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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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THURSDAY

SEPTEMBER 25, 1997

OPEN SESSION

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ROCKVILLE, MARYLAND

The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11565 Rockville Pike, at 8:00 a.m., Judith Anne Stitt, Chairman, presiding.

COMMITTEE MEMBERS:

JUDITH ANNE STITT, M.D.	CHAIRMAN
DANIEL F. FLYNN, M.D.	MEMBER
JOHN GRAHAM	MEMBER
ANDREW KANG, M.D.	MEMBER
WILLIAM B. NELP, M.D.	MEMBER
DENNIS P. SWANSON, M.S.,B.C.N.P.	MEMBER
LOUIS K. WAGNER, M.D.	MEMBER
THERESA WALKUP, C.M.D.	MEMBER
JEFFREY F. WILLIAMSON, PhD.	MEMBER

ACMUI INVITED GUESTS:

NAOMI ALAZRAKI, M.D.

MANUEL CERQUEIRA, M.D.

RUTH McBURNEY

CATHY RIBAUDO

ALSO PRESENT:

CHIP CAMERON

DONALD A. COOL

DIANE FLACK

CATHY HANEY

DONNA-BETH HOWE, M.D.

SAM JONES

MARJORIE ROTHSCHILD

BARRY SIEGEL, M.D.

JOHN SZABO

A-G-E-N-D-A

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

(8:39 a.m.)

MEMBER HANEY: Good morning, I'd like to start the meeting, if possible, and we'll go on the record at this point.

Good morning, ladies and gentlemen. I am pleased to welcome you to Rockville, Maryland to the NRC Headquarters for this public meeting of our Advisory Committee on the Medical Uses of Isotopes. My name is Cathy Haney. I'm the Section Leader for the Medical and Academic Section of the Industrial Medical and Commercial Branch, Division of Industrial and Nuclear Medicine Safety. I will serve as the designated federal official for the Advisory Committee for this meeting. Typically, Larry Camper is the designated federal official, but due to a death in his family he will not be able to be here for the meeting.

This meeting is an announced meeting of the Advisory Committee. It's being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the Federal Register on September 5, 1997. That notice stated that the meeting would begin at 8:30 a.m. with a closed session from 8 a.m. to 8:30 for an ethics briefing.

The function of the Advisory Committee is to advise the NRC staff on issues and questions that arise on the

medical use of byproduct material. The Committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission.

The NRC solicits the opinions of the Council and the Council values the opinions of this Committee very much. The staff requests that the Committee, whenever possible, reach a consensus on the various issues that will be discussed today or in any of the ACMUI meetings, but also values stated minority or dissenting opinions.

I ask that if you could, please clearly articulate those dissenting opinions as we discuss the specific agenda items.

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

I would like to take this opportunity for the record to introduce the Committee Members that are with us today. We'll be starting down at my far left: Dr. Jeffrey

Williamson who is a medical physicist representative specializing in radiation therapy; to his right is Ms. Theresa Wallcup who is a Certified Medical Dosimetrist; Dr. Lou Wagner, representing Medical Physics, specializing in Nuclear Medicine; Dr. dennis Swanson, Radiopharmacist, representing the radiopharmaceutical concerns; Ms. Ruth McBurney, a State Regulator representing the various state regulator perspectives; Ms. McBurney is sitting here today as an invited guest since that slot has not been filled yet. To her right is Dr. Will Nelp, Nuclear Medicine physician representing research and Dr. Judith Stitt, who is Chairman of the Committee.

Now going on to my right, Dr. Andrew Kang, representing the Food and Drug Administration; Mr. John Graham, representing Health Care Management perspectives; Dr. Daniel Flynn who is a Radiation Therapist; Dr. Manual Cerqueira, Cardiologist, representing the Cardiology perspective; Dr. Naomi Alazraki, Nuclear Medicine Physician, representing Nuclear Medicine perspective; and Ms. Cathy Ribaudo representing Radiation Safety concerns from a Radiation Safety Office of a large institution.

Also tomorrow we will have joining us a Mr. James Anderson who is a Chapter Chairman of Us Too. He's a cancer survivor support group representing patient rights who is not here today. He should be here tomorrow after noon.

With that introduction I'll go into two administrative items for the members of the public that are not familiar with the building. To my rear, you'll find a hallway. At the end of the hallway to the left and right are the rest rooms. On the first floor of this building, there's a cafeteria where you can get coffee and they also serve lunch in those locations.

One more introduction, at this point we do have a new staff person that is handling the Advisory Committee for me and that's Pat Vacherlon. You've seen here working around here this morning. She'll be sitting at that back table in case you need anything of an administrative nature with regards to you coming into this meeting.

Dr. Stitt?

CHAIRMAN STITT: Yes, could you tell me who is voting and who is not voting? Naomi is not --

MEMBER HANEY: Right, Cathy is not. Naomi is not. Manuel is not and Ruth McBurney.

CHAIRMAN STITT: So they can participate in all discussions?

MEMBER HANEY: Correct, right. As far as, we do have nominations for those positions. After this meeting is finished, that will be our next priority to fill those slots. We have a very formal process that we must go through in order

to get the different nominees reviewed and approved. So we hope to have those individuals seated by the next meeting.

CHAIRMAN STITT: All right, you all know Judy's rules. You don't speak unless you're spoken to. And everybody gets a chance. I try to scan the crowd and anybody has their hand up -- Don Cool?

MR. COOL: Okay, now I echo. I don't like echoing so I will talk softly. And I did not bring any sticks. I am pleased to be here today with you and to welcome you to this particular meeting of the Committee.

Over the last several meetings the last year or two, each time I have come up here I have talked about the fact that we are embarking on a process, first it was we are going to embark upon a process fairly soon, then, we believe we are embarking on a process. Last time we were here we have pretty much embarked on the process where the Commission had told us to move forward with the revision on Part 35. At that point we were in the process of providing the Commission with detailed schedules and plans and we did so. In fact, two Commission papers went forward to the Commission. I believe you have seen copies of those which provided the outline and the staff process that was proposed. The Commission came back to us and made several things very clear. Probably, one of the most important for all of us is that in no uncertain terms

thou shalt have a final rule in June of 1999, now less than two years away.

They approved a process which continued to have some measures of public involvement and input to the design and activities and sent us off to move forward and to do good. I won't add any other modifiers to that particular thing. So that's basically where we are now in this process.

When the Commission approved the plans for the revision of Part 35, we immediately undertook some steps to try and move the process forward as rapidly as we could. Pulled together a number of folks within NRC, both folks within my staff here and Headquarters and folks who are in our regional office, in particular Region 1, to help us draft some initial possibilities of rule language in the various modality areas. We've talked a number of times about looking to see if this rule could be moved yet a little bit farther down the line of a modality-based approach as one possible methodology for dealing with some of the issues associated with making it a rule which could be more performance-based, more risk informed and something which could be more easily modified to deal with emerging modalities issues techniques as they came along.

That writing group prepared some initial draft materials. We tried to assemble the things that had come out of that, some of the issues and ended up focusing on I think

it's five or six significant issues which we have now developed a set of alternatives to. Those are the documents which you have in front of you and formed the key pieces of the majority of the agenda that you have in front of you today. With this meeting today, those documents are being made publicly available. They will form the baseline for three additional meetings to come up over the next six, seven weeks or so, that being the meeting of the Organization of the Agreement States. That session will be on Saturday, October 17th, 18th. Two weeks after that there will be a facilitated public meeting which will be held in Philadelphia of two and a half days' duration. Approximately two weeks after that in the second week of November, there will be a second facilitated public meeting which will be held in Chicago, Illinois.

Chip Cameron who a number of you may know who is our special counsel for public liaison and one of the world's smoothest individuals when it comes to dealing with people, is going to be doing the convening and the facilitating for those two meetings. He's also been tapped to do all of the facilitating associated with the Organization of Agreement States meeting and so we're going to be keeping him rather busy.

The alternatives, of course, don't deal with every single aspect of the rule. There are a number of other

things which go on in the rule and the staff is continuing to look at those issues and we'll be starting to try and draft some approaches to deal with those as we move forward in the development process.

At this point, what we expect in schedule is roughly the following, that following the public meetings, so once we get past about the middle of November, then the staff will be getting back together and we'll be developing a proposed rule text. That will be done on the basis of the input that we have received in this meeting, from you folks, from the states and the Agreement State meeting and from the public, the community at large in the two facilitative meetings, at least in those areas dealing with those particular alternatives. That draft will be available for scrutiny as it's in the development process. There will not be a formal published version which is out for a little mini-comment period or something like that, but rather an almost continually developmental cycle where pieces that are available can be scrutinized over a period of time.

We are going to be attempting to draft in parallel with putting that rule together a series of the guidance documents that would go along with that draft. As you are acutely and probably chronically aware, what you say about how to implement the rule and what it takes in terms of license application, inspections, even enforcement sorts of

areas become critical in the overall perception of the rule and how it plays out. So our plan is to attempt to provide to the Commission the set of guidance documents which would go along with this particular rule. Now I'm not sure exactly what the form and substance, if you started to pile them that will take because a number of the things just as in the rule will be very, very similar.

For those of you who are not familiar with the kind of model and process that we have been using in other areas within my program, the Materials Regulation area, we have been moving in a direction of trying to have a consolidated guidance document. It's the NUREG 1556 series. Ruth is smiling. Some of her folks have helped us with these, where in one place we attempt to have all of the information necessary to apply for and be a licensee in a particular arena. I've sort of nicknamed it the Ragu series. You remember the ad, all that good stuff that's in there? So it's all condensed in one place. That is the idea that we're trying to pursue with these, that there would be a series of documents when they were brought to full maturity which would have all of the things necessary for dealing with a particular area within the part 35, just as there is one that deals with radiography which has just been published for comment: reportable gauges, fixed gauges, well logging, and on and on. You could go through the various overall processes.

There will be a total draft for at least one of those and then likely the more program specific aspects which you would substitute in to deal with the other particular modalities when we go to the Commission which needs to be in the May time frame of 1998. Presuming the Commission moves relatively rapidly, we would expect then the proposed rule. This is the official proposed rule, the formal public comment period as required under the Administrative Procedures Act during the summer of next year. The exact timing on that, obviously dependent upon exactly when the Commission completes its deliberations, give the staff approval to publish the rule.

We are in hopes to hold at least a couple of public meetings during that comment period, again to facilitate the comment and discussion process associated with that rule and then go back through the development process once more so that by the May time frame beginning of June of 1999 we can take the final rule to the Commission.

We would expect that this Committee would need to meet again next spring in order to have an opportunity to look at the proposed rule and the guidance document as part of the review process on its way to the Commission. And then from there, I'm not exactly sure how we would sequence in part of the advice you might be able to give us. It's exactly what

other points within the process you believe the Committee could be particularly useful in that development cycle.

We're pleased that we get to have you be the first ones to look at the options. The options are not up necessarily for large wholesale editions to the process. Hopefully, you'll find that there's a relatively broad range of views in here. Rather now we need to move on and do what the next stage is which is to say all right here is this range of options. There are certainly some pros and cons. You may agree or disagree with the pros and cons. That's good. What we need to do now, what I would like for the Committee to try and do with these is to look at and focus on what are your particular recommendations within that range of options for a way in which to proceed? Why is it that this particular option or some combination of the options, that's certainly a possibility, is the one that you prefer and why, as well? Why are the ones which you do not prefer not preferred? What are your particular rationales to support the nonselection as well as the selection because all of that information becomes critical to us as we develop the statement of considerations and try to put together the proposal.

The staff will have the meeting minutes of this meeting available as a document for the public meetings. I do not expect that we will here today or tomorrow specifically agree or disagree as a staff on a certain direction to take.

We need to see what all of the inputs are through the public meeting process and otherwise. Your input is one of the valuable key inputs to us in determining the way that we will proceed when we start to draft a single rule come the middle of November type of time frame. But I would ask that you give us as clear and specific advice associated with a direction to proceed and a rationale for how to proceed in each one of these options areas.

I will remind you, I'm almost done, I will remind you that the Commission gave us a fair amount of very explicit direction in giving us the approval direction to proceed forward with the rule. If that staff requirements memorandum from March is not available, we probably need to make sure that -- it is available, good.

They ask us to look at a number of things. You will find that the areas where there are alternatives and issues for you to discuss match that very closely. There are a couple which were not included in that staff requirements memorandum list which we also believe are very critical. They have come up time and again. You have needed to deal with them time and again. That, in particular, is the area of training and experience which will not addressed in a staff requirements memorandum, has been an issue that you as a group have wrestled with a few times in the past and which has already been very clear in some of the interactions that we've

had at some of the professional society meetings, has a wide range of viewpoints within the community. We have met with a number of professional societies already. We have a number of other presentations and discussions scheduled and in fact, I fly tomorrow afternoon to talk to the American Association of Clinical Endocrinologists. We will be down to ASTRO in Orlando and a number of the other meetings throughout this fall. Again, as additional opportunities for people to provide us with their inputs and thoughts in this particular process.

With that, I will entertain any questions. You have a very busy schedule. You've only got two days to do this. In fact, you have in addition to that some things which I think you're going to take on very early this morning which is the fate and role of this Committee in terms of its continued role and interaction. That's one of the things that the Commission also asked the Committee and it's the first time I think the Commission had ever addressed a staff requirement memorandum to the Chairman of the ACMUI to provide some advise as to how you would continue to play in the whole medical community and arena, both as we proceed through this rule making where there's, I certainly see a very valuable and key role, and once that rule is developed, exactly where your role is in the on-going process of the next generation.

With that, Dr. Stitt, I'd be glad to try and answer some questions.

CHAIRMAN STITT: Maybe we were a little harsh in our meeting with the Commissioners in May. They're wanting us to reevaluate ourselves.

Actually, I had two specific questions for you, Don. One is in view of what we're currently doing, what the staff is doing, will we -- is there a need for us to meet with the Commissioners in the spring, as we commonly do? I think we're still licking our wounds from the last session. I think my guess is right now unless something changes, probably not.

MR. COOL: I'm going to say the classic answer, a little too early to tell. I think in terms of the need to support the process, it's going to be critical for this Committee to meet relatively early in the spring in order to be able to look at the draft and provide us advice. Certainly, at that point an opportunity would not be a reasonable time for you to be meeting with the Commission. However, I could easily imagine that the Commission would want to hear from the Committee, perhaps during the deliberation when the paper has gone forward to see if you have any specific views.

So it may be that they will wish to meet with you in the May-June time frame, when the paper has gone forward. I expect that the staff will certainly have a briefing to

brief the Commission. They may wish for you or several of the members to be available and have a part of that presentation and discussion, just as a guess.

CHAIRMAN STITT: Another specific question, in reading through this, there's a tremendous amount of work that's been done. Things are lined up with a variety of options. Each is discussed. We commonly try to reach consensus and then we have something that goes in the minutes. We have dissenting comments that go in the minutes. Are you looking for that from us or more of a discussion with some sort of waiting towards one option or another or -- I know my Committee can get just boggled down in mindless detail, depending on which side of the room I'm looking at.

What's going to be most helpful? Obviously, I'll have to see how this group is working today, but I mean we really -- remember last time when we were talking about those words? I keep looking at you, don't I, Mr. Graham.

Do you want us to come up with a consensus vote on each of these options? I mean not each of the options, but each topic?

MR. COOL: To the extent that you can give us a consensus view with regard to a particular option or some combination of the options that you regard as the best approach that you would recommend for the staff to consider, that would be very helpful to us.

What we have proposed to do in our public meetings and I will offer to you to consider whether or not it might assist you in going through these, what we have proposed to do for the public meetings is to start out at a relatively high level with the options and the pros and cons conceptually with those and as those groups perhaps tended towards an option or to then to have the meeting focus more and more upon the particular details within that options and where the rub points are within the process, as a way of trying to not slog through the endless detail on every single one of the options.

We have played that game internally in the staff marching through in rather detailed lockstep with each of the options and each of the pros and cons and the language of the options and let me assure you that if you try to do that, you will still be here on Sunday.

CHAIRMAN STITT: Everybody got that? All right, comments for Mr. Cool?

MEMBER NELP: Haven't you also, besides the alternative, you have made a suggested change according to what your considerations at this point, haven't you? Like you say, here's a suggested rule.

MR. COOL: We have not a single suggestion. What you do have is some possible text that would match up with each of those alternatives, but you will find suggestions that could, that would go along with each of the alternatives for a

particular issue. The staff does not have a single suggested text at this point, very deliberately and carefully.

MEMBER HANEY: Let me just add to it, when we developed the suggested text, even the group recognizes that we would do further refinements in that text if that option were chosen because some of the text is still very prescriptive and there would be ways in the fine details that that could be made a little bit more performance oriented, but the goal was just to give you an idea of what the rule text would look like if this was the preferred option.

MEMBER NELP: Is that your preference as staff of people? Is that what you think would be good to serve your purpose or did you just put down something that would be -- we could read? I presume that's your consensus of what you'd like to see happen and change?

MEMBER HANEY: No, not really because we developed rule text for each alternative and we modified it. It was more just something putting out there as a starting point of someone to think about.

MEMBER NELP: Thank you.

MR. COOL: We have placed the rock on the table. We have not attempted to facet and polish it by any stretch of the imagination. So there is a lot of refinement that would need to be done. If this group moves relatively quickly towards a consensus on a particular option, and therefore

could provide us within your time frame some suggestions and specifics on that wording that supports it, that would be very, very useful. I know that there were --

CHAIRMAN STITT: Dan, you had a comment?

MEMBER FLYNN: Yes, I'm going one step ahead of this though also because the time is going to be short by the time it gets to next spring. Once you go through these alternatives for Radiation Safety Committee, for Quality Management Rule, Patient Notification, Training and Experience, these are the difficult -- and a lot of debate will occur. But when you get into actually writing the first draft of the staff draft of 535, I strongly urge you, if possible, if you could approach it like in a modular form. You may be doing this already, brachytherapy, teletherapy, nuclear medicine and while you're doing these modular sections like brachytherapy, be working on a draft for the Reg. Guide at the same time. The reason why is because when you look at the regulation and then you look at the Reg. Guide sometimes when you try to write the details in a Reg. Guide as to how you meet the regulation, you see that there's a confusion. You only notice that when you're trying to look at the Reg. Guide. I mean I can give you an example like in for brachytherapy, after implanting the sources, usually make a survey and make a record of each survey. Well, do you keep the record or is the record going to be audible? Are you

going to post it on the patient's door? Do you leave it in the isotope lab after you're all done. I mean when you start to write a draft Reg. Guide as to how you might meet the regulation, you may come up with some confusing areas or some misinterpretation of how someone might misinterpret the regulation when they come up with their own radiation safety program, if they choose not to use the Reg. Guide, but write their own safety program of policies and procedures in order to meet the regulation. In other words, if you can work it both because then when you have this final rule in June of 1999, you're going to have to come up with Reg. Guides real fast, at least if there's another -- if another year goes by, by the time you have the Reg. Guides written, it makes the implementation of the new part 35 very difficult in July of 1999.

It would be nice if the Reg. Guides are completed in June of 1999 also. That's my point.

MR. COOL: I agree with you completely. The staff plans to have the Reg. Guides with the final rule and in fact, the drafts with the proposed rule for 1998 and 1999 such that when we publish the rule, the guidance documents that go along with it are there with it simultaneously. We do not want to have the scenario you just suggested where it's a year or more later before anyone figures out how they actually have to get there from here.

CHAIRMAN STITT: Dennis?

MEMBER SWANSON: Will the guidance documents include in addition to Reg. Guides inspection guidance and will we have a chance to see that?

MR. COOL: I believe that we will try to do that. The inspection guidance might be a little bit farther behind, although in my ideal world they would all be together.

We just have to see physically how much time there is. I'll be very frank with you, the rule is first. The licensing guidance that goes along with it is second and the inspection guidance that comes along with it is third. And ideally, 1, 2 and 3 all end up together.

CHAIRMAN STITT: All right, we're pushing 10 minutes behind, so I'm going to go ahead and ask Cathy to make a presentation. Thank you, Don.

MEMBER HANEY: I believe in the last meeting we had been to we had been given status on what we had done the previous recommendations that we had seen in July. So that's what I'm here to do now.

From the last meeting there were three recommendations. The first dealt with a recommended revision to the medical policy statement. You had proposed certain words to us. Those exact words are in your book if you look under the tab, but I'm not going to go through those right now.

What they did with that recommendation was to incorporate it as one of the alternatives for revision to the medical policy statement. The work considered that item and it became an alternative 2 in the package. We have a special section on just revisions to the medical --

(Microphone was turned on.)

There's a specific section of today's meeting dealing with the medical policy section, so I'll just end that discussion right now and let Diane pick up that when she starts addressing that particular item.

The second recommendation was that the -- we would continue the current regulatory approach for part 33. If you remember from the last meeting, advanced notice of proposed rulemaking was issued. We received public comments on the ANPR and some questions that were posed in it. We went through with the Committee what the public comments were. Since that time period staff has looked at part 33 and is in the process of preparing a Commission paper which would, it's basically our mechanism for getting information back to the Commission. One of the things that's being considered in that paper is to request that we not go forward with the rulemaking on part 33, that we address some of the concerns that got us to the point of the ANPR. We discuss that in guidance space.

In that Commission paper, we would forward the ACMUI recommendation so the Commission wouldn't know where we

stood on this. At the next meeting, I'll go ahead and commit to giving you a further update on where the 33 packages right, but that one will be moving along.

The last one had to deal with making modifications to the quality management inspection procedures. Our focus obviously the last couple of months has been with part 35 and getting these alternatives kicked off and the rulemaking kicked off. No action has been done at this point on making modifications to the inspection procedures so therefore I'll give you an update next time that we are here on that.

Does anyone have any specific questions? I'll be happy to go into more depth if you'd like?

CHAIRMAN STITT: Dennis?

MEMBER SWANSON: One thing that's missing on the agenda, you might address it now was we had expressed some concerns about the Reg. Guide for the Patient Release Rule. In fact, we were asked to give comment on that and I'd like to know what the status of those comments are.

MEMBER HANEY: Could you be more specific? The nature of the comments?

MEMBER SWANSON: There were actually when the Reg. Guide came out on the release rule there I think that they tended to be very prescriptive in nature and we pointed out that there were many comments in the Reg. Guide that

basically rendered the rule much more prescriptive than the rule was originally intended.

MEMBER HANEY: Those were comments on the draft guide?

