followed or observed unless they have severe medical problems and their very elderly.

Another point with this treatment is that it's done in an outpatient basis in one day. It's cheaper. The physician, whether the urologist or the radiation oncologist, is compensated less as is the hospital. So, if you're looking for a procedure that might be more -- might be equally or -- equally effective or more effective with possibly less complications although the long term we haven't seen yet, and cheaper, it's going to be something that everyone's going to latch on to very quickly. So we have to worry about the potential downside in terms of complications.

CHAIRMAN SIEGEL: But in terms of the immediate

effects, is the frequency of impotence less with this therapy than it is with the other two?

MEMBER FLYNN: Yes. That's the report. Both impotency and incontinence, much less.

CHAIRMAN SIEGEL: It's clearly going to be more appealing.

MEMBER FLYNN: And the article shows you -- I chose an article by Grimm and Blasko because these two individuals have done over a thousand and they've trained more than 50 percent of the -- these two individuals have trained more than 50 percent of the radiation oncologists who are currently doing the procedure in the United States. Therefore, their article on technique is important. And also the course in Florida which is the other major course adopts the same technique.

Where, through a template with ultrasound guidance the -- using the ultrasound technique, the seeds are places in the operating room. Radioactive seeds are placed in the operating room. Prior to that operating room procedure, two weeks prior to that perhaps, there's a treatment planning procedure where the ultrasoundographer plays a major role. And the radiation oncologist plays a major role two weeks prior to the procedure to find the target. And a physicist plays a very major role in designing the distribution of seeds in the treatment plan which is already completed prior to the

procedure in the operating room.

In the operating room, you're using ultrasound to place the seeds on a template, the urologist and the radiation oncologist as a team, together with the physicist. And then post-procedure, you look to see where the seeds are either with ultrasound, fluoroscopy, or both ultrasound and fluoroscopy in the OR where you'll see any cold spots where seeds may have not been places absolutely as intended. Then you make up with additional seeds in the cold spots while the patient is still there. And then you dismiss the patient. He goes home. A few weeks later he comes back and has usually a post-planning CT scan. And then you go on from there. And you can get a post-plan or at least see how well the actual delivery has agreed with the planned delivery that occurred two weeks before in the operating room.

CHAIRMAN SIEGEL: Is this all done transperineally or is this done --

MEMBER FLYNN: Transperineally. If you turn to the second page of the article, page 194, that's the key. If you have to look at one page, just look at that page, the second page of the article shows two diagrams, Figure 1 and Figure 2. It shows the male patient in the lithotomy position with the scrotum taped up onto the abdomen in the -- and the seeds are placed through a template, through needles in a template transperineally with the ultrasound in the rectum.

If you look at that diagram.

CHAIRMAN SIEGEL: No problem getting the right seed distribution in the posterior lobes of the prostate with this approach?

MEMBER FLYNN: There's always problems. But you're going to be very close to the rectal wall and you're actually seeing that with the ultrasound probe.

MEMBER STITT: In fact, you get better distribution with this than with the open technique where you're using the iodine gun and it's all done very clinically, and you used to implant your finger plus the OR floor and this is actually more precise. I've done it.

MEMBER FLYNN: I was just going to go through the five misadministration which links into the brachytherapy issues paper. And hopefully I can finish in half the time.

Five misadministration. The first one was in Ohio in 1990 where 86 seeds of iodine 125, and typical source strength, .3. Now, thousands of implants are being done with iodine. .3 is a typical. .3, .35. They're implanted in order to give that dose, the same dose. X-rays following procedure demonstrated that the seeds were beyond the prostate. They had missed the prostate. And the reason why is because it was one of their first cases and they didn't have fluoroscopy and it was urologist driven. The radiation oncologist was more -- played an ancillary role.

I talked to the institution since then, two weeks ago, and this misadministration caused the team work to be better and that the radiation oncologist played more of a role and the urologist deferred certain decisions. Fluoroscopy, if it had been present, that wouldn't have happened. There was no injury to the patient. He had back pains subsequently because the seeds were disbursed. They were fanned out in the sacral area and none in the bladder and none in the rectum but in the pre-sacral space.

The second misadministration in Ohio but a different institution. Not the same institution. A CT scan following the procedure two weeks later demonstrated that 21 of 56 seeds were outside the prostate. The normal tissue surrounding the prostate received a greater than intended dose. Prostate received only 42 percent of intended dose. So this was reported to Region 3 at that time. No injury to the patient.

Some of the slides got busted up on the plane here. But, misadministration number 3. Misadministration number 3 was Florida in 1991 but wasn't discovered until 1993. This was a malpractice case. The State of Florida is looking into it. NRC has no knowledge of the case. Well, they have that a case exists. But anyway, it involved palladium 103. And a typical source strength for palladium is 1.4 millicurie. And the total dose is less.

The seeds were implanted unknowingly in the anterior rectal wall and the posterior part of the prostate. Now, the licensee disagrees. He feels that the prostate, at least part of the prostate, received the seeds so that it's not a misadministration. Patient developed severe complications and had a colostomy. And in my view, after looking at the case, it was the wrong site. And if you look at the seeds, they're like the diagram on page 2, the seeds are down here in the prostate, peri-prostatic area. But the CT scan, this was done at the time of the implant. They didn't take a lateral film which was a problem, or a CT scan, which is a problem. The CT scan was obtained two years later when the patient had a colostomy. And the CT scan shows that all the seeds, the prostates up in here. All the seeds are in the rectal wall. The prostate -- they missed the prostate.

Now, they claim that maybe the seeds migrated but the Seattle group have done over a hundred cases of following up CT scans. The seeds don't migrate. The prostate's like hard rubber. Seeds don't migrate through that kind of tissue consistency.

CHAIRMAN SIEGEL: What's the status of the cancer in that patient?

MEMBER FLYNN: I advised him that he needs to see a cancer specialist right away because his cancer is not treated and he has a complication.

Misadministration number 4, I think Judith looked into this one in Connecticut, at a big institution in Connecticut was the parent facility to this facility. And it basically is the wrong source strength by a factor of 10. They meant to have .4 millicurie seeds but they had 4 point something millicurie seeds. So the patient required an emergency radical prostatectomy and subsequent surgery to that.

When I looked through the report, the one thing I disagreed with the Idaho Engineering report is that a lot of the initial ordering was by a nuclear medicine technologist. And the nuclear medicine technologist didn't-- wasn't aware that .3 or .4 millicuries is the typical seed strength. So then when the vendor called back and asked the nuclear medicine technologist are you sure this is what you want, are you sure you want 4 point 4 millicurie seeds, the nuclear medicine technologist, just reading off of a piece of a piece of paper, said yes. Now, had a medical physicist been involved, that never would have happened because it would realized that if thousands of cases are being done at .3 and .4 millicuries, it would have -- a red light would have gone off if the physician or the physicist were called that this is ten times the source strength. So, that's why it's important to have a medical physicist involved early in the course.

Now, this patient is still at risk for severe

complications in the future.

Misadministration number 5 I looked into. And this happened in Ohio at another institution from the other two institutions in Ohio. Region 3 asked me to look at this one. And 55 seeds in the bladder. And now, having seeds in the bladder is very common actually. The thing is, at the time of the procedure in the operating room, you look in the bladder with a cystoscope and you take out any seeds in the bladder. There's no harm to the bladder. The problem is not with the bladder. The problem is that 55 of 190 seeds weren't implanted into the cancer. So the cancer is about 30 percent underdosed. At the time, they decided not to reimplant the seeds. It appeared to be a urologist driven procedure.

I looked at the operating room notes, the nursing notes, there was no evidence that the radiation oncologist was even in the operating room according to the notes. And when I interviewed the physicist, I asked him, is this a team approach which is being advocated or is it more a urologist, a surgeon driven procedure and the radiation oncology department just supplies technical support? He said the latter. It's more -- in that institution it's more of a surgeon driven procedure and the radiation oncology department provides just the technical support.

Now, the reason why that's important is when I interviewed the surgeon by phone, he didn't realize, number

one, that the prostate was much too big for this procedure. He didn't know what Quimby implant was. He didn't realize that it's not just total dose that's important. With this large -- this huge prostate which was much too big to be implanted, more than the guidelines, more than the training course would advocate, that the anterior rectal wall, a greater surface area of the anterior rectal wall got that dose and the urologist didn't realize -- he told me he didn't know that it's not just the dose that's important but the volume of tissue exposed to that dose. He didn't realize with the bigger volume implant because it is a Quimby implant with equal spacing of the seeds, that the urethra also got a higher dose.

And here we have my problem with this case is that it seemed as if someone other than the authorized user was making decisions which had implications in terms of radiation safety and effect on the patient. And this is not a turf battle. This is a radiation oncology brachytherapy procedure which is now being shared in a team approach with a urologist. But in cases where the urologist takes over a procedure, the one and a half day training course he's gone through can't substitute for four years of radiation oncology training. And so, this is where I have the problem.

The two -- the major issues, then, since I'm finishing way early, is one, what does the committee and the

NRC feel in terms of when you're using therapeutic levels of isotopes, not diagnostic, the role of the authorized user in terms of supervision of the procedure. So, training and experience.

And number two, a bigger problem in terms of brachytherapy is that what constitutes a misadministration in a volume implant? Is it the -- if you, in this case, one-third to -- according to the licensee, according to the urologist and the radiation oncologist, according to them, one-third to one-half of the prostate cancer did not receive any seeds. And so, they responded by making up the treatment by giving the patient 4,000 rads of external beam radiation to the pelvis which they had not planned because part of the prostate cancer didn't get treatment at all.

It wasn't that 33 percent of the seeds were uniformly in the prostate. Actually, half to two-thirds of the prostate received full dose because all the seeds were there. But there was a big, what we call a cold spot in that one-half to one-third of the prostate received no seeds where the cancer was actually, also.

Now, because they added on this external beam dose, which I think they were forced to do, the problem is that part of the rectum is now going to get full dose from the seeds and full dose from the external beam. And so the patient is at a higher risk of complications. He's also at a

higher risk for failure of his cancer treatment.

But they didn't feel this was a misadministration either. They didn't feel that and is the definition of misadministration for brachytherapy for a volume implant clear enough? I think it was -- I believed it was a misadministration because part of the target was missed and because the dose was off by at least more than 20 percent because even if the seeds were uniformly distributed, if you're missing 55 out of 190 just in my head even though they didn't send the dosimetry, that's 30 some odd percent of the dose, besides wrong site.

So, these are two -- these five misadministration bring in as to my belief that the physicist needs to have a more active role. That the physicist is essential. You can't have nuclear medicine technologists ordering sources and verifying those sources are correct. And that the authorized user has to assume the responsibility as licensee for supervising the procedure. These are therapeutic isotopes and it's not because of any turf battle. This is meant to be a brachytherapy procedure by radiation oncologists which is now shared with the urologists on an equal basis in the operating room. And the turf issue is not really the issue. It's the issue would the NRC be comfortable in a nuclear power plant setting with someone who is untrained and is not licensed by the NRC, or identified by the NRC, running

a nuclear power plant. Do you think that the person responsible for running those controls can walk away and have someone from the neighborhood come and take control of a nuclear power plant for part of the time.

So, that's all I have.

CHAIRMAN SIEGEL: 3525 covers this, yes?

MR. CAMPER: Well, that's an interesting point. I was going to say something about that.

The way we -- You said a couple of things that I'm struck by. One is I sense some issue of competency here about the ability to properly, or I should say the inability, to properly implant these seeds. And that's -- would appear to be a medical competency question which is not in our purview.

By contrast, though, you said something early on in your presentation that I was struck by and that is that the urologist was doing this, had the lead in doing this and that the oncology department was sort of a tag along. Just sort of there, if you will, to some degree. And that, of course, is arguably contrary to the approach we take in our regulations. Our perspective is, and it's a complicated one, and I'll get back to your 3525 because it does have a direct bearing.

We currently issue the license to XYZ Hospital. And you have identified specific authorized users. One of those might be a radiation oncologist. Well, our perception,

when we issued that license, is of course that that radiation oncologist is going to be actively involved in the kinds of procedures and things for which you would be using those materials. In this case, palladium and I-25.

Now, it gets complicated, though, in the sense that 3525 talks about supervising. Thou shall supervise. Thou shall follow. And so forth and so on. But clearly if one goes back and reads the 87 statements of consideration from the last time Part 35 was revised, you'll find out some interesting language in there. And it says something in essence which says that practice of medicine laws vary from state to state, et cetera. And that the authorized physician user is the best position to determine the degree of supervision which should be rendered.

Now, that translates then into the issue you have here. What this might mean is that the authorized user in question in the facility you were talking about has determined that that's the appropriate level of supervision for the urologist to be involved in this. And if that's true, while it's problematic to us, it doesn't seem to be working the way that it's supposed to, certainly from a licensing standpoint. We would need to do something about that, though, in regulatory space to tighten up, if you will, or more clearly specify supervision requirements. That's one observation.

And the second observation is obviously we don't

license the urologist as an authorized user. And if it turns out that the urologist is playing the lead role, is really supervising the use and the implantation of the seeds and the surrounding staff, et cetera, et cetera, then it raises the question of whether or not there should be a different approach in terms of the role of the urologist from an authorized user perspective in our world.

MEMBER FLYNN: What happens now is the patient is referred by a family practitioner to the urologist. It's the urologist's patient. It's only at his invitation, his or her invitation, that the urologist will allow the radiation oncologist to even see the patient. Now, the one misadministration, that last one, the radiation oncologist never examined the patient, talked to the patient, saw the patient, until the time of the procedure where he got a phone call and gave his okay. Because in some cases it's a matter of the authorized user being reminded of what their responsibilities are under the license.

I don't think that an authorized user should be allowed to maintain a license if they're not -- if they don't realize their responsibilities in this regard in terms of making sure that they have an adequate -- they supervise adequately the procedure. Because, in the end they must realize they're going to be held accountable.

MR. CAMPER: You've raised something here that we

wrestle with from time to time and it's an issue that, if not today, that at some point with the advisory committee soon we can explore this more specifically as an agenda item. But this question of what's the proper role of the authorized user is something that we're going to have to re-examine clearly when we revise Part 35 if not sooner if there's some compelling reason to do so.

But interestingly enough, if you look in Reg Guide 10.8, and it's only a guidance document, you'll find that amongst the responsibilities, the so-called following special responsibilities of an authorized user, you'll see the following things. And the first one on the list interestingly enough is examination of patients and medical records to determine if a radiation procedure is appropriate. Now, that's not a regulatory requirement but it's certainly something that we perceive is to be happening via the authorized user. And in your scenario that's clearly not happening.

And so, the next one is prescription of the radiation dose or dose and how it is to be administered. Actual use of or direction of technologist or other paramedical personnel in the use of by-product material. And then finally, of course, interpretation of results.

So, this is something we will need to explore and get some advice from the committee with. I mean, what's wrong

with the role of the authorized user in the scenario that you're describing?

MEMBER FLYNN: And now in most places it's being done correctly as a team approach, in most places. And I'm talking about -- Peter Grimm couldn't be here and John Blasko's out of the country so Peter Grimm had to be up there doing implants in Seattle. He wanted to be here. But he told me to pass on the word that he's very concerned because they're getting phone calls from their trainees. They trained over half the people who are doing this. They're getting calls from their trainees saying, oops, this happened. What do I do now. They're feeling-- He told me to pass on the two major concerns are, one, appropriate pre-planning and the involvement of a qualified medical physicist. Pre-planning with a medical physicist and authorized user. Number two, quality assurance. That there are a lot of problems out there.

And I'm only passing this on because the NRC, in terms of brachytherapy, brachytherapy is now much bigger a problem relative to teletherapy. And within brachytherapy, this could be the most common procedure in the next couple of years. And a lot of things are happening out there that aren't being reported because of the -- the question as to whether it fits the definition of misadministration to be reported. The one in Florida wasn't reported. And there are

many things out there happening that aren't being reported because the licensees don't believe they're misadministration. But they're like -- they're similar to these. Maybe not as severe in some cases but they're very similar.

CHAIRMAN SIEGEL: Doug.

MEMBER GRAHAM: Well, I guess the only observation, given the pattern of cases in Ohio, and I understood your countenance that this is not a turf issue. But had anybody reviewed whether there are reimbursement locations specific to Ohio that might make this a more probably in that setting?

MEMBER FLYNN: It's not even reimbursement issues. It's more of personalities. It's a surgeon's patient. He wants control over the procedure. It seems like a simple procedure when you first do it but the surgeon's aren't trained to realize the implications as to selection of patients, if they have other diseases whereby it puts them more at risk for complications with radiation, or whether the brachytherapy process itself. And each -- Both the radiation oncologist and the surgeon actually get reimbursed less, significantly less than if they do radical prostatectomy or external beam treatment. So this is a very attractive procedure to some people because if it's more effective, if it has less complications, and it's cheaper, this is exploding right now and you're going to see this explode a lot further.

MEMBER GRAHAM: I understand on the large scale it would appear to be more cost effective higher quality, but it's still the issue that you could have a situation where within that lower reimbursement there is a model in which there's a split reimbursement, where there's a defined role for the radiation oncologist and the surgeon, and they can both submit billings versus -- and I have no idea. I'm speculating Ohio might have a situation where they have declared at some major payer that the rad oncologist has no role. It's only a surgical procedure and therefore only the urologist is getting paid. And therefore there's an economic disincentive for the authorized user to have as much oversight as they probably should.

MEMBER FLYNN: I don't know.

MEMBER GRAHAM: I don't know but I guess I'd want to take a look at that.

CHAIRMAN SIEGEL: It's certainly possible Well, I mean, it's certainly possible that some third party payer has made an arbitrary decision to that effect without having all the facts.

MEMBER SWANSON: Isn't this truly a licensee management issue? I mean, it seems that that's where the issue really needs to be addressed at is that the license is given to the institution and the management of that institution needs to address this issue.

MEMBER NELP: Was this a small community hospital or a broad license, or a big place?

MEMBER FLYNN: Two small community hospitals and one major teaching institution.

MR. CAMPER: Well, in answer to your question, Dennis, if you go back to the explanation I was providing a few minutes ago in terms of this supervision issue. Then, yes, arguably you could construe this to be a supervision problem on behalf of the licensee and that the authorized user apparently is not properly supervising.

On the other hand, if it's a situation where it continues, there's this trend where urologists seem to be doing this thing absent an appropriate level of supervision, then at some point I suspect we would have to take a look at that and say what do we need to do about it from a regulatory perspective. Because obviously if that continues and we have -- if it's truly as depicted, and I have no reason to believe that it wasn't. I think Dr. Flynn has properly characterized it. That the supervision aspect of the authorized user is not working. It's not working the way it's supposed in this context.

MEMBER NELP: We're talking about one specific incident out of -- a small number of incidents out of a large number of therapies. And it's not clear to me that the licensee didn't do his job.

MR. CAMPER: That's right.

MEMBER NELP: -- his expected responsibility.

MR. CAMPER: I would agree. And it may well be that one of our next steps would be to monitor these misadministration and at some point in the near future develop an information notice about this question of supervision and some of the examples of some things that are happening.

MEMBER FLYNN: As I say, in most cases it's a team approach. But I think a bigger issue that's much more difficult is that I think the NRC -- I'm not sure if they've decided what constitutes a misadministration in terms of a volume implant. Is it the -- If the actual dose is 20 percent different than the intended dose. Or--

MR. CAMPER: Well, we are working -- on the case that you were discussing, that you were the consultant on, we are in fact -- we're at this very point. So I can't say. But we are interacting with the Office of General Counsel and so forth on this very case.

What I wanted to do, though, in that regard was take advantage of having the collective group here and get some perspective from the committee on that question. If I look at the definition under brachytherapy for a misadministration, it says, when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose. I'm assuming that your prescribed

dose in this procedure is prescribed for the prostate gland itself. Is that correct?

MEMBER FLYNN: There's different ways of doing it. Some are prescribing it by the number of seeds and activity per seed, and some are prescribing it by a MPD, a minimum peripheral dose. The prostate plus it may be a millimeter or so around the prostate. I don't know if Jeff has any --

MR. WILLIAMSON: I think it illustrates something very interesting about brachytherapy. And that's that there's a real spectrum of precision, of target volumes, that are localizable. If one takes sort of the traditional approach to low dose rate intracavitary brachytherapy, I mean, there really isn't a well-defined target volume and the parameter that's often used is as simple as the product of source strength and time. At the other extreme of the spectrum we have three dimensional imaging modalities that are able to in quantitative or maybe -- or at least semi-quantitative form specify a target volume in advance.

And then you can sort of meaningfully ask the question, how well did I cover that target volume. And so it would be sort of interesting to know for a large number of cases what is the standard deviation. What is the statistical distribution of minimum doses? What is the statistical distribution of volumetric coverage of the predefined target

volume? I think there are certainly -- it's not going to be exact. I don't know since I have personally not been involved in these -- in ultrasound guided prostate implants what that would be. I wouldn't be surprised if the error bar is on the order of 10 percent or so.

MEMBER FLYNN: It's actually more than that. I mean, some parts of the prostate and in these thousand cases up in Seattle, got 12,000, 13,000 as opposed to 16,000. But if they go back in and try to put more seeds, they may be increasing the complication rate. And because they've been following these thousand cases for five years now with good control of the cancer, low complication rate, low PSA, mostly negative biopsies on all the cases, they feel that perhaps although the prescription was for 16,000, 12,000, or 13,000 was adequate because it did the job. And then you don't fight with success.

My question is how far -- some of these cases are far off where they're actually missing the cancer. How off do you have to be and I don't have a good answer.

MR. CAMPER: Given that the course is going to be dose the surrounding tissue and so forth, if you look at the definition, and again, it comes back to what do you mean when you create your written directive or your treatment plan, you prescribe your dose? I mean, if you look, for example, from our perspective under written directive for brachytherapy, we

have the prior to implantation. We're looking for the radioisotope, the number of sources, and source strength. Post-implantation but prior to completion we're looking for the radioisotope, the treatment site which is right where we are, and total source strength and exposure time, or equivalently, the total dose.

So this comes back to this question that when you prescribe X number of rads to the treatment site and then that dose falls outside of the primary target which is the prostate in this case, is that inconsistent with your prescribed dose? What do you mean by prescribed dose? Given that surrounding tissue will be exposed, of course.

MEMBER FLYNN: The problem is that although you may biopsy the cancer in the right lobe of the prostate, there could be cancer in the left lobe of the prostate. The target -- the intention of all the physicians, the urologists and radiation oncologists, is to treat the entire prostate. And 16,000 is the standard dose for iodine. 11,500 or 12,000 is about the standard dose for palladium. And everybody is using those doses when they're doing brachytherapy alone. They discount them if they use external beam and brachytherapy for the more -- little bit more advanced lesions. But everyone -- that's their intention, is to treat the entire prostate. The cancer could be anywhere in the prostate or throughout the prostate. So the whole prostate has to be treated. It's a

volume as opposed to a point.

MR. CAMPER: Intuitively when we see a dose that's, say, 40 percent lower than what was to have been for the gland -- I mean, intuitively one looks at that and says well, it's a misadministration. The gland got 40 percent of what it was supposed to. The problem that you get into, though, is when you get into this world of what is the treatment site. Is it, in this case, the prostate is the primary target within a treatment volume, so do you relate the treatment volume at large, in toto, or do you relate only to the subject gland within a treatment volume? And this is the issue we've explored before, this question of treatment site. And we skipped over it earlier. But it's something that causes us a lot of wrestling with and we're wrestling with a case right now. It's a tough call.

MEMBER NELP: Are you intuitively concerned about over administration? I don't see why you would be particularly concerned about under administration in terms of radiation, adverse radiation effects to an individual.

MEMBER STITT: Add to this --

MR. CAMPER: Well, the under administration means that the patient is unfortunately undertreated. But he isn't -- he isn't in danger in anyway directly by radiation.

MEMBER STITT: The thing that complicates this even more is the doses you're talking about, the time period.

That is, the fractionation is a year. And that dose of 16,000 is over a year as an isotopic case. So add that into the equation.

The other thing just to bring up for information is that this is a newish technique. A newish way of putting that isotope into the prostate. But prostate implants with iodine 125 have been done for 20 years. This is not new. It's just that the ultrasound guided process is new. So there's a lot of background information. A lot of patients have been treated. And the more classic -- the older technique is an open approach so it still involves a radiation oncologist who has control of those sources, or should have, or else they're not practicing good medicine, working with the urologist. So this -- Although I certainly agree with Dan's point. Because it's easier to do this and because the population's aging with the PSA, et cetera, we amy be seeing a lot more of this technique. But this is an old isotope being and used has been used for 20 years. And there is a lot of results as far as local effects. Tumor control as well as sequela with iodine 125 in prostate implants.