MEMBER SWANSON: Right.

MEMBER HANEY: Okay, the final guide was issued. I believe it was in the March time frame. There were significant revisions, changes to it from the draft guide that went out. It did allow the licensees the option of using what was in the Reg. Guide or coming up with their own procedures and that was written into the Reg. Guide that they had the flexibility, where I think in the draft version that was not as stated as explicitly as it is now in the final version. I haven't addressed your concern completely, I don't think.

MEMBER SWANSON: No. I did express several concerns and I've never seen any response from the NRC regarding any of those concerns that we were asked to provide.

MEMBER HANEY: It was the meeting before last, wasn't it?

MEMBER SWANSON: No, I think it was the meeting before the meeting with the Commissioner.

CHAIRMAN STITT: Naomi, were you part of that?

DR. ALAZRAKI: No, I think that was -- I think what Dennis is talking about, I was not at that discussion.

MEMBER HANEY: Can I give you an update tomorrow morning? Will you give me until tomorrow to do a little bit of quick research?

MEMBER SWANSON: Sure.

CHAIRMAN STITT: There's a member of the public in the back.

MEMBER HANEY: I was going to introduce Barry when we got to the part 35, but let me go ahead and tell you, Barry is working as a consultant to the working group so he is here today as equivalent to a staff member, adding us with, providing us with guidance. So I give your introduction now.

MR. SIEGEL: This may not sound like a staff comment. I think a specific issue that relates to this regulatory guide, relates to the fact that the regulatory guide that was reviewed by the Committee had a two compartment model to evaluate I-131 elimination and retention and the Reg. Guide that was finally published included an ersatz three compartment model in which it was assumed that some 20 percent of the radioactive iodine was essentially not eliminated during the first eight hours or 80 percent was not eliminated during the first eight hours and there's really no biological basis. In fact, for that kind of an assumption it just doesn't make sense and it was unclear how that alteration among a few others crept into the Reg. Guide after it had seen public comment.

CHAIRMAN STITT: So that is what the Committee is asking for a response to, is that correct? Where did that come from, since we'd never seen it.

MEMBER SWANSON: I think some of the other areas that crept in the final Reg. Guide that we didn't see were specific tie downs as to occupancy factors or contact factors, etcetera that you had to include in your calculations and as I said, it all of a sudden became very prescriptive in how we address patient release.

MEMBER HANEY: All right, well, let me see what information I can get and maybe if time permits tomorrow morning we can take a couple of minutes and I'll have a little bit more for you by then.

MEMBER SWANSON: The AMCUI was specifically asked to provide comments on that and it's a variety.

MEMBER HANEY: All right.

CHAIRMAN STITT: Okay, you want to go on?

MEMBER HANEY: Yes, let me do that. I'm going to step now into the evaluation of the Committee membership and the Committee. These documents are in the SRMs that I'm going to reference are in your package. There's a tab there. I don't think I'm going to be doing it in the order that it is behind the tab. I'm doing the easier ones first.

I'll give you the opportunity to find it. If we're referencing SECY 97-143, in that package, we went -- in

the Commission paper, we asked that certain members of ACMUI be reappointed. The Commission came back and said yes, go ahead, we agree with you. You can reappoint those individuals, but then they added a few extra items and those are the items that I just wanted to bring to your attention now.

One is that they asked on future reappointments that we add into the Commission paper a brief performance evaluation of that individual. They also asked that we allow ample lead time for the Commission to make reappointment decisions. In other words, they didn't want us turning it in and asking them we need to know week whether this person can be reappointed or not.

They ask that we consider the appointment of a radiation safety officer with health physics experience at the next earliest opportunity. The next earliest opportunity is when we go out to solicit nominations for future positions that would be opening because we need to do that by a Federal Register notice. But they also asked that in the interim period that for the purpose of discussions on part 35 that we ask someone with that type of experience to attend the meeting. Because of this particular item, we contacted the Health Physics Society, asked if they could have someone attend the meting this time and that's why we have an added member here today as an invited guest.

We did it rather short notice for the Health Physics Society. Unless I hear an objection what we will do is probably send a letter to the Health Physics Society asking them if they can appoint someone that would be just act as the invited guest to this Committee until we have a formal, until we formally evaluate whether a radiation safety officer should be seated on the Committee.

The next thing in that SRM was that they asked after part 35 is completed that we evaluate the composition of the ACMUI and what they're looking for there is to determine if changes are needed to meet the needs of the Agency as we implement the revised rule and the medical use program. That particular action for us, we have got due dates associated with everything. It's not due until the Year 2000. So that is something that is further on down the line, but I just wanted to bring it to your attention so that as we go through this process the next two years, that it's something that you are considering.

Any questions on that particular item?

(Pause.)

The next one I'd like to discuss is 96028. Again, it has somewhat the same thought in it, looking at the evaluation of the ACMUI and their particular role. In this document we were instructed to reexamine the role of AMCUI following the determination of where we would go with the

materials medical program. This is what was the DSI-7 where we got to at the last meeting.

We will need to go back to the Commission, again via a Commission paper with statements regarding the role and at this point, the document is due back to the Commission in December of this year. The due date was 180 days after we received their decision on the DSI-7.

One of -- what I'd like to put on the table right now is does the ACMUI have any preliminary thoughts on what you would like to see going into this paper as well as is the timing correct, given the previous SRM that really almost and the next SRM that I'll discuss that really have put you as a very key organization in reviewing along how we're doing part 35.

So the question is is the timing right for this? Would you like us to make any statements regarding the timing and then as swell as what would you like in the paper? Wide open.

CHAIRMAN STITT: I think you've got us overwhelmed here. Does the Committee have any comments. I think our minds are sort of geared up to starting with all these options.

MEMBER HANEY: We just wanted to throw you off a little bit.

CHAIRMAN STITT: I see.

MEMBER HANEY: And if -- I know this is kind of catching you off guard with this. It's something we can handle in the next couple of months if you'd rather not discuss it right now, that's okay. I'm looking, actually probably my key thing, do you see the timing as correct to be examining the role of the ACMUI.

CHAIRMAN STITT: The timing -- you're supposed to send something back in 180 days you said?

MEMBER HANEY: Right, which the 180 days is December of this year.

CHAIRMAN STITT: Naomi?

DR. ALAZRAKI: I guess the question relates to the fact that until the regs are completed you really don't know what the involvement of NRC is going to be in any of these programs and therefore what's the role of ACMUI, how can we say what the role is until we know what the regs are.

All my initial reaction to that is as long as there is any role whatsoever of the Nuclear Regulatory Commission in regulating in any way radiation safety and extensions thereof in medical centers, there's an important role for ACMUI. So ACMUI should be involved in anything that NRC is involved in or thinking about that relates to functions in handling radioactive materials in medical centers.

CHAIRMAN STITT: Other comments? That's a nice summary statement. I think it's hard to become very detailed

when we've got these other things on our agenda in front of us. December is a short time before anything more expanded.

Dennis, did you?

MEMBER SWANSON: Well, I'll comment. The role of this Committee is already pretty well defined under our charter. So I'm not sure why we're going to spend a lot of time on this.

CHAIRMAN STITT: And Jeffrey, why did I think you were probably going to have your hand up?

MR. WILLIAMSON: It's not clear to me what the issues are from NRC's perspective or the Commission's perspective, so it's hard to respond.

MEMBER HANEY: During -- my understanding is that during the strategic process that we went through a couple of years ago, one of the items that we ere looking at was all the Advisory Committees across the board and the next SRM that we're going to discuss and again you may want to defer some of the discussion on that also. Really, ACMUI got thrown in with all the other Advisory Committees and these are things that we are doing across the board and therefore this discussion.

CHAIRMAN STITT: I'd like to ask that Naomi make a motion out of her statement because we've been asked to make consensus statements in the form of motions where we can and I believe we ought to act on this.

Would you do that, Naomi?

DR. ALAZRAKI: Well, I would move that it is the Committee's view that ACMUI has an important role to play in any activities of the Nuclear Regulatory Commission which relate to regulatory of radiation safety and extensions thereof in the medical community.

CHAIRMAN STITT: Naomi, I'm asking John Graham to make that motion since the feeling is --

DR. ALAZRAKI: That's right.

CHAIRMAN STITT: I'm not sure that you can make a motion.

Did you listen well enough, John?

MR. GRAHAM: Could you repeat that?

CHAIRMAN STITT: Yes. Can we do that? Can we second that? Does anybody know Robert's -- is Robert here?

MEMBER NELP: I will second.

CHAIRMAN STITT: Okay, so we have a motion and second. Discussion?

MEMBER SWANSON: Point of discussion. I'm not sure that's what the Commission is asking us for. They're asking each Committee to produce a set of criteria under which it performs the Committee will be evaluating in the future. I don't think the questioning is contained in the existence of this Committee.

CHAIRMAN STITT: The point is this is just a very general --

MEMBER HANEY: Well, the SRM does go on to -- and Dennis brought this up, it does go on to say that we need to produce a set of criteria for the Committee and then the Committee should periodically review itself against this. Now that particular action is not due until March of next year. So that's further off. And that might be something that we could help you by at least bringing you a rock and letting the Committee work from there.

CHAIRMAN STITT: This is only a portion of a 15-minute discussion so we can't develop a program here. I think if we can do anything at all it's to make a statement and if we can't do that, then we'll move on.

John, did you -- we're still in discussion phase of a motion in front of us.

MR. GRAHAM: I think this is in follow-up to Dennis' earlier comment, possibly if you could discuss this with Dr. Cool to whom this Committee reports and provides advice.

In affirming the useful role of the Advisory Committee in the medical use of isotopes, as long as the NRC has any active involvement in the review of the medical use of isotopes or patient safety or radiation programs anywhere in health care, the frustration that continues to get discussed and the clarification that would assist this Committee in its future actions is the feedback mechanism, feedback from the

staff and/or feedback from the Commissioners. It is only when this Committee has spent hours and solicited outside medical opinions and come up with a consensus which clearly from my perspective as a lay member of this Committee represents a balance of medical opinion and then the final regulations as published ignore that recommendation, having gone through an extraordinary process of due diligence, that we begin to question who is it that we're advising and why.

So it's this feedback that in this entire process of the next two years, we're going to go through what Dr. Cool described as as continuous development and revision process, if there's no feedback mechanism, we won't have a clue as to whether or not we're recommending an option which is in favor, out of favor and/or the why of it. I don't think this Committee has ever objected to the fact that staff walked back in and said we don't agree with you, but that feedback is the essential missing element.

MS. ROTHSCHILD: Cathy, it's Marjorie Rothschild from the Office of General Counsel. I just wanted to note in regard to the comment about the Committee's charter that that has to be renewed every two years and we believe it was last renewed in April 1996, so I think the date of April 1998 is relevant that this may not necessarily be set in stone because that charter has to be renewed periodically. I just wanted to note that.

MEMBER HANEY: Thank you.

CHAIRMAN STITT: Other comments from the Committee?

Ready to vote? Everybody know what the motion is?

All those in favor, raise your hands? Let's see. Okay, those opposed? All right.

Next.

MEMBER HANEY: The next SRM that I would like to discuss is the one that came about that was directed to the ACMUI after your briefing with the Commission and this gets us a little bit closer to the part 35 issues that we have. Again, the SRM is in your briefing book, if you'd like to look at it. What I would like to do at this point is to bring to discussion some of the questions that were posed in that SRM. There were four sets of questions and in each two of the four are more of a general nature. The last two that have to do with events and the thresholds for evaluation, I'd like to hold those until tomorrow's discussion on patient notification and the threshold for then. I think it would be more appropriate there.

However, I'd like to maybe spend a couple of minutes talking about the first two questions there. The first one dealt with the industry standards and again, we've touched on these at previous meetings, but just if we could

maybe run through some of these questions and just hear your views again. In the case of -- and you have a copy of this in the handouts that were placed on your desk in front of you this morning of these vu-graphs. They're also in the SRM that if you would like that.

I'll read through the three questions and then you can address them as you'd like. The three questions that were under number 1. First is how should NRC determine which industry standards, including voluntary ones are adequate to meet the NRC's regulatory responsibility for patients, worker and public safety? To what extent should NRC allow the licensee flexibility in interpreting or selecting an industry standard? And how should the concept of quality improvement be incorporated into reliance on the industry standards and accreditation type of approach to licensing and inspection?

CHAIRMAN STITT: You want to open that up?

MEMBER HANEY: Yes, that's what I'd like to do at this time.

CHAIRMAN STITT: I'll just remind you folks that we've spent a long time -- I actually think maybe we're making some progress. I could swear that some of the things that we offered up and spent a lot of time putting together to offer to the Commissioners are starting to come back to us.

We have reviewed each of these in some details. Are there comments anybody would like to make about industry standards to start off with?

We could do this for an entire day.

MEMBER HANEY: Well, that's what -- yes.

CHAIRMAN STITT: That's what bothers me about --

MEMBER HANEY: I have that question I'd like to spend the morning session on and then the other one -- let me just go through the second one real quickly and then you can decide how you want to spend your time. I think we have until 10 o'clock on this, this section?

CHAIRMAN STITT: That's right.

MEMBER HANEY: The other question I'd like to get into this one is what are the necessary transition steps the NRC should take in order to implement a more positive enforcement program that, in fact, encourages or rewards good performance while addressing the outliers?

The other one is what metric should the NRC use to decide whether the approach is working? One aspect of this question that's particularly important and I'll touch on that in the session after the break is that the part 35 working group added into its charter one of the items of reviewing the enforcement policy associated with part 35. So your comments on this one will be useful to the Commission, but also very

useful to the working group in meeting that particular, addressing that time of its charter.

So those are the two key areas of that SRM that I'd like to address, I guess now in the next 25 minutes. So at this point I'll go sit down and leave it up to the group to discuss it.

CHAIRMAN STITT: All right, do you want questions 3 and 4, or sections 3 and 4 to be left alone for now?

MEMBER HANEY: Well, 3 and 4 in looking at it are very tied into tomorrow's presentation.

CHAIRMAN STITT: Right.

MEMBER HANEY: Rather than get into a fragmented presentation, I think I'll leave those to tomorrow.

CHAIRMAN STITT: Okay, I think that helps to focus us. Can we have a little light whoever is in charge of the lights? We're losing some members here. It's not even late morning.

All right, so our task until 10 o'clock is to look at the sheets of paper that discuss or that have questions about standards, how to interpret standards, how to measure and issues regarding enforcement.

So let's just start down this end of the table.

Dennis?

MEMBER SWANSON: Cathy, maybe you can answer this. With regard to Question 1, "How should the NRC

determine which industry standards, including voluntary ones, are adequate to meet the NRC's regulatory responsibility?" are there barriers to the NRC actually working with professional groups in the mutual development of their standards?

MEMBER HANEY: Not that I know of. Marjorie is with our office of General Counsel.

Are there any barriers to NRC working with professional societies to develop standards and then we would, in fact, endorse -- put them into our rules space, our reference and guidance space.

MS. ROTHSCHILD: The only thing that I can think of offhand is possibly the Federal Advisory Committee Act. That probably would be applicable. It wouldn't necessarily mean it couldn't be done, but if it were done and the Federal Advisory Committee Act was applicable, then it would have to be done in conformance with that statute.

MEMBER HANEY: To do it in conformance with that statute, basically just a public forum?

MS. ROTHSCHILD: Well, it's a little more detailed than that. I think we have regulations in 10 CFR that deal with Federal Advisory Committee Act and those are more detailed. That would probably -- being public might be one of the criteria, but there's more than that.

CHAIRMAN STITT: Dennis, did you have any further suggestions on how that might work?

MEMBER SWANSON: Well, I think to include the NRC as in the active discussions and formulation of the standards of the professional groups is actually a way to address your issue 1. That gives the NRC assurance that things they think are important are addressed and that was the purpose of the question. I think, in particular, as you get to things like training and experience requirements where you're going to want to recognize the standards of professional organizations, it's going to be particularly important that the NRC is involved in the development of those standards as it relates to the radiation safety of occupational workers and patients. And again, I think by the NRC being actively being part of that process, it will give you the assurance that your issues are covered.

CHAIRMAN STITT: So rather than being an act and react, you're saying can we kind of discuss this together.

Several Members here are on these different scientific panels. Can I just ask for a response to that?

MS. ROTHSCHILD: Dr. Stitt, could I just one thing before you continue. On the previous question about working with professional societies, two additional points. One is that if the Committee or group is subject to Federal Advisory Committee Act, one of the main things that they would need would be a charter. If you have -- and also approval by OMB. The other thing is that if you -- if there were a group

and it recommended that certain standards would be relied upon, NRC couldn't just adopt those. That would basically be subject to whatever the requirements on rulemaking most likely.

Thank you.

CHAIRMAN STITT: Go ahead.

MEMBER FLYNN: See, there also could be a problem if you dealt with one professional society to the exclusion or gave one professional society some special standing and other professional societies an observatory role or had some members of the general public given special standing and other members of the general public either excluded or not given the same standing. That would be the problem. But the way that I would see it is that if you look at the regulated community, for example, let's say in radiation oncology. If you're looking at professional organizations and societies, you can, for example, in some way determine which organizations' membership comprises the majority of the regulated community on that issue. So in radiation oncology, there may be three or four major societies. Maybe there's one more specifically for brachytherapy, American Brachytherapy Society. So that society has the vast majority, 95 plus percent of those that do brachytherapy. But so does ASTRO and a subject ACR, which has a much broader membership as does American College of Radiation Oncology, so that I think if the majority of the

regulated community are members of that society, that limits the number of societies right there, that if over 50 percent of the regulated community is a member of that industry, if you will, that society, then that limits the number of societies. Then otherwise, you could have a real laundry list of organizations that would be hard to sort out.

CHAIRMAN STITT: Much of the membership is overlapping and it's a very small laundry list.

Jeff and then Lou.

MR. WILLIAMSON: Well, I think you know the first question, how should NRC determine which industry standards including voluntary ones are adequate or at least potentially adequate. Certainly, it would be possible to ask, for example, this Committee, which societies to our knowledge are the most prominent and relevant ones for a given rule making activity and I think just through some process of soliciting input from the regulated community, I think you could, with a relatively small amount of effort focused on research, collect a finite number of documents that would make, be relevant to a given activity such as the revision of part 35.

I think there's lots of issues involved in how might these documents be included in, to use Larry Camper's phrase, quote unquote regulatory space. One could make lots of statements. One would be I should think that one would not want a regulation that conflicted with what appears to be

consensus statements of the community, what's important for maintaining, for example, patient safety. I think you would get an awful lot of information and background if you were to review some of these documents, especially concerning NRC's efforts to regulate safety of patients and quality of treatment rendered to patients. One of the central problems we have with the current regulatory system is there are a lot of conflicts between some of the more prescriptive guidance documents and regulations that exist. For example, for remote afterloading brachytherapy, there are very serious conflicts between some of those documents and the industry standards that most institutions attempt to follow.

CHAIRMAN STITT: Lou Wagner.

DR. WAGNER: I think there's an implicit problem, in my opinion, in just in the way the question is worded. The biggest difficulty that I see is moving what a professional organization might write as a standard recommendation, a policy, whatever, into the regulatory process and the enforcement.

Much of what the professional communities do are recommendations to individuals, but no one is bound by them so there's flexibility. When these policies move in the process into a regulatory community, it becomes law. You've got to do it. Now the flexibility is gone. Much of the recommendations that have been made are the policies that have been set up.

And therein lies a lot of the conflict with regard to the writing of regulation on the basis of standards. There's no transition there to look at the regulation and now say okay, if this enforces the regulation, it means everybody has got to do it and how is this going to hamper everybody? Is it really going to apply across the board? Is this really important to do for everybody? What kind of flexibility should be built into it? I think therein lies much of the problem with the regulatory process, is we look at the standards. We adopt that standard and then everybody has got to do it. Well, before they become the regulatory process and a regulation, we really have to investigate whether or not that standard put out by that society should apply to absolutely everyone or what flexibility should be built in.

So I see the problem not so much as the standards, I see it as the process of moving those standards from that to the regulation and the enforcement of that regulation, once it is made a rigid rule.

CHAIRMAN STITT: Excellent point and that's the second statement on this first page. I was involved in the AAPM Task Force 56 which was what, high does rate? I don't even know the title.

MR. WILLIAMSON: Brachytherapy physics code of practice.

CHAIRMAN STITT: Right, not being a physicist, it was a pleasure. I'm going to actually have my name in the Journal of Medical Physics, I've socked on to these guys who really know what they're doing. But I was there as the clinician and it was very impression to me that we would write an initial draft and then send it out to the physics community and I do mean community. All sorts of institutions, different sizes, different geographic areas and we would have these long, long, long conference calls about this very thick document and what was the standard for me couldn't even be approached, couldn't come close in, I don't know, somewhere, Texas, just to pick on your state. And it was very impressive to me that my standard was not somebody else's standard so then you try to take up something that's been written down. So we therefore made modifications in 56, but the hazard is then putting that into a regulation and saying this is the black and white, this is what you'll follow and then all of a sudden, Clinton, Iowa, does not do the same thing that Madison, Wisconsin does and therefore, they're in trouble. So the flexibility issue in the second point is very difficult.

I'd like to ask for more comments, particularly regarding that. Starting down this row, Naomi?

DR. ALAZRAKI: One of the things that societies, professional societies do when they issue whatever policy statements they're going to issue which we might want to look

at, is that sometimes they're pretty parochial, but when multiple societies buy in to the same policy or guideline or whatever it is, then I think it has a lot more significance and in terms of what NRC might feel about it because it means that multiple groups and each of these societies, there are differences in their compositions and in their interests. For example, if the American Society of Nuclear Cardiology issued some guideline and the Society of Nuclear Medicine and the American College of Radiology bought into that, that would be a lot more meaningful and have a lot more weight behind it than just something isolated that the American Society of Nuclear Cardiology might have approved. So I think that might be a factor in terms of how we would evaluate anything.

CHAIRMAN STITT: Anybody else down this line while I'm looking this way?

I think our goal between now and 10 is to just get some comments into the record so those who can read, will read them.

Theresa and then Will?

MS. WALLCUP: I'm just wondering if it would be prudent instead of specifically defining which industry standards, that that would be left up to the facility that they feel best and then because the second part of the medical policy statement says "the NRC will regulate the radiation safety of patients where justified by the rest of patients and

by voluntary standards or compliance where these standards are inadequate." They don't specifically, they're not specific in that statement either and if you can back it up by your quality improvement program, to me, that would be more flexible.