MEMBER FLYNN: With the old technique the patient has general anesthesia, is opened, stays in the hospital for a period of time. This is a -- patient's awake. The patient walks in in the morning and walks out in the afternoon. Not under general anesthesia. And it's a -- it's gaining in

popularity so rapidly that it's -- what's happening is that there are so many community hospitals now that have, every month there's a training course now. Every single month there's a dozen urologists and a dozen radiation oncologists going through this. And so that it's hitting all the community hospitals very rapidly. And so that you're going to -- you should expect more problems being reported to you.

MR. CAMPER: In answer to your question, Dr. Nelp, we're concerned about both. The regulation says that dose differs by greater than 20 percent.

MEMBER NELP: But really what --

MR. CAMPER: Well, the reason is because --

MEMBER NELP: If I under treat a patient with hyperthyroidism, that's too bad. I mean, but it's easily correctable.

MR. CAMPER: Well, the reason is two-fold. One is because there can be negative consequences to under dosing, not just overdosing. And secondly, again, go back to the concept of what the misadministration is supposed to be. It's an error in the delivery process from what you as a physician prescribed.

MEMBER NELP: But we were talking about intuition.

MEMBER BERMAN: I'd like to point out that virtually all the misadministration were associated with the

wrong localization of where the seeds ended up. And I think it's a circumstance where frequently an imaging specialist would be a useful adjunct to the team. We talked about the urologist. We talked about the radiation oncologist. We haven't mentioned the possibility of the inclusion of an imaging specialist such as the radiologist more familiar with the ultrasound or potentially the CT studies that would be done to avoid misadministration.

MEMBER NELP: And in this team is typically the ultrasound done by the urologist or do you have a radiologist in there, or ultrasoundographer?

MEMBER FLYNN: It's usually an experience ultrasoundographer. And it's usually -- the imaging problems have occurred when people had just started to do the procedure. Usually they're -- learning curve, yes. And because they didn't have fluoroscopy. Because if they had fluoroscopy in some of the cases, they would have saw that the needles were far beyond the prostate. They had difficulty interpreting the ultrasound image. But the fluoroscopy, there's no problem for interpreting where the needle is. It's just there in front of you. You see it.

CHAIRMAN SIEGEL: So what does the NRC need to do? Does the NRC need to generate an information notice at this point to let people -- What?

MEMBER NELP: Ear to the ground.

CHAIRMAN SIEGEL: Or generate an information notice to let the folks in the world be aware that problems are being reported and that there's some issues of concern related to who has control over the radioactive sources and the involvement of the radiation oncologist, the involvement of the medical physicist.

It also sounds to me like there's a real need here for professional organizations to sit down and hammer out some standards. The American Neurological Association and ASTRO need to put a joint task force together and come up with some standards that say this is some -- this is a growing area and it needs to be a team approach.

MEMBER FLYNN: That's what the group in Seattle feels strongly about and they would -- one of them would have been there if it was possible. But that's what they're advocating.

CHAIRMAN SIEGEL: It seems obvious. That that's a first starting place. On the other hand, I'd hate to see the NRC make a regulation right now that says it has to be a team approach because there's no reason that a radiation oncologist who is properly trained in the surgical technique couldn't do this procedure quite competently by him or herself. And visa versa. A urologist who took the time to get the requisite training could do this procedure competently as well working with a medical physicist.

MEMBER WOODBURY: The CL group isn't asking for NRC's -- for more regulation now, are they?

MEMBER FLYNN: I'm not asking for -- I wouldn't suggest regulation. But it's almost to the point where soon or later it may be an information bulletin might be justified just to bring it to people's attention, including to try to recommend developing quality assurance and to define in their own program what constitutes -- I should not use the word misadministration, but an unintended deviation from the -- from what was planned.

MR. CAMPER: I assume you mean information notice not bulletin?

MEMBER FLYNN: Information notice, yes.

MR. CAMPER: Because a bulletin, of course, is a different vehicle. A bulletin requires typically that licensees do specific things and respond whereas an informational notice is simply that. It's informational.

CHAIRMAN SIEGEL: You know, I have always had a generic problem related to these surgical procedures understanding in my own mind what constitutes a misadministration if things don't come out the way you intended. On the one hand it's obvious to me that if I prescribe by written directive 10 millicuries of I-131, and the technologist gives the patient 100 millicuries of I-131, that my directions weren't being followed. On the other hand,

if I say it's my intent to put these seeds in the place where the prostate's going to get 12,000 rads and because of whatever came up during the course of the surgical procedure it didn't come out right, I'm still the one who was doing it and I thought I knew what I was doing through the whole surgical procedure. Is that a misadministration? Does that really capture what you meant or is that now getting strictly to the professional competence issue which may or may not be something the NRC wants to be involved with?

MR. CAMPER: Right. Well, we certainly don't want to be in the competency question. And historically there have been cases where seeds during implantation missed the prostate gland. And that was viewed as normal consequence of the procedure. But that's distinctly different than what's happening here. Here you're having, in the one case for example, every seed was outside the prostate gland. Then the question we would ask you is, is that consistent with the normal standard of practice. And I think I know the answer.

MEMBER NELP: I think the answer is this is something new. There's a tremendous learning curve and if it follows the pattern of behavior and practice, it will improve and self regulate itself. Percentage-wise, these should be very small.

CHAIRMAN SIEGEL: I actually agree.

MEMBER NELP: So I say watchful waiting.

CHAIRMAN SIEGEL: I think we --

MR. CAMPER: Is that the -- watchful waiting as opposed to information notice? I'd like to get --

CHAIRMAN SIEGEL: Aren't they sort of related? I mean, I think information --

MR. CAMPER: A delayed information notice?

CHAIRMAN SIEGEL: No. No. An information notice doesn't --

MEMBER NELP: It's a watchful information notice.

CHAIRMAN SIEGEL: No, I mean I think an information notice to make the community aware that you've started to get some reports from a new procedure that there are some problems will heighten awareness and while you still are little gray in terms of your own definitions about what constitutes a misadministration. I know that's a problem to still be gray but I think you need some more data before we start tweaking regulations.

MR. CAMPER: All right. What we would do, then, is we would develop an information notice with the assistance of Dr. Flynn. We would ask him to work closely with us on that. And for that matter, Dr. Stitt or any other members of the committee that would provide input on that.

CHAIRMAN SIEGEL: All right. Let me ask a logistical question now because we've got a tough one. We are now 15 minutes past the time we were supposed to break for

lunch. Trish thinks she probably has anywhere between a half an hour and another hours worth of things. And she has to leave this afternoon at 2:30. So --

And are you here tomorrow, Trish?

DR. HOLAHAN: Yes, I am.

CHAIRMAN SIEGEL: What do you think? How do we want to juggle this agenda to try and --

MR. CAMPER: Jan is suggesting that the discussion of Reg Guide 10.8 tomorrow morning will not take two hours.

CHAIRMAN SIEGEL: I agree.

MR. CAMPER: Perhaps we could try to make an hour toward the brachytherapy in the morning and an hour toward your presentation?

DR. HOLAHAN: That's plenty.

MR. CAMPER: Would that work?

DR. HOLAHAN: Yes.

CHAIRMAN SIEGEL: I think that will work better. So I think what we'll do now is break for lunch in a moment. Plan to get back here -- Let's split the difference. Let's get back in an hour. And then we'll work through the afternoon's agenda and take it from there.

So, barring anything else, we'll adjourn for lunch and see you in an hour.

(Whereupon, the hearing was recessed at 12:29

p.m. to reconvene at 1:30 p.m. this same day.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:40 p.m.)

CHAIRMAN SIEGEL: We are back on the record.

We're juggling again, because we've got lots of different folks who -- well, but we still love you.

(Laughter.)

Lots of different folks who've got to sort of be in and out, and so what we're going to do is between now and 2:30 we're going to try to work through a few more of Trisha's questions, while we can still get them -- while Drs. Williamson and Brezovich are here.

So, Trish, those that are most physics related are the ones we should focus on, and we'll do some additional catch-up tomorrow. We've got to do Bob Ayres' stuff briefly some time this afternoon because he won't be here tomorrow, and then we'll just work through it. And we have to end up being here a little later than 5:15, that's life in the big city.

So, Trish, I know we gave you about 10 seconds notice to take the stage again, but we're ready whenever you are.

MS. HOLAHAN: I believe in being flexible.

CHAIRMAN SIEGEL: Good.

MS. HOLAHAN: Okay. I'm going to try -- and I may sort of flip through the slides as we're going, but some

of these sort of are the more physics related.

This one is, again, one that I hope won't be too lengthy, is the use of portable shields. Currently, within licensing guidances for low dose rate remote afterloaders, portable shields are allowed. But for medium and high dose rate remote afterloaders, they are not authorized for use with those, except on a temporary basis if they're making changes to the facilities.

And the question related to that is, should NRC consider the use of that -- of portable shields? Some licensees have proposed somehow fixing the -- fixing temporarily the portable shield. Or, what are the safety implications associated with that?

MEMBER STITT: My notes are very explicit. They say, "I have no idea. Ask physics."

(Laughter.)

MS. HOLAHAN: I'm glad I did that one today.

CHAIRMAN SIEGEL: Dr. Williamson, do you have an opinion?

DR. WILLIAMSON: Well, I do have an opinion, actually, and it's -- I guess it's rare I don't have one. I would say on a routine usage, i.e. in an HDR facility that's meant to be more or less a permanent one, I would say for that strength source it's rather ill-advised, both on practical grounds and safety grounds.

I think that, you know, one might imagine certain applications of high dose rate irradiation, such as intraoperative radiation where, you know, maybe there's some sort of a compromise that has to be made between patient welfare, i.e. schlepping the patient back and forth from the operating room while the surgical wound is open, you know, versus having the best shielding.

So one might in -- you know, under very specific circumstances where patient welfare outweighed the benefit of the, you know, sort of very conservative safety factor that structural shielding offers have perhaps an out, you know, under that circumstance. But I would not think under routine conditions for a permanent facility it would be wise.

CHAIRMAN SIEGEL: Any disagreement with that concept? Okay.

MS. HOLAHAN: This is another issue that Dr. Williamson addressed a little bit in his comments this morning with regard to the facilities and the access to the HDR unit. These are the current licensing guidance requirements in terms of what an HDR treatment room must have, to include mechanisms to allow only one device to operate at once, and the permanent radiation monitor being mounted as well as electrical interlocks.

And I guess the question is is should NRC codify these within the requirements?

CHAIRMAN SIEGEL: And I think we actually have answered that at a previous meeting where we basically suggested that just as teletherapy facility requirements are codified, HDR facility requirements should be codified. Does the Committee recall that we did that at a prior -- two or three meetings ago, or am I the only one? That's okay, too. We can find it in the minutes.

MS. HOLAHAN: I believe it was the last meeting that we did ask the general question. Okay.

CHAIRMAN SIEGEL: Does anyone have any problems with this? I mean, this -- again, it seems logical that we want to move away from guidance and towards regulatory space on this kind of stuff. Okay? That was easy.

Dr. Williamson?

DR. WILLIAMSON: Well, I would agree with high dose rate. I think the issues with pulse dose rate, especially when it comes to the structural shielding, maybe that will be dealt with later or a little different.

MS. HOLAHAN: Yeah. I'd like to, if possible, deal with pulse dose rate separately than the high dose rate. Okay?

CHAIRMAN SIEGEL: Okay.

MS. HOLAHAN: Okay. I just jumped.

CHAIRMAN SIEGEL: That's fine.

MS. HOLAHAN: Okay. The other issue is in terms

of survey instruments. Currently, licensees are required for brachytherapy to have both a radiation measurement survey instrument and a radiation detection survey instrument. However, in terms of release of patients following a temporary implant, the patient survey must be conducted with a radiation detection survey instrument to ensure that all sources are removed.

When Bulletin 93-01 was issued following the incident in Indiana, Pennsylvania, NRC recommended at that time that the surveys associated with the HDR devices be performed with the radiation measurement survey instrument, primarily because of the concern that if the source was out the radiation detection survey instruments could peg and you could get -- would actually not detect that the source was out.

And it does conflict with the requirements of 35.404(a) for patient surveys, so we have allowed licensees to use the other survey instrument. And I guess the question is if there's a need to clarify Part 35 to -- with respect to the survey instruments. For example, should the licensee be allowed to choose the most appropriate instrument for the particular use, or if there's any recommendations or concerns as to which survey instrument is better in terms of the HDR surveys.

CHAIRMAN SIEGEL: I guess I'm a little bit

confused by the technical problem, in that looking at 35.404, at least current language --

MS. HOLAHAN: Do you mean there?

CHAIRMAN SIEGEL: Right. And a detection instrument is just -- is conceivably something that could just have a binary response? Whereas, a measurement instrument --

MR. AYRES: The problem is the detection instrument is -- this is Bob Ayres with the staff.

CHAIRMAN SIEGEL: But use the microphone so the transcriptionist can hear you, Bob.

MR. AYRES: The problem is the detection instrument is a lower sensitivity instrument and is normally a GM tube, and there was concern about it saturating, which would give a zero indication in a high radiation field. I was responsible for the measurement instrument which is normally an ion chamber and it doesn't saturate high radiation field. That was the issue.

CHAIRMAN SIEGEL: Fine. I mean, it seems to me that if they could have a false negative response under circumstances where there's a high field that you probably needed to change the rule to make it clearer.

MEMBER WAGNER: But I guess I would leave it a little more simple than what's stated up here. It seems to me that the regulation on the instrument could read that it should not give a false reading at exposure rates above 100 mr

per hour. That would mean that other types of instruments would also be useable.

CHAIRMAN SIEGEL: Say that again, Lou.

MEMBER WAGNER: It's just that the regulation should be that the instrument that's used should not give a false reading at exposure rates in excess of 100 mr per hour. That is, the data will peg; it could peg.

MEMBER NELP: That's pretty obscure.

MEMBER WAGNER: Well, the problem is -- the problem is is I don't see that it's necessary to know exactly what the rate is once you get above 100 mr per hour. You know you've got a big problem there, and you've got to search that problem down. Now, I'm not sure that there would be any more information to be obtained. It might give you a broader scope of instruments that you could use.

If that thing pegs like she described, you know you've got a high rate. The problem that she was referring to is the fact that it never left its zero mark. It was so saturated it gave a reading as if nothing was there. That was the problem.

MEMBER NELP: But why don't you address saturation?

MEMBER WAGNER: That's what I just said, is that it did not give a false reading at rates less than 100 mr per hour.

MEMBER NELP: I thought you said it shouldn't saturate.

MEMBER WAGNER: Well, either way. Yeah.

DR. WILLIAMSON: There are radiation detection instruments with ranges up to 1,000 mr, and that is what we prefer to use as a very wide range detection instrument that can read down in the microroentgen range, as well as up to 1,000 mr. So I think you should -- I like your suggestion of an appropriate instrument that does not saturate at the high exposure levels expected around an HDR source.

MS. HOLAHAN: Yeah. And I think that was what we were trying to clarify is that currently the detection survey instrument that's required only goes to 100 mr per hour.

Okay? Moving through these much more rapidly.

Okay. Again, with the licensing guidance, P&GD 86-4 -- for anybody who is not familiar, it's the current licensing guidance for remote afterloaders -- is there's a requirement for various quality control checks and calibrations to be done by the licensee's authorized physicist, which gets back to the earlier point that the physicist would have certain -- a certain role.

These are very similar to the requirements that are already in Part 35 for teletherapy -- basically, monthly checks, source positioning, accuracy, and linearity. And, in addition, there's a requirement in the guide that licensees

must confirm the source homogeneity for each source contained in the device.

Now, there have been comments received from the medical community that this particular requirement is burdensome because the sources have now become so small that for the majority of licensees it's very difficult for them to do the source homogeneity. These are some of the questions that I've got as a result of this.

First of all, should we, again, codify by regulation a QC check similar to those required for teletherapy, in terms of the monthly required checks?

CHAIRMAN SIEGEL: Are you limiting this to HDR alone, or is this all RAL brachytherapy?

MS. HOLAHAN: This is -- currently, in the licensing guide it is all remote afterloader brachytherapy. Is that correct, Bob?

MR. AYRES: Partially.

MS. HOLAHAN: Okay. Sorry.

MR. AYRES: Again, Bob Ayres with the staff. The one that isn't is the calibration. For long-lived sources in low dose there isn't that --

MS. HOLAHAN: Okay. That's right.

MR. AYRES: -- the calibration requirement. Most of the rest of it is.

MS. HOLAHAN: Thank you.

CHAIRMAN SIEGEL: Okay.

MS. HOLAHAN: So, again, should we proceed the route that -- in terms of codifying it?

MEMBER STITT: Well, I think in general we've been making those statements that we should. I'd like to hear those physicists who do high dose rate and remote afterloading talk.

DR. WILLIAMSON: Well, I think it's not inappropriate to have some mention in the regulations of appropriate acceptance testing and quality assurance. I guess I find some of the specific tests in the appendix to be very rigidly defined. It to me is not obvious that the precise frequencies that you've specified are necessary, and there might be alternative ways to do it.

I guess my overall suggestion would be that this is something that could be successfully pursued, you know, by NRC involvement and discussion with the -- for example, the appropriate task groups in the AAPM. The AAPM task group -- I believe it's 56, brachytherapy code of practice, is working on some recommendations for protocols for acceptance testing, commissioning, and periodic QA.

And I think, you know, the advantage of working through that is is that there would be -- you know, the physics community would have an opportunity to have detailed input into these things and be able to build in a certain --

you know, a desirable level of flexibility.

MS. HOLAHAN: Yes. As I mentioned earlier in the day, what we are also looking for and sort of seeking input on is the standards that are out there and what are currently being developed. I know that a number of the societies are developing standards in various areas, and I think where there are standards is similar to the way that in the teletherapy regs. we reference TG 21 is we could consider doing that type of activity in the brachytherapy arena.

DR. WILLIAMSON: Yeah. Just, you know, for example, I think one could argue about the utility of monthly testing and whether, you know, I think sort of the minimum frequencies of some kind of testing problem, in my mind -- speaking as a working physicist -- would probably be annually, quarterly, and daily, and there are different ways you can split up some of the -- address some of the concerns that are in the monthly test, in the daily test, and so on.

So it's sort of a very detailed kind of thing that could benefit by some detailed discussion with the, you know, appropriate professional community.

MEMBER STITT: Again, I think in general we should move from where we are to bring this into the regulatory language. I think it would be inappropriate to have an NRC listing of quality control checks, calibrations, a calendar of this or that, and find that that's somewhat

different than the national standards that are in progress right now.

And the folks writing the standards are not just isolated groups that aren't speaking. They are actually pulled from all of the national groups -- physicists, physicians, etcetera. So if we can put a qualified yes or something to that question, that might be reasonable.

MS. HOLAHAN: Okay.

CHAIRMAN SIEGEL: But a qualified yes is reasonable because once there's really intent to put things into regulations, there will be a need to generate some sort of a consensus that makes sense, and that will come by way of things like workshops, I suspect, and you've got a bunch of those in mind, as well as further discussions with us and the public comment period.

So there's plenty of opportunity in the process of getting this into a rule language to get the rule to match what is current standard.

MS. HOLAHAN: Right.

CHAIRMAN SIEGEL: I don't see a problem with it. I just think you should go forward.

MS. HOLAHAN: Okay. And then the other question that I have while, you know, we have our physics members here with us is, should NRC require confirmation of the source homogeneity of -- for sources contained in remote afterloading

devices?

CHAIRMAN SIEGEL: Jeff or Ivan, either one?

DR. WILLIAMSON: Well, I would say no, because there is no practical way to do it for a high dose rate source. In fact, there's very scant literature on how to quantitatively assess source homogeneity, even for LDR sources. Certainly, taking autoradiographs and transmission radiographs can give you an idea of, you know, are there gross problems and deviations from structure? But, you know, nobody has really validated that you can show by looking at a contact autoradiograph that the source is homogeneous within 10 percent.

High dose rate has the problem that you can't manually manipulate the source and get it in good contact with films, and so on, so I would, you know, say no. It's certainly not something that's standard or practice. I don't believe there's any indication that there is a problem with the current generation of sources, so I'm not -- I'm not sure it would show anything very interesting.

We've done some research work with it and found that the source construction was very close to what was specified at the degree of dose anisotropy that we measured, was very close to that which was theoretically predicted from the design, so I'm not sure there's a real problem.

CHAIRMAN SIEGEL: Isn't this more a front-end

certification problem, to make sure that the -- the source manufacturing process has got the appropriate homogeneity checks? Or are these things changing as a function of time? I guess partially I'm asking that question out of stupidity here, so I don't -- I don't understand the issue.

Jeff, can you help me?

DR. WILLIAMSON: Yes, I think I can. I was speaking with Bob, actually, before the meeting, and the concern originally arose over the older design. Correct me if I'm misquoting you, Bob. That the original sources were made of little pill-shaped segments and disks, and I guess there was the concern that maybe some of the disks could be blank or something like that.

Now they're made out of a solid extruded piece of metal, and, you know, I think the way sort of these metal alloys are made the likelihood of there being any inhomogeneity or cavities or things in a pure chunk of, you know, irridium wire is extremely remote. The whole wire is inserted into a nuclear reactor, and the degree of heterogeneity of the activity distribution within the source would be related to the uniformity of the neutron flux distribution over this little tiny three-and-a-half millimeter area.

So I don't think it's a -- given all of the problems that we have to deal with in the clinical world, this

is not like high on the agenda of things that we need to test in practice.

CHAIRMAN SIEGEL: And my follow-up question is, is the source homogeneity variability in dose delivery relevant when you consider biological variability? Have there been real problems related to source homogeneity in current practice that anyone is aware of? Judy? Dan?

MEMBER STITT: No.

MEMBER FLYNN: No.

CHAIRMAN SIEGEL: Either of you? Ivan?

MR. BREZOVICH: I mean, I would say the way the sources right now are constructed it's not a problem. Maybe there should be some discretion left to the physicist. But if he suddenly comes out with a totally differently designed source it may become a problem, but not to codify it so that we have to do it when we know there can't be a problem is unnecessary.

CHAIRMAN SIEGEL: Okay.

MR. CAMPER: I have one more question. I want to make sure I understand what I'm hearing on this question of acceptance testing. I get a clear signal that you favor the idea of codifying due diligence, and what have you, but with regards to accepting testing itself being included within the quality control checks.

Now, two things about acceptance testing. Number

one is not everyone knows how to do them. There are some standards out. One can bring to bear NEMA considerations. One can bring to bear certain AAPM guidelines. But, you know, the actual format to be used in conducting an acceptance test can be problematic. Not everyone knows how to do it.

And for those who don't know how to do it, they're going to find someone and pay someone who does know how to do it. And the cost for conducting an acceptance test on a device like this would probably run $3,000, $4,000, or $5,000, something on that order.

So I guess my question, then, with that in mind is, is it appropriate that acceptance testing would be a requirement within quality control checks? What's the feeling of the Committee on that?

CHAIRMAN SIEGEL: None whatsoever.

(Laughter.)

DR. WILLIAMSON: What do you mean by "acceptance testing"?

MEMBER STITT: Yeah. I am confused by your question.

MR. CAMPER: Well, I mean, classically, you're taking a device, having it undergo an independent evaluation by a physicist or an engineer of your choice, not a manufacturer's employee, following whatever guidelines are available. And this is what I'm saying. There are some NEMA

specifications that have a bearing. There are some AAPM guidelines that have a bearing. And in some cases, AAPM has gone further with certain modalities than they have in others in defining specific acceptance testing criteria.

But basically, what you do -- and it has gotten better over time -- is you come up with -- a physicist comes up with an appropriate set of criteria, to see to it if, in fact, the device functions according to the manufacturer's specifications. And in many cases, not necessarily HDR's, but many imaging devices, for example, do not, will not meet the manufacturer's specifications despite their literature.

And what I'm saying is is that an acceptance test is not just something that does one just like that. And, therefore, the idea that we would require that -- is it a good thing to do? Clearly --

MR. BREZOVICH: Yes.

MR. CAMPER: But a requirement is yet another thing, because I think there are some costs involved and we have to be concerned about cost in our regulations.

CHAIRMAN SIEGEL: If we're talking about the entire device here, I mean, the Food, Drug, and Cosmetic Act, as amended, is designed to allow one to believe -- and "believe" is the operative word -- that if you buy a device that's supposed to do something that it will do that, and that whether you need to go a step further by requiring acceptance

testing is not at all clear to me.

You know, I think the FD&C Act is doing the job here. I think prudent purchasers do acceptance testing to do those fine checks on specifications, but the question is is whether fine checks on specifications are the issues that are going to be addressed by the kind of acceptance testing the NRC would be concerned with, which would be major device failures, I think.

Jeff, do you have a comment?

DR. WILLIAMSON: Well, I think the issue of what acceptance testing means is kind of ambiguous in this discussion. I think there is a sort of level of very extensive acceptance testing that can't be done in the field non-destructively. There are sorts of things the vendors do in terms of, you know, testing each individual bit of hard-wired code and simulating all of the different hundreds of internal error states the machine is supposed to be able to check. We can't, obviously, do that in the field.

I think it would be nice to do a little more than we do, but I think acceptance testing, as understood in the medical physics community, involves basically independently assessing things like the degree of positional accuracy that can be achieved for the different types of applicators that would be used, looking at some very -- some critical responses to simulated safety problems, those that can be done, again,

safely and non-destructively with respect to the piece of equipment, a few other -- you know, so it's not that much more extensive, really, the list from what is specified in the routine quality assurance testing. It's basically a slightly expanded superset.

The AAPM Joint American Brachytherapy Society, task group 56, is going to, you know, basically come up with a recommendation of what is the sequence of testing that should be done. And I think, you know, Larry is right. At the moment, I don't think there exists, you know, complete unanimity in the community exactly how to do this.

MR. CAMPER: Yeah. I mean, from our perspective -- I mean, let's play this out. Let's say there was a regulatory requirement, and it would say that, "The HDR device will undergo acceptance testing to meet the AAPM whatever, or it's equivalent," for example. And then the AAPM, or whatever organization, would need to develop the acceptance testing, and then this could be embodied within guidance, and so forth.

That can probably be gotten to, and certainly from a regulatory standpoint we should be using whatever acceptance testing criteria of an industry standard that exists.

But stepping back from that, if one assumes that's how it would go, this fundamental question of should acceptance testing be a requirement, the reason I ask it in

the way that I do is it does carry with it, I think, arguably a significant burden to the regulated community, in terms of either being able to perform it, to satisfy a regulatory requirement, and/or perhaps a cost burden.

CHAIRMAN SIEGEL: Yes?

MR. BREZOVICH: I just wanted to point out with linear accelerators, which are of course more complicated than HDR, there the manufacturer very clearly says the final responsibility for its use is up to the physicist. So not to require -- I mean, that's part of when you purchase it. It's part in the specifications. So the question is, is an HDR the only -- that much simpler that we don't need any of that?

I'm not sure I know the answer, but some kind of a test I think should be -- maybe it should be just before you put it in operation you do your monthly check or something. What I want to prevent is that a unit gets from the manufacturer into a clinic and something goes wrong which happens during the transport, and so on. So that by the time of its first monthly check, some people may already have been treated incorrectly with it.

CHAIRMAN SIEGEL: Surely the manufacturer does some checks on the device as it's installed at your facility and says, "It is performing according to specifications. Here is our certificate that says so." They do, don't they?

MR. BREZOVICH: Well --

CHAIRMAN SIEGEL: It just doesn't come in a box and you unpack it and get your screwdriver out and put it together.

MR. CAMPER: Two observations.

CHAIRMAN SIEGEL: I hope not.

MR. CAMPER: Well, two observations. One, someone brought up the FDA earlier. I mean, if I'm a manufacturer and I want to produce a teletherapy unit, or an HDR unit, or a CT unit, I go to the FDA and I seek approval for this device. And I undergo the review and approval process, and I'm going to build, you know, model XYZ HDR device. That's fine. Then, you have approval to go do that.

But that doesn't mean that serial number 2204 of that device that you end up with in your shop functions the way it is supposed to. And the value of doing an acceptance testing is seeing that your unit meets the manufacturer's specification and performs according to the established criteria.

CHAIRMAN SIEGEL: GMP should imply that serial number 2204 is functioning according to specifications.

MR. CAMPER: I understand. But the reality of the matter is is that not all devices perform according to the manufacturer's specifications.

MR. BREZOVICH: Yes, I strongly agree with what Larry said.

MEMBER STITT: I think we should look at a qualified yes like we've done before. But I think we really ought to look to the direction of the groups that are spending a lot of time and effort putting specifics into this topic -- that is, the task force, the AAPM, etcetera.

DR. WILLIAMSON: I would suggest sort of holding on taking a final action because the task group is in progress, a draft exists, there should be -- it should be clear in the next six months what the final recommendation is. It may well be that the additional mileage gotten out of an acceptance test -- testing versus what one would do on a quarterly basis, let's say, may be very minimal. And the kind of yield that you would get would be not at the catastrophic level of error but at the sort of three/four millimeter level of source positioning, and stuff like that. That's where I suspect it would make a difference.

I certainly have found, despite what the vendors say, deviations from the performance, even of these relatively simple devices like the high dose rate, and it has had impact on the way they've designed -- had to redesign and reengineer some of their accessories.

CHAIRMAN SIEGEL: Okay.

MS. HOLAHAN: Okay. All right. I'm going to -- again, with the safety checks and things like that that are in licensing guidance, again, I think we've sort of gotten an

indication that you think, yes, go ahead through the rulemaking process and we'll get comments as we do that. So I'm going to move on now to relocation of remote afterloading devices.

Currently, licensees are authorized to move LDR devices to patient rooms, provided they have the appropriate portable shielding necessary. But the movement of PDR, MDR, and HDR devices is restricted to the specific -- or the use is restricted to a specific room described in the application. And relocation of the device to another room requires prior NRC approval.

The question is -- and the question has come up as to whether or not licensees can move their device from one room to the next and have two rooms that they can use not simultaneously, but in the same day and move it back and forth themselves. So the question is is what are the safety implications of relocating an HDR remote afterloading device within the licensee's facility?

And again, and this is following up on some of our earlier discussions with standards, have standards have been developed to provide some specific guidance on this issue as to what would be expected once the device has been moved?

CHAIRMAN SIEGEL: And the primary issues are related to the Part 20 requirements --

MS. HOLAHAN: Well, not just the Part 20

requirements.

CHAIRMAN SIEGEL: -- about what the dose rates would be, or are you more concerned about the machine not working right because it was physically moved from Point A to Point B?

MS. HOLAHAN: Yes, the latter. It's more as to what needs -- do certain checks need to be done on the machine following its movement, or should it even, you know, be considered?

CHAIRMAN SIEGEL: Well, I mean, in a way it's sort of akin to what you have to do with a dose calibrator. If you move it to a different location, you have to do some of the safety checks that are required on an annual basis on the dose calibrator when it's moved. And if there is, in fact, the opportunity for a machine to malfunction because it has been physically moved, it seems reasonably prudent that you ought to check it.

Now, what I don't know is, do they malfunction when they've been moved? Jeff?

DR. WILLIAMSON: Yeah. I guess I'd like to make maybe two or three comments about this. I think I would distinguish between two sets of issues. One is a manufacturer's issue. Is the machine designed to withstand, you know, the additional stress, vibrations, etcetera, accidentally bumping into a wall, without it, you know, going

haywire or producing a hazard? My impression is that the devices are, although maybe the Nucletron and other vendors may want to comment on that.

The second issue, does it work properly once it's moved? I actually think the response of NRC, initial response, saying, "This is a reinstallation and requires a vendor to be on site and reinspect the machine," and so on, that's really overblown, I believe, and greatly exaggerated.

Moving, for example, the Microselectron HDR from one room to another would entail unplugging the power, unplugging the machine from its cabling harness, doing the same for its console, and basically trucking it to the new room and plugging it in. Does it always work? Well, you know, what the vendor would essentially do is what we would do. They would go through a daily quality assurance protocol that would check, one, does the machine function?

If there's a problem with that multi-strand cable being properly seated in its socket, you'll know very quickly. And so, you know, I don't think there is a very serious question here regarding functionality. I think it would be appropriate to say that if it is moved from one location to another the agreed-upon daily quality assurance protocol should be repeated in that new site before you go ahead and use the device for treatment.

We've had much experience moving the little

brother of HDR around -- the PDR. We've moved it many, many times, and we've never had a problem.

MEMBER QUILLEN: Isn't this argument or discussion related to the mobile HDR?

MS. HOLAHAN: That's the next issue. I mean, this is not devices that are manufactured as a mobile or transportable.

MEMBER QUILLEN: Okay.

MS. HOLAHAN: This is the standard device.

And currently, you know, we'll allow the movement of the transportable device. But again, as Dr. Williamson indicated, is that a device when it's moved is considered a reinstallation to NRC.

CHAIRMAN SIEGEL: But your licensing requirement that you know exactly where it's located, that relates to Part 20 requirements. You want to know what the --

MS. HOLAHAN: Well, it relates more than to just Part 20, because for -- within the HDR licensing guidance, we require a description of the facilities as well. So when we ask for the area of use, we're also ensuring that the facilities have everything that is required in terms of the viewing system, the interlocks, the monitor. So on the license application and the license it will list the area of use as a specific room.

CHAIRMAN SIEGEL: And I guess the next question

-- practical point of view is how often a new room of use would pop up in an institution, such that you couldn't provide the information to the NRC in a reasonable timeframe.

DR. WILLIAMSON: You've raised a third issue, which is, does the room have to be specially equipped? Well, the answer is absolutely, you know, yes it does. You can't just roll an HDR into any room and use it. That's not what I'm advocating. The room needs to have a special cabling harness. It needs to have a power conditioner. It needs to have shielding. It needs to have the various independent safety systems. It needs to have the door interlock.

All of that is permanently installed by the vendor, and I would assume by license amendment you would say, "I want to use it in rooms X, Y, Z, in Barns Hospital," or whatever, and, "Here is how I would plan to move the unit around and the testing I would do." So it's --

MS. HOLAHAN: Yeah, you're right. There are two issues. One is the actual facilities, and you are asking why is a specific room listed, and it's more than just the Part 20. It's a facility. But this is also, then, we go beyond -- is what happens to the device when you move it from one room to the next?

CHAIRMAN SIEGEL: Bob, please.

MR. AYRES: Bob Ayres of staff. There is actually two other issues involved in there, too. One about

manufacturer's installation. You talked about it a little bit earlier, but in the device evaluation there's a restriction placed on the device that it must be installed by the manufacturer. So to license in any other way would be in violation of the Part 32 device evaluation.

The other issue is a safety issue in the movement. Unlike the transportable devices, the other generation devices have not been tested that the source will remain secure during a movement if it was tipped over or something. The transportable mobile devices are class -- the source safe is a Type A container certification that the source will remain secure.

CHAIRMAN SIEGEL: Okay. Have we sort of answered these questions, or have we not? I mean, it sounds like you need to have licensing information about what rooms the thing is going to be used in and it -- and the period. It's just it shouldn't be something that the licensee should just be able to move these things about on their own without the NRC knowing about it. Is that what we're saying?

DR. WILLIAMSON: Well, I think the question is whether you can move it from one room to another, with or without prior agency approval. I think they're considering saying, "If I have two Microselectron PDR rooms, one on the fourth floor and one on the seventh floor, I can't move the unit when I have -- had a neck patient on the seventh floor

without having the vendor come and push it up there and plug it in, you know, themselves, as opposed to, for example, my staff or I doing it."

MS. HOLAHAN: And what I'm hearing, though, too, is that there are no specific standards for moving it, but you are saying that the regular QA/QC checks that would be done on normal daily operation would need to be applied whenever the device is moved.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: And I think it's important to point out that what you're also implying is that you don't need to have the company recertify the machine once it's moved.

MR. BREZOVICH: Yeah. Could it be maybe done so that both rooms have to be agreed upon and certified by the manufacturer, and then going from room to room is up to the user? In other words, if the manufacturer agrees to this dual use.

MS. HOLAHAN: Well, again, that's still the -- the whole question is, is that still considered a reinstallation each time it is moved? Which --

MR. CAMPER: Well, I mean, are the current -- is the approach that we're currently using today, with regards to having a room, specified ahead of time? If you want to move it to another facility, it has got to undergo an amendment.

Is that a reasonable approach, in view of the technology and what's needed in a room? Or are, by contrast, there's the safety implications -- so minimal or not so profound that one could move it and notify us after the fact in some predetermined or specified period of time, for example?

DR. WILLIAMSON: Well, I have no problem with in my license amendment specifying in advance the facility. With any of these machines that we're talking about, you can't just decide tomorrow to go move it to another room. It really does require an installation process to occur, because some permanent equipment has to be installed in the room that's left behind when you move the machine to another room. So you'd have to have several independent setups. That's indeed what we have.

What I am kind of objecting to is calling this simple relocation of a device from two previously certified and allowed rooms, making that very difficult and burdensome. If I have to, you know, have a Nucletron person come out there, that is going to cost $1,000, and it's going to become an enormous hassle to use a pulse dose rate machine on several clinical services.

So I think there is sort of good reason to give people the flexibility to move it around from previously certified -- between previously certified sites in the same building. I guess that's what I'm arguing for, that it does

not seem to me to be a problem at the practical level unless there is some issue further up the line that has to do with the manufacturing specifications, which it sounds like that could be addressed by additional testing of these devices.

CHAIRMAN SIEGEL: I also am not sure we've got the whole answer right now either. I'd be very curious -- there are none in the audience -- to know what the manufacturers would think about their devices being moved from one room to another, and whether in the event that there's problems whether they've designed things adequately to handle that or if that's going to markedly change liability issues.

So I think although I'm -- I think I agree with Jeff's concept that it could be made simpler. I think this issue needs more data before we give you an unequivocal answer.

MS. HOLAHAN: It should be explored with the manufacturers.

CHAIRMAN SIEGEL: I think so. I think they need to have some input.

MS. HOLAHAN: Okay.

CHAIRMAN SIEGEL: Bob, you had a comment?

MEMBER QUILLEN: Well, I was going to say the same thing you just did. But also, I was going to add that it would seem to me that if a licensee wants to move this and have already gotten approval for the various locations, the

only issue that remains is this manufacturer certification for the location. And it would seem to me that the licensee, if they felt that they could -- had the resources and abilities to do so, could ask for, in their license, that authority to do so, for a specific exemption to NRC normal licensing criteria.

DR. WILLIAMSON: Well, I think that's all reasonable if we're allowed -- I thought we were discussing being allowed to do it, or like every week I have to call the vendor in to come and roll the machine from room X to room Y. I'm objecting to that as a burdensome requirement.

MEMBER QUILLEN: What I'm saying is, why don't you ask for the authority to be able to do it?

DR. WILLIAMSON: Well, that's what I'm suggesting that this council support is the authority for -- by a license amendment for users to do this.

MEMBER QUILLEN: I support that.

CHAIRMAN SIEGEL: We support it, but we think you probably need better data from manufacturers.

MS. HOLAHAN: Explore it further, okay.

CHAIRMAN SIEGEL: Because they might not support it.

MS. HOLAHAN: Right. Okay.

CHAIRMAN SIEGEL: For a variety of reasons, one of which is they get money from it.

MS. HOLAHAN: Let me move on to a related topic -- mobile HDR. Currently, there are two manufacturers that manufacture mobile or transportable HDR units. They are both -- in both cases, the remove afterloader and radiation shield and comprise a single unit. However, one -- the entire coach is considered -- is what has received the sealed source and device certification, and in the other case it is a transportable unit that is carried around on a truck, but it is a unit itself that is approved.

To date, NRC has not issued any licenses for the mobile HDR technology, and we have a number of questions with regards to it, in terms of they -- the quality control procedures that might be necessary, and the emergency procedures. When the patient is being treated upon a coach outside the hospital perhaps, but with no OR facilities immediately available on the coach in the event of a stuck source or something like that is are there considerations to be made in terms of the mobile HDR issues?

And maybe I can just walk through the questions. First of all, there are some unique quality control issues that we should consider. Now, this issue is -- we have had some meetings with the manufacturer, and I believe we will be getting an application in the near future, and so these sort of are very pertinent at this point in time to try and get some input on these issues.

MR. CAMPER: And, in addition, the State of California has, in fact, issued such a license.

MEMBER QUILLEN: We also have received an inquiry in our state for such a license.

MS. HOLAHAN: Okay.

CHAIRMAN SIEGEL: Well, Jeff, anyone, in terms of quality control -- I mean, it seems to me that if you've got a device that's being jostled around in a truck, you probably need to make sure it's working to a higher level of certainty on any given day of use than you would for a device that's sitting in a building.

MS. HOLAHAN: I guess the question is, as a followup to the relocation of a device, where you may have to do the quality control, is there anything beyond what you might normally do as your daily quality control checks, that when you have moved it X number of miles on a truck, on -- well, it depends how bad the roads are, but if there's anything else that should be considered.

DR. WILLIAMSON: Just a question of clarification. I understand one of the -- I thought the concept of mobile HDR is it basically is an HDR that rolls off the truck and then gets installed in a room in the hospital. That's not --

MS. HOLAHAN: That's a transportable one.

DR. WILLIAMSON: Okay. All right. We're not

talking about --

MS. HOLAHAN: The coach unit is there is a device permanently fixed on the coach. The shielding and everything, they've got the setup to do all of the dosimetry. The coach goes around. It provides, you know, a medical physicist, dosimetrist, radiation safety officer, and then the facilities provide the authorized users.

MEMBER FLYNN: I've seen the coach display, and the concept, I understand, would be that the -- as you say, the medical physicist would be with the coach traveling to different locations. There will be different physicians --

MS. HOLAHAN: Correct.

MEMBER FLYNN: -- but the coach, and maybe a technologist or a nurse, would be the same for all of the procedures.

DR. WILLIAMSON: So the operator would be with the coach. It wouldn't be driven to different hospitals and then staffed. Okay.

MS. HOLAHAN: Generally, the physicist that was operating the unit, at least in the one we've seen to date.

MEMBER FLYNN: The main problem that would occur would be that the physician would tend to use this type of service if he does HDR very infrequently, because he would be sharing this HDR resource with a number of facilities with only like a 200- or 300-mile area. And most of the concern I

would have would be not with the equipment but maybe with the authorized user, who would be something infrequently.

But at least the physicist would be with the unit, traveling with the unit, and so then I would -- you know, I would have less concern, that being the case. That it's not the institution's physicist who also would be doing it very, very infrequently. He would be doing the procedure with a physician who does it very infrequently.

MS. HOLAHAN: I guess the question there, though, is would that be any different from a small cancer clinic that has private practice oncologists coming in and maybe using their HDR unit on an infrequent basis?

MEMBER STITT: I don't think it would. I mean, certainly, that is -- those are always areas of risk when you don't do something very often. But then the medical aspects should have been addressed in the materials that we went over in the morning that had to do with definition of an authorized user, types of training, etcetera, etcetera.

DR. WILLIAMSON: Well, there certainly is one advantage that Dr. Flynn has pointed out. It's probably better for there to be one unit roving around amongst, you know, a bunch of little hospitals where -- with at least an experienced full-time technical staff running it.

That's probably, in the end, a lot safer than having five or six little units around that are used 20 times

a year with -- and perhaps those hospitals don't have, you know, an adequate technical staff or a technical staff that gets enough clinical practice with the device. So, in that sense, maybe it should be encouraged.

I can't, off the top of my head, think of any additional quality assurance requirements. I would assume that the manufacturer would have to perhaps subject it to more rigorous testing -- you know, that the device maintains its mechanical integrity, you know, as a function of mechanical trauma and all of that.

In general, I would have to say I think some of the facility survey requirements for stationary HDR systems are quite ridiculous. I think it's -- you know, there is no need to like do, in my mind, quarterly facility surveys. But I think perhaps with a truck with sort of -- with heavy lead shielding that could be jostled around, it might be actually wise to require more frequent facility surveys of the device, a very thorough daily quality assurance checkout every time the thing moves, not just at the beginning of the day. But I should think every time the truck stops and is about to treat a new patient, I would think at a minimum the technical staff should go through the daily quality assurance check, which might be then several times a day as opposed to once a day in a stationary facility.

MEMBER FLYNN: Unless those nice new highways in

Southern California and the south would be different than the northeast with the potholes.

MS. HOLAHAN: That's why I mentioned the quality of the roads.

MEMBER FLYNN: In Boston, they'd probably steal the truck if they parked it.

(Laughter.)

MEMBER STITT: That's a different question here. How do you secure your source? Trisha, does the nursing staff go with the unit, or do they come with the hospital? Or does it depend?

MS. HOLAHAN: The one unit we've seen they provide the nursing staff.

MEMBER STITT: It comes with the --

MS. HOLAHAN: Yes. The only thing the facility provides is the authorized user and the patient.

MEMBER WAGNER: Well, some of the issue here is, you know, we've talked about how they're doing it. The question then should be, should it be a regulation that they have a physicist assigned with the unit? And what kind of regulation should require that in the event we have more of these applications, what should they also be restricted to do in terms of the physicist and the operator, etcetera? Should there be a requirement that they be assigned to the unit?

And the other question was she brought up, you

know, what if a source is stuck in a patient. The issue is, well, what are they going to do to take care of that patient at that time, and do they have the facility to transfer that patient into the hospital for surgical removal or something? I think that also is an issue that -- at least an issue of safety, from different points of view that might have to be addressed.

MEMBER STITT: Some of these things can -- might be able to be likened to free-standing radiation therapy facilities or any other sort of out-patient clinic where you're not at a hospital where you can have immediate access. Now it's in the medical treatment realm, but what happens if somebody has a medical emergency while they're in the coach. I mean, it's -- the cycle goes on and on and on. Some of this would be regulated by other non-NRC types of things.

MEMBER FLYNN: Who is the licensee in this case, and who decides how often the source is changed? You know, every three months or every two-and-a-half months or --

MS. HOLAHAN: The licensee is the company in California, and they are responsible -- I mean, they maintain the responsibility for the source rather than the different facilities. And so they still comply with all of the source change requirements and everything like that.

CHAIRMAN SIEGEL: So the authorized users --

MS. HOLAHAN: Are listed on their license.

CHAIRMAN SIEGEL: -- at multiple hospitals get listed on the --

MS. HOLAHAN: Yes, they're listed on the mobile licenses.

CHAIRMAN SIEGEL: So, John, if you're running a network, is this the way you want to do this? Or do you want to move patients to the specialized tertiary center that does this?

MEMBER GRAHAM: I'll never be able to go to the country again if I answer this wrong.

(Laughter.)

There are parts of the country that are trying to accommodate rural communities that have populations that are objecting to travel time -- and particularly in excess of 50 to 60 miles. Seems to be the barrier.

In a heavily populated, metropolitan area like Detroit, I think the obvious answer is you ought to consolidate in a couple of large institutions --

CHAIRMAN SIEGEL: Right.

MEMBER GRAHAM: -- and have people drive there.

CHAIRMAN SIEGEL: But in Montana --

MEMBER GRAHAM: But in Montana, all of our technology is being developed in a mobile format to try to keep those patients as close to their families as possible. So I think I have to answer that if we can set the regs. up,

there has to be at least the opportunity to provide that service.

MS. HOLAHAN: But I think Dr. Stitt made a valid point about the free-standing clinics, and when we have talked with the individuals that are practicing in free-standing clinics we have told them, you know, basically, the procedures that would require surgical intervention if the source broke off is they'd need to have a mechanism to handle that.

CHAIRMAN SIEGEL: How much more do you have left, Trish? Because you have to leave, we have to move on, and --

MS. HOLAHAN: Yeah. I mean, I had some other issues. Pulsed dose rate was really the only other one I was going to try and cover this afternoon, and I don't know how. That could be lengthy.

CHAIRMAN SIEGEL: It could be quite lengthy. I think we'd better try to do it tomorrow.

MS. HOLAHAN: Okay.

CHAIRMAN SIEGEL: And if we can't resolve it, I -- I --

MEMBER STITT: I don't think anybody but Jeff is going to be helpful with pulse. I mean, so either --

CHAIRMAN SIEGEL: I also really -- I want to reiterate what I said earlier. I have a sense that this has turned out to be a much more complicated discussion than perhaps we had anticipated, and that the last thing I want

anyone to perceive is that the ACMUI rushed through these issues.

So I hope you all will see this as a first cut, take our initials judgments and work from there. But I think it's clear that these issues need workshops for further discussion. And if you want more advice from the ACMUI, I think a subcommittee meeting, public subcommittee meeting that really can take two days and talk through these things at great length, and consider all of the ramifications, is essential. Okay?

MR. CAMPER: We hear that.

CHAIRMAN SIEGEL: Good. Thank you.

MS. HOLAHAN: Thank you very much.

CHAIRMAN SIEGEL: So where is it? It's 1:15 now, whether you know it or not, and Janet --

MR. CAMPER: Yeah. We thought we would give Janet, you know, a non-controversial topic -- training and experience criteria.