CHAIRMAN STITT: Will?

MEMBER NELP: My comment is I think anything of this nature would go into guidelines and not into regulations. I would presume it would refer you to how to implement the rule using a guideline which would be a voluntary standard and I think this discussionis fairly pretty mature because we really can't answer then until we see what the rule changes are going to be. I think we can get very sidetracked at this point trying to go down this pathway before we hit the rules and see what changes are going to be actually solidified, if any. So this will come out when we make the rule.

CHAIRMAN STITT: Three comments down the row and then I'd like to -- we've got 10 minutes to talk about the second page, which is enforcement.

Jeffrey, you're going to be the last one to comment. You, in particular, had brought up accreditation type of approach when we talked with the Commission, so I'd like you to make a comment on that.

Lt's start with Ruth, then Dennis.

MS. McBURNEY: Someone involved in the rulemaking process, myself, I know that it is very difficult to when you go from a voluntary standard such as the NCRPs or ACR guidelines, that a lot of time they should and try to fit that into a regulatory mold where you say "shall."

It's much better to address what is your outcome that you're looking for, a performance end point and simply make the rule itself address that, and like Lou said or maybe you mentioned that what applies in a large, major institution could meet all those voluntary standards and have a gold standard, whereas a very small facility with limited resources could not meet that, but what we need to put into regulation is the minimum standard and also the end point, what the performance outcome could be.

CHAIRMAN STITT: Dennis?

MEMBER SWANSON: I just wanted to comment on Dr. Nelp's statement. In fact, the regulatory statements will refer to standards because they do refer to the certification processes and certification examinations are based upon the standards of practice, so in fact, it does appear in regulatory language with reference to the standards.

CHAIRMAN STITT: Jeffrey.

MR. WILLIAMSON: I'm glad you invited me to comment on the issue of enforcement and accreditation. I really think that this is another very critical aspect to

determining how society professional standards might fit into regulatory space. I think if you take examples, look at some of the AAPM standards which are very technical in nature and address either the accuracy of treatment delivery, largely, they're in many ways far more prescriptive in some ways than any regulation perhaps, you would dream up, but built into these documents is our statements, the need to exercise clinical judgement and flexibility and tailoring a program to the specific institution.

CHAIRMAN STITT: Jeff, I want to jump in -- I have a comment that's complementary. You're referring to those standards that are very detailed. A nice companion piece to those is American College of Radiology, low dose rate, high dose rate, brachytherapy standards, that really come, address the same issues except purely from the clinical viewpoint. So if the NRC is to take these documents, look at them in parallel, see how they overlap, they could address the first statement of number 1.

MR. WILLIAMSON: I think the problem is is if you have a regulatory model, enforcement model that says there are specific laws you must do all of these specific things and every incidence of violating one of these specific rules will be punished no matter what the overall quality of the institution is, then you've got a problem trying to incorporate any industry standard into a living clinical

practice. If, on the other hand, you try to look at it somewhat from the perspective of clinical judgment how we as the regulated community would see it, we see it as road maps, as broad plans for helping to build a program that has overall good quality. We don't fire or dismiss our employees, if they make single errors. We attempt to correct things and we basically look at overall quality. That's the main aim and that is a far more important indicator to us is trying to run a successful clinical practice than avoiding 100 percent of the time all infractions of our quality assurance rules.

So I think if you adopted an enforcement model that was more of accreditation type where the regulatory end point would be some measure of overall program quality, you have a good practice, okay, good, you're licensed for a while to continue practicing your subspecialties until the next inspection. You don't pass, you have a bad program, there are central elements of minimal quality assurance programs that are missing or dysfunctional. There aren't qualified staff, etcetera, whatever the reasons are. Rather than basing it on specific infractions, whoops, you failed to calibrate your cobalt source within 30 days and did it at 31 days. That's not a measure that's not relevant to the overall quality of the program. So I think if you could sort of turn it around and make your standards for good program performance, be more compatible with those that are existent in the community,

there would be a lot less dissonance than conflict and I think you'd be overall a more positive force in trying to keep the, get the outliers closer to the mean in terms of good versus bad programs.

CHAIRMAN STITT: Nicely put.

DR. KANG: In regard to the standard, at FDA what we are doing, I guess I'm not speaking for the entire FDA, but in the device section-wise, we do not really want to develop our own standards, just exactly the reason what Mr. Wagner said. We do not want to mold the standard to make the manufacturers abide. So we are trying to recognize the voluntary standard. There are several international standards as well as United States national standards. The organization in an example, like IEEC, developing international standards in Europe and the national manufacturing associations standard for the device. Again, we just simply are trying to recognize and not adopting as our own standard, so that it all depends on the manufacturers. How many, the majority of the device manufacturers, are following which standard? If that majority of the manufactures are following certain standards, then we try to adopt that standard as a recognizable standard.

If the FDA has a need to evaluate the device or the drugs, so as long as the voluntary standard meets our requirement, then that voluntary standard can be acceptable.

Again, it is up to the user which standard to follow. We are not forcing the manufacturers to follow exactly certain particular standards, so that we are considering mostly what IEC, the manufacturers of European countries usually follow the IEC, recognize IEC and United States, the manufacturers in this country usually follow our national manufacturer association standard. So both of them are acceptable for us.

CHAIRMAN STITT: But those of us who love regulation are a little bit nervous with the FDA having loosened up on everything now. It's a joke, Andrew.

Barry, we need to give you a flag so you can -- you were throwing the yellow flag a minute ago, right?

MR. SIEGEL: Just a comment. In way, I would probably answer this rhetorical question with a rhetorical question.

CHAIRMAN STITT: Sounds reasonable.

MR. SIEGEL: Which is how does NRC determine that industry standards, including voluntary ones are inadequate to meet its regulatory responsibility for patient, worker and public safety? Isn't that really the issue? Is where does one set the bar and why was the regulation made in the first place? Was the regulation made in the first place because it was concluded that the industry was sufficiently immature, that it had to have prescriptive requirements imposed upon it

or was it made and that then became standard practice or was it made in reaction to a single, adverse event, so-called government by yo-yo. I finally get to get that in. And I think that if you look at that and think about that that really the question is where do you want to draw the bar? How mature is the practice these days and if it is clear that things that are part of regulations have become part of routine practice, that that should be an indication that they no longer really have to be part of the regulations. I've suggested once in the past or twice in the past that there's the old story about the person who wears -- a person who lives in the United States who wears an amulet to ward off tigers and when questioned about why because there are no tigers, the person concludes the amulet is working. And to some extent, NRC regulations can be viewed in the same way. We have no infractions because of the NRC regulations or in fact because this community is practicing to a high level of practice quality.

So I suggested once to Chairman Selin that he should be a randomized control trial where you took have your licensees and gave them no regulations and the other half, continued the regulations and then looked to see what the event rate was in the two sets of licensees. That would be a way to determine whether or not voluntary standards or mandatory standards were, in fact, achieving their goal.

CHAIRMAN STITT: Barry, you should be sitting in this chair. You still are better than anybody else. I think it was very clearly pointed out to us that the reason radiation medicine is in good shape, the Commissioners tell us is because they're doing their job well and that was maybe not this last meeting, but certainly the one before that. So that's the answer to your question. It's the amulet.

Okay, one comment on my part and then John has a comment. Barry, your rhetorical question to the rhetorical -- your rhetorical answer to the rhetorical question is interesting and I would say that since I've been on this Committee, both as a Member and then the Chair, the issue of voluntary standards has changed across at least the therapeutical radiology societies. There were very few standards. Probably the physics group had most and they tended to deal with external beam types of treatments. Just over the recent years there are a number of standards and I'll just confine it to radiation oncology having to do specifically with all sorts of therapeutic isotopes that we use. So there's probably some of both sides, both camps in this. I think that now there are standards that were never there before that should the NRC want to use them are adequate to meet NRC's regulatory responsibility.

It's not your turn. Okay, go ahead.

MR. SIEGEL: I guess there are really two issues. One issue is can an industry standard be given deemed status in the regulations where you would say that the licensee, in order to meet this regulatory requirement, shall comply with the standards of ANSI or shall comply with the standards of ASTRO, whatever it is, or the AAPM. That's one issue because that is, in effect, taking an industry standard and making it a regulatory standard. A separate issue that I really was addressing is how you determine whether there is a need for a regulation.

CHAIRMAN STITT: And then the other important view of that is how do you interpret that if you're the NRC and what's the flexibility. John, it is your turn.

MR. GRAHAM: I guess to concur with Naomi's earlier comment, I think that any standard that this group would recommend on to the NRC has to have a pluralistic background to it. The potential use of stints that would include radioactive material, I think, will be a concrete example where there's going to have to be a very broad review of how the criteria for the use and the implanting of those devices should occur.

I think we've spent an extraordinary number of hours discussing Barry's rhetorical response to the rhetorical question and should reiterate that we have proposed formally to the Commission in the past that the assessment of the risks

justifying such regulations will reference comparable risks and comparable modes of regulation for other types of medical practice and we went on to say that the NRC will not intrude in the medical judgments affecting patients and into other areas traditionally considered to be part of the practice of medicine. The fundamental role of this Committee is to continue to remind the NRC that there's a practice of medicine, there are voluntary standards and groups that review those standards that have developed a state of practice of medicine that is higher than any other country in the world and that there has to be an overriding concern about the risk to the patient, worker, public safety before any regulation is promulgated.

CHAIRMAN STITT: I'm going to call a break. You put that beautifully and in fact, those specific things that you brought up are later in our agenda and we'll be discussing them in detail. We've got a tight agenda. We need to be back at 10:15, so I'm going to stp this discussion.

(Whereupon, the proceedings went off the record at 10:05 a.m. and resumed at 10:22 a.m.)

MS. HANEY: You have copies of what I am going to be putting up. Some of the items are redundant with what Don Cool said this morning, so either I will not go through those again or I will go through them quickly. For some of them I have a few more details than Don had.

As far as the Working Schedule that you see, this is the Part 35 Working Group Schedule.

Don mentioned that we had until June to get a final document. Knowing that once we start documents into concurrence they tend to come back for some minor changes, so we are working internally against a May date.

As Don mentioned, once we got the SRM direction to go ahead, in the June timeframe a writing group was formed to develop a rule based on a modality-based approach. This is the composition of the writing group that was formed.

The group went forth and developed documents for each one of the modalities that we had identified. It would be a document that would be a stand-alone rule for that regulation.

These documents went to the working group and were considered by the working group and I will touch on that in a little detail. Suffice it to day at this point that we ended up with about three and a half inches of paper going to the working group on just the modules.

In August, the working group had their first meeting. Again, these are the people on the working group. I think that it is important to note that we have regional people on the working group as well as two representatives from the states.

These individuals are coming to us from the CRCPD and from the Organization of agreement states. In particular, David Walter is on what CRCPD calls the SR-6 Committee. This is the group that is writing and is responsible for writing the equivalent regulations for the suggested state regulations.

So, he is more or less our liaison with that particular committee.

One of the items that we did during our meeting in August was to come up with a charter. You should have a copy of that charter. I am probably not going to be able to see it up here, nor am I going to go through all of the items.

Basically, it says that we are going to go forth and write and draft the rule. We will work with a steering group to do that. We also will be looking at the enforcement policy.

At that first working group, we came up with an outline for Part 35. This was recognizing that we really couldn't have a document that was about three inches thick going into the Rule.

In reviewing the modalities that the working group had written, we found that there were very many common things throughout the document. It became very repetitious to use. It also was not very user-friendly for a licensee where they would have multiple modalities.

So, we came up with this tentative structure for keeping the Rule.

A key difference from the current Part 35 is the recording keeping and reporting sections. What we are going to be doing is taking all the requirements for records and putting them in a stand-alone section. For those of you that are familiar with Part 20, it is following the same approach as in the current Part 20.

At this meeting, the working group also came up with the first version of the alternatives, which you have, and we will leave the discussion of those for later on.

The product of that first meeting went to the steering group the first week in September. These are the members that are on the Part 35 steering group. Again, do note that we have the involvement of the states on the group; Tom Hill who is currently with the State of Georgia.

The steering group reviewed what we had done. They, in most cases, asked why we did some thing the way that we did it. We had to justify how we came up with our particular alternatives. Why, in some cases, we did not consider other alternatives.

They also tended to add a new alternative. In some cases they went a little bit beyond what the working group did so we had to make some changes to those documents.

In fact, that is the document that you have in your book right now.

We plan to solicit input on these documents via three mechanisms. One is meetings with professional societies. Another is with public meetings; Don mentioned these. Then, also, through the Internet. These documents will be going on the Internet.

Basically, we have a chat room set up so that people will be able to write into us to give us comments on the Rule.

As far as professional societies, who we have met with, these are the organizations that we have already done presentations for: The American College of Medical Physicists, American College of Radiology, Oncology Nursing Services, and the American College of Radiation Oncology.

Those have been done to date. These are the organizations that we are currently scheduled to meet with: The American Association of Clinical Endocrinologists, American Hospital Association, American Society of Therapeutic Radiology and Oncology, American College of Cardiology, and on down. I am not going to talk as much.

The public meetings, Don referenced the dates here and the location. A *Federal Register* notice will be going out informing the public of these meetings.

As I said we have access through the Internet and that is the location on the Internet where you will be able to find these options papers.

CHAIRMAN STITT: Cathy, can I ask a question?

MS. HANEY: Sure.

CHAIRMAN STITT: On your list I don't see AAPM. I see the college. I see the American College of Medical Physicists.

MS. HANEY: These are the organizations that contacted us. We did a mailing to all of the organizations. I know that we did pick AAPM.

MEMBER FLYNN: ADS also?

MS. HANEY: I can't confirm that we did that one, but I am pretty sure that we did.

CHAIRMAN STITT: What are you shaking your head at?

MEMBER WILLIAMSON: They did contact the ADS board.

CHAIRMAN STITT: Okay. How about AAPM?

MEMBER WILLIAMSON: I don't know.

MS. HANEY: And we just to date have not gotten a request from that organization. So, if you do have contacts with that organization you might just want to give them my name and ask them to call. We will be happy to come out and visit.

MR. COOL: Let me add to that. I think, in fact, there has been a contact. In a couple of cases we missed the window for the meetings because of when we got started.

So, we may not have them scheduled in because of scheduling conflicts and some of that sort of stuff because what we asked for, initially, was an opportunity, at the mid-year or annual meeting, be able to interact so that we would be able to interact with a fair number of folks.

Unfortunately, some of those have not been able to line up on schedules. I am quite confident that AAPM was on the list that we sent out to. So, we are still in the process.

CHAIRMAN STITT: But their meeting probably came right at the wrong time.

MR. COOL: I think that is what happened.

CHAIRMAN STITT: Fine.

MS. HANEY: As far as where we are going from here, now that we have gotten these documents out into the public for comment, the working group is going to start looking at the Rule language associated with items not covered by these options.

So, we will be starting our thinking process now for what the proposed Rule should look like.

We are working toward a December meeting of the working group to really get into the nitty-gritty of the Rule.

And to also come to a conclusion on which alternative will go forward in the Rule.

Once the proposed Rule is issued, it will be out for a 75-day comment period. During that comment period there will be two more facilitated public meetings. And again, we are working toward the final Rule in the Spring of 1999.

I will take any specific questions.

CHAIRMAN STITT: Okay. We have one hour to discuss the Medical Policy Statement, something that we seem to feel strongly about.

So, let's address any final questions to Cathy before that presentation.

Any comments or questions?

DR. ALAZRAKI: The meetings with professional societies, I don't see a meeting with the Society of Nuclear Medicine on here. Is there a reason?

MR. COOL: Dr. Alazraki, that was probably an omission. I spoke to SNM at their June meeting in San Antonio.

DR. ALAZRAKI: And a second question on the public meetings that you have. Some of them are two days, one is one day. What is the difference? And who goes to those meetings, who conducts them?

MS. HANEY: Chip Cameron is working at the facilitated public meetings. I guess the best thing is if I

just turn it over to him and he can provide the Committee with some information about those meetings.

MR. CAMERON: Sure. Both meetings are two and one half days each. There are two public meetings. One is in Philadelphia and one is in Chicago, both for two and a half days.

I am in the process of convening the meetings now which means to ensure that the right people are at the table, that all the interests are represented, that I hear about what the concerns are of those interests.

I have been working with a number o the associations, boards, societies, colleges, whatever, in terms of recommending people from their interest group to be at the table.

The challenge is to keep the size of the group around the table manageable so that we can have a through discussion of the issues. But also to ensure that all the discreet interests out there in the medical community are represented.

MS. HANEY: And then I can address the difference in the length of the meetings. The two meetings at the bottom are what we have been calling the facilitated public meetings. The meeting at the top is we have a workshop at the all agreement states meeting, so that is, in fact, a public

meeting. But it is not equivalent in nature or purpose as that of the facilitated public meetings.

DR. ALAZRAKI: Then Chip Cameron brings this back to the working group?

MS. HANEY: The working group will be at those facilitated public meetings, to listen to what is said.

CHAIRMAN STITT: Dan?

MEMBER FLYNN: On this proposed outline that you had on the modalities specific sections, you had eight different modality sections, is the working group divided up so that several people work on each sub category, or is it one person for each category? How does it work?

MS. HANEY: Right now it is one person per modality. But that isn't to say that a particular staff person has expertise in multiple areas that they aren't adding support to another group.

What we had wanted to do was to have one key individual responsible for that particular section and then to present it at a meeting like this to the working group for discussion.

What I anticipate happening, too, is that a similar breakdown will occur with the guidance development. In the December timeframe, the focus will be on the Rule and in the January timeframe, the focus will be on the guidance.

What I would like to see happen is some kind of subcommittee of the working group be developed that would be working on guidance in parallel to the main group working on the rule.

DR. CERQUERIA: At the agreement states meeting will there be opportunity for public input at that meeting or is it strictly presentations or how will that work?

MS. HANEY: Strictly presentations. But I guess as time allows, the public would be able to provide. But the main purpose of that is interaction with the agreement states.

DR. CERQUERIA: And for the other two, two and a half days seems very long. Is there going to be sort of a free-for-all discussion, will there be sort of structured input on different parts of the proposals? How will that be organized?

MS. HANEY: Well, you are not the first one to raise a question about the length of the meeting.

What we anticipate is a structured format where, similar to what you are seeing today, we will just choose an option of one of these particular options or key areas, and address it during a particular time.

Chip, did you want to?

CHAIRMAN STITT: I would just add on that two and a half days was our best estimate of what it might take to discuss these issues. It is obviously not scientific.

It may be that it is a little too long, but I don't think it will be too long by much.

There will be a pre-set agenda for the meetings that will talk about these cross-cutting issues and also other things that have been identified to us through some of the convening process.

But the most important thing is that even though there will be a pre-set agenda to keep things structured and organized, we are going to go to the people around the table to see if there are other related items that might be added to the agenda for discussion.

So, it is not all locked down; there is some flexibility there.

CHAIRMAN STITT: Dennis?

MEMBER SWANSON: Sorry to get off the subject, but I did want to back up to the previous conversation before the break.

You asked us to respond to issue two, which are transition steps to implement a more positive enforcement program.

And all I want to say is I think that this committee would recognize that a more positive enforcement program is necessary and I don't want it to be lost simply because we didn't discuss it. I think we need to come back to that at a a future meeting.

MS. HANEY: Right; we will.

MEMBER SWANSON: Okay, because this is a critical part of the whole process, in my opinion.

MS. HANEY: What I would anticipate happening is that the working group would do a first review of the enforcement policy based on the new Rule.

Once we do a first cut, we would present that to the ACMUI for their comments.

CHAIRMAN STITT: Let's go around. Andrew?

MEMBER KANG: In revising Part 35, there are some similarities with the currently available FDA medical device regulations, so I thought the committee might be interested in hearing and reviewing, very briefly, the FDA medical device regulation, not in the content but in the structure. How the FDA device regulation CFR is formatted and structured.

It would take about ten minutes for me to present, briefly, the FDA device regulation.

CHAIRMAN STITT: Is it going to help us in how we discuss this?

MEMBER KANG: I think the device regulation is very similar in the structure.

CHAIRMAN STITT: Do you have anything that we could read at lunch? I think we know what we want to do, we just want to start doing it.

What do you have that is going to be different or helpful?

It looks like three inches of something there.

MEMBER KANG: No, it would only be five or ten minutes.

CHAIRMAN STITT: Why don't you tell us right now what might help us. Sit at your microphone and tell us because we now have only fifty minutes to discuss something that we feel strongly about which is the Medical Policy Statement.

So, do you have something that is going to help us discuss these modules?

MEMBER KANG: I think it is better to show you but I can explain to you the FDA medical device regulations are formatted as classification of the three different classes.

CHAIRMAN STITT: You know Andy, I am going to stop you. I really do want to go on.

If you have something to had out, I am going to ask you to had it to the members and we will look at it at lunch. If there is something that we want to have as a formal presentation, I will get the members' input, okay?

MEMBER KANG: Sure.

CHAIRMAN STITT: I would like to go one to the Medical Policy Statement. Diane Flack?

MS. FLACK: While I'm putting this on I would like to make a comment.

We have arranged for a contractor to prepare a NUREG summary.

MEMBER WALKUP: Those would be distributed to us?

MS. FLACK: They will be available.

MS. HANEY: Those meetings will also be transcribed.

MS. FLACK: The staff was directed to recommend whether there were any changes needed in the 1979 Medical Policy Statement.

As was noted at the last ACMUI meeting, the Medical Policy Statement is important to the entire process of revising the regulations.

It was also noted at the last meeting that rather than change the Medical Policy Statement, what might be needed is to better insure that the regulations reflect the Medical Policy Statement.

With those introductory remarks, these are the options that the group have come up with.

Those who are working on a steering group as Cathy mentioned worked on developing these options and also the pros and cons which are in your notebook.

Option 1 that was in the 1979 statement essentially will remain unchanged in all of the options in your handout.

It was felt that it reflected the traditional regulatory function for NRC for all uses of special nuclear material, and really there was nothing to change it.

I would also like to mention that my comments on this particular status quo option were primarily taken out of the rationale in the *Federal Register* notice or the Medical Policy Statement.

So, some of the rationale may not be current, but we need to understand where it came from in 1979.

The second statement, "The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards or compliance with these standards, are inadequate", you will see different variations in the options.

The original statement was based on the 1979 interpretation that NRC had the authority to regulate the radiation safety of patients.

The FRN also reflected the fact that NRC wanted to work closely with professional groups in designing voluntary new voluntary guidance for practitioners to limit unnecessary patient radiation exposure.

The third one, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine."

We recognize that this physicians have the primary responsibility for their patients. It also left open for the NRC to set limits for the higher risk areas in order to insure patient safety.

But it also recognized the consequences that too much regulation might result in poor health care.

So, the bottom line is they felt that this was quite a balanced approach at that time.

Option 2, that the working group and steering group came up with. This is a little repetitious for some of those that have been involved all the way along, but I know that there are a fair number of people sitting in today that were not on ACMUI last April.

This is the April, 1979 recommendation of the ACMUI. The changes that were recommended are underlined.

In the second statement, the word 'only' was added twice to place emphasis on the fact that the, "NRC would regulate the radiation safety of patients only where justified by the risk to the patient and only where voluntary standards of compliance with these standards are inadequate."

ACMUI also recommended that an additional statement be added on which is also underlined. "Assessment of the risk justifying such regulations will reference comparable risk and comparable modes of regulation for other types of medical practice."

On the third one there was really just one change and that was adding the words, "will not intrude into medical judgements".

In this regulation, some of the pros for these recommendations are it is still risk-based which we are all striving for in the revision of Part 35, especially in statement two you can see where justified by risk.

Another plus one for this is the "acceptable level of risk associated with regulating the medical use of byproduct material may be lower than in other areas of medicine."

Somebody referred to this, this morning. It clearly states in statement three that the NRC will not be involved with physician/patient interfaces.

Again, like Option 1, the status quo, it also recognized that physicians have primary responsibility for protection of their patients.

Some of the cons that people mentioned was that NRC really did not have the authority, expertise, whatever you

want to call it to assess the risk in other areas of medicine. This would definitely be a new area for us to get into.

Another concern that was raised was that there could potentially be a conflict between segments two and three.

In two, we say that we will regulate only when justified by risk, et cetera. Then in three, we say that the NRC will not intrude.

So, that was listed as a con.

MEMBER SWANSON: Excuse me, could you expand on that? I don't understand.

MS. FLACK: Yes. It was felt that in two, is says that "the NRC will regulate the radiation safety of patients where justified by the risk."

So, what it is saying is that if there is a high enough risk because of a certain medical modality that development of regulations in that area and interaction with NRC would be appropriate in order to insure radiation safety of patients.

Then we get down to number 3 and it says that "the NRC will not intrude into medical judgements affecting patients."

The concern that was raised there was that even if we have the situation that I talked about in number two, where we have a very high risk modality, that three would

prevent any interaction, any setting of limits, and therefore we would be unable to insure that we have fulfilled our mandate under the Atomic Energy Act to insure the protection of workers and the general public.

And that is what the medicine options one, three and four, the group noticed that it was consistent with the NRC's authority in the Atomic Energy Act and that was not listed in Option 2.

Again, these are all open to discussion. We are actively looking for your help.

Option 3 has a problem in the handout. For those of you who have it in front of you, please look down to pros number 5. It says that the option "provides additional emphasis that NRC's policy is not to minimize intrusion into medical practice." Please cross out the 'not'.

That is just if you have the handout from September 15. The one in the back is fine.

Now let's talk about Option 3.

This was some people's recommendation to come up with a balance between Option 1 and Option 2.

There is no change in the first statement. We have kept in the word 'only' because we want the regulation to be risk-based; we are thinking about that all the time as we developing.

The part that was removed there from Option 2 is obviously comparing the risk to other areas of medicine which, as I said, people were concerned that it was not within our authority or expertise to do that.

We added a couple of words in this one, "continually strive to minimize involvement". We felt that it provided additional emphasis that the NRC was not just going to jump in and be involved in the physician/patient interface and maybe this was stretching a little bit further than the original statement 3 of NRC's commitment not to get involved in the physician/patient interface.

However, by minimizing, it does allow for some involvement, when needed, in the higher risk modality.

Again, please remember that in statement three we still recognize that the physician has the primary responsibility for the patient.

I am not going to go through all of the pros and cons because I want you to have the maximum time for discussion.

CHAIRMAN STITT: Let me ask you a question on con number one on Option 3; it looks like the pro number two on Option 2. There is one word that is different.

MS. FLACK: On con number one on Option two?

CHAIRMAN STITT: On Option 3 it is con number one and on Option 2 it is pro number 2.

MS. FLACK: I am not sure that I am following you. You are right that the pros and cons do switch around.

CHAIRMAN STITT: It is making the same statement, that risk may be lower.

MS. FLACK: Right.

CHAIRMAN STITT: But when you are looking at it on Option 2 it seems to be a positive, and when you are looking at Option 3 it seems to be a negative.

MS. FLACK: There are two facts here. One is that the risks that in the standards that the people in the use of medical byproduct material are held to could be lower than in other areas of medicine.

So, not to recognize that is wrong. So, that could be either a pro or a con, depending on which option you have it under.

The only thing that we wanted to do was to get away from evaluating the risks in the other areas of medicine.

So, the con one, that it may be lowered, that is a con because you may be held to a lower level of risk. It might work against you.

MEMBER SWANSON: Let me just comment on Option 3. I think that insertion of the words, "will continue to strive to minimize", you have it down as a pro, that it provides additional emphasis on the NRC's policy. I tend to think that

it has less emphasis on the NRC's policy than the current version.

The current version says that "you will minimize" and you say that it will "continually strive to minimize". My interpretation of that is the opposite.

CHAIRMAN STITT: I think it is the effect of the more modifiers that you put in the less likely you are to achieve the statement that you are allegedly making. That has how many modifiers?

MS. FLACK: It's an interesting exercise.

CHAIRMAN STITT: Right.

MS. FLACK: The other thing in here is that we don't have intrusion anywhere; we use involvement which we thought was a softer word.

MEMBER FLYNN: Procedural request: Can we go through all four options and then come back and debate them?

CHAIRMAN STITT: Go on to Option 4. We are getting short on time.

MS. FLACK: Option 4 is a very different one than the others. It has no change in the first statement, again.

The changes made in this option were made to more precisely reflect what NRC's role actually is. The group felt that really our role for patient safety was to ensure that the physician's prescription is accurately delivered to the correct patient.

It does not question what the actual prescription is.

So, this was an attempt by the group to put this on paper. It is risk-based. The regulations would be consistent with the risk posed by the radioactive material.

Then, it hones in very closely and precisely on what our role might be. Remember, this is just an option: "In regulating the radiation safety of patient, NRC's role is to assure that the physician's prescription is accurately delivered to the correct patient."

In number three, it says that we "will not intrude into the medical judgement forming the basis of the physicians' prescription."

Now, one of the cons of this one might be the fact that it is too narrowly focused. But it was an attempt to put down on paper what NRC's actual role is also the areas that we are not interested in intruding in, and that is the medical judgement that is behind the decision.

CHAIRMAN STITT: Okay, let me tell you what the rules are. In addition to Judy's rule, which is that you speak when you are spoken to, let me just remind you where we started a year or so ago.

When we started having discussions prior to going to the Commission, we spent the good portion of one day, deciding as a group, that the Medical Policy Statement was of

utmost importance and that everything else that the committee did followed from the Medical Policy Statement.

That is something that we took on. Don was kind of the clerical person and the final spokesman to put all the little words in there.

So, what I am leading up to, is we can't do this by lunch we are going to have to shorten lunch because I think that everything else that we do follows from here.

Don Cool said this morning that he wants our comments. He would like our whys and why nots as to preferences and I think that rather than have one of our notorious debates, if there are some things that you like I would like to hear them and focus on one or two options.

If there are some parts that you might want to pull from others, that is fair game, too.

I just want to say that because Option 4 is quite a bit different than anything that we have thought about, those of you who are therapeutic radiology, those of you who are diagnostic, just be thinking about Option 4 in the context of how you practice.

All right, Jeffrey.

MEMBER WILLIAMSON: I would like to propose that we drop consideration of Option 4 from what we would recommend.

CHAIRMAN STITT: Well, that is a blatant statement.

MEMBER WILLIAMSON: It could, perhaps, simplify the process.

CHAIRMAN STITT: Are there some parts of the group that think that Option 4 is just dandy?

MEMBER FLYNN: I would like to second that and I want to explain why.

Option 4 isn't that bad, in some aspects. However, look at the last sentence in statement two. It says that the "NRC's role is to assure that the physician's prescription is accurately delivered to the correct patient."

Now, I happened to research the teletherapy problem because I wanted to see how often the incorrect patient was treated.

Now, with Cobalt-60 teletherapy, approximately in the last twenty years there has been variation. There are less cobalt machines, but if you averaged over twenty years, I added up with 100,000 cancer patients treated per year, over twenty years.

Each patient gets approximately twenty treatments, so that is two million treatments for twenty years, or four hundred million treatments.

I looked at all the abnormal occurrence reports that the NRC has. Granted not everything is covered, but it goes into the late Seventies.

I found seven patients that the incorrect patient was treated. So, the numerator is seven and the denominator is four hundred million.

It doesn't happen often, and we do have things in place now to prevent it. We have two means to identify the patient.

Typically in a radiation therapy department, as you know, the technologist goes to the waiting room and announces, "Mr. Smith, it is time for your treatment."

When I looked at how did these seven people, the wrong patient, come to be treated, in several instances the name was called out and the wrong patient got up; a confused patient or a patient with the same name.

The therapist also didn't recognize the patient, assuming that the patient walking to the room was the correct patient and went ahead and treated the patient.

Now, in most radiation oncology departments, including professional standards, the second way that you identify a patient is there is a Polaroid photograph in most radiation therapy department in most of the country, not just in my department. This is almost standard practice now.

So, if a therapist doesn't recognize the patient, they have called out the name and that is one way to identify the patient, there is a visual identification; the Polaroid photograph of the face of the patient right in the chart.

Now, these patients are treated for three, four or five weeks. Come the second and third week, she recognized the person to be who they say they are.

When I came in this morning, I said, "Hello, Judith." I called your name and you responded. I also recognized you visually.

So, those are the two ways to identify the person. So, it hasn't happened, to my knowledge, recently. It may have, but I just don't know.

But that is an example of a very rare event in teletherapy. Where you have two million treatments in a year and most years there is not a single incorrect patient that is treated.

I think the voluntary standards are working; the two means to identify the patient. We realize that that is a serious issue, but it happens very infrequently.

Of the seven licensees that I found, and I searched hard to find more, for one licensee it happened twice and that was a licensee in Washington, DC, it happened over a period of ten years. An incorrect patient was treated to teletherapy twice over a period of ten years.

So, that is why, although I liked number four at first, but when I looked it over several more times I realized that it is very narrow, "the correct patient".

CHAIRMAN STITT: Actually, it reiterates some of the things that come up later one regarding other parts of how we do our practice. It is very, very focused.

Jeffrey? And I would like to hear comments about Option 4 from you practitioners.

MEMBER WILLIAMSON: Could I briefly articulate my rationale, why I made the motion?

CHAIRMAN STITT: Please.

MEMBER WILLIAMSON: One is the statement two, it simply says, "consistent with the risk posed by the radioactive materials." There is no qualification whatsoever regarding the necessity for standards of practice to be non-existent or not adhered to when they are.

So, it is an absolute risk inherent to the material itself and totally independent of the sophistication of the practice surrounding it. So, I really think that it opens up the community.

The second comment I will make is that I agree with Cathy in that it very accurately reflects the current attitude and practice, in effect, of NRC regulations now.

To me, when I look at this statement, this is clearly inconsistent and much worse than the current 1979 formulation.

So, without any performance indicators, it is completely non-performance based. No matter how well you are performing, it gives NRC the mandate to regulate every detail of the treatment, planning and delivery process.

Secondly, it protects physician judgement from regulation, in so far as it affects patients, only for prescription. So, it very much limits the activities of the physician that involve patients that are exempt from NRC scrutiny.

So, I think it really leaves every other aspect of the physician's practice and activities as totally fair game for all kinds of regulations without any kind of qualification about what kind of risk needs to be established.

CHAIRMAN STITT: Lou, can I ask you for comments?

MEMBER WAGNER: I think that it is necessary that this committee review why this all came about, because I think that we have lost focus of what we are doing here.

This came about because of the IOM report. The IOM report and all the other concerns that were brought up in regard to the NRC, we mentioned that the IOM report did not do an investigative history as to why the regulations evolved the way that they did and came out to be what they are.

How did we get to this mess? That was the whole focus of the discussion, prior to these recommendations.

At our meeting, reviewing that report, we looked at this 1979 policy because we wanted to get to the idea of how things evolved to this point.

The reason that they evolved to this point is because there was an incident that occurred. This policy was changed in 1979 as result of an incident that occurred.

Our objection to this policy was that it was this policy that opened the door for the NRC to be intrusive in medicine. I know that the NRC doesn't view what they do as being intrusive in medicine, but we in medicine do view what they do as intrusive in medicine. And that is the whole point, why we wanted that policy reviewed.

So, when we are reviewing these other options here, the question should be the doors that are opened up by these policies with regard to intrusiveness in medicine. That is the problem and has always the bone of contention here.

So, when we look at these, let's look for the windows, and number four obviously gives a blatant window to be worse than it was before, not better. It is blatant.

So, it is out as far as any recommendation that I can see, at least from my point of view and obviously from other's, too.

Option 2 seems to me to be the better modification, although I wouldn't call it ideal at this time.

But I disagree with the idea that those cons are cons. I mean, my goodness, you mean that the NRC will finally have to actually do something to educate themselves in medicine? They have been regulating us for so long with regard to what goes on in medicine and what our policies are.

These are not cons; these are pros.

CHAIRMAN STITT: I think we are going to burn Option 4. Let's talk about Option 2 some more.

To refer to your comment about con number one in Option 2, "requires NRC to assess risks in other types of medical practices". I don't know if that requires the NRC to assess risk. I think there are data all over the place, books, papers, that discuss radiation medicine in respect to medicine as a whole.

Anybody over here? Will and then --

MEMBER NELP: Well, I thought about that a lot. And I think that the person from the NRC brought up the point that they're actually going to have to reference this somehow in writing and regulation. I think that's going to be very difficult to do without getting into a real bag of worms. And that's the issue that I see.

I think it's very appropriate to justify the risk based on the general practice of medicine in other areas of

medicine, but they feel that with this kind of a statement, you're going to have to compare it in writing. It says will reference comparable risk and comparable modes. And, therefore, I think that we're stepping into an area where we'd really like to simplify it much more than that.

I'm very much against that, even though my good friend John Graham did that in a very eloquent fashion. I think it really does raise an issue where they're going to dive in there and start looking at regulations for anesthesia or regulations for surgery and things that I just don't feel they have the capacity to reference in writing or either in implication. And I'm not sure that we do when you get right down to it.

As a physician, I'd like to get rid of that.

CHAIRMAN STITT: Dan?

MEMBER FLYNN: I don't think it should be us, and I'm sure the NRC doesn't want it to be them. But on this issue, this particular issue, assessing the risk in terms of other risks in medicine, this is where I think money would be well-spent.

This is where the IOM money would have been better spent. This is where some of the engineering human factors, big budgets must have been spent for some of these big documents I've been getting. But this is where money should be spent for an outside major study of risk by a third

party, a disinterested party, not the regulated community, not the NRC, but an outside contract, which might take a year or two. But this would form the basis, then.

And it wouldn't have to be, you say, referencing risk, but as long as whatever the regulations are, it's at least on the same order of magnitude or within an order of magnitude of other risks that --

MEMBER NELP: Correct.

MEMBER FLYNN: -- this outside consulting group, which would be some major consulting group --

MEMBER NELP: The language clearly says such regulations will reference, and I presume in writing, comparable risks and comparable modes of regulations in medical practice, which really is so broad, you know, somebody could step in and find things that were very incompatible with our goals.

CHAIRMAN STITT: As an example, the misadministration just this past year that resulted in serious consequence compared to the numbers have documented in the literature serious outcomes of the two weight loss drugs. Now, if you want to talk about comparable risk, and those things don't compare at all, meaning the risk of that misadministration is tremendously low compared to that.

I think that assessment of risks could continue to be suggested to the NRC. And we don't have to get into the

details if it's written or it's a graph or whatever. Let's just pick everybody. We'll just start in a line and go on around, starting with Naomi.

DR. ALAZRAKI: Actually, I think the point is that if you look at high-risk procedures performed in medicine, which can affect the patient with an outcome of death as a complication of the procedure, there are no regulations. What regulations are there? There are none. They don't exist, even for the highest-risk procedures.

Radiation is regulated. It's just about the only thing that I can think of unless someone can think of something else which is regulated and held to the kind of enforcement standard that we are.

So in a sense, it's useful to have that in there because until other high-risk procedures fall under some sort of government regulation that -- I don't know. I can't imagine, but maybe that's going to happen in the future somewhere. In a sense, the statement says that there's no comparable regulation in any other area of medicine.

CHAIRMAN STITT: Let's go on along the line.

DR. CERQUIERA: I have lots of problems with this in the sense that I think all the diagnostic things we do could be taken out of this category altogether because I don't see those risks in comparison to everything else I do as a cardiologist is that great. And so I think what we're left

with is the therapy. And there I think the standards are a little bit clearer. And, as you said, the complication rate of misadministration is relatively very low.

So I think if you actually looked at this, I don't think you really need to deal with the risks for diagnostics in any way but really just would concentrate on the therapeutic. So I see that as less of a problem.

CHAIRMAN STITT: Dan, do you have any other comments?

MEMBER FLYNN: No. I mean, I think it may not be -- for example, when you go into a hospital and you have patients who are under medication or confused, you notice that any hospital you go into, the patients always have some kind of a wrist band to identify them in case they can't identify themselves or in case the nurse or doctor doesn't know that patient.

So there's a reason for that. And I'm sure the reasons are very good reasons. So I think there are areas of medicine where there are certain standards that are expected in any hospital. I can't imagine walking into a hospital and going through patient room after patient room and the patients don't have some means of identification.

So I think there are standards out there and there are reasons for the standards. It may not be in every subspecialty.

CHAIRMAN STITT: Are you fidgeting for a reason?

MR. SIEGEL: I'm fidgeting, yes.

CHAIRMAN STITT: Okay. Go ahead.

MR. SIEGEL: I'd like to demure at Dr. Nelp's comment because I think its suggesting that what the Committee suggested at its last meeting should be withdrawn also suggests that when the Committee has been suggesting for about the last seven years should be withdrawn, which is that the NRC should not have Atomic Energy Act tunnel vision and assume that that's the sole basis for which it should charge forward in its regulatory stance.

Even if one allows that the Atomic Energy Act provides the NRC the authority to regulate components of the practice of medicine, -- let's take that as a given -- the Atomic Energy Act is sufficiently narrowly worded in that area or sufficiently vaguely worded that it also provides the NRC with a whole lot of regulatory discretion in terms of how it regulates the practice of medicine.

And the purpose of the proposed Policy Statement Number 2 was to provide a legal cure for Atomic Energy Act tunnel vision, which was to say that when you make these regulations, you simply cannot ignore how the risks of this part of radiation medicine compare with the risks of the other parts of medicine.

Will it be difficult? Sure. Is it appropriate? Absolutely. And is there expertise in the building? Probably not, but perhaps it's time that there was expertise in the building to go about making these kinds of judgments.

You simply cannot ignore the risks of a teletherapy treatment by comparison with neurosurgery or phen-fen or you name it when you make a regulation that impacts how medicine is practiced.

There are only so many resources available to practice medicine. The resources have to be put in the place that does the greatest societal good, not just the greatest good as viewed within the narrow window of the Atomic Energy Act.

MEMBER NELP: Since my name was mentioned --

CHAIRMAN STITT: All right. We'll go down this line. Go ahead, Will.

MEMBER NELP: Well, Barry, I agree with you. I don't disagree with the purpose of the statement that's trying to be portrayed. The way it's written, it says to me that the NRC might have the license to go in and put on paper comparable risks. And God knows what they're going to come up with that would be comparable risks.

I don't know what the statements are in anesthesia for operating room procedures, for sanitation, environmental contamination, and things like that that are all

-- they may be very picayune. I really don't know. And I could see how this would give an opening for them to try to reference those things in writing, and it could become very cloudy.

That was my concern, and that was a concern I think the NRC said, "We don't know anything about medicine, and you're asking us to get involved." And we're trying to get them out of it. And that's where I think that there's a contradiction here. I'd like to get them out of the other areas of medicine, including the areas of medicine associated with radiation therapy.

CHAIRMAN STITT: I think you made our point. My response is there's lots of information about risk in medicine, all aspects of medicine. This is not new. It's easily available.

We focused a lot of our presentation on radiation medicine. Our first slides when we presented to the commissioners were entitled, "Risk of Radiation Medicine." So this has been felt to be very important to this group, at least according to the old man in the room long before the rest of us were even on the Committee because I think you've been hanging around longer than any of us if you said seven years.

Lou, you've got your hand up and anybody else that would like to make a comment.

MEMBER WAGNER: Yes. I'd like to make a comment on Number 2, "Cons." It says, "Implementation of statements 2 and 3 could be in conflict when the level of risk justifies intrusion." Read 3. Three says, "The NRC will not intrude."

The point is that they're trying to justify intrusion. That's what their con is really implying, trying to justify more intrusion. And I want to get back to that point that this is where we have to recognize where the disagreement and the conflict are.

The NRC needs a mindset change. Medical practice is medical practice. Medical practitioners should practice medical practice. The NRC doesn't have the expertise to do this. This is why we don't want them intruding.

They botched up the system. That's why we're in a mess right now. And that's the intrusion problem again that's creeping in here. It's the mindset. Let's turn it around.

CHAIRMAN STITT: Jeff? Dennis, you're going to have to come up with something in a minute.

MEMBER WILLIAMSON: Yes. Well, I guess I would like to speak in support of Retaining Item Number 2 of Option 2, which is you know our addition of "Assessment of the risks. justifying such regulations will reference comparable" medical specialties, et cetera.

I think one question to ask is: How did we get from Option 1, which was a statement of intent that intrusion into medicine should be limited by NRC and when it's done should be justified by some sort of risk assessment, to Option 4, which says we don't have to establish any actual statistical risk to patients at all just because there's a theoretical risk because it's a high activity source, we can go and regulate any detail we choose to?