CHAIRMAN SIEGEL: What would a meeting be like if we didn't talk about training and experience?

MS. SCHLUETER: Good afternoon. I'm Janet Schlueter, and I'm in the Medical and Academic Section as well, and we thought we'd have something light and breezy this afternoon.

(Laughter.)

Training and experience criteria. Our discussion today is limited to training and experience criteria for authorized users.

There has been some -- in order to sort of characterize the focus of this discussion a little further, as you know, there has been some discussion earlier today about a much broader effort, a much more broader effort to address training and experience issues as part of the overall revision to Part 35. That's not what I'm here to discuss today.

Today, we're here to discuss how the NRC staff has gone about developing some guidance for our regional offices to allow exemptions to our current training and experience criteria for certain types of authorized use.

The overall effort for T&E will be rolled into the advance notice of proposed rulemaking for Part 35 and the major revision of Part 35. Now, we need an interim fix for the current criteria that's on the books, and that's what we're going to be discussing today.

Excuse me for the laryngitis Monday. I'm lucky I still have a voice today.

As you probably know, each Subpart J section provides for either two or three training pathways for each type of authorized use. As we mentioned earlier, Board certification is not the only training pathway that we recognize. There must be an "or" category, a pathway that

allows individuals that are not Board certified to become authorized.

Most sections do require Board certification, or they require classroom hours coupled with supervised clinical experience or supervised work and clinical experience. We routinely receive, both in our headquarters offices and in our regional offices, inquiries from both our licensees, agreement states, and other interested parties as to whether or not there can be exemptions to our current training and experience criteria.

And, in particular, can the required 500 hours of clinical experience and 500 hours of work experience identified in 35.920(b) be obtained in some concurrent fashion? And, if so, to what degree? And that's the primary focus of this discussion today.

In order to provide some guidance to our regional offices on this issue and several other training and experience issues, we developed a draft policy and guidance directive, which was issued in April of 1994 to our regions for comment. And we received several comments on that P&GD and are in the process of finalizing it, and that's one reason that we bring this discussion to you today, because it is about granting exemptions to current criteria, not revising that criteria but allowing exemptions from it.

The policy and guidance directive initially was

going to be finalized in that form, but since that time we have decided to integrate the policy and guidance directive on T&E into Reg. Guide 10.8 as a licensing module, and this is the agenda item which is on for tomorrow morning. There is a large effort to revise Reg. Guide 10.8 and add licensing modules to it, and this guidance on T&E will be added as one of the modules.

10 CFR 35.19 requires that the NRC staff seek the guidance and advice of the ACMUI when we do grant exemptions to the T&E criteria. So instead of trying to do this on a case-by-case basis for some of the issues that we'll be discussing today, we wanted to bring it to you in a much more generic manner, so that we can finalize our guidance.

There is really two areas of discussion today, and the first one was also summarized in the briefing book material that we had for T&E, and it's about duration requirements, the presence or lack of them in certain sections of Part 35, and also our proposed minimum number of hours of training and experience for certain categories of use in Subpart J. And obviously, we'll start with the duration requirement discussion.

As you can see by the chart, there are several sections in Subpart J that do not have any duration requirement associated with them. For those of you that aren't real familiar with the sections, 35.930 addresses

radiopharmaceutical therapy, 932 addresses hyperthyroidism, 934 is thyroid CA, 941 is the use of the strontium 90 eye applicator, and 950 is sealed sources for diagnosis.

In the six-month category is 35.910, uptake dilution excretion, item (c), and 920, imaging and localization, item (c). But as you notice by the asterisk, and many of you know, there is an incorrect reference to a six-month duration requirement in item (c) of 910 and 920, in that currently it states that you could have used as a training pathway -- completed a six-month training program in nuclear medicine approved by ACGME or AOA.

There is no six-month training program in nuclear medicine approved by ACGME or AOA. It should read something to the effect that, "You have completed a residency training program approved by ACGME or AOA, which has as a component nuclear medicine, which is of various duration."

MEMBER NELP: I'm sorry. I didn't understand that.

MS. SCHLUETER: Currently, the text in 910(c) and 920(c) is incorrect, literally incorrect. It states that an applicant may be authorized --

CHAIRMAN SIEGEL: Go ahead.

MS. SCHLUETER: Okay. May be authorized, if they have completed a six-month training program in nuclear medicine approved by ACGME or AOA. ACGME and AOA, as you

know, approve residency training programs. Some of those residency training programs have a nuclear medicine component, but that nuclear medicine component is of a varying duration. It is not six months. It may be one year, two year, three year, depending on the specialty board.

CHAIRMAN SIEGEL: Yeah. What it really should be --

MEMBER NELP: What it means -- you have to have six months of nuclear medicine training in a program that has been approved for nuclear medicine training by the ACGME.

MS. SCHLUETER: No. It could be any Board specialty program which is approved by ACGME or AOA, which has a nuclear medicine component.

MEMBER NELP: Well, I know of only two.

CHAIRMAN SIEGEL: Currently, that's correct. The only two are --

MEMBER NELP: There are only two -- The American Board of the -- or the ACGME-approved programs in radiology and the ACGME-approved programs in nuclear medicine. There are only two, and they both have nuclear medicine training programs, theoretically, of six months in duration in radiology and two years in nuclear medicine.

MS. SCHLUETER: The point is is that as that paragraph is currently written, it doesn't reflect what ACGME and AOA do, so it needs to be revised. The only other two

sections that do have a duration requirement explicitly stated in the regulations are 35.940(c), which is brachytherapy, and 35.960(c) for teletherapy.

So out of all of those Subpart J sections for authorized users, there is only two with a duration requirement explicitly stated in the regulations.

Now, the issue of the duration requirement and concurrent training has never really been much of an issue with 35.910(c). It has been an issue from time to time with 35.920(c), because that is the section which authorizes the use of materials for imaging and localization. So while resolving some of these T&E issues that I mentioned in developing the policy and guidance directive, and in consultation with OGC staff, NRC staff recently concluded that in fact there is no legal requirement for applicants to demonstrate a duration of at least six months to meet the requirements in 35.920(b).

We have had, though -- having said that, the NRC has had a policy, a past policy which has been based on Federal Register notices, statements of consideration, Part 35, SECY papers to the Commission, and Commission memoranda back to the staff, staff requirements memorandum, which does reflect a six-month duration requirement. Let me explain that a little bit further even.

Prior to 1976, the requirements were limited to

30 hours. From '76 to June of 1984, the duration requirements were for the items in 35.920(b), which were previously in Reg. Guide 10.8, Appendix A, to be completed in three months duration. From June 1, 1984, forward, or to present we could say, it has been a six-month training duration requirement.

However, all of the duration requirements and guidance on T&E for authorized use for imaging and localization has been in guidance documents. Those guidance documents were superseded by the 1987 revision to the rule. The revision to the rule, the rule as it states today, and its corresponding statements of consideration, do not discuss, nor explicitly state, or include, a reference to a six-month training duration requirement. Interesting?

MEMBER NELP: What does the rule state?

MS. SCHLUETER: The rule identifies a required number of hours for three categories of training and experience, and that's what we work with.

Now, in order to clarify this even further, this discussion with OGC and NRC and this determination that, in fact, there was no legal requirement has been recent, as recent as the last four weeks.

MEMBER NELP: I know that. I can refer to that. But could you give us the hours so we're all on the same --

MS. SCHLUETER: Sure.

MEMBER NELP: -- so we're on the same page here.

MS. SCHLUETER: I don't think I put it in here anywhere. In 93.920(b)(1), you have 200 hours of classroom training, which is very specific with respect to radiation biology, radiation safety, and so forth.

In 35.920(b)(2), you have a required 500 hours of supervised work experience, which is your hands-on laboratory experience. And in 35.920(b)(3), you have 500 hours of supervised clinical experience -- the actual patient evaluation, administration of the dosage to the patient, interpretation of results, and so forth. So one training element, two experience elements, 200, 500, 500, for a total of 1,200.

MR. CAMPER: And the important point here, too, is if ones goes through those parts you'll find that the connecting language is "and," which then, of course, translates into 1,200 hours.

MEMBER SWANSON: Which is, in effect, six months.

MR. CAMPER: Which is, in effect, six months. But as Janet will go through here in a moment, we have been on record as saying this training can be obtained concurrently. Well, "concurrently" means different things to different people. So what we're trying to do today is to -- is to clarify what we mean by "concurrent training."

MEMBER NELP: "Concurrently" means at the same time, I believe.

MR. CAMPER: Well, it does. We'll go through that.

But the point is is that Janet is setting up the background for you to understand that there is no requirement that it be six months. There has been some operative understanding that it's six months.

MS. SCHLUETER: That's right.

Now, all of this discussion of duration leads in to Part 2 of the discussion. And before I talk more about the chart and the table which is in your book, which I'll have up on the screen in just a few moments, I need to explain a little bit about the basis for our table and the assumptions that we used to get there.

First of all, no consideration was given to revising the Board certification pathway, or looking at the duration of these Board certifications, or what have you. This is all focused on the "or" category of training, the "or" pathway.

There was no allowable reduction in the required number of hours of classroom training. We consider the 200 hours to be the right amount. There was no effort to look at that for possible area of reduction because it simply does not overlap with the required experience elements. It stands on its own -- the 200 classroom hours.

We did not consider Subpart J sections that

required only classroom, because in 35.950 that's the only kind of requirements you have. Or, classroom and either supervised work or supervised clinical experience, because if you only had training elements and experience elements, those are two very unique types of training and experience. They do not overlap. There are inherent differences in the training and experience.

What we did look at were those Subpart J sections that required all three training elements, and what I mean by that is classroom, plus supervised work, plus supervised clinical experience. That only leaves three sections that were eligible for some sort of consideration for exemptions. And since they did contain supervised work and supervised clinical, we considered them to be eligible for an exemption, and in theory they allow for concurrent training.

And as Larry mentioned earlier, the idea is concurrent training to what degree? That will be the question we'll try to answer.

As a result of all of the bases and assumptions that I mentioned previously, granting exemptions to the following sections was not considered. The first five listed there -- 920, 930, 32, 34, 41 -- all only require classroom training plus clinical training. The bottom one actually requires classroom training, and it goes on to further state "to include training on the use of the device." So it is, in

fact, classroom and/or clinical training. Those were not considered for exemption.

As I mentioned, the eligible sections turned out to be three of them, and I think it may work best to discuss 940 and 960 first. You'll notice that this table is different than the table that you have in your book, and that's because a little further thought, shall we say, went into the numbers on the table for 940 and 960, and we realized that perhaps our logic wasn't carried through all the way.

Because if you look at 35.920, we have the total number of required number of hours as 1,200, which is item (b)(1), (2), and (3). If we had done the same thing for 940 and 960, we would have 6,940 there instead of the 700 that you see in your table. Make sense? Everybody is nodding yes.

CHAIRMAN SIEGEL: Oh, sure.

MS. SCHLUETER: Okay. So, in 940 and 960(b), the third element of the (1), (2), and (3), 200, 500, item (3) is a three-year supervised experience. That includes one year in a formal residency training program and two years under the supervision of an authorized user.

So the total hours for 35.940 and 960 are based on item (b)(1), which is 200 hours classroom; item (b)(2), which is 500 hours of supervised work experience; and item (b)(3), which is the three-year residency training program. Each section has those three identical elements, for a total

of 6,940.

If we assume that the 500 hours of supervised work experience that is required by item (b)(2) of each of those sections is subsumed in its entirety during the three-year supervised work experience -- excuse me, supervised clinical experience -- then you can reduce the total number of required hours for categories 35.940 and 960 by 500 hours, because during that three years of training it is assumed that they will -- that the applicant, the authorized user, will have successfully completed 500 hours of supervised work experience.

Five hundred hours in a three-year residency only equates to about seven percent of the time, a very small fraction.

MEMBER NELP: I think you're mixing apples and oranges. The heart of the training experience that you're referring to occurs only over a two-year period. And it exclusively excludes the first year. It has nothing to do with radiation or nuclear medicine.

CHAIRMAN SIEGEL: Well, this is radiation oncology we're talking about right now.

MEMBER NELP: Oh, I'm sorry.

MS. SCHLUETER: Yeah, 940 is brachytherapy and 960 is teletherapy.

MEMBER NELP: I'm sorry. Excuse me.

MS. SCHLUETER: So you have someone -- in other words, for item (b), this is a physician who is not Board certified. He is going through some other formal training program, and for item (b) it requires that that physician have 200 hours classroom, 500 hours supervised work, and three years in a formal training program -- three years training, one year in a formal residency training program and two years under the supervision of an authorized user.

MR. CAMPER: Let me help to clarify that. In the 500 hours that Janet is referring to, you have things such as ordering, receiving, and unpacking radioactive materials safely; checking survey meters for proper operation; repairing, implanting, and removing sealed sources; maintaining and running inventories on material on hand; using administrative controls to prevent the misadministration of by-product material; using emergency procedures to control by-product material. That's what the 500 hours consists of.

MS. SCHLUETER: So we're saying if we were going to look at an applicant coming in, wanting to grant an exemption to 940 or 960, we can -- we are assuming that the required 500 hours of work experience has been subsumed in the formal training, through the residency training program and under the supervision of an authorized user for that two years as required.

So you only get down to a reduction of 500 hours,

a seven percent reduction from what's on the books today.

Here's where it gets interesting. For 35.920(b) -- Barry is already shaking his head. So now we move up to the top line item. Okay. So for 920(b), once again, (b)(1), (2), and (3) require 200 hours classroom, 500 hours supervised work experience, and 500 hours supervised clinical experience.

If we apply that same logic that we used in 940 and 960 to 920, and say that the 500 hours of supervised work experience is subsumed in its entirety, one for one, in the 500 hours supervised clinical experience required by 920(b), 930, then you have a total required number of hours of experience and training of 700, for a difference of 500 or 42 percent.

And remember, there are for physicians coming in, training pathway D, non-Board certified, that are looking for authorization for imaging and localization.

MEMBER NELP: You've lost me completely -- the transition. You switched now back to imaging?

CHAIRMAN SIEGEL: Yeah. Now we're talking about imaging.

MEMBER NELP: But you've used this as your example for the logic?

MS. SCHLUETER: Do you mean 940 and 960 as our example for the logic to be applied to 920?

MEMBER NELP: Yes.

MS. SCHLUETER: Yes.

MEMBER NELP: Why did you do that?

MS. SCHLUETER: It was a starting point for discussion.

MEMBER NELP: Okay.

MR. CAMPER: Now, the problem here is -- what we're trying to get to -- is one looks at the 500 hours of supervised work experience, you've got such things as ordering, receiving, unpacking, calibrating dose calibrators, calculating safety, preparing patient dosages, using administrative controls, and so forth.

Then, you go to the 500 hours of --

MEMBER NELP: Now, that's specifically under 35.920?

MR. CAMPER: That's correct. And then you also have a 500-hour of so-called clinical experience, and that first category is what we call types and quantities experience. Then, you have your 500 hours of clinical experience, and there you have such things as examining patients and reviewing their case histories, selecting the suitable radiopharmaceuticals, administering doses, collaborating with the authorized user in the interpretation of results, patient followup. Okay?

And as Janet said, what we -- the logic that we

thought is a starting point in the discussion is is that, look, these things are occurring along a continuum. If one did the things that you have to do under the first category, types and quantities experience, 500 hours, certainly you're going to be doing those as part of the process of achieving many of the things described in the clinical phase.

So then what you're stuck with is, well, how do you properly weight those along the line? Because, in fact, if you stop and think about it, if you do 500 hours of clinical experience, and you really turn around and do 500 hours of experience with types and quantities, you're going to be doing experience with types and quantities in the absence of clinical involvement, because 500 hours of pure experience -- opening packages, calibrating dose calibrators, and so forth -- is a lot of hours.

So the thing we had to wrestle with is, okay, if we can't come out and weight this continuum, but we understand that 500 hours of clinical experience must occur, is the relationship between those 500 hours of clinical experience, is it similar, does it parallel the duration of three years? Although the timeframes are different, of course. But are we subsuming those 500 hours of types and quantities within the 500 hours of clinical experience? And it's a discussion starter.

CHAIRMAN SIEGEL: Let me open the discussion.

Why are we doing this now, ahead of the major discussion of training and experience?

MR. CAMPER: It's very simple.

MS. SCHLUETER: Yeah. It --

CHAIRMAN SIEGEL: It strikes me as a back-door approach to lower the training and experience requirements for imaging to four months when, in fact, six months isn't the right answer, four months isn't the right answer. Almost nobody really has 200 hours of classroom experience because it's virtually impossible to design 200 hours of meaningful classroom training.

Nobody in the world has ever spent 500 hours doing the work experience, not a physician alive has ever done it, and we have told you repetitively, politely, that you need to redo the whole approach to training and experience. And this patchwork fix is not a good idea, and I tell you, I really would be -- I think it's unconscionable for the NRC -- for the ACMUI to sign off on this in a short discussion when this is a major, fundamental issue. So the -- I've said what I feel.

MR. CAMPER: I mean, whether you choose to sign off on it or not, of course, is --

CHAIRMAN SIEGEL: It's irrelevant.

MR. CAMPER: -- is your opinion. But here is why we're doing this. Yes, you are correct that we -- that the

training and experience criteria is problematic. We've discussed this at great length, and we recognize that when Part 35 undergoes a major revision there's a high probability that the training and experience criteria will undergo change as well, and there's a lengthy process that we'll go through as we do that.

But there is an immediate problem that faces us today, and the truth of the matter is is that whatever training and experience criteria we end up with in a revised Part 35 is three, four, five years away. It will take that long to have the major revision occur. But we get, right now, probably on the order of 20 to 25 physicians a year who are going the "or" pathway, who are seeking approval as an authorized user, and they're coming in and saying, "I have obtained my training concurrently."

There are organizations that are on record that are saying that -- that have quoted my predecessor as saying concurrent translates into 700 hours, and there is confusion. We have regions who come to us -- and technical assistance requests, and say, "Okay. How many hours are enough? What does 'concurrent' mean?"

Now, we have one of two choices. We can bring these cases to the ACMUI one by one, or we can develop some working criteria that with -- we're still going to go through a case-by-case review of each applicant, because we had to do

that. But we can have some guidance that the regions can use that has been scrutinized and hopefully ultimately approved by this Committee, or we can bring 20 of these things a year to the -- or whatever number is in question, to the Committee one by one.

But we can't -- we cannot not react to the applicants at this point in time, because there is going to be some change in our training and experience criteria.

CHAIRMAN SIEGEL: All right. But then let me ask you the following question. Let's assume that you agree that that's the way you've got to do it, and that it really is 700 hours and you're stuck because of the language in the regulations. When the American Board of Radiology comes to you and says, "Well, gee, we've had a misunderstanding all along, and as of tomorrow we're going to notify our training program directors that they're really only required to provide four months of nuclear medicine training, to include the elements specified." How are you going to handle that?

Because, I mean, if -- why would radiology program directors commit to six months of training if the alternative pathway can be accomplished in 700 hours? And is that really what you want to be doing?

MR. CAMPER: Well, first of all, the 700 hours, again, is -- this is what -- we want find out what the perception is from this Committee. The logic has been

explained. There may be better ways to go, but we're trying to work through that.

But with regards to these organizations that you cited, I mean, the Board certification pathway, Boards have come to us previously and have said, "We are going to provide X amount of training. It entails the following." And along the course of time, we then -- we've done a staff review, and we've taken those submitted credentials and activities to this Committee, and they've said, "Yes. This Board certification passes muster and add it to your regulations."

If the Boards wants to change their process, they would still have to come in and go through the very same process once again, because currently their recognition in our regulations is based upon what they have previously told us. If they want to change their programs, and change what criteria a physician has to meet to be able to set the Board certifications, then they'll have to come in and tell us what they want to do differently and we will review each one of them case by case, just as we've done previously.

MEMBER NELP: When you wrote these regulations, it was your intention, and it was the intention of your advisors, that the language you put in there was equivalent to six months of training. There is no question about that.

MR. CAMPER: Well --

MEMBER NELP: That's the reason that the American

Board of Radiology then went to six months of training, because they didn't want to be undone by the cardiologists who are trying to get in the door of imaging. That's the political background. It's very straightforward.

A cardiologist -- I would imagine, of those 25 people a year, they want to do nuclear cardiology. Is that correct?

MR. CAMPER: Many of the applicants want to do nuclear cardiology, yes.

MEMBER NELP: Ninety-nine percent of them. And they want to do it in four months because they don't want to do it in six months. So it's a political football, and I think we ought to put the issues directly on the table. It's clear that the implication from groups that you met with before was six months of training seems to be a minimum amount, in an environment of training that's equivalent to an ACGME-approved program.

It makes a person be capable of doing what he wants to do and doing it safely -- for himself, for the public, and for his patients. And why don't we put that on the table and say it like it is?

MEMBER BERMAN: But I think, then, at the same time you have to put on the table the total lack of reality between the kind of hours that are being required here for something that is of minimal hazard, compared to the hours

that are required to avoid the catastrophes that we were hearing earlier dealing with radiation therapy misadministrations. We're dealing with diagnostic use of radiopharmaceuticals.

I agree with Barry. There is no way that you can get 200 hours of classroom time devoted to the physics necessary for handling these diagnostic applications of radiopharmaceuticals. Yet, that's not even being code tested here.

I'm head of a nuclear medicine residency program. I had to structure the 200-hour course, and it's -- for the nuclear medicine residents, who are dealing with the entire body, not just with one organ, and not just with a limited number of radiopharmaceuticals, but everything, and it's hard to come up with the 200 hours.

But let's put that one aside and say we've got the 200. Now, opening up packages and doing all of this kind of calibration is another 500. We've already heard that there probably isn't a physician -- a nuclear medicine physician or a radiologist, or any of the others, who are doing those 500 hours of that particular type of work.

I think we're dealing with something that is -- that is -- on the face of it is just excessive. And what has come out here is a position saying that if you put together the hours that you need to have in order to handle the stuff

appropriately, and the hours of clinical experience, and allow those to be done at the same time, you end up with something that is kind of a reasonable compromise.

It has to be -- at least it --

MEMBER NELP: But it's all coming through the back door.

MR. CAMPER: Well, no, wait. Let me clarify something. Let's get ourselves focused.

I recognize, we recognize, that there are clearly differences of opinion, as Dr. Berman is pointing out, about what is the appropriate number of hours? Previously, there have been expressions by this Committee that, look, it's not about hours at all. It's about testing and demonstrating some level of competency. But I submit to you that's not the question before you.

The question before you is -- in 35.19 says the following, "Specific Exemptions. The Commission may, upon application of any interested person, or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

The Commission will review requests for exemptions from training and experience requirements with the assistance of the Advisory Committee of the Medical Uses of

Isotopes." What we're focusing upon today is the granting of an exemption to our regulations, and in so doing what is the appropriate criteria, minimally, that we should accept in granting of an exemption?

It's not about whether the criteria is properly focused, whether testing is the way to go, whether who wants to do it, it's not about turfdom. It's about our granting an exemption.

MEMBER NELP: But, again, it's purely a political issue.

MR. CAMPER: Well, it might be. It may well be.

MEMBER NELP: And it has to deal with granting exemptions to cardiologists to retranslate the language, and you're trying to do it by retranslating the language you put into the reg. Now, if you want to grant them an exemption, grant them an exemption.

MR. CAMPER: We're not translating any regulatory language here. We are --

MEMBER NELP: Well, you just did. You --

MR. CAMPER: No, no. No, we're pursuing your advice on the granting of an exemption to existing regulatory language. We are not proposing any change to regulatory language. This is clearly about granting of an exemption.

MEMBER NELP: To whom?

MR. CAMPER: To --

MS. SCHLUETER: When a physician applicant comes to the NRC --

MEMBER NELP: No. When a nuclear cardiologist, or when a cardiologist wants to get imaging qualifications in a four-month period of time, when the intent -- when you originally intended it to be a six-month period of time, that's exactly what you're saying.

MR. CAMPER: Well, I wouldn't draw that -- well --

MEMBER NELP: That's exactly what you're saying.

MR. CAMPER: No. What I'm saying -- I'm not drawing a distinction to cardiologists. We are saying that there are physician applicants --

MEMBER NELP: This would not exist if it weren't for that issue.

MR. CAMPER: Well, the point is the issue does exist. We do get applications, and we are discussing what criteria under which you think is advisable to grant exemptions. They do exist. They do come in. We don't create that. They come to us.

MEMBER NELP: I realize that.

MR. CAMPER: Now, the question is, what is the appropriate criteria, in the opinion of the Committee, that we should use as a minimum number of hours in granting an exemption? That's the question.