I think the intent why we put in this qualification was to prevent NRC from concluding because there's a possibility of a patient injury from a technical error, therefore, there's a significant risk to the patient.

I think that's the reasoning that prevails in the agency today. And Option 2 was modified by our group and voted on because we were trying to at least force them to go through some sort of a process to quantitatively justify imposing a regulation which intrudes into the practice of medicine by really looking at: Is there a realistic risk? Are standards inadequate? Are they not being followed on a large scale instead of reacting to single events? So I really strongly feel we should keep that component of the statement that we approved before.

One thing we might consider is I think -- it is a good point they've made down here that maybe Statements 2 and 3 are in conflict. One could potentially maybe imagine a

situation where the qualification we've added in Item 2 might be violated and might require from their perspective to impose some restraints on the way the field is practiced.

CHAIRMAN STITT: You had your hand up first. Do you want to go or do you want to --

MEMBER GRAHAM: I'm politely waiting, Madam Chairman.

CHAIRMAN STITT: Go ahead.

MEMBER GRAHAM: I think it's interesting that in the options that were discussed that are in here, Options 1, 2, 3, and 4, the first part of the policy statement that "The NRC will continue to regulate the medical uses of isotopes as necessary to provide for the radiation safety of workers and the general public," that wasn't a point of dispute today apparently. That wasn't a point of dispute when we went through this back in April. And it's interesting if you read the background material to the 1979 statement, it was not an issue at that point in time.

I have a problem with the fact that in the review of the options, the statement, the pros that's under Option 1, which was the status quo, first pro is that "Consistent with NRC's authority in the Atomic Energy Act of 1954, as amended, to regulate domestically the uses of byproduct material, including medical use, to protect public health and minimize danger to life and property."

That's a pro as identified for the status quo. It was clarified in the verbal presentation of options this morning that it is not considered to be present in Option Number 2, which was the language that this Committee recommended back in April.

Going back to the original policy statement, -- and it's on Page PSMU-2 -- the central question is a question of policy, not authority, namely: To what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material?

From the standpoint of authority, it is clear that the NRC can regulate the medical uses of byproduct material to protect the health and safety of users of this material; for instance, patients. In licensing the possession and use of byproduct material, NRC establishes limits within which physicians exercise professional discretion.

From the standpoint of policy, these limits depend on how NRC views the potential hazard to the patient's health and safety in the uses of the byproduct material.

So I would reiterate, as it was stated back in 1979, that there's never been a question of authority. There's a question of policy that's being debated.

It goes on to state in the next column that the NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are

adequate regulations by other federal or state agencies or well-administered professional standards. And to put it in context -- and Dr. Cerquiera?

DR. CERQUIERA: Yes, yes.

MEMBER GRAHAM: I want to make sure I try to pronounce that correctly.

The concern that this group has debated in the past, if you read this original language in '79 in the third column, the Commission believes that the diagnostic use of radioactive drugs is in most cases clearly an area of low radiational risk to patients. Therefore, NRC will not control physicians' prerogatives on patient selection, et cetera, et cetera, but that we will have regs floating all over the place that have created problems in the way the practice takes place today.

CHAIRMAN STITT: I'd like to make a comment that in Option Number 2, I think it directly relates to PSMU-2, the phrase that you just read to us that these limits from the standpoint of policy depend on how NRC views the potential hazard to the patient's health and safety in the uses of byproduct material.

What we are asking is that the NRC view those hazards in the context of comparable risks and comparable modes for other types of medical practice. I think it's

support we're asking. We have put in a sentence that supports the statement from September of 1995.

MEMBER GRAHAM: I would suggest, in summary, that we may as a Committee want to discuss whether the recommendation from the ACMUI is simply modified to move Statement Number 3 into Position Number 2, "The NRC will not intrude into medical judgments affecting patients in other areas traditionally considered to be part of the practice of medicine." That's the overriding concept.

I do not believe the implementation of Statements Number 2 and Number 3 could be in conflict if they truly follow Statement Number 2 and then only get into issues that get in to an assessment of risks because if you leave the practice of medicine open, then any assessment of risk is going to get into a comparisons of things like open-hearted surgery and neurosurgery and the unbridled ability of physicians to prescribe drugs as they perceive the need for their patients will best be met. I think, again, that's what we're trying to emphasize.

I would recommend at most we rearrange the sequence of the three statements. But I would leave it with the recommendation the Committee made back in April because the emphasis that we're trying to convey back to the Commission is that the practice of medicine is why the area of

patients is different than the other areas for the general public's safety.

MEMBER WAGNER: Is that a motion?

CHAIRMAN STITT: That's just what I was going to ask.

MEMBER GRAHAM: So moved.

MEMBER WAGNER: Second.

CHAIRMAN STITT: You guys are doing a good job. I think it's because you're hungry.

Let's discuss the motion that's on the floor.

MEMBER SWANSON: I would actually recommend an additional change to current Statement Number 2, which would now be Statement Number 3 under the motion. I'm a little concerned in that I would like to tie down the issue of the second clause in the first sentence, "and only where voluntary standards or compliance with these standards are inadequate."

And I would suggest that a way that we can tie that down is by changing the second sentence of Number 2 to be "Assessment of the risks. justifying such regulations will reference comparable risks and comparable voluntary standards and modes of regulations for other types of medical practice."

CHAIRMAN STITT: Naomi?

DR. ALAZRAKI: I think that's very good because the voluntary standards are really the only thing that exists

in other areas of medicine. And that's what we would like to move toward and away from, the regulatory enforcement.

CHAIRMAN STITT: Go ahead.

MR. SIEGEL: Well, that's not entirely correct, Naomi. I mean, there are regulations that regulate blood banks, for example, which is part of the practice of medicine. There are some FDA regulations that do get into having some influence over the minute by minute practice. So I don't think that we should ignore that there is some other government regulation.

Moreover, depending on how you choose to be reimbursed by the Health Care Financing Administration, if you choose to be JCAHO-accredited as the deemed basis for being reimbursed, then that's one approach. But if you say, instead, "We don't want to do that. We'd rather be regulated by direct Medicare inspection," then you have to comply with all the Medicare regulations about the precise nature of how your practice is structured and how your institutions does things.

So there is other regulation in medicine. I think voluntary standards and regulation would be a reasonable change to this, but there is other regulation.

MEMBER NELP: I have a pertinent comment. If you look at Option 2, Section Number 2, when you say, "Assessment of the risks. Justifying such regulations will reference

comparable risks and comparable voluntary standards and modes of regulations," do you mean of governmental regulation?

If you say "governmental regulation," then you're pretty free and clear. But if you say "regulation," you're talking about infectious disease control in the hospitals. You're talking about blood bank. There may be governmental things for blood bank.

But I'm wondering if you said "governmental regulation," I don't know what the government regulates in medicine, frankly, but I know there are all kinds of regulations out there for things that are vaguely related to the practice of medicine. And I think you want to avoid that.

Is that what you meant, John or Barry, governmental regulation in here, modes of governmental regulation?

MR. SIEGEL: I think what that second sentence means is that the regulation of medicine should be medicine-informed, to coin another new phrase, not just risk-informed but medicine-informed. It has to be viewed in the context of the overall practice of medicine.

CHAIRMAN STITT: I think that is what this says, but my comment is I like the voluntary standards. That keeps coming up in all of the material we've been given. We've discussed it all morning. So it makes a reasonable addition. Do you want to --

MEMBER SWANSON: Can I make a motion to amend that?

CHAIRMAN STITT: Yes. That's what I wanted to get to next.

MEMBER GRAHAM: Could Dennis read back the proposed amendment to the original motion because I didn't follow it?

CHAIRMAN STITT: Now, we've done this before, though. I know we will walk ourselves through this. Go ahead, Dennis. And we have to deal with that next.

MEMBER SWANSON: I propose that the second sentence of Item 2 under Option 2, which would become Item 3 under your motion, --

MEMBER GRAHAM: Correct.

MEMBER SWANSON: -- would read, "Assessment of the risks. Justifying such regulations will reference comparable risks and comparable voluntary standards and modes of regulations for other types of medical practice."

MEMBER GRAHAM: So it is the addition of the words "voluntary standards"?

CHAIRMAN STITT: That's correct.

MEMBER SWANSON: "Voluntary standards," yes.

CHAIRMAN STITT: Are we ready to vote on that?

MEMBER GRAHAM: I accept that.

DR. ALAZRAKI: Can I just --

CHAIRMAN STITT: Naomi?

DR. ALAZRAKI: What about the idea of government in there for government regulation? Could we have some other discussion of that?

CHAIRMAN STITT: My feel was that that was implied that regulation referred to government regulation. I don't know if it needs to be overtly stated.

DR. ALAZRAKI: Okay. Barry, I think that any regulations that you can think about in other parts of medicine are by voluntary organizations, and they're really guidelines.

MR. SIEGEL: What about the JCAH? Now, that's not a voluntary --

DR. ALAZRAKI: That's a private organization. It's totally voluntary.

CHAIRMAN STITT: The FDA regulations for mammography, those are not voluntary.

DR. ALAZRAKI: Those are not voluntary, correct, but those are implemented through the American College of Radiology. The FDA has more or less turned that over to the professional society.

CHAIRMAN STITT: Do you want to deal with the amendment we've got? And then if somebody wants to make an amendment to stick "government" in there, we could do that separately.

I'd like to vote on the amendment to the motion, and the amendment is to insert "voluntary standards" following the word "comparable." Everybody in favor?

(Whereupon, there was a show of hands.)

CHAIRMAN STITT: Opposed?

(No response.)

CHAIRMAN STITT: All right. Is there an interest of the group to insert "government regulation" or is there an interest of the group to insert "government"?

(No response.)

CHAIRMAN STITT: Okay. If there's no motion, then let's deal with what we have on the floor. And because you made it, you repeat it.

MEMBER GRAHAM: You have to be kidding.

CHAIRMAN STITT: Well, as I understand it, it was to move Point Number 3 --

MEMBER GRAHAM: "The Advisory Committee on the Medical Use of Isotopes is reiterating its recommendation to the Nuclear Regulatory Commission that the statement of general policy to guide regulation of medical uses of isotopes would be changed," that Item Number 1 would have no change, that the sequence of the following two items would be modified. Item Number 3 would now become Item Number 2 with no change in the wording.

Current Item Number 2 would become Item Number 3 with the addition of the wording "voluntary standards and" into the second sentence that refers to the assessment of risks.

MEMBER WAGNER: Point of clarification. That's for Option 2.

MEMBER GRAHAM: This is Option 2.

CHAIRMAN STITT: All right. Let's vote.

MEMBER GRAHAM: Call the question.

CHAIRMAN STITT: Those in favor of the motion that was just eloquently stated by John Graham, raise your hands.

(Whereupon, there was a show of hands.)

CHAIRMAN STITT: Those not in favor?

(No response.)

CHAIRMAN STITT: 11:31.

MR. SIEGEL: Judith?

CHAIRMAN STITT: Sir?

MR. SIEGEL: There may be some confusion about how former Option 2 actually reads in terms of where the inserted phrase goes. Dennis, why don't you read it and insert the phrase you have in mind just to get the record straight?

MEMBER GRAHAM: Do you want me to read it?

CHAIRMAN STITT: Go ahead, John. You seem to be the reader.

MEMBER GRAHAM: What is now the third phrase of our recommended general policy would read, "The NRC will regulate the radiation safety of patients only where justified by the risk to patients, and only where voluntary standards or compliance with these standards are inadequate." There's no change from what we voted on in April.

The second sentence would now read, "Assessment of the risks. Justifying such regulations will reference comparable risks and comparable voluntary standards and modes of regulations for other types of medical practice."

CHAIRMAN STITT: Everybody clear in the back row?

(No response.)

CHAIRMAN STITT: All right. We're going to have an hour for lunch. I want you to be ready to roll at 12:30. We've got a rough afternoon, one of your favorite topics: quality management programs. We will not be allowed to break until it's down.

(Whereupon, a luncheon recess was taken at 11:36 a.m.)

1

A-F-T-E-R-N-O-O-N P-R-O-C-E-E-D-I-N-G-S

(12:41 p.m.)

CHAIRPERSON STITT: Everybody ready to roll? Let's see, what is the time limit. We have two hours to hear Sam Jones discuss with us quality management program.

MS. HANEY: Sam Jones is a member of the working group and is going to do the presentation on quality management program, but before he started, I would just like to draw everyone's attention back to the SRM that got us started on this, the DSI-7. It's not necessary for you to reference back to it, but basically what it gets at is that the Commission said that the quality management program provision should be re-evaluated and revised to focus on those requirements that are essential for patient safety, EG conforming, confirming patient identity, requiring written prescriptions and verifying dose.

To the maximum extent possible, the requirements should be revised to be risk informed, giving this objective a mixed approach of performance based rules and otherwise prescriptive regulations should be pursued.

I guess I am just mentioning that because to bring to home that no QMP is not an option. We are really starting with this as our baseline of direction and then going from there. It is under the section that is update of revision of part 35. It's one, two, three, four pages down.

So when you are considering Sam's presentation and the alternatives that the working group put forth, this was the starting point for those discussions.

Okay. Sam?

CHAIRPERSON STITT: Sam, you and I talked about how we like to try to run these two hours. Why don't you review that for the group?

MR. JONES: Okay. What I would like to do is have the slides. I have the slides over here in the projector. Then Pat has electronic versions of the slides and also an electronic version of the rules. I want to accomplish four things within the next couple hours here. I want to start off with a general review of the full alternatives that were developed by the working group and the steering group. We have them electronically.

As we go through those four alternatives, we are going to try to get those comments in real time on this projector over here so you can see them and we have them captured electronically. It will save us some time later.

The second thing I want to do is actually review the rule itself, go through each section of the rule and then for all the committee to be reading the rule language, which will be electronically on your left. We'll go through it section by section. Then I want you to look at it and say is there a specific problem with this section. What is the

problem. Identify the problem and state why it's a problem. Then come up with a resolution for the problem.

The third thing would be we'll go through the pros and cons for the four alternatives that were developed by our work group steering group. That information is in your briefing books, as well as the rule language.

The last thing I would like to do is take a few minutes to let you tell us anything that you think might be another alternative that we haven't thought of.

Is everybody agreeable to that format? Let's just try to step through it. Penny is going to keep me honest on the time over here.

The first alternative was to maintain the current requirements. It's essentially going with the status quo, no change at all.

MEMBER NELP: Next.

MR. JONES: Okay. The second option would be to have a written QMP only. Essentially that would be A of a current status quo or the current rule.

The third one would be to require a quality management program retaining a written, or actually retain each written directive and a record of each administered dosage requiring a written directive, and for the licensee to perform audits.

The fourth one would be to require the quality management program which is essentially A, to retain records of administered doses and keep the written directives, and then to retain records of recordable events.

Now I want to go back through and start with the first one. We're going to go through the pros and cons later.

But maintain the status quo. I'll tell you what let's do. Let's go next and we'll come back to this. It might be better if we go through the actual rule language itself.

So the current rule language is in alternative one. If you look behind alternative one, it gives you the current rule language. The rule language will be electronically up here as well.

CHAIRPERSON STITT: We're on page three, for those of you who are working off the paper, right?

MR. JONES: There's only one file on that one.

Let's read from here then, section A. What I would like from the Committee is to read section A, determine is there a problem with section A. What is the problem and what needs to be fixed? Or can we say that section A is okay and we can move.

What I am trying to do is determine what you see is is the problems with individual sections of the QM rule.

CHAIRPERSON STITT: Is it correct that section A is a part of all the four alternatives? That's the way I read it.

MS. HANEY: There is a section A, but the section A's do not match. Basically what happens is alternative one gives you all the A, B, C, et cetera. For the rest of the versions, alternative A becomes that part of a QM program there should be some objectives.

So there is a comparison, but it is not a verbatim comparison because we started to make some changes in the rule text.

MR. JONES: If we didn't change 3532 A at all would that be a problem?

CHAIRPERSON STITT: John, did you have a comment or are you just gasping?

MR. GRAHAM: It's a process question. Could we have the Committee discuss the four options and identify whether there's a clear consensus on a preferred option and then probably discuss the difference between the current language and the language that would be introduced under the preferred option?

CHAIRPERSON STITT: That is how we worked the first section. Is there a reason you want to do it differently? I think we're struggling.

MR. JONES: We could do that. We could do that. Okay. What I was thinking of doing first, you know, we have options in the back that we will discuss. I was trying to see right up front, you know, identify the problems with the current language.

Okay. Let's go through each alternative then if you want to. We'll forget the rule language for now. It's getting a little cumbersome.

No change. Okay. The perspective here, this is the perspective of the NRC working groups and the steering group, the pros and cons. The first pro would be no additional regulatory burden of licensees, status quo, nothing would change.

The second pro, well you can read through these pros and cons. Do we have any comments on these pros and cons?

MS. HANEY: Well, Sam, I would say why don't you just go through all the alternatives, present them, and then we'll just open it up to the group to discuss it.

MR. JONES: We'll go through all the options?

CHAIRPERSON STITT: Yes. I think so.

MR. JONES: Okay. Go back to page one.

MS. HANEY: What the working group basically did is we decided, you know, we always use status quo as the first alternative. For any alternatives after that, we said what's

important to a QM program. There is a requirement for some objectives. Whatever those objectives may be, we're not going to say right now. But you need to have an objective.

Then the next important part is an audit. Then the next one is some record keeping component of that.

So all the different alternatives are really a different variation of those three things. Once you get beyond that step, then we started looking at if we were to change rule language, rather than being as prescriptive in alternative one where we said that prior to each administration a written directive is prepared for and we go teletherapy, gamma stereotactic, brachy therapy, we just went at that point to maybe taking it to a dose base, that saying only a written directive is required if you are greater than 50 rem.

There are several benefits to doing it that way. One of course is with emerging technologies. It's also giving a licensee more flexibility in taking some of the prescriptiveness out of the rule.

So those are some of the things that you start to see in the rule text. So the first thing is from the standpoint of which components of the QMP program do you feel are important. Can you live with just objectives or do you need the further variations of it? Then after that, maybe as

you decide on what alternative you would like to have, then we can start looking at the rule text.

CHAIRPERSON STITT: If you could tell us how one through four vary, I think that will --

MR. JONES: Cathy, you put this together, so you can do some of this for me, okay?

MS. HANEY: I'll tell you what caused this to come about. As the working group member developed these different things, I started reading through the different alternatives and I started asking myself what was different between one and two, and two and three. So I was responsible for these charts being created, which I'm not sure the members of the working group were thrilled about.

But anyway, what we went through are in our minds, the key items for consideration. If you look, these items are really reflected in the pros and cons. In some cases, we turned say a con into a pro statement just to have it fit into this table a little bit better.

So we always felt that no matter what alternative we were dealing with, that you needed some type of objectives. Then we felt the next key thing was the audits. In only alternative one and three did we put in an audit requirement.

The next thing that we considered was the need to retain written directives and the records of administration.

Again, that just showed up in alternatives one, three, and four.

The next item was whether they needed to submit, the QMP licensee needed to submit to NRC. That was only under status quo.

Then whether the licensee was required to maintain recordable events. That showed up in alternatives one and three.

Now this is where the recordable events becomes a little bit of a sticky issue because recordable events surfaces again tomorrow afternoon when we start talking about the threshold for reportable and recordable. So depending on what alternative you take there under that, you may no longer have recordable events, so this last item is moot point.

MEMBER SWANSON: Actually there's an error there. It's not under option three. It's under option four.

MS. HANEY: Okay. We'll stand corrected on that. So you might want to just, if you approach it from the way the working group did, it's what's important to a QM program, with these Xs you may be able to kind of focus down on one of the alternatives.

CHAIRPERSON STITT: Okay. I think we are getting there. Do you want to spend more time just explaining two through four or do you want us to jump in?

What does the group feel like you are ready to do? Jump? John is ready to jump. How about the left side? We're kind of in the dark. Looks like they are anxious. Okay.

MR. JONES: Is a written quality management program, which is common to all these, necessary first of all? Do we all agree that you need a written QMP?

CHAIRPERSON STITT: I think we were told we had no choice. So we can all agree on that.

Jeffrey, you are wide awake. Go ahead, take it.

DR. WILLIAMSON: Why are you calling it a quality management program? I mean what is the purpose of it from your perspective? What is the sort of bottom line? I mean I'll tell you what I think yours is. I think it's to sort of regulate the accuracy of treatment delivery relative to the physician's prescription. That is what you mean to go in this quality management program, isn't it?

MR. JONES: Right. What the physician prescribed.

MS. HANEY: And as far as the term quality management program, I think we have the flexibility of changing the name. We would of course have to justify the name change and go into that, but for the sake of the short time frame that we were dealing with, we didn't want to get

into let's call it quality something something else. It was easier just to work with this term.

DR. WILLIAMSON: I guess it is easier for me to like participate in a discussion if I sort of understand what it is about. I guess we all agree it's about regulation of quality or accuracy of treatment from a technical point of view.

CHAIRPERSON STITT: Regulation of what? Quality or accuracy?

DR. WILLIAMSON: Technical quality and accuracy.

CHAIRPERSON STITT: I don't think we have time to talk about the name change, but I do agree that quality management, I mean it's invoking all of the business theory of CQI and a whole bunch of things that fall within that. This is not a quality management program in the sense that probably anybody in business would use it. So when you have time to talk about name changes, I think that it would be appropriate to change it to what it is, which is regulating the doses that physicians prescribe.

So now that we have the name discussed, let's talk about the content. Yes?

DR. WILLIAMSON: I could just make a sort of procedural suggestion to --

CHAIRPERSON STITT: We're open to most anything.

DR. WILLIAMSON: I think in any kind of a sort of a regulatory package focusing on accuracy of treatment, it probably would be helpful maybe if we focused on part A, which is common to all these alternatives and make suggestions whether we think those are good objectives or not.

CHAIRPERSON STITT: But A actually changes, as Cathy pointed out. A is only A in alternative one, which is status quo. It is different in the other ones.

MEMBER SWANSON: Can we make comments on the general things, the general categories of requirements. For example --

CHAIRPERSON STITT: Start there.

MEMBER SWANSON: We have no choice. We are going to maintain a QMP. I don't think we need audits. I frankly think we probably need to retain written directives and records of administered doses. I don't want to submit a QMP modification to the NRC, and I don't want a requirement to record reportable events. I mean that's the way we look at it.

MR. JONES: Let's start with the audits, the internal reviews. You feel that they are not necessary to be a regulatory requirement?

MEMBER SWANSON: I don't think they are necessary to be a regulatory requirement. Fundamentally, at our institution, I think most institutions, when we have an event,

we do look into it, we do follow up on it as per the requirements.

I am not sure what the purpose of the audit function is to begin with. All of those things are reported to our radiation safety office. They are maintaining an ongoing audit of us at all times. I can never really understand what the purpose of that audit function was to begin with.

MR. JONES: You are saying for your facility that's standard procedure to do that, in absence of a regulation.

MEMBER SWANSON: I think it's going to be standard anywhere. I mean I can't imagine a facility that we're not going to report these things to a radiation safety office as part of their policies, standard policies and procedures that are out there. Or if it doesn't have a radiation safety office, if you are a licensee, the licensee is going to be -- I mean the burden falls on that individual anyway. So they are going to be notified of those events. I mean I think that is standard practice that those things are going to be reported to the radiation officer through the licensee.

MR. JONES: So you are saying it's being done now under voluntary compliance?

CHAIRPERSON STITT: Let's hear from some other institutions. Jeffrey, and then Ruth?

DR. WILLIAMSON: Well, at Washington University in the brachy therapy program of therapeutic radiopharmaceutical program, we have a very careful implementation of the NRC audit requirements, ever since the rule was implemented. In my experience of having spent a lot of time on these audits, it has not turned up one incident of clinical significance. What it has turned up is simply incomplete paperwork, maybe that we have had to address, but there has not been one incident I can recall where it has contributed to the quality or improvement of one single radiation oncology patient's treatment.

So I consider it as sort of a purposeless requirement. It doesn't do anything. It's not the primary mechanism by which we catch errors. It is an unrealistic look at how brachy therapy I think is practiced, to think that you are going to find something with a very high likelihood from this method.

The way one avoids errors and detects them is by having a very carefully designed, perspectively designed and executed treatment delivery process with a lot of checks along the way that monitor the different actions that happen, not going over a bunch of paperwork, because there's just nothing to really be learned.

We do do various sorts of voluntary record audits of all kinds in our institution that are similar to the QMP. They are directed at specific problems we're trying to solve. If it has come to our attention we have a certain problem with some kind of record keeping quality or accuracy, it might have nothing to do with the NRC requirements, we'll undergo an audit to find out what the problem is, implement a solution, and then test whether it works. When we are satisfied that we solved the problem, we will stop and move on and focus to some other problems. So it seems it's just not a useful expenditure of resources.

CHAIRPERSON STITT: Thank you. Ruth?

MS. McBURNEY: Coming from an agreement state program that has not implemented the quality management rule, simply because of the cons shown on option one, we felt that it was a regulatory burden on the agency itself as well as a regulatory burden on the licensees. I would prefer to see a program that required the licensee to establish and maintain some sort of quality management program and to retain the written directives and records of administered doses, and then depending on what happens with the definition of recordable events, to have that one in.

So perhaps a modified option four would be the preference that I would like to see.

CHAIRPERSON STITT: I think we are getting somewhere. Let's keep trucking. How about this line? There he is. Go ahead.

DR. SIEGEL: I just want to reiterate what Jeff said, which is I think the purpose of the audit is part of the original QMP or quality management rule was based on the belief that licensees would detect precursor events and would self correct before they turned into real problems. I think experience has shown that these audits are really not an effective mechanism for finding precursor events. So I reiterate what Jeff says.

While I have got the microphone for 30 seconds, I will say that when Sam and I were playing with actual wording for the entire rule as it applied to nuclear medicine, we actually proposed that this section be called radiopharmaceutical administration procedures. There was similar language I think coined that went with brachy therapy and teletherapy, so that that's a way out of calling it QM. It achieves the same objective without getting confused with this term that none of us really understand.

CHAIRPERSON STITT: Thank you, Barry. That makes sense.

So of us who have been through JCHO and certainly John probably has those regulations memorized, you have to look at a whole variety of things. If you have been looking

at these things, find that you have no problem with them where they are not contributing to your overall quality program, then those no longer have to be looked at. That is sort of what I am hearing from a number of the clinicians here. We have been doing this, and we have been doing this. It's not helpful. It did not pick up precursor events.

I think Sally made those comments to us when she presented the last meeting. It sounds like what I am hearing, what we're saying is that there is some reason that audits can be left blank under alternative.

Somebody over here. Naomi?

DR. ALZARAKI: Just another example of why the audit is really just paperwork and not really useful. Most departments, and I'm in nuclear medicine, really the number of therapy administrations given is small. I know every single therapy administration given anywhere in four hospitals that I'm at at any given time. To audit that is useless to me. We have been through all of these and if there has been an error made, which is very very rare, particularly in a therapy, we would be talking about that for years.

So to audit all of these administrations, we know them.

MR. JONES: Does anyone have any experience with audits? I have heard everyone say that audits are not necessary, we don't need them, they are not useful.

CHAIRPERSON STITT: That's what you are hearing.

John, you had a comment you wanted to make.

MR. GRAHAM: This is a procedural question. Could we do a straw poll of the Committee's preference in option one, two, three, and four? Then if we determine that there was a fairly strong consensus towards one of the actions, we could focus our discussion in that direction?

CHAIRPERSON STITT: Well, I actually prefer going down the key items for consideration and then seeing where we come up with. I think we are honing in on that, but I think it makes more sense to discuss the specifics, which are the key items, rather than the alternatives.

MR. GRAHAM: We're just going to go down this list?

CHAIRPERSON STITT: Yes. I am ready to move from audits unless there's anybody with a final cogent comment.

MEMBER SWANSON: I make a motion that whatever you want to call this, the quality management rule, does not include an audit.

CHAIRPERSON STITT: All right. We have had a lot of discussion. Is there anybody that has something to add that hasn't been brought up at this point?

MEMBER WAGNER: Second that.

CHAIRPERSON STITT: That was a second? Let's vote? Any discussion? All those in favor of the motion? Those opposed?

All right. We're on a roll. I think we're moving into this now.

MEMBER SWANSON: Was the count unanimous, Madam Chairman?

MR. GRAHAM: I think everyone voted in favor.

CHAIRPERSON STITT: Everybody voted in favor. Everybody who can vote voted in favor. Isn't that correct? I didn't see any negatives.

MEMBER FLYNN: I did, but this doesn't mean that a licensee, they can't have a voluntary audit.

CHAIRPERSON STITT: Absolutely.

MEMBER FLYNN: It doesn't have to be part of a QMP, but it doesn't mean that there can't be a voluntary audit.

CHAIRPERSON STITT: You can do anything you want to voluntarily, Daniel Flynn. We're talking about federal, government regulation. In the privacy of your own home, you can do that.

I'm ready to move on, Jeffrey. What do you want?

DR. WILLIAMSON: I think somehow I have gotten a sense we have left Sam with the impression that audits are a

useless tool under any circumstances. I don't think that's true.

MR. JONES: No. The issue is is there necessary for a regulatory requirement to require an audit.

CHAIRPERSON STITT: All right.

MR. JONES: What I am getting is that no, because they are being done on a voluntary basis.

CHAIRPERSON STITT: There we go.

Next. Licensees are required to retain written directives and records of administered doses. Let's discuss that. That appears in alternatives one, three and four.

Gee, why do the physicists have their hands up? Lou?

MEMBER WAGNER: I just have one question. Going back to what the philosophy of the ACMUI was, was in regarding to how the NRC should act. Is this not common practice to have a written directive and a record of administrative doses? I mean is there really a problem out there? Is it going to solve a problem by having it as a regulation? Have we identified that there is a real need in terms of a problem? That's just information. It's a question.

CHAIRPERSON STITT: Well, this is how we all practice. I'm not saying that it's a requirement for any sort of regulation. But if you are prescribing penicillin or gray,

you write it down in one fashion or another and it is put somewhere.

So that was your question that you sort of want to leave out there for us to be thinking about.

MEMBER FLYNN: I was trying to answer his question though.

CHAIRPERSON STITT: But Jeffrey had his hand up first.

MEMBER FLYNN: Okay. Sorry.

DR. WILLIAMSON: I was going to try and answer the question too. Hospitals spend hundreds of millions of dollars every year trying to maintain the integrity of records. I mean is there, going back to our statement, our review of the medical policy statement, is there some problem with the sort of maintenance of that practice standard or adherence to that practice standard? It just seems it's not necessary to make it a requirement because there is such a primary emphasis of all health providing organizations.

MR. JONES: So you are saying this is standard practice, is what you are saying.

CHAIRPERSON STITT: This is a standard of practice, absolutely. I mean if you look at any external record which is what, 95 percent of all radiation oncology, it is chronicled in detail.

MEMBER FLYNN: That's true most of the time, but when I was in the ACR accreditation committee, I was chairman of the pass/fail criteria. I looked at all the institutions, which I will not name, who did not pass ACR accreditation, looking for common root causes, because Dr. Hanks, who is chairman of the committee and knows a lot more than I do, thought that that would be useful for me to do that, and I did it.

There were several programs which the radiation oncologists insisted on giving oral directives, where we would never countersign. That was one institution. Another institution, the brachy therapy was so poorly documented as to when it was put in and when it was taken out, that both of those two institutions were not given ACR accreditation at that time.

So it is probably not a common practice today. These tend to be older practitioners, by the way, also. But I think that is going to be a rare event. It probably is very unusual. But of the hundred some odd programs that applied for accreditation, these are two programs of about 10 that didn't get it. There were good reasons.

CHAIRPERSON STITT: But I think you made a very interesting statement in describing that story. These people didn't meet accreditation standards. The standards are set up

as voluntary standards by one of the national, I mean the national organization in the country. So --

MEMBER FLYNN: But they continued to practice that way. I think there's a jeopardy to patient health and safety. The ACR couldn't force to do the right thing. But I am sure these institutions have changed their ways and I'm sure these practitioners, both of whom were quite frankly a lot older than the average practitioner and had very stubborn ways of looking at things, didn't feel they had to comply with a certain standard of today that we all train in.

CHAIRPERSON STITT: Naomi and Barry?

DR. ALZARAKI: We are of course talking practice of medicine here. Everybody is aware this is practice of medicine, not radiation safety. But in terms of practice of medicine, in using radionuclides unsealed sources for therapeutic administrations, the dosages prescribed can vary. So it is an individual patient decision frequently as to what dose you are going to use for a given patient. It could be 100 millicuries, it could be 150, it could be 200, it could be 400, depending upon what we're talking about.

Of course all of that would be recorded in the report which is dictated, but that's done after the fact. Before the fact, it is either a verbal order for a particular dose which is going to be different from patient to patient for the same type of disease perhaps. So I think that in

terms of practice of medicine, it's reasonable to say there shall be a prescription written for these doses. I don't know that it is the NRC's purview to write this as a requirement, but I agree that in terms of practice of medicine it's reasonable.

CHAIRPERSON STITT: Barry, you were next in the line.

DR. SIEGEL: If you go back historically and just thinking chiefly from a nuclear medicine point of view, the problems that led to the QM rule being formed in the first place derived often from oral instructions that were misunderstood. Part of the original version of this rule was really a prescriptive rule that said there should be a written directive. Then everybody got upset about that and they turned it into a performance based rule, which meant that you had to write a program that said that there shall be a written directive, which is basically the same thing.

There is, I think, enough evidence from past experience to suggest that certain relatively high risk activities warrant telling the people who are going to do them in writing that they should do certain specific things, rather than just letting a telephone communication or shouting down the hall be the basis.

If you accept that premise, then the question is, what level of comfort should the NRC have in knowing that you

have implemented the process. One approach would be to say I said I did it, therefore trust me. But that's not the way the government often works. They want some record that in the event there's a problem, even under a performance-based approach, you have to be able to investigate to understand why the problem occurred with that particular licensee.

As a very minimum, keeping these records in an auditable form provides the NRC that level of comfort that they can go into an institution and figure out what happened.

If you think about where these records would be absent a written directive kept in nuclear medicine or radiation oncology, they would be buried in the charts of lots of different patients and would be exceedingly difficult to audit.

So I would argue for retaining the written directive and retaining the retention of written directives as a necessary evil of keeping this rule in place.

CHAIRPERSON STITT: All right. Let's start down here. Anybody want to -- Ruth and then Jeffrey.

MS. McBURNEY: He hit on what I was going to say. That although everybody here probably has written directives and so forth, we are looking at minimum standards that are auditable and inspectable. So this is one mechanism that the NRC or an agreement state could actually see, that this part of it was being done.

CHAIRPERSON STITT: I am going to let Lou and -- everybody on there has a comment. Lou, Theresa, Jeffrey.

MEMBER WAGNER: I think the important thing here is that there is no other regulatory agency that is overseeing this type of written directive and requiring written directive. I mean I guess if the FDA requires it, we write prescriptions for prescription drugs, et cetera. We have that kind of thing. But we don't really have that for some of the radio therapy procedures. The FDA doesn't oversee that.

So there is no other mechanism by which we can get that. In lieu of the fact that there is no other mechanism, and there certainly is a potential for a major problem from this, putting those two things in combination, I would vote in favor of retaining item three until such time as we can get a health oriented, medically oriented regulatory body to take over this.

CHAIRPERSON STITT: I didn't think you were going to let it go without a qualifier.

We are starting to come together on this. Theresa and Jeff? Then we're going to see if somebody wants to make a motion.

MEMBER WALKUP: As part of the medical dosimetry community, I have in order to protect us, we really do need to have that written directive. Otherwise, we are taking that

into our own hands. We need that. We need to fill a definite prescription of the doctor's orders.

CHAIRPERSON STITT: Jeffrey?

DR. WILLIAMSON: I didn't realize we were debating the issue of whether a written directive should be created or not as regulatory requirement versus record keeping requirement that I question, whether there is any evidence we need to have.

So I want to go on record saying I agree completely with the utility of having written directives. In fact, if there's one part of the quality management sort of a constellation of regulations I like, it is the requirement that a written directive be written and signed by the attending physician. But I disagree that we need to have a special federal requirement to keep the written directives and treatment records in the sort of auditable form.

My impression is is that there is not a major problem in this country with retaining those records. I really can't imagine an institution writing a written directive and making a treatment record and then throwing them away. Occasionally through no one's particular fault, you know, an occasional patient record or chart may be incomplete or parts of it lost. That happens. I don't think institutions should be punished for very small error rate in record keeping that is bound to occur in any large institution

that's trying to manage this huge amount of information regarding patient treatments.

CHAIRPERSON STITT: In its most simplistic view, if we can trust Barry, it is really retaining something that we're already doing, but putting it in a location where it is easy to find. Now what are the permutations of that that get us into trouble?

John?

MR. GRAHAM: I am going back to the staff requirement memo, that the quality management program provisions should be reevaluated and revised to focus on those requirements that are essential for patient safety, e.g. confirming patient identity, requiring written prescriptions and verifying dose.

Now it was presented to us that's a given. So I skipped any discussion about whether this whole thing is a practice of medicine and shouldn't even be a point of discussion.

CHAIRPERSON STITT: Would you like to make a motion?

MR. GRAHAM: We are talking about it. Now this is one of the few times I disagree with Barry. I guess I am being more Republican. I think if you start to set up the retention of written records, it is retention that is uniquely different in options one, three, and four. Option two in the

language that's in our packet requires a written directive. It does not require retainage. More importantly, it doesn't require retaining in a specific format to facilitate federal audit.

I think as soon as you get into retaining, you are headed down a slippery slope where you beg for an outside audit periodically. We have an extraordinary number of complicated, potentially very dangerous procedures that are performed in my hospitals every day. We have some incredible records that document what as done and who ordered it, and how it was performed. We don't seem to have any difficulty auditing open heart surgery or neuro surgery, or the administration of a very lethal drug. I don't understand why these specific prescriptions are any more difficult for us to review and monitor than any other medical information we're currently collecting.

MEMBER NELP: They are currently retained. There is no question that they are retained for long periods of time.

MR. GRAHAM: For regulatory purposes.

MEMBER NELP: No. Your hospital retains --

MR. GRAHAM: Medical records have legal requirements to keep them in there for seven years, minimum.

CHAIRPERSON STITT: Okay. Lou, and then somebody be thinking about a motion because we're going to have to go one way or the other.

MEMBER WAGNER: Yes. That is a very important point that you make, John and Jeff. The issue is whenever regulatory body requires us to keep records, the regulatory body should ask itself whether keeping of those records is actually conducive to the protection of an individual or some end goal for the stated direction or charge of what they are trying to do. Or is that record being kept so that a regulator can come in and go check it off easily and then leave. That doesn't necessarily add to patient care.

Then we keep getting these burdens where we have to do stuff that's not related to the patient care. It's a regulatory requirement and we do it for the regulators. We should be doing this stuff for the patients. It is clear that the written directive is required. That is a standard of practice. I agree with the idea that now they snuck in this records of administered doses as an additional thing, sort of like Congress always attaches things to bills and wants to get them put through.

So in this case, I would recommend that the Committee -- I would like to move that the Committee endorse item three only in the first clause, the licensee be required

to retain written directives, and drop the other part of that sentence, and records of administered doses.

MEMBER NELP: Could you explain what that means?

MEMBER WAGNER: Simply that you have the written directive. There is a written directive to be retained, be in the patients' records, it will be somewhere. But you want to keep a special log for auditing, which is the second part of that.

CHAIRPERSON STITT: But we all have written directives and we all have records of the doses administered. That is different than -- I mean at face value, you can't, I would not disagree with this but there is a different portion of this that's not on the paper. It's the second part of the clause that would be record keeping specifically for the regulators.

MEMBER WAGNER: I'm sorry. But the problem --

CHAIRPERSON STITT: So I think we have to be careful about the motion that we make because we all retain written directives and records of how dose is administered.

MEMBER WAGNER: I agree.

CHAIRPERSON STITT: That is in the chart. That's there for decades.

So how do we as a committee view the part that's not on this piece of paper, but must be somewhere, which is

we're keeping logs and retaining this for purposes of NRC. There's something that's missing.

MEMBER NELP: I can respond for nuclear medicine. I think it's like Naomi said. We just write it down in a book every time we do it, and also put that in the patient's medical record. But you can walk into my shop and I'm sure yours. I can give you, if you wanted to see what we have done since 1950, I can pull the books off the shelf and that's a record.

Apparently with radioactive sources, you don't do it. Ours is very simple to do and probably very commonly done. But with multiple treatments or with complex treatments with radioactive sources, you don't' keep a separate log entry book I presume.

CHAIRPERSON STITT: Yes, we do.

MEMBER NELP: So it seems like we are doing the same thing.

CHAIRPERSON STITT: So what is the question here that we are supposed to answer?

MEMBER NELP: I mean you could audit my experience over the last three years in a matter of -- I mean I could provide you with the material in a matter of five minutes.

CHAIRMAN STITT: Is the issue records being available for inspection? There's a con under alternative two

that just says -- refers to licensees retaining written directives and records of administration. Thus, these records would either be or not be available for inspection.

So I think it's really the manner in which -- what we're already doing for patient management is being collated, collected, put in the purple NRC book. I think that's the crux of the matter.

MEMBER GRAHAM: I would move that the Advisory Committee on the Medical Use of Isotopes recommend the requirement of written directives and written record of administered doses, period.

CHAIRMAN STITT: Is there a second?

MEMBER SWANSON: Could you repeat that?

MEMBER GRAHAM: The ACMUI would recommend the requirement of written directives and written records of administered doses, period.

MEMBER WILLIAMSON: Do we need to second it to discuss it?

CHAIRMAN STITT: Uh-huh.

MEMBER WILLIAMSON: Second.

CHAIRMAN STITT: All right, discussion?

Go ahead, Jeff.

MEMBER WILLIAMSON: Well, I thought we were discussing the issue not of whether treatment records would be required and written directives would be required, but whether

we ought to agree or endorse a concept of having a federal law requiring us to retain said records in auditable form.

So I would like to modify -- propose modifying John's motion to add "but that we disagree that a federal requirement to maintain said records of treatment and written prescriptions is necessary for patient" --

CHAIRMAN STITT: Or you can make that a positive, meaning we -- we feel that no separate record keeping mechanism --

MEMBER WILLIAMSON: We do not feel that a federal law regarding maintaining or retaining of these records is necessary.

MEMBER NELP: Well, how about saying maybe maintained in accordance with the current standards of practice, is what we're saying?

MEMBER WILLIAMSON: Well, I don't think a federal law saying we have to keep them in accordance with the standards of practice is needed. They're already, I'm arguing, kept probably quite well in the vast, overwhelming majority of institutions.

CHAIRMAN STITT: I think we're all trying to say the same thing. I think it's just getting the words on paper correctly.

Naomi, you're nodding your head.

DR. ALAZRAKI: Well, I was going to say the same thing. As per standard of medical practice, written directives for doses administered are regularly given or written. A federal regulation would seem not appropriate.

Also, it's practice of medicine.

CHAIRMAN STITT: Dan?

MEMBER FLYNN: Does it help if it's records of administered therapeutic doses? Does that help at all in terms of --

CHAIRMAN STITT: I think we ought to watch that for the time being.

I think the first part of the clause is probably where -- your sentence works fine, but we need some qualifier to indicate that we're not interested in having a regulation define other log books or other modes of already duplicating what we're doing once.

Is that one of the -- is that some of the gist of what you guys are trying to say?

MEMBER WILLIAMSON: Well, I was trying to say the ACMUI agrees that the new Part 35 should require written directives and records of treatment. Okay, end of sentence.

Second sentence: The ACMUI does not feel that patient safety requires a separate federal law requiring the retaining and/or maintenance of said records in any particular form to facilitate federal audits.

MEMBER GRAHAM: Let me attempt a modification of the motion.

CHAIRMAN STITT: You have been known for that, so go ahead.

MEMBER GRAHAM: The ACMUI recommends requirement of written directives and written records of administered doses, but does not advocate the extraordinary retention of these written directives or records beyond the normal practice of medicine.

MEMBER NELP: Well, that's pretty sensible.

CHAIRMAN STITT: All right, so we're getting some people nodding up and down here. Looks like it's being typed up there for us.

We're appreciative. So far you're doing better than we are.

MEMBER NELP: What is the legal basis for your requirement, John, in your hospitals? Who tells you that you have to keep your records, medical records, for seven years/

MEMBER GRAHAM: I believe it is state regulation, but I'm not an attorney, so --

MEMBER NELP: I mean, somebody tells us we can't throw away our x-ray records for five or seven years.