CHAIRMAN SIEGEL: No exemptions.

MEMBER NELP: See, the idea is if you take a professional like Barry Siegel, and myself, who spent cumulative over 50 years doing medical imaging --

CHAIRMAN SIEGEL: So 40 for you and 10 for me?

(Laughter.)

MEMBER NELP: -- doing medical imaging, it's very difficult for us to conceive that you could have a level of confidence which would do things properly, taking all of the things into consideration there, with less than six months of training. And that's why they built the hours up to equal six months. Unfortunately, we categorized them in a very awkward set of terminology.

CHAIRMAN SIEGEL: There was a time when the language was going to be 1,000 hours of combined clinical training and supervised work experience, without breaking it down into pieces, and that was going to make more sense because that was going to be the continuum.

MEMBER NELP: You're trying to undo what was improperly or awkwardly done by saying you want to grant exemptions. And you're going through a course in logic, which to me is not highly -- directly logical to the issue. And, you know, you've got a whole population of radiologists, because of your language and because of your change -- change the training programs for thousands of individuals in this

country, based on their interpretation and your interpretation of that language at the time the regulations were put in force. Now you want to change that.

I imagine if you consulted with them that you would not get the -- you would probably get a response and would have to more thoughtfully consider this whole issue.

MR. CAMPER: Please understand --

MEMBER NELP: There are thousands and thousands -- hundreds of thousands of dollars, the way they plan their programs, around this one regulation.

MR. CAMPER: Well, please understand, we don't want to change these hours. That's not the thrust today. That's not the reason for raising this with you. As I said, ultimately, I suspect that our training and experience criteria will undergo change with the revisions to Part 35.

Our sole purpose is this question of what -- the granting of exemptions to existing regulations. It's not that we want to change the regulations, although I think we would agree with you that the current --

MEMBER NELP: It seems to me you want to grant exemptions.

MR. CAMPER: Our regulations allow the capacity for granting exemptions under certain criteria.

MEMBER NELP: So if you have this conversation with every director of a radiology training program in the

United States of America, you want him to come to you a priori and say, "Now, look, I'm planning this guy's career, and when I'm finished I want the exemption to apply to him. And I don't want to take any heat if you won't approve him for a clinical use of medical imaging after he does this."

And that's the problem that you have. You have these guys that are -- they're going to hear about this immediately, I'm sure.

MR. CAMPER: Well, I --

MEMBER NELP: Then you're going to have a hell of a lot of people knocking on your door, a lot more than you have now.

MR. CAMPER: Well, it certainly -- amongst the possible advice that you could give to us -- I mean, if one looks at 35.19 -- and I think I have someone here from -- no, I guess I don't.

MS. SCHLUETER: Marjorie is here.

MR. CAMPER: Oh, Marjorie is here? Oh, good. Marjorie? If someone -- if we look at 35.19, and I'll defer to counsel, but just not being a lawyer, if I look at 35.19, and we review requests for exemptions for training and experience requirements with this Committee -- and that's what we're doing here -- and the Committee advises that, "We don't think you should grant exemptions of this nature. We don't think you should grant them for reasons A, B, and C," then we

will take that advice under counsel.

CHAIRMAN SIEGEL: The Chair would entertain such a motion.

MEMBER WOODBURY: So moved.

MS. SCHLUETER: To this section?

CHAIRMAN SIEGEL: To what Larry just said.

MS. SCHLUETER: You need to be specific on what you would not grant an exemption to, 35.920(b) or T&E requirements in Subpart J in general? Because we have, on a case-by-case basis with this Committee, reviewed exemptions to other sections. Teletherapy comes to mind.

MEMBER FLYNN: And as a matter of fact, I was going to bring that up. In teletherapy, we had two applications that we looked at, and one was clearly acceptable, and was clearly not acceptable. It's too bad that we don't have at least 25 or 30 applicants to look at, because there is probably some variation as to how the --

MS. SCHLUETER: Now, that --

MEMBER FLYNN: -- how the work experience is being interpreted. Is that right? Well, there may be some variations as to what -- what constitutes supervised (quote) "work experience" and what -- there may be people who are really trying to stretch the definition here.

CHAIRMAN SIEGEL: Let me backtrack. I mean, let me back up a little bit to your question, Janet, and that is

that I am more comfortable for the moment recommending that you continue to come to the ACMUI to deal with individual cases for very specific situations. And I certainly am having the ACMUI recommend that you can do an across-the-board drop in the number of hours for granting exemptions, and then just let the staff go ahead and grant those exemptions.

I think there are strong principles that have been discussed for five years running and for 10 years before that that have to be dealt with in a very open, deliberative fashion before we just would come down and make this recommendation.

So the motion -- let's see how we can -- how we had that motion worded. David, you made it. Do you want to restate it? Let me state it for you, and then you can --

(Laughter.)

The Chair would entertain the following motion. That the ACMUI not recommend a reduction or -- or not recommend a minimum number of hours that be used for purposes of granting exemptions to the training and experience requirements in Subpart J. Period.

MEMBER WOODBURY: So moved.

CHAIRMAN SIEGEL: Is there a second? Is there a second?

MEMBER NELP: Second.

MR. CAMPER: That would apply to your --

MS. SCHLUETER: All of them.

MR. CAMPER: -- your 940 and 960 categories as well.

CHAIRMAN SIEGEL: And the reason I made or entertained the motion the way I did is I just think this is too important a topic to do in little bits and pieces, even though there might be some perfectly legitimate radiation oncology arguments to cut out seven percent, the seven percent and 42 percent on the table at once is just too much. And I'd rather just leave the language of the rule exactly where it is and not say that the ACMUI thinks you should mess with it right now. I think it's important that you go on and do the big discussion and not --

MS. SCHLUETER: That's true. But in the interim, we will have exemption requests coming to us.

CHAIRMAN SIEGEL: And we --

MS. SCHLUETER: And we'll have to bring those to you.

CHAIRMAN SIEGEL: That's fine.

MS. SCHLUETER: And at that time we'll have to identify the minimum number or the criteria that we would use to grant an exemption, if that applicant appeared to be qualified.

CHAIRMAN SIEGEL: Well, I think that the ACMUI policy in that case would be relatively straightforward.

We've been more often asked to identify whether the training that met the numbers was training of sufficient quality, rather than whether the hours were met. And I think our answer is simple if you bring those cases to us.

If they come in and say, "We have 300 hours of training, and we want to do what normally takes 1,200," we'll say no. On the other hand, if they say, "We've had 1,200 hours of training, but the training has been -- 20 percent of it has been in a practice environment," rather than within the setting of an institution that has many approved training programs, and we can get a sense of the quality, then we might recommend that you approve that individual.

I think that's got to be, for us, a relatively clear policy until the big issue is faced. And I'll go down with the ship on that one, I'm telling you.

MS. SCHLUETER: So no recognition of concurrent training, concurrent experience?

CHAIRMAN SIEGEL: Except as it is listed in the incorrect version, Option C.

MEMBER NELP: I think exemptions are like what was discussed just a minute ago. If someone has an unusually good background, and an unusually good training opportunity and experience that combines elements which you recognize of high quality, then you can grant an exemption. That's what the -- my understanding of what an exemption should be for,

but not based on simply hours or something like that.

MEMBER WOODBURY: If you follow that course, Larry, you know, you're going to have a flood of applications because why would anyone opt for six months if you can do it in four?

MR. CAMPER: Well, let me make a -- something to help clarify this, and then I think Marjorie would like to say something.

Rather than viewing what we're bringing what we're bringing to you as a relaxation or an attempt to relax regulations, I would suggest to you that it's an attempt to formalize the review process with this Committee's input. Let me explain what I mean.

We are on record as saying that this training may be obtained concurrently. Now, that's an interesting term if you stop and think about it. I bet you we get a lot of different opinions around the table as to what that might mean. And the reason that we're on the record as having said that is because from a practical standpoint, if one looks at the two categories of 500 hours, one quickly recognizes that you can do all of these things in a continuum along the way.

I mean, I can get the package to the front door. I can assay it. I can stick it in a dose calibrator. I can wipe the package. I can go give it to the patient, you know, and so forth and so on, from soup to nuts.

Now, arguably, that I'm doing that concurrently. Well, then, what does that translate into? Because when someone has to say, "Okay. You've obtained your training concurrently," our reviewers look at this and say, "Well, gosh, you know, concurrently is subjective. What does that translate into in terms of number of hours?" And there comes the rub.

Now, historically, we have used this term "concurrent." The problem is when one explores this, and one talks with my colleagues in OGC, this idea this is obtained concurrently doesn't necessarily work real well because, in fact, what you're doing is seeking a granting of an exemption to the regulation. So what we're doing is we're trying to formalize that process with you, not circumvent it.

CHAIRMAN SIEGEL: Right. But --

MEMBER NELP: This is an example of concurrently. I go to medical school and I go to law school, and at the same time I graduate on the same day, and I get my law degree here and I get my medical degree here, and I did it concurrently because I spent extra time and extra effort which condensed into five years instead of seven or eight years. That's what concurrent means.

CHAIRMAN SIEGEL: Right.

MEMBER NELP: And it doesn't mean you say, "Well, we'll count this two for one."

CHAIRMAN SIEGEL: The problem with the "concurrently" language is the fact that this thing got messed up in the way it got translated into Part 35 from the way it was discussed ad nauseam with the ACMUI at the time it was discussed 10 years ago. And that is that it was supposed to say a thousand hours of supervised clinical and work experience, and the assumption was is that the 200 hours of classroom training could go on at the same time that you were in this six-month thousand-hour clinical rotation and that was the concurrent.

It was splitting the 500 and 500, which first of all is silly for the reasons we've already pointed out, but splitting those two has created a problem. That's the fundamental problem. The ACMUI, in the past, and at least I think most of the ACMUI for the past four years, has not wanted to back off from the thousand hours of training. And that's six months.

MS. ROTHSCHILD: Marjorie Rothschild from the Office of General Counsel.

I have a general comment, but now that Barry has mentioned this 1,000 hours I have a question for Barry. Maybe you could answer.

You said when it was supposed to say a thousand hours. In what form? I mean, I was just looking through the proposed rule stage. I don't think it said a thousand. So

are you saying that was the ACMUI recommendation and it didn't somehow get into --

CHAIRMAN SIEGEL: It is my recollection, without having any of the records before me, that that was the recommendation of ACMUI.

MS. ROTHSCHILD: Okay.

CHAIRMAN SIEGEL: That would take us back roughly 10 or -- at least 12 years, more like 12.

MS. ROTHSCHILD: Okay. Because at the proposed rule, proposed 920(b), I'm not sure if my math is correct but it doesn't look like it enumerates, you know, or even mentions a thousand hours. So you're saying maybe it was at even before the proposed rule?

MEMBER NELP: When was that proposed?

MS. SCHLUETER: 1985.

MS. ROTHSCHILD: July 26, 1985.

MEMBER NELP: Counselor, may I ask your legal definition of "concurrent"?

MS. ROTHSCHILD: What? I prefer not to get into --

MEMBER NELP: It's a very serious question.

MS. ROTHSCHILD: Well, I think you can just give it the dictionary definition. But I think what we're --

MEMBER NELP: What would that be?

MR. CAMPER: It's a continuum.

CHAIRMAN SIEGEL: It means simultaneously. That's what "concurrent" means.

MEMBER NELP: That means at the same, right?

CHAIRMAN SIEGEL: Right.

MEMBER NELP: So it means you do two things, two different things at the same time.

CHAIRMAN SIEGEL: But concurrent isn't in the rule, anyway.

MR. CAMPER: No.

CHAIRMAN SIEGEL: Concurrent has been a policy statement and --

MS. SCHLUETER: Well, it hasn't been a policy -- it has been a -- right, not a formal one.

CHAIRMAN SIEGEL: Operating --

MS. SCHLUETER: Well, it's been in the Federal Register notice as early as 1982, that the required training elements could be performed concurrently. So it goes back quite a ways. And, unfortunately, as I mentioned before, these are -- these statements are in guidance documents, which were superseded by the '87 rule.

MEMBER BERMAN: Well, no one would disagree about the concurrently. I mean, we've already pointed out you're not going to take a block of time and spend it purely on 500 hours of opening up packages and testing radiation safety. So that concurrent is I think something that was probably

understood, even though it wasn't in the rules, was understood all along.

The question is whether or not the total number of hours of 1,000 has to be there cast in bronze. That's it. There are no exceptions. Or, since Larry has pointed out, Mr. Camper has pointed out that, in fact, there have been many exemptions that have been made, either through the NRC or because of what the NRC did through the agreement states, many over the last several years in which the total number of hours outside of the 200 hours for the course, this total number of hours has been 500 rather than 1,000.

Now, what we would be doing at the time of this would be going back, I think in a retro -- in kind of a reactionary fashion, going back to something and saying, "Well, wait a second. That was a misinterpretation." Now, you can impose again the 1,000 that hasn't been now imposed for a few years on a systematic basis.

And I think that, to me, that's a clear step back in -- at a time in which the public health and safety is not -- is really marginally effective, just to do it for the sake of politics.

MEMBER NELP: What are you going to do, though, Dan, with all of the program directors of radiology programs? How are you going to let them know that they've got literally many dollars and much time spent or committed to structuring

programs now that fit the spirit of this regulation at the time it was written?

MEMBER BERMAN: I think that Larry's answer was the appropriate one for that, which is that that mechanism of coming through the American Board of -- one of the Boards, either the American Board of Radiology or the American Board of Nuclear Medicine, would be the method by which that would be addressed.

So if having heard this, it's -- to me, it's a different issue, because they're talking about the desire to -- the reason I think it's a different issue is it's the desire to do all of nuclear medicine. That's what a radiologist does after his training, and it would seem to me that there would probably be a different set of considerations as to what is a necessary requirement to do all of nuclear medicine compared to doing it for diagnostic purposes on one particular organ.

However, they could come -- they would probably, possibly, would come back and say, "Well, now that you've allowed cardiologists to do it for one organ, we want to do it for the whole body with four months, perhaps, but to be more" --

MEMBER NELP: But the regulation doesn't say anything about any organ. It says "medical imaging" and that can be any organ you want to choose. It turns out that the

organ of interest is the heart.

MEMBER BERMAN: That's why it turns out that these applicants, these 20 to 30 per year that are going to turn into 100 per year at the present rate -- I think it -- 20 to 30 comes to the NRC. In the whole country, there are hundreds per year coming through this mechanism. And when they're coming for this variance, they're not doing it for the whole body. If they were doing it, asking that there be imaging of the whole body with this much training, they would probably get turned down.

CHAIRMAN SIEGEL: Okay. But we are now raising again the whole issue of limited licensure.

MS. SCHLUETER: Right.

CHAIRMAN SIEGEL: And we're getting, once again, into the discussion of whether what the NRC is licensing has to do with the clinical competence necessary to study a bunch of organs versus the clinical competence necessary to study one organ. And we don't want to do that. We don't want to have that discussion again in this forum, in this length of time, without doing what we said we wanted to do now nine times, and that is discuss a paradigm shift and a whole new approach to this.

Consequently, there's --

MEMBER BERMAN: If I could make just one more comment.

CHAIRMAN SIEGEL: Sure can.

MEMBER BERMAN: I believe that to take -- to step back, and to go back now after having it become widely disseminated, that the NRC's interpretation that has been that these -- that the 500 and 500 could be reduced so that the total could be 700. Having -- if we take the step back, I'm just saying that I think what you're doing is inviting, again, the messy political process --

CHAIRMAN SIEGEL: I disagree.

MEMBER BERMAN: -- that will occur with now the American Society of Nuclear Cardiology and all of the people who are the advocates of the single organ system going to their congressman and saying, "We're being blocked out, on the basis of politics, from doing what we -- what is appropriate for us to" --

CHAIRMAN SIEGEL: First of all, that will be terrific because that will be something that will force us to discuss this issue properly once and for all. So congressional pressure to get us to really do this out in the open is okay by me. That's number one.

Number two, I'm not sure I understand what you're saying. You're saying that agreement states are currently only requiring four months of training for licensure?

MEMBER QUILLEN: Can I comment on that?

CHAIRMAN SIEGEL: Please, Bob.

MEMBER QUILLEN: We did a survey of agreement states a couple of years ago on how many hours they were requiring, and I can say from that survey that it was a very inconsistent number. I mean, there was -- some agreement states were only requiring 500 hours, and it seems to me there was at least one that was requiring even less than that. It was like 200 or 250 hours.

CHAIRMAN SIEGEL: Good for them.

MEMBER QUILLEN: So there is not a consistency within agreement states.

MR. CAMPER: No, and it's not an item of compatibility in our regulations for the agreement states.

MEMBER NELP: Does the agreement state have -- does the agreement permit them to license with lesser -- with lesser qualifications than NRC would license directly?

MEMBER QUILLEN: It's an issue of compatibility regulation. There's no compatibility criteria, so it's the option of the state.

MR. CAMPER: The answer to that is yes. The states have different criteria.

MEMBER NELP: I can -- yeah.

MR. CAMPER: In some cases, it's less than ours.

MEMBER NELP: I can -- in certain areas, I can impose more stringent regulations but never less regulations. In the case of an agreement state, they can impose less

regulations than the NRC.

MR. CAMPER: It depends upon the level of compatibility assigned to the regulation. Most of Part 35 is not an item of compatibility. Only when you get into assignment of compatibility do you get into this question of whether the state must be verbatim to us, division 1 that's called.

Or they can have -- get into areas where they can be more restrictive than we are, but not less restrictive, and you get into division 2 and division 3 when you get into that realm, or you have no compatibility. And for us, very little in Part 35 is an item of compatibility.

MS. SCHLUETER: Subpart J is not an item of compatibility, but it is important to note that the conference of radiation control program directors, which represents agreement state program managers, also formulates in its SR-6 Committee suggested state regulations. And as recent as November of '94, they have revised their Subpart J compatible section of T&E to recognize other training pathways besides Board certification. And those are a reflection of the NRC's. They're almost identical.

Now, that's a set of suggested state regs. that each agreement state may or may not use. But they are not required to use those. Some do.

CHAIRMAN SIEGEL: Let me correct something I said

earlier. My recollection is slowly coming back here. It may be that there was nothing in official NRC language that ever combined the thousand hours. But as I recall, there certainly were strong recommendations from several professional societies that the numbers should be lumped into a single block of time.

And actually, the political history of this is fairly interesting, because if you recall, Dan, the cardiologists were at the time actually arguing for training as short as just a couple of months. The ABNM wanted two years but was willing to go as low as six months to accommodate the radiologists, who really wanted four months of training, and the radiology program directors of the United States swallowed six months quite reluctantly as a way of working out an apparent compromise that had seemed like the NRC could live with and the ABNM would sit tight with.

I really think that this topic is so important that for the ACMUI to do anything other than say, "We can't help you at the moment" would be a terrible mistake for the ACMUI, and if it forces the issue to bring up the paradigm shift discussion and get it on the table, all the better.

So I'm going to call the question unless anyone feels like we shouldn't do so.

MEMBER NELP: Call the question.

CHAIRMAN SIEGEL: Call the question. Fine. All

in favor of the motion as made, indicate by saying -- raising aye? All opposed? Dr. Berman is opposed. All abstaining? Are you still not official? He's still not a member yet, so we had -- who abstained?

MEMBER QUILLEN: I abstained.

CHAIRMAN SIEGEL: Okay. So one didn't vote because he can't, and one abstained, and the rest were in favor, save Dr. Berman who was opposed. Let the record so reflect.

Any more questions?

MS. SCHLUETER: Not from me.

(Laughter.)

Not today.

MR. CAMPER: I have two.

MS. SCHLUETER: Oh, wait a minute. Wait a minute. Larry, we do have that related topic.

MR. CAMPER: That's right. I'm going to bring that up in a moment.

MS. SCHLUETER: You're going to do that? Would you like my notes?

MR. CAMPER: No, go ahead. But just one question before she brings up the related topic, and that is, do you have any -- do you care to venture a working perspective on what "concurrent" might mean to us?

MEMBER NELP: I think it would be very, very

important to get a written definition of concurrent. I'd start with Webster. Did you have a --

MS. SCHLUETER: Can you grab your mike, please?

MEMBER NELP: I said it might be very important for you to have your definition of concurrent, and you might start with Webster, in case this discussion surfaces. I'm not sure that my definition is correct is what I'm saying. I'm not sure I can give you the correct definition.

CHAIRMAN SIEGEL: Where is the concurrent language? Where does it appear?

MR. CAMPER: Well, we have -- the language appears in communications which have been signed by management representatives of our organization, my predecessor amongst them.

MS. ROTHSCHILD: Larry, doesn't it -- excuse me. But --

MS. SCHLUETER: Historically or in --

CHAIRMAN SIEGEL: I mean, I'd like to see the way it's used in the sentences that we think are the operating sentences, to understand exactly what it means.

MS. ROTHSCHILD: It was in -- excuse me. I think it was in this -- there was a 1982 Federal Register notice. Now, remember, that was before even the proposed rule. Correct? And wasn't there some part -- now, that notice was not -- it was not part of a rulemaking, and it wasn't a

statement of policy.

MS. SCHLUETER: Well, the 1982 was because the 1982 -- December 2, 1982, Federal Register notice was the one that increased the duration requirement associated with 35.920(b) from three months to six months, effective June 1, 1984.

CHAIRMAN SIEGEL: It doesn't sound like to me if you're increasing it to six months that you could make it concurrently with these time limits, because these time limits are designed to be six months.

MS. ROTHSCHILD: But that -- now, that pre-dated, though, this -- I mean, this current version of Part 35.

CHAIRMAN SIEGEL: So let me ask you a question. In the statements of consideration of the 1985 rule --

MS. ROTHSCHILD: Right.

CHAIRMAN SIEGEL: -- was the "concurrent" used in the statements of consideration?

MS. ROTHSCHILD: No, it wasn't. But it does say, while we're on that subject, that the criteria identified in these sections were developed by the staff with the assistance of the ACMUI over the past several years.

CHAIRMAN SIEGEL: No argument that we assisted you.

MS. ROTHSCHILD: Okay.

(Laughter.)

CHAIRMAN SIEGEL: We didn't always follow our recommendations, and I would -- as I've said before, there was -- it was a different breed of ACMUI 10 years ago than the last four years.

MS. ROTHSCHILD: Well, I think from a legal point of view what we're dealing with is the language of the reg. says -- it says 500 hours and -- but the staff has a historical interpretation or policy or position that at least it could be obtained concurrently. That's -- I think legally speaking, that's what you're dealing with.

CHAIRMAN SIEGEL: And my answer is is I'm sorry you're dangling, but that provides you with an opportunity really face this issue head on, as a way of getting out rather than asking us to recommend that you reduce the minimum number of hours, that we say that there should be a reduced number of minimum hours.

MS. ROTHSCHILD: But from a legal point of view, I'm wondering if we're mixing apples and oranges. The issue is not should this part, you know, provision of Part 35 now be amended to reduce the number of hours. The issue is there's a provision in the regulations for granting exemptions.

MEMBER NELP: And we advise that you do not do it.

CHAIRMAN SIEGEL: We advise that you keep coming to us.

MS. ROTHSCHILD: Okay. Well, I don't think there's any difference of opinion on that, and I don't think anybody proposed, did they, Larry, that necessarily that even there were agreement on some generalized criteria, was there -- would that necessarily --

MR. CAMPER: It would -- yes, it would. It would mean that you wouldn't necessarily have to bring every case to the ACMUI if the ACMUI has, in fact, endorsed some minimum level of language or minimum number of hours they would find acceptable for granting of an exemption.

We would still have to review each applicant case by case, but the regional reviewers could be doing so following a policy and guidance directive.

CHAIRMAN SIEGEL: Right. Well, I think we answered your question. Did you have another --

MS. SCHLUETER: Yeah, I guess.

Do you want to do this, Larry?

MR. CAMPER: Yes.

MS. SCHLUETER: Okay. I thought it was going to be, you know, just --

MS. ROTHSCHILD: Janet, before I sat down, I just had -- there was one dangling issue from my point of view, which was a little earlier there's been reference to whether a requirement is imposed in a license condition versus whether it's in a regulation, and certain procedures that apply when

you have requirements that are imposed by regulation, and that's true.

But it -- a requirement that's in a license condition is not somehow defective or inferior to a requirement that appears in a rule. There are just certain procedures that, you know, people are obviously aware of that apply when you have rulemaking. And licensing and license conditions -- that's a different subject. I just didn't --

CHAIRMAN SIEGEL: In a perfect world, I agree with you. But in a world where the regulatees often feel powerless relative to the regulators, it is a lot easier when the community at large is discussing a rule than when individual licensees are negotiating license conditions with the Nuclear Regulatory Commission, or the FDA, or what have you. So the world is not perfect, so we like rulemaking better as a general rule.