MEMBER GRAHAM: But I'm not sure who that person is.

MEMBER NELP: Does anybody know?

DR. SIEGEL: A starting point would just be tort law. I mean, try defending a malpractice case and not having any records. You'd have to at least retain records for the statute of limitation related to malpractice liability.

DR. ALAZRAKI: Which is?

DR. SIEGEL: Varies from state to state.

CHAIRMAN STITT: Does the comment "does not" -- we've got the first statement that we're agreeing that we write things down and we hang onto them. Does not advocate retention of records. But aren't we also trying to --

MEMBER WILLIAMSON: Wait a second. It's not that we're not advocating retention of records, it's that we're not advocating a federal requirement to retain the records.

CHAIRMAN STITT: Or to have a separate set of records.

MEMBER GRAHAM: The word missing was the extraordinary retention of records beyond the normal practice of medicine.

MEMBER SWANSON: But the issue is, I think, what we're not advocating is that that has to be addressed in regulatory space. Okay, the retention of records does not need to be addressed in regulatory space. It's standard of practice to retain these records, period.

We don't need a regulation to tell us to do that, okay?

CHAIRMAN STITT: So you could say does not advocate federal regulations.

MEMBER SWANSON: Or you could say ACMUI recommends a requirement that written directives and records of administered doses be maintained, but does not feel that this needs to be addressed in regulatory space, period.

MEMBER NELP: Well, he said in accordance with current medical practice.

MEMBER GRAHAM: Dennis, I've got a feeling of the committee that they wanted to have something that clarified that we're saying you shouldn't have a retainage reg. That's the only reason we added that.

MEMBER WILLIAMSON: That's what I've been trying to say.

CHAIRMAN STITT: Well, are we saying that in our words that we have up on the screen?

Jeff, go ahead.

MEMBER WILLIAMSON: I don't like the phrase extraordinary retention. I would prefer we put something clearer that says --

CHAIRMAN STITT: Yes.

MEMBER WILLIAMSON: -- the NRC does not advocate a Part 35 requirement to retain records beyond, you know -- just period, to retain records period. And we could add as a comment of an explanation that we feel the standards of

current practice adequately address the problem of retaining records.

CHAIRMAN STITT: Were you making some --

MEMBER SWANSON: I actually think we're all saying the same thing.

CHAIRMAN STITT: But we're not putting it in words very well.

MEMBER SWANSON: Well, are you getting the message?

DR. ALAZRAKI: Well, I think Jeffrey said it in words pretty well.

CHAIRMAN STITT: All right, let's see if it's up there. ACMUI recommends requirement and administered doses, but does not advocate a Part 35 requirement to retain records.

MEMBER WILLIAMSON: To retain records.

MEMBER NELP: Beyond the normal practice.

MEMBER WILLIAMSON: No, that's then saying that they'll be a Part 35 requirement that says we have to follow normal medical practice.

CHAIRMAN STITT: Right.

MEMBER WILLIAMSON: I would prefer to add a sentence saying that we -- the ACMUI feels that standards of practice in adherence to said standards of practice adequately addresses the problem of maintaining patient records.

CHAIRMAN STITT: Theresa?

MEMBER WILLIAMSON: Okay, yes; the ACMUI believes that current, voluntary standards of practice and acceptance of such standards of practice adequately addresses the problem of maintaining patient treatment records, period.

CHAIRMAN STITT: Except those aren't voluntary. We're doing that because we're required to by various tort law.

MEMBER WILLIAMSON: That's irrelevant. We're not talking about other agencies' laws. We're only talking about Part 35.

CHAIRMAN STITT: I'm not sure I agree with that.

MR. JONES: Yeah, but if you removed it from the regulations in Part 35 -- if you remove this requirement, then your reason to remove it is because of --

MEMBER WILLIAMSON: It's already being done.

MR. JONES: Because it's required by --

CHAIRMAN STITT: You name it.

MEMBER WILLIAMSON: Not that it's being necessarily required by anybody, but that we view it as such an essential component of practicing medicine that we all do it. We focus a lot of energy on it.

MEMBER NELP: See, I think you're wrong. I bet you it is required by somebody, but --

CHAIRMAN STITT: It is required.

MEMBER WILLIAMSON: And it may be required in some other settings for various --

CHAIRMAN STITT: Theresa, you've had your hand up three times.

MEMBER WALKUP: Yeah, I just -- maybe I need to be clarified on this, and we may touch it when we get to the radiation safety committee. But I know in our radiation safety committee, we have to state we had four brachytherapy implants and two radioiodine doses.

There were no misadministrations, nothing. So a log will -- I mean, unless that changes in the radiation safety meeting, then a log will still be kept. I mean, --

CHAIRMAN STITT: Well, you can do institutionally what you what. We're trying --

MEMBER WALKUP: Is that just for institution?

CHAIRMAN STITT: Now your institution may have set that up in response to Part 35. That's pretty common.

MEMBER WALKUP: Okay, that's what I didn't know. Okay.

CHAIRMAN STITT: We've got all sorts of things and still don't have a good -- we have a sense of what we're trying to say, but I don't know that we're stating it very well.

MEMBER FLYNN: I have another version. Can I try another version?

CHAIRMAN STITT: You can try most anything, Dan.

MEMBER FLYNN: All right. Well, if you say the licensee -- forgive me this part. The licensee is required to continue to retain written directives and records of administered doses in accordance with existing medical practice.

CHAIRMAN STITT: Do we want to add the clause though that says we don't need additional federal regulation? I think a positive statement -- I mean, a statement of what we don't need --

MEMBER FLYNN: It's simply saying that we're continuing to retain records in accordance with what we're doing already in current medical practice.

CHAIRMAN STITT: That's still -- so far we agree pretty well on --

MEMBER FLYNN: They're not telling us to do it. We're doing it because it's -- we're doing it because of current medical practice. And we've already been doing it, and we'll continue doing it because of current medical practice.

CHAIRMAN STITT: We all are doing well on the first part. It's the second part we aren't doing well. I think what you're saying is essentially what we've already put down there.

John, do you have it ready?

MEMBER GRAHAM: Let's see. This began -- I hate whereas's, but -- Jeffrey, whereas, the ACMUI does not recommend a federal regulation for the retention of records, and whereas, medical records are retained, under existing regulations within the practice of medicine, therefore the ACMUI recommends that directives and written records of administration, period.

MEMBER NELP: You get wrapped around the axle.

MEMBER GRAHAM: Back to my original motion.

CHAIRMAN STITT: Just phrased a little differently.

Go ahead, Wil.

MEMBER NELP: It seems to me the only thing they want us to do is keep the records for three years, which you already do, and keep them in a form that somebody can come in and make an audit, which we already do. So we're making a big issue out of this.

MEMBER GRAHAM: But we just voted that we don't recommend audits, so I'm trying to write the next motion moving us in that direction.

MEMBER NELP: I'm not sure we need to make all these motions, but give them a considered opinion and let them deal with it.

CHAIRMAN STITT: Well, we could stop with what we've got, which is just that very first phrase, that we feel

we should retain records of directives and administered doses.

One more round of comment.

I don't even know what motion was seconded.

MEMBER NELP: Well, I don't even think we need a motion.

CHAIRMAN STITT: Well, we have to put something pretty strong --

MR. JONES: I have one question.

CHAIRMAN STITT: Yes.

MR. JONES: The "because". You don't needs records because, and you had said that because of existing regulations in the practice of medicine, it's already being done. Okay, what requirements or regulations are you referring to?

MEMBER GRAHAM: I'm not referring to a specific regulation. I'm saying that whereas, medical records are retained under existing regulations within the practice of medicine. That's a statement of fact I'm real comfortable making.

MR. JONES: Okay, I'm just asking what regulations. You know, what existing regulations.

CHAIRMAN STITT: JCHO, your own hospital -- there are lots of different regulations.

MEMBER GRAHAM: Requirements.

CHAIRMAN STITT: Now we could simply vote on what we're not having trouble with, license -- we agree to retain written directives and records of doses -- vote on that and then just leave commentary.

MEMBER GRAHAM: The motion on the table -- the motion that was supported that's on the floor was that the ACMUI recommends written directives and written records of administration, period. That's the motion. There's no -- the word retain is not in that motion.

CHAIRMAN STITT: Okay. And that was seconded by somebody.

MEMBER GRAHAM: And that was seconded by Jeffrey.

CHAIRMAN STITT: One last round of discussion and we're going to vote on that.

Jeff.

MEMBER WILLIAMSON: Okay, well I would agree with John's most recent pseudo-motion. I guess that's not really the motion. The one with the whereas's. With the one addition that instead of whereas medical records are already retained because of existing regulations, I would propose to replace existing regulations and adherence to voluntary standards of medical practice.

And then I would find that an acceptable substitution for the initial, official motion that is on the floor.

CHAIRMAN STITT: Let's have a few more comments while he's rethinking that and we'll decide what to do with the motion we have and then the pseudo motion.

Lou.

MEMBER WAGNER: Let me get the gist of this. I think all we're saying is the following:

A written directive and a record of the administered dose must exist, not in any special form, but in the form consistent with the practice of the facility.

CHAIRMAN STITT: That is the motion that's on the table.

MEMBER WAGNER: That's it. That's the gist of it, is it not?

CHAIRMAN STITT: That's right.

MEMBER WAGNER: That's it? Thank you.

CHAIRMAN STITT: Dennis and then --

MEMBER SWANSON: All I'm suggesting is that motion needs to be expanded to give specific statement to the NRC that we do not need that requirement to be put in a Part 35 regulation.

CHAIRMAN STITT: Why don't we vote on the motion we've got. We can have a second motion. I think that's the quickest way to do things. Because none of us are disagreeing with motion number one.

I'd like to call for the vote on the motion which is one statement, which is -- do you want to read that back?

MEMBER GRAHAM: The ACMUI recommends written directives and written records of administration.

CHAIRMAN STITT: All right, let's vote.

All those -- that was seconded, but you go ahead and third it.

Vote. Everybody in favor? Those opposed?

All right, is there any further discussion or any further motions?

MEMBER SWANSON: I make a motion that we say the retention of written records does not need to be addressed in the Part 35 regulation.

CHAIRMAN STITT: Would you like to second that?

MEMBER GRAHAM: Second.

CHAIRMAN STITT: Any further discussion? We've really discussed this. Unless you've got something new to say -- everybody in favor of that motion?

Oh, we're doing very well.

Everybody opposed?

What did we just say? We're still on alternative two. Did we already -- all right, we have two more to go, but Cathy says we've really kind of been through this discussion, right?

Licensee required to submit QMP modifications to NRC.

What, John?

MEMBER GRAHAM: I move that the ACMUI recommends that a licensee is not required to submit QMP modifications to the NRC, period.

CHAIRMAN STITT: Lou, do you want to disagree with that?

MEMBER WAGNER: No.

CHAIRMAN STITT: You wanted to second it?

MEMBER WAGNER: Absolutely.

CHAIRMAN STITT: I'm hassling you.

We will have limited discussion.

MEMBER WAGNER: Yes.

CHAIRMAN STITT: Yes, Lou was happy to second that.

CHAIRMAN STITT: Dennis.

MEMBER SWANSON: I'm ready to raise my hand.

CHAIRMAN STITT: Okay, Dennis is excited.

Jeffrey, do you have a comment?

MEMBER WILLIAMSON: No, I was just seconding the motion.

CHAIRMAN STITT: Oh, everybody wants to vote?

Everybody in favor of that motion?

Don't you wish you could vote, Naomi?

Those opposed? Okay.

She's voting with her smile.

Licensee is required to maintain recordable events. I'm going to jump in to say recordable events is going to be discussed in some detail.

MS. HANEY: I would say you might want to table that one until tomorrow.

CHAIRMAN STITT: Well, we're good at that. Can I just say we're not going to discuss it or do we have to have --

MS. HANEY: No, you can just put it off until tomorrow.

CHAIRMAN STITT: I'm just going to put that off until tomorrow.

Jeff, you have a comment?

MEMBER WILLIAMSON: Well, it's a request.

Can we discuss Section A, what should be the goals of the QMP or whatever we're going to -- whatever it's going to be called? I think it would be appropriate to focus some attention on --

CHAIRMAN STITT: Well, that's where he tried to start us, and we actually balked. I think it would be very appropriate to --

MEMBER WILLIAMSON: I think we've dealt with everything else.

CHAIRMAN STITT: Yes, I think that would be very appropriate now that we're a little more grounded and centered.

Yes, sir.

MEMBER GRAHAM: Just by a clarification, regardless of how the discussion on a recordable event or the definition of a recordable event turned out tomorrow, I'd be curious in the sense of the committee regarding a recommendation that would not require licensees to maintain recordable events.

To facilitate discussion, I would move that the ACMUI recommend that licensees are not required to maintain recordable events, period.

MEMBER WAGNER: I'll second that.

CHAIRMAN STITT: Okay, it's been seconded.

So John has exercised his power of ignoring my refusal -- no, I mean, what you're saying is, regardless of how we discuss recordable event, no matter what answer we would come up with for recordable event, we can make a motion and discuss the issue?

MEMBER GRAHAM: That the maintenance of logs, records that tie to recordable events is not a recommendation.

CHAIRMAN STITT: Well, it certainly goes along with the discussion we've already been having.

MEMBER GRAHAM: And that's based on three years of listening to this group discuss this topic.

CHAIRMAN STITT: People want to comment?

We've had a motion that's been seconded. Time for discussion.

DR. SIEGEL: I'm having a bit of a problem here. Thinking NRC for the moment. Think out of the box and think real performance-based, which is the licensee shall have a program intended to ensure that authorized users -- or that byproduct material is administered in accordance with the directions of the authorized user.

The components of the program should be a written directive, a record of the dose, period. Or patient identification, and we could add whatever else we still think we want to include.

In a performance-based rule, as long as nothing is happening, it probably never gets inspected. It's just the licensee continues to practice well and things go along just hunky-dory. When there's a problem, the NRC is going to feel a need to come in and try to understand the problem and determine whether corrective action is necessary with that particular licensee.

In the absence of certain specific records that are kept to help the NRC do its job, even though we may not want them to do the job, the NRC has a problem because they

can't just walk into the hospital record room and say we're here to go through your records.

I think there are confidentiality issues that would prevent them from just walking into the average hospital record room and starting to go through randomly selected patient charts to see if there's been any misadministrations, or whatever term you like, of byproduct material.

So keeping in some minimal record retention requirements provides some level of comfort for the NRC and provides some -- an insurance policy for us that we're not opening all of our records open for NRC purview.

I throw that out for your thinking.

CHAIRMAN STITT: In talking -- if we have to report whatever a recordable event is or will be, the NRC would have all those records. And Dawn said they're going to have a wonderful computer system?

DR. SIEGEL: Well, they wouldn't have the source records though. I mean, they wouldn't have the source documents. They just have some notification of an event, not the original source documents that show why the event occurred and who did what at what point in time.

CHAIRMAN STITT: That's not necessarily true.

DR. SIEGEL: I mean, that's what's true now. Right now, you submit a summary description of misadministration. It names a few people, but it doesn't name

the patient, obviously; and it provides a summary, but it doesn't -- you don't send in a photocopy of the written directive as part of the misadministration report.

MEMBER FLYNN: After looking at about 60 misadministrations as a consultant, Barry is right. And I end up asking the licensee for more records. Now, two-thirds of the time, the summary provided to the NRC is correct and nothing much added.

But about one-third of the time, additional things that the licensee wasn't aware of but didn't understand happened that made a dramatic change as to how the event is subsequently interpreted. So I think I agree with Barry.

CHAIRMAN STITT: Okay, Dennis, you were commenting?

MEMBER SWANSON: That last key item is -- it refers to requirement to maintain recordable events. I actually think you could address your concern if you went back to option two and item number four under there where it says you're going to have a quality management program and it says that any unintended deviation from the written directive is identified and evaluated and appropriate action taken.

You could do a simple modification of that statement that says that any intended deviation from the written directive is identified, documented, and evaluated, and appropriate action taken.

That way, you have the requirement that there's documentation of this, but we don't have to get into a rule that addresses maintaining these records, which is what we just discussed with the other written records.

DR. SIEGEL: And I guess I'm still worried that there's going -- when the lawyers sit down and look at this recommendation, they're going to say but we still have a problem in terms of what degree of licensee we have to just start rummaging through all of the records of a hospital.

Whereas, a well defined set of records make it in part clear that these are the records that the NRC has free reign to look at as part of any inspections that it conducts. Absent that, I think that there's going to be some collisions, and I just -- I'm not sure I know exactly what the collision points are.

But, you know, patient confidentiality laws and a variety of other things may create problems for the Agency that would force them to reject this suggestion.

CHAIRMAN STITT: Theresa, then Jeff.

MEMBER WALKUP: Could not just a log be kept of those patients and that's it? And if they want to pull it, then at least you'll be able to go I need John Doe and Jane Doe and -- and that way, you don't have to keep this separate written directive and a separate -- because it should be in the chart and somehow just put that into it.

CHAIRMAN STITT: Certainly could be.

Jeff.

MEMBER WILLIAMSON: Well, I wanted to respond to Barry's premise, which is that the NRC cannot request access to medical records -- in radiation oncology do. They say show me the list of patient records that you audited.

Okay, now bring me four patient records in the same modality that you didn't audit, I want to examine them. And we go to our list and we find them. So in -- two points are clear to me. One, certainly I think they do have the right under current laws, evidently, to just simply go in and request a class of records.

And it's obligation of the institution to be able to respond to that. And if they can't, they're in trouble. I don't know why there needs to be a federal law.

In addition, second -- let me finish, please. Let me finish, please.

Secondly, in radiation oncology, we keep no special parallel record for the NRC. We don't. We simply will make available to them the radiation oncology chart with -- which has the brachytherapy and radiopharmaceutical documentation in it.

CHAIRMAN STITT: We have a comment from the general public.

MS. ROTHSCHILD: I just wanted to note as far as the NRC authority to go into a hospital and look at patient records, if this is an NRC licensee, there's specific authority in the Atomic Energy Act, Section 161(c), for the NRC to obtain such information as it deems necessary to perform its functions.

Also, as far as patient confidentiality, I don't want to -- that may come up more tomorrow, but I just wanted to note that our understanding of the applicable -- I guess there are ethical standards of the American Medical Association -- are that a physician shall safeguard patient confidences within the constraints of the law.

And that a duly promulgated federal regulation would be -- you know, for that purpose, would be considered a law.

Thank you.

CHAIRMAN STITT: Just restate the motion that's on the floor and has been seconded.

MEMBER GRAHAM: That the ACMUI recommend that licensees are not required to maintain recordable events.

CHAIRMAN STITT: Okay.

Wil?

MEMBER NELP: You know, let's go with it. They're asking -- and we say that recordable events,

misadministrations, really don't happen that often. We always -- we keep the records. And I agree with Barry.

If I were in the role of the NRC, I'd want to be able to go to some of these institutions that aren't like the ones we represent perhaps where they need some help and you can go in and review their records.

And it's a very small thing to ask. And it's not pervasive at all as far as I'm concerned. And I think we're barking up the wrong tree. And I'd like you to withdraw your motion and let's get on with better business because this is a very simple requirement.

CHAIRMAN STITT: Well, we can vote on the motion and get a --

MEMBER NELP: Well, we could do that.

CHAIRMAN STITT: Other comments? I mean, we've heard some interesting commentary on both sides.

Jeff.

MEMBER WILLIAMSON: Well, with the recordable event reports, I suppose more generally thinking of them as kind of like internal quality assurance event reports and documentation of what you've done and so forth, it's not clear how I would vote on this.

It seems to me I would need to know one, what is the purpose of the recordable event in the first place?

Secondly, within what sort of a regulation context does the requirement to have these appear?

So, for example, if there were a requirement that you have a program where you do have to document them in the first place, then I would think that an additional requirement to retain a record in some special way would be redundant and unnecessary because I don't imagine, you know, for the same reason hospitals don't throw away intentionally patient records, they wouldn't throw away deliberations of their own quality assurance actions.

CHAIRMAN STITT: Well, it's possible then --

MEMBER WILLIAMSON: So I can't say I would vote for this motion without some reservations and qualifications.

CHAIRMAN STITT: It's possible though -- what you're saying is you need to see more of the discussion here -- what the discussion is going to be tomorrow, which means we could --

MEMBER GRAHAM: But I'll pull the motion. Having been duly chastised for --

CHAIRMAN STITT: Can you do that?

MEMBER GRAHAM: Yes.

CHAIRMAN STITT: Right, for speaking out of turn.

MEMBER GRAHAM: -- trying to usurp the wisdom of the Chair in deferring it to tomorrow, I withdraw the motion.

CHAIRMAN STITT: I think that's wise.

(Laughter.)

Now this will be heard up again. I think we can all agree to that.

Do you -- does the group want to -- we're doing a good job, particularly time-wise, and we're getting -- do you want to walk through ABCD --

Okay, let's look at the rule. We have -- under the alternatives chart that we started with, we are looking at alternative two, except for the final licensee required to maintain recordable events will be discussed later.

We need to look at part (a) under alternative two.

MR. JONES: Dr. Stitt, I have one question.

The motions that you made essentially changing the current requirements, okay, and we have two or three up here. One about modification of QMP, written directives. Okay, could you give me a little more on what you think -- if we make this regulatory change that's been recommended, what's the rationale for that change?

CHAIRMAN STITT: I think you've been hearing it all along.

MEMBER GRAHAM: I think we're down to a couple of options, aren't we, at this point?

MS. HANEY: Well, based on what I've heard, you've narrowed it down to alternative two.

MEMBER GRAHAM: And I think the committee -- there are representatives on the other side of the table, I think, that can be much more eloquent discussing the advantages of how a written program would be developed because we've been told we have to have one.

MS. HANEY: No, what I -- going by what the motions have been so far as far as what you would want in a QM program, and if you're looking at this matrix, the only thing that at least I heard the committee was in favor of having is just the requirement to have a QMP.

And again, that was almost -- that's a given that we have to have that.

CHAIRMAN STITT: All right, the only one -- we also voted that you need to retain directives and doses, but we also -- no, but we didn't want to be regulated to do that, so I think -- the purest approach is that we're looking at alternative two because we qualified point number three.

MEMBER WILLIAMSON: Would it help if we reviewed page six, which is the draft language, of the --

CHAIRMAN STITT: That's what I was trying to get us to do.