MS. ROTHSCHILD: Although I think we have heard it many times, at least from agreement states is, please, for our sake don't put your requirements -- or don't force us to put our requirements in regulations. It's much easier, gives us more flexibility, if they can be done, you know, as part of licensing. So I guess I'm just saying that -- that, you know, we hear different things.

So I just wanted to be clear that a requirement imposed on -- as part of a license condition is not somehow

legally inferior to, or suspect, because licensing happens to be different from rulemaking. I just wanted to correct any implication.

CHAIRMAN SIEGEL: But you can change license conditions tomorrow if you choose to, because you perceive a need to make a quick change, and the community disagree with you. Whereas, you can't do that with rules.

MS. ROTHSCHILD: Well, you can have immediately effective final rules, but it's very, very rare.

CHAIRMAN SIEGEL: They are quite rare.

MS. ROTHSCHILD: Right. And, of course, there are, you know, due process requirements when you're talking about orders and certainly enforcement action.

CHAIRMAN SIEGEL: No argument. Okay.

MEMBER BERMAN: I don't think you answered Mr. Camper's question. I think he has said, "Will you define 'concurrently'"? And we're not going to define it.

But if someone comes to him as an applicant saying, "I don't have a thousand hours, I don't have 500 plus 500. Instead, I've got something short of that," is -- and they don't have the -- I -- instead of having my full 1,200, I'm coming up with something more on the line of 700, is this Committee saying no exceptions? Anything less than a thousand for those two categories should come before the Committee? Is that what we're saying?

CHAIRMAN SIEGEL: That's what the motion says. The motion said not to recommend exemptions from the language in Part 35.

Janet?

MS. SCHLUETER: Okay. On a related issue, as I mentioned earlier, all Subpart J sections have required classroom training. And to date, virtually -- the NRC has virtually received no requests for physician applicants coming to us that have documented training where they have received some portion or all of the required classroom training in an off-site, non-traditional training mode -- for example, the use of videotapes, corresponding workbooks, CD-ROM, other telecommunication methods.

We recognize that the use of these types of off-site training modes are common in the college graduate, post-graduate level education. So we assume that eventually the NRC will receive requests from applicants that have received some portion or all of the required classroom training through these non-traditional modes.

So our questions to you today are based upon our review of these types of applications and, in other words, we need to have a feel from you whether or not there are specific issues that need to be addressed, such as is there some portion or some fraction of contact time that is necessary between the student and the preceptor, or the lecturer, or the

tutor, or whatever?

Is the use of one modality independent of all others sufficient, or should one modality be used in concert with another modality, such as a videotape and a workbook combined? Are there things in particular that we need to look at if we receive a request for physicians, or even other individuals? I mean, we have T&E criteria for radiation safety officers, and physicists, and so forth, that we should be particularly sensitive to when reviewing an application of this nature.

And also, what would come to concern would be the methods used by the training program for proficiency testing.

MEMBER NELP: Do you have a specific example, or is this just looking ahead in anticipation?

MS. SCHLUETER: Just looking ahead.

MEMBER NELP: I would suggest rather than getting into a detailed discussion of this issue that when this issue arises I would be happy -- and I'm sure others might be happy to help you evaluate that degree of -- or that kind of material. Supervision is a very important component, and I imagine there are some very innovative approaches out there, some of which might be very worthwhile and some might be very skimpy.

CHAIRMAN SIEGEL: I think the general sense of where we've been in the past is that we encouraged that --

have encouraged that the basic science training in all areas not simply be a recording of a number of hours but actually ultimately involve some certification by the person who did the training that the individual has mastered the material. That was part of the direction we were heading in the paradigm shift we were advising you about, and so to back track and say that we want to recommend videotapes at this point --

MS. SCHLUETER: Yeah. But that --

CHAIRMAN SIEGEL: -- that strike me as --

MS. SCHLUETER: -- the preceptorship would be with respect to the supervised work or clinical experience.

CHAIRMAN SIEGEL: No, no.

MS. SCHLUETER: Not classroom necessarily.

CHAIRMAN SIEGEL: We previously said that we think that there needed to preceptorship in relationship to the didactic basic science material as well.

MR. CAMPER: Well, the problem, though, that -- again, is is that if one looks at the existing regulations today, it says 200 hours of classroom and laboratory training. Now, we can go back and find staff positions. We reviewed one the other day from 1987 I think it was. Someone had inquired about this, and we responded by saying that classroom hours mean the typical contact time between an instructor and a student that one normally finds, you know, consistent with the university approach.

Well, it's now 1995, and a whole lot of very good universities are using videotapes and maybe CD-ROMs. And the question that I have, then, is -- and our concern is driven by radiation safety considerations, not clinical competency. I guess my question really is is it, in the opinion of the Committee, that it's acceptable for physicians to obtain training in radiation protection, mathematics, radiopharmaceutical chemistry, and radiation biology, via videos and/or CD-ROM approach?

MEMBER NELP: That's certainly no different than reading a book. It might be much more effective, but that's not the educational process. The educational process involves a process of reiteration and testing of the material, and, you know, that's only part of it.

MS. SCHLUETER: Well, in other words, it wouldn't be enough for an applicant to just come in and document to us that they had completed X number of hours with five videotapes. I mean, we would have to take a look at exactly what did the videotapes contain? What was the interaction between the student and tutor or lecturer or preceptor or --

MEMBER NELP: That's what I'm saying. I can be a qualified carpenter if I buy five videotapes on woodworking and listen to them in my van. That's a start, but that doesn't make me qualified to do anything in a woodshop. I can -- there are programs out there. I called for a CME program

for physicians to have common training and interests.

There are CME programs where you can go to a hotel at a resort area and listen to a tape, and the tape goes on every week in continuum, and you can come in any day of the week and leave any day of the week and get credit for sitting in that room for what part of the time you sat in that room. That's totally ineffective.

MS. SCHLUETER: Well, we would want to see some measurement of proficiency of the student. I mean, we wouldn't just exercise some sort of carte blanche approval of non-traditional classroom training.

MEMBER NELP: May I make a suggestion that when this issue does come up in a format where you have a concrete example, then I think it would be worthwhile to talk about it. But you're talking about a theoretical consideration.

CHAIRMAN SIEGEL: Dennis?

MEMBER SWANSON: Just a comment. I think -- didn't we -- we sort of addressed that when we did the training and experience requirements for the radiopharmacists in that we said 700 hours of -- in a structured educational program. And I would strongly suggest that that's -- that's probably the way that we need to look at this also.

CHAIRMAN SIEGEL: I mean, videotapes can be very helpful --

MS. SCHLUETER: Right.

CHAIRMAN SIEGEL: -- as part of a structured educational program. But they certainly shouldn't be the whole shooting match.

MEMBER FLYNN: Larry, you're talking about undergraduate colleges now. You're not talking about post-graduate medical education, are you?

MS. SCHLUETER: We're talking about training programs that are designed to meet the required number of classroom hours identified --

MEMBER FLYNN: Well, you gave examples of videotapes and CD-ROM and --

MR. CAMPER: Well, I am aware of --

MEMBER FLYNN: -- correspondence courses. You can get credit for correspondence courses for undergraduate degrees. That's true.

MR. CAMPER: I'm aware --

MS. SCHLUETER: I'm sure --

MR. CAMPER: I'm aware of a graduate degree program that one can take to obtain a master's degree from a prestigious institution in a scientific technical discipline. It may well be health physics for that matter. But their program is primarily -- I don't know if it's totally, but it's certainly primarily through videotapes, proctored testing, and interaction with instructors, long distance interaction with instructions.

MEMBER STITT: That's right. I'm getting all of these hours cranked up as --

(Laughter.)

CHAIRMAN SIEGEL: All right. Have we sort of answered your question?

MS. SCHLUETER: Yes.

CHAIRMAN SIEGEL: We'd rather wait for a real example. I'm sort of reminded of a Mel Brooks routine in the 2,000-year old man that -- a bunch of psychiatrists are being put to -- talked to at a -- by a talk show host, and one guy said he was a psychiatrist from Texas. And he said, "Do you mean the University of Texas?" He said, "No, the State of Texas. One day I was walking out in the prairie, I put my foot up on a rock, looked up at the sky, and said, 'I am a psychiatrist,' and I've been one ever since."

And so I get the feeling that we can take this self-training stuff a little too far.

(Laughter.)

I had a dream that I had 200 hours of classroom experience, and, therefore, it must have happened.

MEMBER WAGNER: How did you know that's the way we do it in Texas?

(Laughter.)

CHAIRMAN SIEGEL: Because I know.

We need a break, but I'm told that the Solicitor

is here from the Office of General Counsel to discuss the petition to review the -- do you want to break? Let's take a five-minute break because we've been sitting a long time.

(Whereupon, the proceedings were off the record for a break from 3:54 p.m. until 4:02 p.m.)

CHAIRMAN SIEGEL: Okay. Take your seats. Time is money. We've lost the committee. Larry, are you coming? We're missing Bob, but that's okay. We're missing David. Oh, he's there.

Mr. Cordes, we're back on the record.

MR. CORDES: Good afternoon. I'm John Cordes. I am with the Office of the General Counsel at the Nuclear Regulatory Commission. My title is Solicitor, which means I am in charge of court cases, defending the NRC in court cases.

I have been asked to make a couple of remarks about one of our court cases that was filed several months ago by the two physician groups, Chou and Jing, (phonetic) the Radiopharmaceutical Rule.

I am really not going to take very much time. I have very little to say about this court case because it's in a very immature stage. All that has been filed in the case is a petition for review in the Court of Appeals, which is a one page document that says the rule is arbitrary and unlawful. That's all it says.

We did meet in the General Counsel's office with

one of the or maybe the only attorney in the case, a man by the name of Sheldon Truebatch, who is also the attorney who represented these groups several years in another lawsuit against the NRC involving equality management rule.

Mr. Truebatch did not have a lot of say about what the issues are in the case. I think he is still developing them himself. He has filed what is called a docketing statement in the Court of Appeals, which lists the issues in the case. They are phrased in a great level of generality.

It is my understanding that the principle grievance with the rule is a compatibility determinations in the rule, what aspects of the rule should be made applicable to agreement states. The petitioners seem to think that the NRC applied too much to agreement states.

There is also a reference to an alleged failure by the agency to follow the advice of this group, ACMUI. Again, I don't have the details on those issues because they haven't been fleshed out.

Let me just briefly explain the procedure. This is a Court of Appeals case. There is no trial, no evidence, no testimony. It's nothing like the O.J. Simpson case. It's much more kind of academic or boring than that.

Each party eventually will file briefs, probably 40 to 50 pages. The 40 to 50 page briefs explaining their

positions. The Court of Appeals, a three judge court here in the District of Columbia will then hear an oral argument in the case, where each side will orally debate the issues. Then several months after that, the Court will decide the case.

The D.C. Circuit, where the case is pending, has a huge backlog of cases. They are way behind. This case likely will not be heard until the winter, at least. And probably won't be decided until at least a year or so from now. So there's really nothing imminent.

Mr. Truebatch has indicated to us that he intends to send us a letter, I may have mentioned this, specifying his issues in the hopes that perhaps the NRC staff could clarify some of the doctor's concerns and maybe the lawsuit would not be pursued. I don't know whether that is true.

I really have, I know you are way behind. Donna-Beth Howe, I think is waiting to speak. I'll be happy to answer any questions anyone has, but I really think my appearance here is sort of premature in that I have nothing really substantive to say about issues that may be of interest.

MEMBER NELP: We need more staff like you.

CHAIRMAN SIEGEL: Thank you. I appreciate your coming. Are there any questions?

MR. CORDES: Thank you. Nice to meet you all.

CHAIRMAN SIEGEL: Sorry we kept you waiting so

long.

Okay. Since there are a number of people who are here to hear the discussion of the guidance documents for the Radiopharmacy Rule, we are going to do that next.

So Donna-Beth. Just to keep you on track on the agenda, we will try our best to do Bob Ayres item on the Strontium 90 applicators yet today before we quit. But we'll probably put the dose range stuff on for tomorrow.

MR. CAMPER: As Donna-Beth is setting up, let me make an administrative announcement so we can use time.

Commissioner La Planque has indicated that she will be by to see the Committee tomorrow sometime between 11:00 and 12:00. She is tied up in a briefing from 10:00 to 11:30, but she will stop by to just speak for a few minutes and say goodbye. As you know, her term is coming to an end soon.

MS. HOWE: Okay. Today I am going to be talking to you about the Radiopharmacy Rule. I have titled it pre-draft regulatory guides. There's a reason for that.

Because a regulatory guide is not a draft regulatory guide until it's published in the Federal Register for public comment. So this is really a document that is before that stage.

We are hoping that at the end of this ACMUI meeting, we will have a clear description of your comments so

that we can work on those and consider them in developing the final draft regulatory guide for publication.

I wanted to give you a little bit of a background about the function of a regulatory guide, because it has come up before. One is, its primary mission is to address item by item how to provide information requested on NRC Form 313. That is, how to file for an NRC license.

It has a certain structure. In our draft reg. guides, we have for the most part adopted this structure where we identify the applicable regulations for each item to show licensees the basis for the information that we are asking.

We try to give them licensing criteria, so they will see what we're judging their answer against. We also try to provide them with some guidance in acceptable responses, so that if we saw a response that looked like this, they would know that that was acceptable to us and their application would go through fairly quickly and without too many questions.

The last thing we do is we have appendices. Now appendices are where we give model procedures and programs that we could consider to be the minimal acceptable programs or procedures for their license application. So appendices are a little bit different from the body.

Now today we're going to be talking about three pre-draft regulatory guides. The first one is the "Guide for

the preparation of applications for commercial nuclear pharmacies."

The second one is the "Guide for application for licenses to authorize distribution to various items to commercial nuclear pharmacies and to medical use licensees."

The third one is not really a reg. guide, but it's a proposed supplement to regulatory guide 10.8 Revision 2. This is the "Guide for preparation of applications for medical use."

Now just quickly to give you a little bit of why each one of these reg. guides looks a little different from the one preceding it. For the commercial nuclear pharmacy guide, we are actually going to on the license authorize the possession and use of byproduct material. So you will see a good number of questions and guidance in these reg. guides that tells the information we need to see on setting up radiation safety programs.

They will all authorize the distribution of radioactive drugs to medical use licensees. That is a primary function for commercial radiopharmacy.

There may be some additional items on the license. They may be authorized to distribute sealed sources to medical use licensees. They may be authorized to redistribute radioactive drugs or sealed sources.

For the guide for the preparation and application

for licensed authorized distribution, this is primarily the manufacturers. These are the Squibbs, the New England Nuclear, the Duponts of the world. These are the manufacturers that are registered with the Food and Drug Administration, or possibly with the state food and drug group.

This particular license that they are issued does not authorize them to possess by-product material. They have to have another license that will authorize possession of byproduct material.

So when you look at these reg. guides, you'll see a lot of issues that say not applicable. Well, why don't they have a radiation safety program? It's not applicable. The radiation safety program is covered under a different license.

Many of these manufacturers are large entities that have research and development licenses and broad scope licenses. That's where they possess the material. So for this particular reg. guide, you're going to see issues that are more focused on labeling and the product.

For the commercial pharmacy, you'll see a lot of emphasis also on their possession and how they are doing things and how they are maintaining a safe radiation safety program within their facility.

Okay. On the next line. We have regulatory guide 10.8. As you are aware, the medical use licensees can

be authorized for any number of things. I put the maybe authorized on the license, because we have different levels of experience and facilities.

We may have people that are just doing the very first one is equivalent to 35.100. The second one is 35.200, 35.300, 400, 500, 600. So we may have just a teletherapy license. We may have just an imaging and diagnostic, which would be say the cardiologist. So those are all the possibilities that you would have for those licenses.

Now the next point is that you have seen the three documents that were in your briefing book before, because in November, you saw an original version of the draft regulatory guides for the commercial pharmacies, the manufacturers, and the medical use licensees.

The document that you have in your briefing book is different from what you saw in November, because it includes information that we added to it, as a result of commission-directed changes when they approved the final radiopharmacy rule. It includes considerations of comments that you made during your November ACMUI meeting.

It also includes the January 4, 1995 final rule clarification. That came out of the ACMUI comments when it became clear to us that everybody on the ACMUI had a different interpretation of part of the labeling requirements in Part 32.

If everybody misunderstood it, then maybe it was time to clarify the rule. So that was a labeling consideration.

Okay. It also includes things that the NRC self-identified for corrections and clarifications as we went through the draft reg. guide to see areas that we thought needed cleaning up, maybe a different focus.

We have regional comments, because we sent the draft reg. guide with included language for the standard review plan out in November. We got comments from the regions on the standard review plan. We've incorporated many of those into this version.

We had two letters, one from Dr. Mark Rotman, and another from the American College of Nuclear Physicians and Society of Nuclear Medicine in March, that was essentially in disagreement with our 10.8. In many cases, they jumped to an erroneous conclusion. Once they jumped to it, they had other things that they didn't like.

So we took that letter and we said, well maybe we've really got to go back and clarify where we were coming from, and try to take out some of the language that was open for misinterpretation.

Then finally, we took all of the above areas and we came up with a new draft. Then we submitted that to Dennis Swanson and to Marlin Pollycove, to get their comment to see

if we had essentially made some clarifications that were now understood by everybody. They gave us some very good comments.

We have tried to consider most of their comments. We still have a few issues in the draft reg. guide that we're going to take longer for us to come up with the right words and the right phrase. In some cases, we might have to go back to OGC before we can go out with the final draft reg. guide.

So this is kind of synopsis of why the document you are looking at today is different from the document that you looked at in November. There is a lot more information into it. It's a more polished document, but it's not the final document yet.

I think what I would like to do next, is I'd like to briefly go through how we changed, some of the major changes we made to each one of these documents to get it on the record. When I finish that, then I'm going to open for discussion to get any comments that I might have from the ACMUI.

CHAIRMAN SIEGEL: We should do that a document at a time, I think.

MS. HOWE: Do you want to do the chnages and then discuss the document, or do you want me --

CHAIRMAN SIEGEL: We've got to do one document. You tell us the changes, and we'll tell you if there's still

something that's troubling us. Then let's go on to the next document. Otherwise, we're going to lose our focus, I'm afraid.

MS. HOWE: That's fine. Okay for this particular guide, these changes, what I have done is I have thrown up a summary slide. It has the headings. But you will see in your package that I have things that look like slides right behind it, that go into more detail behind the headings.

Okay. For administrative changes, the difference between the document you saw and -- Sal, you'll leave that one up.

Another change was in the administrative changes. We had the technical editor up in the Office of Research go through the documents. So we had a number of administrative changes, which included adding figures for the regional offices in the agreement states, adding boiler plate and format changes that are specific to draft regulatory guides.

We added new regulatory citations. There were some cases where we had not, we'd referred to parts of the regulation within the body, but we didn't have it up in the citations section.

We renumbered certain items so that they were matching with the Form NRC 313. We guided applicants to use figures 1A and 2A in Appendix A. Most of those were just minor clean-up operations.

In the next area, we removed text that might be interpreted as requiring formulation or reformulation procedures. It was never our intent to ask for specific formulation or reformulation procedures, so we went through the radiopharmacy guide very carefully. Where we thought it might be misinterpreted, we took that language out.

We distinguished between photon high energy beta emitters, alpha low energy photon, low energy beta emitters in measurement, monitoring and personal dissymetry (phonetic) programs.

We revised the characterization, the kind of amendments expected. It was interpreted that we were asking for amendments for particular procedures on how to prepare radiopharmaceutical. We had not intended that to be interpreted that way, so we took the language out to make it clearer.

We had some areas that were focused primarily on radiation safety. They were clarifying that the institution is responsible for radiation safety programs for commercial pharmacies located in medical facilities. We've referred applicants to the ALARA effluents reg. guides.

We suggested that longer TLD exchange intervals would be justified, if applicants came in and requested it. We removed distinction between capsules and liquids for large quantities of radioiodine. We added radioactive halflife to

routine decay in storage authorizations.

We were asked by the ACMUI last time to make certain parts of the radiopharmacy reg. guide conform with regulatory guide 10.8, so we added calibration of two points on each scale and decade for survey instruments. We revised constancy, accuracy, linearity and geometry dependence to match Reg. Guide 10.8.

There were some errors in Reg. Guide 10.8 on linearity. We corrected those errors.

We reminded the pharmacy of the Part 35 requirements on molybdenum breakthrough in being given to patients, being administered to patients.

We revised Appendix E to match Reg. Guide 10.8. We revised the product labeling section. That was in response to the changes from the Commission and also the January rule clarification.

For things I have put into a category called Others, we clarified that an authorized nuclearpharmacist can prepare or supervise the preparation of, earlier it just said they had to prepare.

We clarified the notification requirements. We distinguished between requirements and information needed in characterizing the type of distribution operations. We revised the redistribution of the generator section. We clarified that the ANP and the RSO need to approve but not

order all radioactive materials.

We let pharmacists know they could ask for exemptions, to measuring unit dosages of alpha or beta emitters, if the unit dosages were passed through from the manufacturer to the customer, with no manipulation or adjustment.

That's pretty much a laundry list of what we did in Reg Guide 6 for the commercial pharmacy. Do we have other --

CHAIRMAN SIEGEL: Dennis?

MEMBER SWANSON: I don't know how specific, I still have some minor wording changes. But I think what I would rather do is address two issues in that guide that I think are broader issues that I think we need some clarification on.

The first issue deals with the measurement accuracy of instruments to measure --

MS. HOWE: Dennis, can you give us a page?

MEMBER SWANSON: If you go to page 28 of the Reg. Guide, basically. It's for commercial nuclear pharmacies.

At the bottom of the page, it discusses what the central nuclear pharmacy needs to have in the way of instrumentation to measure alpha and beta emitting radionuclides. That is where I have a problem, I guess.

Right now, it says if you were redistributing

unit dosages of beta or alpha emitting radionuclides directly from the manufacturer to the customer, that instrumentation only needs to meet accuracy tolerances that enable you to prevent misadministration and detect gross errors by the manufacturer.

I think what we get down here is in the issue of semantics, in that when we in the centralized nuclear pharmacy, when we get prepared radio pharmaceuticals from a manufacturer, and let's talk about current beta emitter Strontium 89 P-32 sodium phosphate, P-32 chromic phosphate. Those are in vials, basically. Those are not unit dosages, per se.

MS. HOWE: Well, they could be in a vial that's unit dose.

MEMBER SWANSON: They could be in a vial that's unit dose, but I think this is where the semantics come into play.

I think we in pharmacy look at unit dosages as you take that vial and you draw up a dose for a patient. That's what we consider to be a unit dosage.

Getting to the issue at hand, if we look at, I've got to jump over to the end-user here, the medical use licensee. The NRC permits the medical use licensee to base their dosages upon the label, if they obtain a vial of the prepared agent from a manufacturer.

MS. HOWE: Yes. Or they obtained it from a pharmacy, and the pharmacy did the measurement.

MEMBER SWANSON: Right. Now can the centralized nuclear pharmacy, if they are simply drawing up a dose from a prepared radio pharmaceutical received from a manufacturer, also base measurements upon the manufacturers label.

In other words, as it currently states here if you go on, however, if you make adjustments to the manufacturers product, which I assume would mean drawing up a unit dose, the measurement accuracy of the instruments must meet tighter tolerances of 10 percent.

So what you are really creating here is a much tighter standard for the central nuclear pharmacy, than what you are for the end users. Did you really intend to do that?

MS. HOWE: Okay. There are two parts to this. One is, that we recognize that the end users may not have the ability to measure alphas and betas well at all. So if they got a unit dose that just went directly into the patient, we weren't going to require them to make the measurement if they could depend upon the label.

Now, if the pharmacy gets it and they draw it up, then I think we're assuming that they are now responsible for the measurement.

We've said instruments, and I talked to you about this earlier. Perhaps we have to change that wording, because

it would be more the method of determining the dosage.

If you used volumetric considerations with the activity the manufacturer gave you, and that was your procedure, that would be fine.

MEMBER SWANSON: Okay.

MS. HOWE: There would be no problem with that.

MEMBER SWANSON: That's the point I want I think clarified at this point.

I'd actually suggest if you go back to the mode therapy regulations that appears later on, there's a statement there that says, for unit dosages may rely on the provider's dose label for the radioactivity of the dosage and other dosage information. If the pre-calibrated dosage must be adjusted prior to patient administration, a volumetric calculation and measurement is acceptable.

I think that is great wording, and it needs to be applied to both the medical use licensee and also to the commercial nuclear pharmacy at this point also.

Again, I have no argument if commercial nuclear pharmacy or medical use licensee is preparing on site their own beta or alpha emitter, obviously they need very accurate instrumentation. But if you're simply drawing up doses of an agent received from a manufacturer, I don't think you want to set that tight of limits on either one of them.

MS. HOWE: Okay. We will accept a combination

between measurement and calculation. So that would be fine. We'll adjust the wording there.

We have seen commercial nuclear pharmacies that will, what they'll do is they won't have enough strontium left because of decay. They will pool things together.

Then they have tried to make measurements in dose calibrators. We would prefer they go back and use a volume activity calculation, because we think there's a lot more --

CHAIRMAN SIEGEL: It's more reliable.

MS. HOWE: It's more reliable. So that's what we are trying to do.

CHAIRMAN SIEGEL: While we're on page 28, before we go on.

MS. HOWE: Yes.

CHAIRMAN SIEGEL: The item about linearity.

MS. HOWE: Yes.

CHAIRMAN SIEGEL: Would it be 30 microcuries to be consistent with --

MS. HOWE: We discussed this among ourselves. The question was, and this is a good issue to bring up to the ACMUI. The commercial nuclear pharmacy is sending out activities at levels lower than 30 microcuries. There may be a fundamental concept if you are receiving something, a pill that's supposed to be 15 microcuries, do you give the radiopharmacy the same tolerance limits at 15 microcuries up

to 30 microcuries, or should it be 15?

If they are sending you a pill that's supposed to be 10 microcuries, should it be 10, close to 10 or could it vary all the way up to 30.

I think there might be a difference between your expectations of something coming from a pharmacy, and your expectations for misadministration in the medical. But I don't know. So that would be a good issue, a good item for you to discussion.

MEMBER NELP: Is that at 28?

MS. HOWE: It's page 28.

CHAIRMAN SIEGEL: Dennis, what do you think?

MEMBER SWANSON: What was the reasoning behind changing it to 30 microcuries for the medical use licensee?

CHAIRMAN SIEGEL: Keyed it to the quality management rule in the I-131 misadministration, plus coupling it with some realization that going down to 10 microcuries was technically not realistic, because those calibrators get noisy below 30 microcuries.

MEMBER SWANSON: Then it's unreasonable to require an accurate assay on the part of the centralized nuclear pharmacy for the same reasoning. If you can't measure that accurately anyway, then why are you imposing that rule on it?

CHAIRMAN SIEGEL: We certainly wouldn't want

otherwise working dose calibrators taken out of use because they couldn't deal with the range between 10 and 30 microcuries. That would be a mistake. It would be burdensome expensive regulation.

That would be nice to know. In fact, we do our linearity tests to less than 30 microcuries, just because we want to know. But I'd hate to have to take it out of use for that last 20 microcuries.

Dennis?

MEMBER SWANSON: Correct.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: Yes, of course.

CHAIRMAN SIEGEL: Anybody else have a comment or concern? Dan, it's cool? So we recommend that you maybe make that 30 mics. again.

MS. HOWE: Okay. It may be the radiopharmacists when they are sending out these low activity ones. I know they have pre-stamped labels that say plus or minus so much percent. That may not be appropriate when they get down to the microcurie levels. I don't know. Okay.

MEMBER SWANSON: Again, another general issue. Page 35, where we talk about precautionary measures for handling millicurie quantities of radioiodine.

I thought we had discussed in the draft that the real concern with radioiodine dealt primarily when you were

dealing with liquid solutions, transfer of liquid solutions, dosing liquid solutions. In fact, when you're dealing with capsules, part of the advantages of working with iodine capsules is it alleviates most of the concerns regarding volatility.

All I am really saying here is that that somehow did not get reflected back in the rewrite here, in that the first paragraph under 10-10 should probably read, "Only applicants with operations -- performing radioiodizations, preparing radioiodine capsules from liquid solutions, and opening and dispensing from vials containing millicurie quantities of liquid radioiodine." You need to respond to item 10-10.

MS. HOWE: Yes. I think one of the reasons, and you may want to discuss this. We took out the reference to liquid because we received a number of questions about whether medical use licensees don't have to have bio assay programs if they are just dispensing capsules.

We don't have a specific exemption from the bioassay program, because they are using capsules. So this was an attempt to make that in parallel.

There still can be volatility questions that might be associated with bioassay.

MEMBER SWANSON: Again, I think this goes back to the model rules later on, on therapy. We need to make the

equivalent change in those model rules or model guidance, to only reflect bioassay requirements for medical use licensees for liquid radio-iodine.

MS. HOWE: I'm not sure the NRC is prepared to make that move at this point. I think, Larry, am I right, we have some TARs in on that issue.

MR. CAMPER: That's right. We have some TARs that we're evaluating right now. We've not done a closure on it.

MEMBER SWANSON: What's a TAR?

MS. HOWE: It's a technical assistance to the region.

MEMBER SWANSON: Okay.

MS. HOWE: That's a question that comes in from the licensee. The region gives it to headquarters because it's going to take a little longer to develop a policy.

MR. CAMPER: That's correct. We're not at closure yet on it.

MEMBER SWANSON: Okay. I think as long as our move is eventually towards recognizing that capsules are not a problem. However we get to that point, okay. I understand the compatibility issue though that you just mentioned.

I have a lot of specific wording issues. I don't know if we really want to address those types of things right now.

CHAIRMAN SIEGEL: Well, what's the mechanism for doing it if we don't do them right now? That's the only concern I have.

MS. HOWE: Sam, you think we could work with the Office of Research and NMSS to talk one on one with Dennis and find out his concerns and work on the wording?

MEMBER SWANSON: There's not, I shouldn't say a lot of them, there are just a few.

MS. HOWE: Sam seems to be shaking his head yes.

MEMBER SWANSON: Great.

MR. CAMPER: Dennis, a question on the bioassays on the capsules.

As I mentioned, we do have a technical assistance request that we're looking at, and we want to get to closure on this. But in your opinion, do you see a problem in terms of if a capsule is crushed or distorted in some fashion during the production process, bioassay?

MEMBER SWANSON: I could see if you wanted to have a bioassay, if that event occurred, yes. But I don't think you need bioassays routinely for people that are working with capsules.

If you look at radioiodine volatility in general, even with the liquids, it's not near the problem it used to be, because they finally got around to doing the appropriate Ph adjustment.

Certainly, as I said, the advantage of going with capsules is to get away even further from that problem. I think we need to recognize that within the NRC regulations, and not require bioassays routinely for people that are working with capsules.

But certainly, you could put a phrase in there that if the capsules were damaged or something, that it would be probably a good idea.

MS. HOWE: I guess I had one question to bring up to the ACMUI.

Dennis, in our last ACMUI meeting, you recommended that we have conformance with Reg. Guide 10.8 for the linearity geometry and dose calibrator.

It ends up, the radiopharmacy community has been dealing with a reg. guide for the last 10 years that the concepts are covered, but it's not exactly covered in exactly the same way.

MEMBER SWANSON: I actually noted that, which is one of the things I was going to discuss with you. It appears that the reg. guide actually now is in conformance with 10.8, but the model regulations that appear in the appendices actually have a tighter standard of plus or minus five percent.

Now I guess you can say if you as a centralized nuclear pharmacy want to adopt those model regulations which

are truly model, because they are even tighter, then that can be your decision. If I were a centralized nuclear pharmacy, I would probably apply for the standard 10 percent though.

MS. HOWE: Yes, now the appendix that we have that is modeled on 10.8, we brought over exactly the same numbers. So 10.8 has the same five percent tolerances that this one has. I know that was one of your comments, everything ought to be 10 percent because that's in the regulations.

I'm not sure how the radiopharmacy community is going to feel about all of a sudden seeing something that looks different from what they have been dealing with. Do you have any feel for that?

MEMBER SWANSON: Well that's a concern. I guess the question I'd ask you is why were not the model regulations changed to conform with the NRC regulations, basically, the Part 35 regulation?

MS. HOWE: The draft regulatory guide for the radiopharmacy was issued in 1985. The reg. guide for 10.8 was issued in 1987. I believe when they developed the reg. guide for 10.8, there are differences because there are trigger levels. The staff I think believed that maybe they should be taking action at a lower level, but the regulation was at 10 percent.

But the radiopharmacy guide actually came first.

So the wording that was in the linearity geometry for the radiopharmacy guide preceded 10.8, but it was never developed as a final guide.

MR. CAMPER: Let me just, I don't know the answer to your question either. I wasn't in the staff at that time. Donna-Beth was here, I think, but it's hard to second guess now.

I think the important thing is though is that we align whatever needs to be aligned at this time. We have an opportunity to do that, because we are dealing with guidance here. Whether it's 10.8 or it's the pharmacy guide, they are guidance. We can align them up, and we certainly should.

Trust me. I've been in situations where when giving talks in professional societies, when not only this, but on the difference between Part 35 and 10.8, embarrassing differences have been pointed out to me. Ultimately, we can correct that.

Certainly, we can do something about guidance now in lining them up.

MEMBER SWANSON: And I would suggest we do that. I think it just adds a point of confusion.

Probably where it really came from, if you look at the previous Part 35, the limits plus or minus five percent that currently appear in the Appendix model regulations, were in fact the NRC regulations at that time.

Now when we did the revision of Part 35 in 1987, they changed those to the ANSI I think requirements of plus or minus 10 percent. Again, what has probably happened is that appendix just has not gotten changed, that model appendix.

Now this was something I pointed out when I did the review. I noted that it still didn't get changed. Again, I don't know if that's a problem with some compatibility issue or something, but it ought to be consistent.

MR. CAMPER: We'll take a look at it.

MS. HOWE: What we do is we actually picked up Appendix C from 10.8. 10.8 was in August of 1987, so it was done at the same time that the new medical use rules were put into place, because it was part of a package.

So what we did was, we picked up Appendix C directly from 10.8 and inserted it with the exception of some errors that were in linearity that we took care of.

So if there are higher numbers or lower numbers, plus or minus five percent versus the regulation 10 percent, that's because the five percent showed up in Appendix C.

MEMBER SWANSON: It probably got missed when they did the revision.

MR. CAMPER: It's hard to say. I suspect you are right. But I think the important thing is, is that with this recent rule change and the flexibility for procurement use for radiopharmaceutical that's in that for Part 35 licensees, this

exercise affords a good opportunity as I said, to line these up. We'll take a look at that and focus on it.

CHAIRMAN SIEGEL: A quick question on page 35.

MS. HOWE: Yes.

CHAIRMAN SIEGEL: This item about the pharmacy will agree to retrieve only those items, syringes, vials, that contain or are contaminated with radioactive materials supplied by that pharmacy.

MS. HOWE: Yes.

CHAIRMAN SIEGEL: Do they know? How do they know if they've got mixed waste, if you used the wrong term.

MS. HOWE: I think the mechanism is, they send drivers out with suitcases. The suitcases go out with the doses in them in the morning. They send them back out the next morning with the new doses and they bring back the old suitcases.

So they are dependent upon the medical use licensee not to slip anything in. But I think there is this exchange of suitcase type of thing in ammo carts that --

MEMBER SWANSON: That's actually what occurs. You get a syringe peg which has a label on it. You have your dose in it. Then you inject your dose. You put it back in there and send it back.

So the centralized nuclear pharmacies are receiving their pegs back with their labels on it, with a used

syringe inside of it. It's pretty hard to stuff two or three syringes in those things, so I don't think they get things that don't belong to them too often.

CHAIRMAN SIEGEL: Do you have a comment? I'll recommend you identify yourself for the record.

MS. SEIFERT: Okay. Cathy Siefert from Syn Corps International (phonetic).

The difficulty comes in that sometimes nuclear medicine departments are serviced by more than one nuclear pharmacy. Sometimes it would be difficult to know whether or not the particular waste came from your nuclear pharmacy. The individual picking up the suitcase to bring it back to the nuclear pharmacy would not have the expertise to look in there and know.

MS. HOWE: I think the main point of this was to make sure that the pharmacy is sending out certain kinds of things to the medical use licensee. Only those kinds of things are coming back to the pharmacy. So they are not using the pharmacy as a waste broker.

MS. SEIFERT: I agree certainly with the intent. But in a pragmatic perspective, sometimes it's difficult to execute it.

MS. HOWE: That probably only happens in big metropolitan areas, where you have got competition.

MS. SEIFERT: It happens on many occasions.

MS. HOWE: In the rural areas?

MS. SEIFERT: Not in rural areas, but there are lots of cities where there are more than one nuclear --

MS. HOWE: Okay.

MR. CAMPER: Well, the distinction becomes inspection space. And that we in the licensing process are looking for a commitment from the radiopharmacies that you are going to accept and retrieve waste only from your client's residual nature.

It's a non-problem unless during an inspection, while our inspections would determine that you appear to be functioning as a waste broker.

MS. HOWE: And that's the key.

MR. CAMPER: It's not that oh, guess what, we got a syringe from Pharmacy B, and we're Pharmacy A. That's not the problem. It's when you are starting to collect waste and function as a waste broker. Then that's the problem.

MS. SEIFERT: It's a problem for us when a nuclear medicine department slips something in that they didn't get from us and we're not licensed to have it either, like particularly a sealed source that they just happened to have sitting around.

Of course we deal with that when it happens but --

MR. CAMPER: Now I know where all those old

radium sources are going.

CHAIRMAN SIEGEL: Okay.

MS. HOWE: I believe Mark --

CHAIRMAN SIEGEL: Dennis, any other items? Oh, Mark. Identify yourself.

MR. ROTMAN: For the record, Mark Rotman. If the committee will indulge me, can we go back to page 32 of this same guide, and look at number seven on the top.

The question I have, while you are all flipping through your pages is, it appears to read that everything that you distribute out of your commercial radiopharmacy is to be assayed in your dose calibrator.

The question I have, would that apply to vials of sealed multiple dose radiopharmaceutical that you would be redistributing after you received them from a manufacturer?

For instance, you get in a vial of I-131 capsules and it's designated to be a whole body scanning dose for a licensee, it's labeled by the appropriate company. Do you need to assay that before you send it out again?

It seems to me that it's already assayed in a manner that meets NRC regulations and FDA regulations. It would pose an ALARA consideration to take it out of its container, put it in your dose calibrator, only to confirm that it was correct and put it back in its peg and ship it out.

I'm just curious, was number seven meant to be that prescriptive or does it perhaps need some massaging of the language.

MS. HOWE: No. Number seven has not changed, with the exception that we distinguish between the photon emitting and the alpha and beta between seven and eight. Seven is an item that existed in the preceding Reg. Guide. We do require that dosages going out of the pharmacy be measured.

We have said further, somewhere else in here that the pharmacies can apply for an exemption for the beta and the alpha, that they are not making any manipulations to.

MR. ROTMAN: Number eight is very clear. It talks about alpha and beta emitting drugs.

MS. HOWE: Yes.

MR. ROTMAN: Number seven is also clear because it says every vial, syringe, ampule or capsule. Now there's a difference in that sort of prescriptive regulation.

That indicates to me that everything must be re-assayed, even though it would be not sensical, scientific or ALARA to do so. That is why I am specifically asking about number seven.

MR. CAMPER: You interpret that correctly. I would suggest that the rationale was for it, is probably for the same reason that we require that all photon emitting be reviewed by the Part 35 licensees. That is, is that mistakes

do happen.

MR. ROTMAN: But still the Part 35 licensees would be the ultimate recipient of whatever is in number seven, is still going to assay it again.

MR. CAMPER: For the photon emitter, correct.

MR. ROTMAN: So it seems a repetitious, useless assay for items that are not going to be manipulated by the radiopharmacy, other than to act as a wholesaler, so to speak. That's really what my itch is that I'm hoping you guys can scratch. Thank you.

MEMBER SWANSON: I interpret that a little bit different in as much as the regulations or the guidance document had previously defined redistribution, which is what I think you are talking about, Mark.

This sentence says distribution and does not address redistribution.

MS. HOWE: That's right.

MR. CAMPER: Yes. That's a good point.

CHAIRMAN SIEGEL: So a capsule would simply pass through? Not have to be measured?

MS. HOWE: No. I believe it still has to be measured.

MEMBER NELP: Why would you want to measure it though?

MS. HOWE: You want to make sure what is going

out the door of the pharmacy is what is supposed to be going out the door to the medical use licensee.

MEMBER NELP: But how I'm reflecting is if the capsule came in and had a beta emitter in it --

MS. HOWE: No. It's different, because item number seven refers to only photon emitting. Item number eight is the alpha and the beta. We have stated elsewhere that the commercial nuclear pharmacy can come in and ask for an exemption to having to measure the alpha and beta if they received it and did not manipulate it and send it directly through.

So we have covered your concern about a beta coming in and then being shipped directly, redistributed to the licensee for medical use.

MEMBER NELP: I was reflecting on that same exemption. There's no need to measure the photon emitter if the same company is a reliable company. That's what I'm saying. In other words, why do you want to handle it again. You induce, it's simple to do, but you also induce the opportunity for error and mishandling. It was the point that was brought up just a moment ago.

MR. CAMPER: I guess I would --

MEMBER NELP: I guess you could get an exemption for that. This is for redistribution.

MR. CAMPER: Well, I guess I would defer to the

radiopharmacist in the group. I mean is it a reasonable standard that a commercial radiopharmacy would assay all doses passing through its shop. Is that a reasonable thing to expect or is that overbearing?

MEMBER SWANSON: I'd be interested to hear from people actually running commercial. I don't think it's a great task.

I actually, I guess I'm curious, and I'd ask this to --

CHAIRMAN SIEGEL: By great, you don't think it's burdensome?

MEMBER SWANSON: I do not think it's burdensome. How much redistribution the business of the commercial centralized nuclear pharmacies is more dispensing of unit dosages. I don't think you are majorly in the redistribution business to begin with, but I'd be interested to hear comments on it.

MEMBER BERMAN: Depends on whether it's thallium or sesta (phonetic) maybe.

MS. HOWE: Thallium doesn't count. We don't regulate it.

MS. SEIFERT: Cathy Siefert again. I think your point is well take, thallium doesn't count. But the things that could happen within an agreement state that would regulate that to be in line with this sort of thing, could

impact us significantly.

One thing that comes to mind is I-123 capsules, which of course --

MS. HOWE: It's not ours.

MS. SEIFERT: It's not yours, but when an agreement state were to look at this, it would be extra exposure to the pharmacist who assay every single capsule individually and hundreds of them, perhaps a day, for no particular reason.

We don't see mistakes from a manufacturer in that regard. They have their own quality control programs. They come in labelled individually.

It seems unreasonable to require additional measuring of a gels (phonetic) like that, that's labelled appropriately.

CHAIRMAN SIEGEL: Especially given that medical use licensee is required to do that assay one more time. Would you really need three assays to be sure that the capsule contains 100 microcurie?

MS. HOWE: It is interesting, because we get a lot of questions from the medical use licensees, who say, "Do we really have to measure it again? It already got measured twice before."

CHAIRMAN SIEGEL: Twice may be enough. The question is, is where do you want the last one. I think we

have argued in the past in agreement with you that right before administration by the person who is going to be in real trouble when the mistake is made, is the best place for the last measurement. Whether you need three instead of two is arguable.

MS. SEIFERT: I think one way of handling this would be any dose that was manipulated in the nuclear pharmacy has to be assayed. To me, that would be reasonable.

CHAIRMAN SIEGEL: We would urge you to take a look at this one, as perhaps being overkill.

MS. HOWE: Okay. We'll look at item seven again.

CHAIRMAN SIEGEL: Okay. Dennis, so you're going to do your specifics on this by transmission to them?

MEMBER SWANSON: Yes.

CHAIRMAN SIEGEL: Are you going to mark up the document or are you going to write a letter or how are you going to do it, just out of curiosity?

MEMBER SWANSON: The way we have done it in the past, we have just gone through the pages and addressed them individually. Again, what I am talking about here, these tend to be mainly wording issues.

MR. CAMPER: In addition to Dennis' comments, Mark Rotman, Dr. Rotman has provided Dr. Siegel with an extensive set of comments, we had provided to Dr. Rotman at the same time we did you.

Mark had already taken a look at them once and made substantial changes. Then we provided a comment at this time we provided this to committee as well for his additional review. He does have a fair number of comments, so that the record will reflect that he has provided additional comments, and the staff will look at those as well.

CHAIRMAN SIEGEL: Okay. Good. Next.

MS. HOWE: Moving right along. We now have the draft regulatory guide for the manufacturers. We didn't have as many changes to this Reg. Guide, because the ACMUI didn't give us a lot of changes at the last meeting.

We did have administrative changes. As we did in the others, we added boiler plate and format changes for draft regulatory guides. We added figures for regional offices and agreement states. We've reordered some sequences in the packaging and shielding. We clarified some of the licensing. We clarified that the emphasis on this particular license is that they can not possess material under the license. And we added additional clarification as to what new licensees need to do for the possession license.

We have clarified the methods and procedures just for instrumentation measurement and calibration. There was some concern that we were asking for procedures to make drugs.

We revised the labelling section to bring it into conformance with the final rule, and also the rule

clarification from January 4.

We had inadvertently, in our diligence to remove all references to generators, removed the generator return program from the distribution license, so we put that back in, because that was an important program.

Do we have comments from the ACMUI?

CHAIRMAN SIEGEL: I do not. Dennis, do you have anything?

MEMBER SWANSON: No comments.

MEMBER NELP: No comments.

MS. HOWE: No comments? Okay.

CHAIRMAN SIEGEL: Okay. That was easy.

MS. HOWE: Our last draft reg guide is for 10., is a supplement to 10.8. It became clear with the ACNP and the SNM letter that there may be a major misunderstanding and that the errata sheet may have somehow replaced all of Reg. Guide 10.8.

So to really make that crystal clear, we renamed this from an errata sheet to a supplement, so it should be clear to everyone.

We added additional language that said, 10.8 is still in existence. 10.8 forms the basis for most medical use radiation safety programs.

So we renamed it to emphasize its relationship to Regulatory Guide 10.8. We did a major change in focus. One

of the comments was that we had somehow said that if you follow the manufacturers instructions, you were operating safely. That was not our assumption.

Our assumption was that you had 10.8 to cover basic radiation safety, if you were doing those kinds of practices. And that if you were going into preparing things other than from commercial distributors, that you might be going into additional radiation safety concerns.

So what we did was we changed the focus and said, licensee, 10.8 is your basis for your radiation safety program. You need to evaluate what you are doing and see if what you are doing can still be covered by the appendices and the guidance that we have provided in 10.8. If it can't be covered by that, then you need to provide us with additional information.

So we changed the focus so that 10.8 is clearly the basis from which you start, and you provide additional information when you go beyond 10.8. Clearly, 10.8 does not cover alphas and betas. So you will have to go beyond 10.8 if you are handling alphas and betas.

Then there may be other procedures that you are doing that you'll have to go beyond 10.8.

So the major change in focus was reclarified. We were not requiring formulation and reformulation procedures. Then we were focusing on radiation safety.

We revised Table 1. The revision of Table 1 will also simplify the license. We have put the focus on radiation safety.

There was an erroneous assumption that for some reason, we had determined 100 millicuries had some safety significance. When in fact, we were just using it as an administrative cut-off as to when we would ask for additional information. So we have taken all of that out of 10.8.

We made some major changes in focus, but actually in sentences, a lot of the 10.8 that we had before was still there. Do we have comments?

MEMBER SWANSON: Two comments. One is, as I mentioned before, if we go to page five, paragraph six, where it discusses assay and unit dosages of alpha or beta emitting radionuclides. Again, look at that wording very carefully.

In that, medical use licensees can receive unit dosages from a central nuclear pharmacy. Many of them also received the vials and draw them up themselves again. The wording needs to be looked at, and probably be consistent with what appears back in the model guide that I mentioned before.

I think the other concern I have goes to page eight. This issue on research, whether or not the research is covered by the federal policy for protection of human subjects, certainly there's nothing wrong with item number one on page seven.

Item number two though states that if research is not conducted, funded supported or regulated by a federal agency that's implemented the federal policy of protection of human subjects, the licensee may apply for and receive an amendment from the NRC. The licensee provides the following information.

If you look at A and B, the type of research isotope or isotopes involved, physical and chemical form and the activity, and be the sponsors of the research. If you require that kind of information, that means that the licensee is going to have to submit an amendment for each research project that they may get involved in.

I really don't think that is what you want. Maybe that's what you need to define to me. What is it that you want from these people that don't have these assurances.

Now Barry and I have talked about this. I can't imagine who would fit under this category, but it would seem to me that what you really want is that in fact there's an IRB in place to review this research, and that you are getting informed consent from the patient, and probably a notification that they are doing research. But do you want all this specific information?

MS. HOWE: In the past, we have gotten this kind of information in order to add line items to the license. That is one reason we have listed it the way we have. We are

open to looking at it again and following specific comments that you might have.

We have added specific line items to use specific isotopes and specific studies for those that are not broad scope licensees, but are limited specific. We're outside of the IND category that was automatically covered by regulation.

CHAIRMAN SIEGEL: I'm still confused by the term regulated by another federal agency.

MS. HOWE: Okay.

CHAIRMAN SIEGEL: Because of the fact that let me just tell you how the search works in my own broad license institution.

We obviously as a big academic medical center, have large amounts of research that is funded by the NIH, funded by the Department of Energy, and other sources, which is all very specifically regulated. And large amounts of research that's under FDA supervision, all of which comes under either DHHS regulations or the specific more stringent FDA regulations regarding human research. Those are no problem.

MS. HOWE: Those are covered by the federal policy.

CHAIRMAN SIEGEL: Absolutely. But in addition, there's a fair amount of research that is funded from private foundation sources, or simply done in the institution by the

staff of the institution, which is not conducted, funded, supported, or intrinsically regulated by another federal agency, but which is done in an institution that has told DHHS as part of its general assurances, that every bit of human research done within its walls will be in accordance with the uniform federal policy.

To my way of thinking, and we've talked about this three or four times before, it's still not coming across that that qualifies as regulated by another federal agency and it needs to.

MS. HOWE: So in that case --

CHAIRMAN SIEGEL: Because that's a contract with the Department of Health and Human Services.

MS. HOWE: Okay. So you have a contract with Health and Human Services. Do they come in and monitor those programs?

CHAIRMAN SIEGEL: Absolutely. DHHS inspects. They don't monitor the specific research. They inspect the activities of our IRB. They periodically look at the adequacy of informed consent.

FDA is obviously in and out for things that are FDA relevant.

MS. HOWE: But Health and Human Services has the ability to ask you for the informed consent for those things that are not funded by the federal agencies, and they have the

ability to ask you for the informed consents and the IRB approval for those things that are not funded or sponsored by the federal agencies?

CHAIRMAN SIEGEL: Yes.

MR. CAMPER: Does that then translate then, Barry, into the fact that if item D is presented, that negates the need for us to see items A, B, and C?

CHAIRMAN SIEGEL: Well, that's what I think. I must admit, my legal certainty is not absolute here.

But from a practical point of view, in terms of your real need, I don't think that -- if item D is a general assurance that all human research conducted within the institution follows the uniform federal policy, then the assurance has been made to DHHS, and that assurances include that the IRB review and informed consent.

I think you ought to stop there. I think that's enough.

Now whether you take it to the next step, does that mean DHHS can come in and specifically inspect the research that it didn't fund? I honestly don't know the answer to that. That's a good question, a darn good question. I don't know the answers. But I don't think it is a practical issue, because I think that the behavior of the institution given that assurance, is that the research is conducted in compliance with the rules.

MEMBER SWANSON: In other words, when we do an IRB review of a protocol or if we have policies and procedures in place for IRB submission of research protocols, we don't differentiate in the institution that this research is conducted by a federal agency that blah, blah, blah. It's in general, any research study conducted on human subjects must have IRB approval and there must be an informed consent, period.

MS. HOWE: I suspect we'll probably have to find out more about the general assurances, and go through our general counsel to see how they interpret things.

CHAIRMAN SIEGEL: I wish you would, because actually, I see this as being a very thorny problem if really pushed to the extreme. I think what you all envisioned and what we envisioned in discussion with you, is almost a non-issue, because there are virtually no institutions where this would apply.

This exception could turn out to be 40 percent of the research with byproduct materials, in which case, you are going to be buried in these issues, and they are going to be irrelevant.

You are going to be spending, I think you are going to find that a large amount of the research is not conducted, funded, supported or directly regulated by one of these other federal agencies, but it is indirectly regulated

by way of a general DHHS assurance filed by the institution that says, everything we do on humans follows your rules.

The question is whether that contract does the job.

MS. HOWE: I think one of the things we have to deal with is that when the rule was being developed, what we were hearing from ACMUI et cetera was that almost all the research is going to be covered. Now we have it down in black and white.

There is a question about the general assurances.

CHAIRMAN SIEGEL: I can tell you, because I made the statement before, that covered to me included the general assurance, which I interpret as meaning covered. I think OGC needs to help on this one, to decide whether that, if they look at some typical DHHS assurances, and what those really involve, whether that means covered.

Otherwise, this is going to be a big problem. I don't think you want it to be a problem, because there's no evidence that it's causing a problem in the community. I mean, there aren't bodies out there as a result of this research that's being done without meeting this federal regulation. It's a non-issue.

MR. CAMPER: Well, it sounds like we need to have some dialogue with OGC and probably also with --

MS. HOWE: Health and Human Services.

CHAIRMAN SIEGEL: You really do.

MEMBER SWANSON: We've looked at this a couple times. Barry and I have had several discussions. I think we both remain confused, which kind of gives you a message as to what is going to happen with the regulated community on the issue.

CHAIRMAN SIEGEL: So I'm inclined to agree with what you said first, Larry. If D is applicable, then it really becomes part of item one.

Now it is possible, an institution can write, I think can write a DHHS assurance that says, what we are telling you only applies to DHHS funded research. But I don't know of any universities that do it that way.

First of all, I mean, it violates the Helsinki principles and all those other good things that we really all believe in. I can't imagine why you would have two sets of books for your IRB, one that meets the federal policy and one that's different, because they all have to conform to the Helsinki Doctrine.

MS. HOWE: Well, I clearly think our intent was not to stop medical research at broad scope licensees, which are the ones that are affected the most.

MEMBER NELP: Virtually no journal which publishes scientific results would publish it also. I mean it's all down the line.

No drug company would give you money to do research, unless you --

CHAIRMAN SIEGEL: No, but if it's a drug company, Buzz, it's not an issue. Because then it's under FDA jurisdiction.

MEMBER NELP: Well, yes. If they think they are going to take the FDA. But the drug company will ask you for your credentials before they will give you the money, with the idea that if the work is successful, eventually it will have to go to the FDA. The FDA may be on the sidelines.

MS. JOHNSON: I'm Terry Johnson, the Radio Safety Officer at George Washington University.

I recently had to file a broad license application where I addressed this issue, because I was asked by the licensed reviewer to supply a lot of information about this human research. It seemed arbitrary to me and also to members of the committee at George Washington University.

But anyway, in looking up the regulations, I am almost, I can't recall word for word what it says, but I am very certain that it doesn't have any reference to funding. That is to say, the sections of the FDA regulations that require an IRB, and assigned the functions to an IRB, and that require an RDRC for that matter and assign the functions of an RDRC, do not make reference to the research being funded.

It's just when drugs are administered to human

beings, or in the case of the RDRC, if radioactive materials for any purpose are administered to human beings, the functions of the RDRC and or the IRB come into play. Funding has got nothing to do with it.

MS. HOWE: Terry, you're absolutely correct. But what we were doing is following the federal policy. The federal policy does address funding, sponsoring.

MS. JOHNSON: The point is, if you are going to administer it to human beings, radioactive materials would have to go through the IRB. That is determined from the regulations of the FDA.

MS. HOWE: As long as it is coming from FDA, then it is covered in the very first part, because FDA would be regulating it. Then that would be human research that is conducted, funded, supported or regulated by a federal agency that has adopted the federal policy. FDA has adopted the federal policy, so if it's an IND, it is covered and regulated by FDA. So that research comes under the category where you don't need an amendment.

It is when you aren't funded, supported, conducted or regulated by a federal agency that you have to have an amendment. So the question now is, whether things that are under a general assurance to the Department of Health and Human Services comes under --

CHAIRMAN SIEGEL: Constitutes regulated.

MS. HOWE: Comes under Part One, where you don't need an amendment, or it comes under Part Two.

MS. JOHNSON: The point is, is there a loophole in FDA regulations, where somehow you can put radioactive material in a person's body, without going through the RDRC or the IRB.

CHAIRMAN SIEGEL: Yes, absolutely. You are confused. Let me clarify.

The FDA, unless the study is being done specifically under the requirements of 21 CFR 361.1, which makes the RDRC regulations applicable, or unless the study is part of an IND, the FDA has no involvement in the loop whatsoever.

I'll give you a perfect example. I am an authorized user in a medical institution. I want to use an FDA approved drug as part of a research project that is not funded by anybody. I just want to do the research.

If my institution does not have an IRB, hasn't filed general assurances, then the research is not regulated by anybody, other than the Helsinki principle.

MS. JOHNSON: Oh, I understand that. That's for a drug that's on the market, in other words. But if you're using it for different purposes.

CHAIRMAN SIEGEL: I can tell you that most research with byproduct material uses FDA approved drugs in

the research setting. That's the component I am terribly concerned about here, because these are things that are not FDA regulated.

MS. HOWE: If they are done under the right criteria, they are specifically exempted from the IND by FDA.

CHAIRMAN SIEGEL: Correct.

MS. JOHNSON: I was aware of that. I thought you were talking about new formulations. Yes, existing formulations that are on the market can be used for our purposes.

CHAIRMAN SIEGEL: And that is what I'm concerned about. The RDRC regulations solve the problem when it's through 361.1 research. But it's a terrible problem if you use an FDA approved drug in your institutionally funded research. You are doing it out of your own back pocket.

We have got to make sure these DHHS general assurances apply. You've just captured a lot of stuff you didn't want to deal with.

MEMBER NELP: That's a principle of bio-medical ethics, that every individual investigator has to comply with, to ethical stance and in the regulatory. I mean, in his own institution.

CHAIRMAN SIEGEL: Right, Buzz. But unless the institution has a legal contract with the federal government, then the NRC's concern is applicable. Do you understand what

I am saying?

MEMBER NELP: Well, I do --

CHAIRMAN SIEGEL: DHHS has general assurance that says, all the research in the institution will be conducted in accordance with the uniform federal policy on protection of human research subjects, which is a contract that then tells the DHHS that it has the ability to reach beyond federal funding. That is my interpretation.

Absent that, then the research is not otherwise regulated by the federal government. The mere fact that we are following ethical principles will not be adequate assurance to the NRC. They then want to see it for themselves.

MEMBER NELP: Well, I think it's overkill, frankly.

CHAIRMAN SIEGEL: It's overkill unless this general assurance --

MEMBER NELP: I mean, everyone has an IRB that will certify that it's taking the interest of the experimental patient in that institution under full consideration.

MS. HOWE: I think you are right when you talk about institutions.

MEMBER NELP: Those are things that include informed consent and so forth.

MS. HOWE: But we also have private practice and

smaller group practices that want to participate in research projects that are not in any way funded or connected with federal agencies.

I can think of one example that I heard about. That was where they wanted to determine whether for airplane pilots, if you have a heart condition then you may be grounded. How do you determine whether the airplane pilot really can fly the airplane, even though they have the heart condition.

Well, they wanted to do a research program where they put the pilots that were grounded through a flight simulator, and then do a thallium stress test afterwards to see what their stress level was before and after.

Now, that was not regulated by any federal policy. It was a small. It was a physician that wanted to do this, because he was interested in flying.

MEMBER NELP: But who did he get, he must have had some mechanism to inform the patient of the experimental procedures, get the patient's consent.

MS. HOWE: He should have. But he didn't have any formalized mechanism.

MEMBER SWANSON: And I think that's the question the NRC is asking, actually is what mechanism is in place to ensure that that happens. At least I think that's what your true interest is in this issue. Okay?

MEMBER NELP: You certainly don't want to be in a position to approve his medical research, if he doesn't have any other source of approval.

CHAIRMAN SIEGEL: That's not true. That is exactly what it says.

MEMBER NELP: Why would you want to do that?

CHAIRMAN SIEGEL: It says that absent any other way of getting this approved by the standard mechanism, it is going to require a license amendment.

MS. HOWE: And in the license amendment, we will at the minimum require informed consent and institutional review board approval.

CHAIRMAN SIEGEL: But do you see the circular problem? I mean if here's a guy in a private practice who isn't going to be able to get an institutional review board approval because most IRBs are unwilling to accept the liability of approving the research of someone who is not under their institutional purview, and in fact, DHHS assurances say that in addition to approving the research, you monitor the research.

If you can't have any regulatory control over the investigator, you can't monitor the research. So it's circular.

However, once again, and I know you understand, if this issue of research that isn't funded isn't also

captured by the general assurance, then you have got a very large issue in institutions, that you are going to end up requiring license amendments for, that you don't want to be buried under, and we don't want to have to provide you with, because they are unnecessary.

MEMBER NELP: As I understand your argument, if I am the guy, I am a pilot and I'm a cardiologist. I want to test my pilots in a flight simulator and I'm in private practice. I want to use systamivy (phonetic) because it's under the NRC, I can apply with the NRC and they can approve my human research.

CHAIRMAN SIEGEL: If you also document that you are going to get informed consent, and that an IRB has reviewed and approved your research protocol and your informed consent document, which I submit you probably won't be able to do.

MS. HOWE: And we may not exactly approve it, but we'll give you a license condition that permits you to use the material in that manner.

MR. CAMPER: That's right. We'll permit your use of the material. The conduct of that research, provided certain criteria.

MEMBER NELP: Under certain circumstances, but you won't approve the circumstances? If I won't submit my protocol to you, and you will approve my protocol. I can go

out and put together a review board --

MEMBER SWANSON: Yes. You will.

CHAIRMAN SIEGEL: No. You can't.

MS. HOWE: An institutional review board doesn't have to be approved by the FDA. The only one that is approved by the FDA is the RDRC.

MEMBER NELP: Many small hospitals put together human subjects review boards.

MS. HOWE: The only ones that are registered with FDA are the RDRC. Are you registered with the institutional review boards?

MEMBER NELP: If I had -- (indiscernible) -- practice in a hospital, I could go to that review board. So I suppose I could do it. It's a little unusual.

But the point is, I don't think the NRC wants to get in this issue of approving the ethical aspects.

CHAIRMAN SIEGEL: Well, I think you've also got yourself in another legal issue here, which is, an institutional review board is a term defined in the uniform federal policy.

Therefore, if you have an institutional review board that hasn't filed assurances with any federal agency, is it an institutional review board?

MS. HOWE: I don't believe it has to file assurances. There is a definition for an institutional review

board in the federal policy.

MEMBER NELP: It does to the federal government. If I put in an NIH grant, I have a check sheet. One of the questions, in my university, I have this IRB, and fully complies with all the federal regulations of IRBs.

MS. HOWE: It says an IRB meets an institutional review board established in accordance with, and for the purposes expressed in this policy. Then it talks about the approval.

CHAIRMAN SIEGEL: And who do you tell? I mean, you must tell someone that you have an IRB. Right?

MS. HOWE: No. FDA is only where it's FDA. You can have other institutional review boards that don't have to do anything with FDA.

MEMBER NELP: Correct. The IRB, this concept came from the National Institutes of Health.

CHAIRMAN SIEGEL: No, it didn't.

MEMBER NELP: Yes, originally.

CHAIRMAN SIEGEL: Well, you can believe that if you wish. It came from first --

MS. HOWE: It came from the Science and Technology.

CHAIRMAN SIEGEL: First out of the end of World War II, and then second out of the Helsinki Declaration that protection of human subjects should be assured.

But I guess, Donna-Beth, I'm not sure that you can have something that you call an IRB that is free-standing and completely independent of the federal government.

MEMBER NELP: You can have a human subjects committee in a community hospital. I don't know if they call it an IRB. They probably don't have any connection with federal funding.

CHAIRMAN SIEGEL: All right.

MS. HOWE: I think you can, because I think institutional review board is like a generic word. The ones you normally think about are associated with an FDA or some other federal agency. But I think you can have one that isn't.

MEMBER NELP: I will tell you that this format for the IRB was generated from the things you have said. But it was the National Institute of Health, was told we will not, you can not give out any further money for human research until you follow this policy.

CHAIRMAN SIEGEL: Got it.

MEMBER NELP: It had nothing to do with the FDA. It came from the National Institutes of Health. They said, unless you can assure us now, since there's been so much attention to the ethical aspects of human research, unless you can tell us that you are going to follow these ethical guidelines, we won't give you any money.

Once you say you have this in place, that's all we want.

CHAIRMAN SIEGEL: Got it.

MEMBER NELP: You are responsible for governing yourselves. We don't want anything to do with it. You just have to ensure us that you're going to do it. That is the IRB. That is accepted by all the federal agencies.

But I would venture to say --

CHAIRMAN SIEGEL: Okay. Enough said.

MEMBER NELP: If you go to Twin Lakes Minnesota Community Hospital, they'll have a human subjects committee, they'll put a human subjects committee together for you, but they may not have a "IRB."

CHAIRMAN SIEGEL: All right. You've beat this one to death. But I think a tenth of the discussion was clear about this item D as a potential problem.

Any other concerns on this?

Was that the end of your slides?

MS. HOWE: Yes. It is.

CHAIRMAN SIEGEL: All right. Good. Thanks, Donna-Beth.

Bob Ayres.

MR. AYRES: We talked to about this a little bit before, so I'll keep it short.

Several months ago, our researchers from the

National Institute of Standards and Technology came to us. We held a meeting. They presented some of their latest data on their calibration measurements on these devices. The next slide simply summarizes it.

There are some unique things about it. There are eight known manufacturers of these devices, but only one still in the business. So the bulk of them are orphan devices, which gets into a little bit different space.

The NRC's position has been lately up to this point, that its the manufacturer's responsibility to take care of calibrations and so forth. But here we have an instance where we have a number of orphan devises.

The results that they presented was that they found the range in agreement or disagreement between the devices that they had been doing calibrations for customers, ranged from 55 percent less than the national standard, which they by law are, to 61 percent greater.

If you calculate that in a range from the highest to the lowest value, in other words, if one physician had one each of the two devices, there would be 136 percent difference between those, a factor of, about a factor of three.

If you had your nominal value was 100 millicuries, that would say one is less than 50, and the other is 150. I did my math wrong. But that's about a range of three between the highest and lowest values. For four of the

manufacturers, they were within 25 percent of the NIST value.

One of the other problems is some of the manufacturers, particularly four of them, NIST had a very small number of measurements, five or less, which means that they didn't have very good statistics on the calibration accuracy for those devices, for those particular manufacturers.

We discussed this, and we are proposing to issue a contract with NIST. This is not in place yet, and in fact, there are several administrative procedures that we need to go through, in particular, an OMB clearance. Even though it's a voluntary program, we still have to get clearance to do a survey. We are proposing to do this in the next fiscal year, fiscal '96.

What we want NIST to do for us is perform some additional measurement comparisons so they can improve the statistical validity of the data. They are going to do this by sending out an invitation letter to our licensees and perhaps agreement state licensees, asking if they wish to volunteer in the program.

As part of that, send a survey along asking them if they participate, to provide certain information which of course describes their source, manufacturer, serial number, et cetera.

The way they are going to do the measurements, is

they are sending a radiochromatic film which they have developed, calibration techniques that they can accurately determine from densitometer measurements, the radiation exposure film, have the participant expose the film with their eye applicator, and return it.

They will ask information about how the participant did that. They will also survey them on their treatment protocols as it relates to the calibration device.

Also, the participants' identity will not be provided to us under the contract. It's just a set of measurement data and a survey of the result.

We're going to also ask them to do a statistical analysis of the measurement data, which they have a lot of expertise in, and particularly, compare the extent and magnitude of the existing calibration error as it pertains to different source vendors. Remember, all these are essentially orphan devices.

Then last but not least, is go out and contract the services of some medical experts who are routinely doing a considerable amount of work, considered experts in the field on using these devices, and ask them to assess the medical significance of what they have found, in terms of measurement error data. That's it.

MEMBER NELP: Could I ask one question.

MR. AYRES: Yes.

MEMBER NELP: And no one else gets to ask it. How many of these devices are in use in the practice of medicine in the United States today?

MR. AYRES: The estimate is about 300. We're also estimating that we have, I got, looking at our license data base, 56 identifiable licenses. But that does not include broad-scope. So we don't know how many are out there in our broad-scope licensees. But certainly, probably a comparable number are medical broad scope.

MEMBER FLYNN: I can tell you, there's a lot of art behind how the treatment is actually given also. Even if you could calibrate all the devices in the country the exact same way, whether it's film or extrapolation chambers, however, some authorized users are holding the devise stationary for these small pterygia in the eye. Some are rotating them over a surface. Some are using local anesthetic in the eye. Some may use a little sterile water.

Because the dose falls off so rapidly, if you have the contact surface, the active surface, sore surface, if you are rotating it, making small concentric circles, as some do, you hold it stationary, there's a lot of difference in the actual dose that is delivered.

I think besides secondary infections and scleromacia and lens opacification, there's a wide range in complications that are reported.

It doesn't seem to parlay that well with dose. This may be one of the reasons. But also, it's the technique.

MR. AYRES: Yes. The other thing is in regulatory space, we've got a problem. These devices come under a quality management program and a plus or minus 20 percent rule. We are aware of the calibration errors. Something needs to be fixed, either the calibrations or our regulations.

So what we would like to do is find out, get some advice on where we should address the problem.

CHAIRMAN SIEGEL: How are written directives for strontium 90 eye applicators being written at the present time?

MEMBER FLYNN: Time.

CHAIRMAN SIEGEL: Hold device against eye for one minute.

MEMBER FLYNN: Ninety seconds, 30 seconds, depends on the --

CHAIRMAN SIEGEL: So therefore, the 20 percent error is if you get the time wrong. Correct?

MEMBER FLYNN: That's how the misadministration have occurred primarily, by time. Someone forgot to stop the stop watch.

MR. AYRES: The place where it could relate to dose, would be a physician who trained on a devise that was at

one end of the scale, and then started using a device at the other end of the scale. His first two or three treatments might have to require, might be some problem until he readjusted for the different exposure.

CHAIRMAN SIEGEL: But the written directive would have been right. He would have said 90 seconds, and then he would have found out that it wasn't a big enough dose, and he would have gone back, and found it again. But he would not have violated the written directive.

MR. AYRES: The actually written directive, I may stand corrected on this. I believe it's got to be in the terms of the dose, and then translated into time.

CHAIRMAN SIEGEL: That's right.

MR. CAMPER: Actually strontium 90, I don't have the follow-up document that was sent out, but if you look down through there, you won't find strontium 90 specifically identified. That's why we sent up the follow-up document.

MR. AYRES: Yes. That's a problem. It was not thought of when the quality management rule was originally issued. Then it was added on. Then this problem comes to light. We need to come to some sort of closure.

CHAIRMAN SIEGEL: I actually think it's very good that you are doing this, even though it's a relatively small problem. I think we pointed out when we discussed this the last time, 18 months ago or thereabouts, that we wanted to

make sure that in the process of getting these things better calibrated, we didn't screw up all these empirically determined protocols that seemed to be working. It's a loose end that needs addressing.

CHAIRMAN SIEGEL: Jeff, do you have a comment?

MR. WILLIAMSON: Yes. The comment was that I think, at least in my experience, absorbed dose in some form or another is usually the practical prescription end point. I mean, one divides the dose rate into that and calculates the time.

It's probably very likely that the 136 percent might overstate the problem to some extent. There are two broad families of calibration standards. The Amersham standards, the NIST standard. It looks like currently, they may be about 30 percent apart.

MR. AYRES: No longer. That has been corrected to closer. But these are some of the more orphan devices. My math is narrowed to 300 percent spread. I did not calculate it correctly between the highest and lowest. But it is a loose end that needs addressing.

CHAIRMAN SIEGEL: Dennis.

MEMBER SWANSON: You are contracting with NIST to evaluate this. Have you taken a look at how much it would cost you more to simply contract with NIST to have all these people sent in to recalibrate it against the NIST standard?

MR. AYRES: I'm sure -- no, we haven't, because I'm sure it would be substantially more. Their calibration technique is a lot more exacting than this film survey.

Of course, any of the results they get from this will be provided back to the people that participate, so they can make an evaluation, whether they want to do something about it themselves.

CHAIRMAN SIEGEL: Bob, thank you. Sorry we delayed you so long, but we'll let you take the day off tomorrow after all.

I guess we'll do dose ranges tomorrow. Does anybody strongly object and feel the need to conclude that tonight?

MR. TAYLOR: When do you want to do that?

CHAIRMAN SIEGEL: Let's see. Let's do it first thing. Is that okay? Bright and early. That will be a nice thing to start our day off.

We are adjourned for the day.

(Whereupon, at 5:37 p.m. the proceedings went off the record.)

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