MEMBER WILLIAMSON: Yes, that's what I propose that we do.

MS. HANEY: And I can tell you the difference between -- really between page six and the current rule other

than we dropped off everything but just item (a). The differences are in (a)(1) where we said that the written directive is based on a dose of 50 rem as compared to specifying what it was for each different type of modality.

Fifty rem came from Part 20, and that is -- you know, 50 was not necessarily a magic number, so that -- we just chose a dose number to get in there.

Item two is the same as in the current rule. Item three out of the current rule is gone -- was deleted. That is the final plans of treatment and related calculations for brachytherapy, teletherapy and gamma stereotactic radiosurgery are in accordance with the respective written directive.

We did not feel that was necessary.

Item three is the same as it was before. And item four is the same. So we went from a five objective rule down to a four objective with some minor changes.

MEMBER SWANSON: Are we open for comments?

CHAIRMAN STITT: Yes.

MEMBER SWANSON: Let me comment that I think the approach taken in item one is a very good approach and much better than the previous approach in that it allows flexibility for new technologies and it's a lot less confusing than trying to remember 30 microcuries versus something else.

Okay, so, you know, I think that's very good. My only recommendation for change would be I think one I referred to previously, that in number four, it be changed to that any unintended deviation from the written directive is identified, documented, and evaluated, and appropriate action taken.

CHAIRMAN STITT: You know, it's interesting because four comes back to the part that we're sort of tabling. I mean, that keeps resurfacing whether we do or don't want to maintain recordable events. Through this mechanism, it has to be done, which makes it a little silly for us to vote against it when we relook at John's withdrawn amendment.

DR. ALAZRAKI: Well, the magnitude of the unintended deviation is not defined here.

CHAIRMAN STITT: That's true.

DR. ALAZRAKI: And so that needs to be defined. It may become -- that would become a recordable event if it --

CHAIRMAN STITT: And any unintended deviation is wide open.

DR. ALAZRAKI: Right.

CHAIRMAN STITT: That's --

DR. ALAZRAKI: It should really be defined here. Any unintended deviation which qualifies as a recordable event.

CHAIRMAN STITT: Barry.

DR. SIEGEL: The wording, if you read it carefully, it requires an audit that any unintended deviation from the written directive is identified. How can you identify if you don't look for it?

CHAIRMAN STITT: If I don't find --

DR. SIEGEL: You are building in an audit whether you like it or not.

MEMBER SWANSON: Fundamentally what happens then is you would take it out and you'd say any unintended deviation is documented. I think the way it really happens is --

DR. SIEGEL: Evaluate it.

MEMBER SWANSON: Right, and evaluate it. Okay, it's documented and evaluated, and appropriate action taken. I would agree.

CHAIRMAN STITT: That any unintended deviation?

MEMBER SWANSON: Well, we have to define that.

MEMBER FLYNN: That's certainly not true. In radiation oncology, the physicist -- different physicist, different dosimetrists check the charts every week.

And one physicist -- this happens all throughout the country -- will find out that an error was made on a previous calculation the previous week, and then they will -- this happens in every single radiation facility in the country every year.

And then the doses are adjusted appropriately. It's usually not a recordable event. And the patient gets the right treatment when they finish the treatment. They get their treatment adjusted. They might have been five percent low on Wednesday. They might get five -- two and a half percent higher on Thursday and Friday.

So this happens all the time.

CHAIRMAN STITT: Well, but as Barry says, depending on who is reading it, this could be -- you know, if somebody from the NRC staff is reading it, it looks like audit to them. To you, it looks like the physicist needs to repeat the dose.

MEMBER FLYNN: Patient pulls the source out five hours early. You know, it's an unintended deviation. You handle it. You --

CHAIRMAN STITT: Well, it's a good description of how we can get into trouble with our words.

A lot of comments.

Naomi.

DR. ALAZRAKI: Yeah, well how do we -- again, in nuclear medicine, how do we identify that there's been a -- what's been called a misadministration? It may have been the wrong patient who got the dose or the right patient got the wrong material. I mean, how do we identify these? Not through audit necessarily.

It's usually identified usually after the event, but it's identified because in going through the inventory of radiopharmaceuticals or in however. But it can be identified on the floor if it's an inpatient by someone in the hospital who realizes the wrong patient went down.

CHAIRMAN STITT: Barry.

DR. SIEGEL: The problem word here is the word identified. It says that you have to have a mechanism for identifying. It doesn't say once you've identified it, evaluate it, figure out what went wrong and institute corrective action.

As long as you leave the word -- those words, is identified, in there, you're implying that you have to have a mechanism to find these things, and that's an audit. I mean, you have a physicist check the chart, and that finds errors and that's great.

But how do you know the physicist didn't make errors? You didn't identify all of them. It says any unintended deviation is identified. And in the current rule, the way that is turned into reality is by way of an audit.

So if you are throwing out the audit requirement, you need to change item four.

CHAIRMAN STITT: Well, you could change -- identify the documenter. That's a different -- I mean, that's what the physicist is actually doing. They go through all

these daily, daily, daily doses. They document gee, they didn't carry their one, therefore this number's slightly off.

That's a very different sort of thing.

MEMBER FLYNN: Can I make a motion that we remove the two words, is identified, and replace it by the word "is documented?"

CHAIRMAN STITT: Why don't we -- can I con you into not making a motion as yet?

MEMBER FLYNN: Okay.

CHAIRMAN STITT: Let's keep discussing it because sometimes we get stuck in our Roberts Rules of Orders and then get -- can't get back on the road. But that sounds like one to write down on the list.

Yes, go ahead.

MS. RIBAUDO: I wanted to elaborate on what Barry said. I didn't realize it until you just pointed it out, but from a health physics perspective, as we enforce what the medical community does, even if you strike the word identify, Barry's right; there's still a requirement the way it's worded.

Any unintended deviation from the written directive is documented and evaluated. There's still the requirement. It's implicit. You have to first identify. So what about if you were to say something like if an unintended deviation is discovered?

Then document and evaluate it. That way you get around the point Barry was making that implicit, no matter how it's -- you see my point? I don't know the legalese here. Can you have a regulation with the word if in it?

CHAIRMAN STITT: I doubt it.

MEMBER SWANSON: Well, you could change it to any identified --

CHAIRMAN STITT: Okay, let's keep discussing four. And then once we've agreed on what we're going to agree to, then we'll make the motion.

MEMBER NELP: I'd like to ask what's the objection to the way it's written? It's not intrusive. It's something you do ordinarily anyway. And I don't understand what all the hubbub is about.

CHAIRMAN STITT: Well, I think that's what Barry was trying to say, that the problem is --

MEMBER NELP: It's just the way you do business right now. You have to do business that way or you're not in the practice of medicine.

MEMBER GRAHAM: But the distinction is between the practice of medicine and the federal regulation that would require you to do it. And I think what we've been discussing today -- unless I'm mistaken, half of this committee doesn't think a QMP ought to exist at all as federal regulation.

Now -- but that wasn't an option that was presented as available on the table. So given that we had a mandate to suggest how a QMP would take place, now we're in the realm of federal regulation. I don't believe that we're benefitting safety of the patients or significantly changing the safety of the public by having this audit piece in here.

Hospitals will do it on their own.

MEMBER NELP: But, on the other hand, if you were the regulator and you asked me to do this, I'd say that's no problem. You're welcome -- I'm welcome to do that for you if you want to assist me in the regulation of safety, and I don't have a problem with that.

I don't feel intimidated or over burdened by making -- saying I'm already doing this.

CHAIRMAN STITT: I have the microphone.

Under point six, the quality management program provision should be reevaluated and revised to focus on those requirements that are essential for patient safety. For example, confirming patient identity, requiring written prescriptions, and verifying dose.

It's possible that four can be stricken completely. Because without four, we still maintain these mandatory QMP points.

All right, we'll do this side of the table. Let's start with Dennis and work down.

MEMBER SWANSON: I think it's back to an essential record keeping requirement that we really need here.

CHAIRMAN STITT: And what should be contained in it?

MEMBER SWANSON: I'm back to, you know, that any identified, unintended deviation from the written directive is documented and evaluated.

CHAIRMAN STITT: Just say it one more time for me, would you?

If any --

MEMBER SWANSON: That any identified, unintended deviation from the written directive is documented and evaluated, and appropriate action taken.

CHAIRMAN STITT: What's appropriate action?

MEMBER SWANSON: Well, okay, maybe we take that out. And evaluate, period.

CHAIRMAN STITT: Documented and evaluated?

Let's keep going.

Theresa and then Jeff.

MEMBER WALKUP: I think -- I disagree with removing four because if a therapist comes to me and said I have a cobalt unit, I gave -- I set it up for two minutes and 15 seconds instead of two minutes and 51 seconds, okay, I've now deviated from my written directive.

And if I'm not allowed to go in and fix it in the next day or two, or if I do -- okay, I gave too much today, so we're going to take away a little bit for the next several treatments. Now I've deviated again unless you give me number four.

MEMBER FLYNN: No, no; you've changed the prescription.

MEMBER WALKUP: Well, right. But you know --

MEMBER FLYNN: You can change the prescription during treatment as much as you want to as long as yo don't change it after the fact.

MEMBER WALKUP: But if you misadministrate, then it was done before it was changed.

MEMBER FLYNN: Every dosimetrist will come to the physician and say this is what happened, what do you think, is it acceptable to give five -- you know, ten more rads the next two days.

MEMBER WALKUP: That's right.

MEMBER FLYNN: And the physician says yes and initials his name. And that's a prescription.

MEMBER WALKUP: But that's why I think we need number four.

CHAIRMAN STITT: You're confusing regulation with practice of medicine, I think. I think they've done a good job with you, Theresa. They've got you working.

You can do -- you can practice medicine with your dosimetrist there and physicians and removing four does not prevent you -- whether it's there or not there doesn't prevent you from doing what you just said needed to be done for that patient.

Jeff.

MEMBER WILLIAMSON: Well, I actually want to comment on three and four together. I think three has enough force. You know, this is an objective. It's not a fully pledged plan of how to execute the objective. It's simply an objective. And I think if someone follows that objective, one thing they would do is, as appropriate for each modality, have some method of identifying unintended errors and so forth.

So I don't think four needs to demand an audit. So I would agree with the comments that suggest we put the conditional in four.

I think there is a role for keeping four, some form of four, as a federal regulation. I think that some institutions I think are a little weak on having a good feedback mechanism, and I really think that this is maybe sort of a good use of federal regulation to encourage institutions in some sort of at least semiformal fashion to use incidents and errors to feed back in order to improve their process of treatment, delivery and planning.

CHAIRMAN STITT: So it sounds like we have some support for four, with a possible change in the wording. And I do remind you that by retaining four, I think it goes back to John's pseudo motion that the licensee is required to maintain recordable events whenever we get that definition discussed.

They go hand in hand.

Naomi.

DR. ALAZRAKI: I think that in addition to the changes that we've discussed, that any identified, unintended deviation from the written directive, I think you have to define that there which meets the criterion of recordable event, whatever that turns out to be, has to be in there.

Because we don't want to identify, you know, very minor deviations.

CHAIRMAN STITT: Go ahead to the left side. I heard Ruth. There's a lot of mumbling over here amongst these three, Ruth, Dennis, Lou. Ruth and then Lou.

MS. McBURNEY: Yeah, I still think you need to keep number four and remembering that the written directive only applies to what's now in number one. That it's only required -- that the written directive is only when the dose to any organ or tissue exceeds 50 rem.

So it would be a deviation from that written directive that would be required.

CHAIRMAN STITT: Lou.

MEMBER WAGNER: Well, the problem you get into is, as always, it's in the enforcement of these rules once you get them in there because again, you've got the unintended -- the identified, unintended deviation. First you get into definitions of what is it.

Okay, number two, did you evaluate it or was it the appropriate action that you took? I mean, one -- an inspector's perspective on that problem is going to be entirely different than the user's perspective on this problem.

And while it's no problem for us within medicine to identify what we mean by that and to actually take action and act on it in a professional quality improvement, as a regulation it becomes a very difficult issue.

And I sympathize with the idea that what we want to do is to try to elevate the -- perhaps the quality standards of some practitioners who could benefit by doing this more often. I mean, I don't have a problem with that either.

The difficulty I have is when we make this a regulation, it applies to everybody. It's got to be enforced to everybody. And again, it's more of a handcuff on those who are practicing good medicine already to have this in there, to struggle with it, to go through all of the paperwork and

everything as identified with it without being very productive in terms of changing what you really do.

CHAIRMAN STITT: Other comments? We're looking at (a), number one, two, three and four.

I'm going to go over this way for a while and then come back.

John.

MEMBER GRAHAM: And I'm looking for feedback from the other side of the table as to how this could work or would work.

If you read paragraph (a), it says each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

Then we've got point number one, which is the written directive; point number two that's confirming it's the right patient; point number three, that you're documenting the administration.

Can point number four simply be describe in your quality management program how you maintain a high confidence that the byproduct material will be administered as directed by the authorized user? That gives you complete flexibility on how you write it, and yet does provide a requirement that

they document that for this outlying, shoddy program that may need a little help.

MEMBER NELP: That's what it says right now. It says if you screw up, make a note of it, --

MEMBER GRAHAM: Mine's much broader than that be design because then it doesn't get into issues like identifying what unintended deviation is defined as and how it was identified and how it's evaluated.

It's something less than just striking item number four. It's saying tell us in the plan how you assure that byproduct material or radiation from byproduct material was administered as directed.

CHAIRMAN STITT: Has something that loose been part of what licensees had to write in their QMP at this point? No, you -- if it was, you'd know it? Okay.

Anybody else over here before I let these guys have their way?

Go ahead.

MEMBER FLYNN: In paragraph (a), for years now, I've been -- I think the -- we debated this before the QM rule was even put in effect with the NRC. But the term high confidence always bothered me instead of -- high confidence sounds like a Mel Brooks movie or something, High Anxiety.

It should be to provide guidance, I think. Because I think it -- I think human error is going to be with

us all along. There's not going to be a zero error rate even if you have a QM program. I thought guidance would be better as opposed to high confidence or high anxiety or whatever.

CHAIRMAN STITT: And how many years has this bothered you? You're just now --

MEMBER FLYNN: Since 1990.

CHAIRMAN STITT: Okay, that's a good comment. I'll put that down here.

Jeffrey.

MEMBER WILLIAMSON: I'd like to comment about provision number two, which is, to me, not an objective; it's a prescriptive requirement. It doesn't say, you know, create a program that, with confidence, makes sure you deliver the right treatment to the right patient; but it actually prescribes a remedy to the problem which is you must have a way of identifying the patient redundantly.

To me, that's over -- it's not only too prescriptive, but it's a grave oversimplification of the basic problem. Because in radiation oncology for some of the more complex treatments, you not only have to worry about the identity of the patient, but you've got to worry do you have the right records, do you have the right treatment planning program.

So there's a sort of a much more complicated issue the physicist needs to deal with in making sure that this concept of identity is being executed in the proper say.

So I would propose that this be written in a less prescriptive way basically requiring that one of the elements of the program be, you know, a procedure to ensure that the with high confidence or whatever one wants to put in there -- that the intended treatment is delivered to the correct patient and leave it at that.

And if that requires dual identification, redundant identification in this very formal way in some settings, that could be put in place in the institution's program. And where other types of internal procedures would be more appropriate, those could be substituted.

CHAIRMAN STITT: Confirming patient identity is one of the elements that's required. It does not have to -- it could be -- the sentence could be truncated after is verified.

MEMBER WILLIAMSON: That's right.

CHAIRMAN STITT: But the first part of that sentence is -- we're obligated to.

All right, so that's another -- any other discussion on the point that Jeff was bringing up?

The remainder of the sentence says by more than one method. We may end up having to vote on these, you guys.

Other comments? We're still on section (a), one through four; but we're getting there, so don't give up hope.

No, Jeff, you can't have your turn again until someone else speaks.

All right, go ahead.

MEMBER WILLIAMSON: All right, well I'm concerned a little bit about the footnote, the second paragraph of footnote one where it talks about, you know, the ability to revise the written directive. And it makes it sound like, to me, that suppose, you know, one's giving a low dose rate brachytherapy treatment that takes 40 hours.

Administering the dose, to me -- that act means starting the treatment. And as I read this paragraph , it says you can't modify the prescription after you start the treatment. And I think it's unclear. It should say you can modify the prescription any time before the completion of the treatment would be more clear.

MEMBER FLYNN: And that's also part of the way the QMP was modified years ago in terms of brachytherapy, low dose rate brachytherapy. You can change the prescription anytime. Because I gave the example -- this is six years ago -- whereby a patient in the hospital is ill. You have to take the implant out.

You know, that she's confused, blood pressure's dropping. You can modify the prescription anytime during the

treatment and remove the implant early. And this happens all the time.

CHAIRMAN STITT: Yeah, it makes no sense that you have to do it prior to use. That presumes you know what's going to happen.

MEMBER WILLIAMSON: Yes, that's right. And I don't think that's the intent of this paragraph. I'm sure it's perhaps just a mistake or an unclarity in the language.

CHAIRMAN STITT: You could say a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure, period. Or provided that the revision is signed and dated, period.

MEMBER FLYNN: For the low dose rate brachytherapy, you can -- according to the existing QMP, you can change -- we got that modified. You can change the written directive anytime during the treatment.

CHAIRMAN STITT: Well, we can do the same for high dose rate. It's just a little less common than for low dose rate.

All right, it sounds like we're not satisfied just to look over one through four, that now we're on the footnotes. How about the nuclear medicine folks in the room?

Naomi.

DR. ALAZRAKI: A couple of things I wanted to address.

What you were just talking about, about writing another -- or being able to change the prescription at the end of the series of, let's say, brachytherapies, in the past, in nuclear medicine, if the dose administered was -- exceeded whatever, 20%, from the written directive but was lower than the written directive -- in other words, instead of 100 millicuries, let's say 50 millicuries was given, that became, quote, "a misadministration" because it deviated by more than the prescribed amount.

But, in fact, the physician could just have administered the remaining 50 millicuries at some -- upon discovery of the mistake.

MEMBER SWANSON: It's still a mistake.

DR. ALAZRAKI: What? Yeah, it's a mistake. Well, it's mistake just in the same way that the external beam therapy is a mistake, which can easily be corrected in the therapeutic process. I'm just making that point because it was in line with what was said and could be applied to the radionuclides as well.

I'm wondering also about in number one the number 50 rem as being the number for criterion as to whether or not a written directive is required and where that came from.

MS. HANEY: Well, it came from Part 20. But it was -- I would offer that there was -- it was a number that we pulled up. It was already in the regulation. And in

justifying this in the statements of consideration, we'd have to go much further than that.

So at this point, we're only throwing it out to get comments on it.

MEMBER SWANSON: And it is fairly consistent with the current regulations which would require a written directive for 30 microcuries of iodine-131, which is what -- how many rads the normal thyroid -- roughly 60?

DR. ALAZRAKI: Yes.

MEMBER SWANSON: Fifty rads per microcurie?

Okay, so it would be consistent with the current requirements for a written directive.

DR. ALAZRAKI: About 30 microcuries.

MEMBER SWANSON: Right.

CHAIRMAN STITT: We're getting close on time here. One thing that we could do would be to -- we could make motions on everything we have discussed one by one. We could make a summary of topics of comments and send them in a bulletin fashion to -- in our minutes.

MS. HANEY: Well, I think it would be helpful, at least from my standpoint, is if the committee does agree that alternative two is the best of all four alternatives, to have that in the record.

CHAIRMAN STITT: Well, I think we can say that. I could ask the committee to make a motion on it. We have

agreed that we're going to discuss the one, two -- the last key item later. But just everything that we've discussed and voted on so far, leave it as alternative two.

Yes, we've voted down everything else.

MEMBER NELP: I think we've had a good discussion. It's all recorded. And if it ends up in the minutes, we can go over those and revise the minutes according to any real deviations from what we said. And I think it will come out -- I think we're all on the same wavelength as we sit here at this point in time.

CHAIRMAN STITT: Is it coming across that way in the minutes? Because if we don't need to make motions on each of these -- each of these discussions we've had of (a) -- I think we are being fairly clear on these.

Jeff.

MEMBER WILLIAMSON: Well, I think it depends whether you, as our Chairman, feel you can -- you have a sense of the consensus here and can summarize it accurately or whether we need to work more to clarify what it is we --

CHAIRMAN STITT: Well, why don't we try at least something that summarizes what our discussion has been about.

As I just read through them, if we look, we are now saying that alternative two, section (a), which has a number of points starting with (a) itself, the comment of high

confidence really refers to guidance is one of the issues that we had a positive discussion about.

That (1) that's enclosed in parentheses, there was some discussion of 50 rem, but I don't know that we want to get into any details of that. We just addressed it and said yes, we hear.

Number two, one of the comments that came up was that, prior to each administration, the subject needs to be identified -- the subject's identity needs to be verified. That may be sufficient for two.

Point number three, we were accepting as is. And point number four had a lot of discussion regarding identification versus documentation and whether evaluation and/or appropriate action even needs to be a part of number four.

I think that we felt number four does need to remain, however. There was also discussion of -- down in the footnotes. Revision of an existing directive and whether that has to be done prior to when a patient's condition changes.

MEMBER SWANSON: It certainly has to be done prior to administering a radiopharmaceutical dosage, so that part can stay in there, okay? I think.

DR. ALAZRAKI: I think we should have the same option to correct when under dosed.

MEMBER SWANSON: You always have the option to correct, okay.

CHAIRMAN STITT: Well, those are the -- yeah, those are the summary of the comments that we have been discussing for the past 20 minutes.

Naomi and Barry.

DR. ALAZRAKI: I think one other thing, as sort of a preamble to all of it, is that I think many of the people sitting around the table did feel that we were discussing practice of medicine rather than radiation safety.

And that if given the option, that discussion would have been deemed not appropriate for this particular regulatory agency.

CHAIRMAN STITT: Barry, do you have something to say?

DR. SIEGEL: Just a comment about the second paragraph under the footnote. It really is just part of the same objective that says before you do it, give written orders. And this just says before you revise it, give written orders. It's again, don't shout down the hall and say turn up the dose rate.

You've got to write it down. And the truth is, if you then fig a little further in the regulation, brachytherapy prescription can be modified in process. It

just has to be written down. It's just not something the technologist does on his or her own recognizance.

It has to be directed by the physician.

MEMBER WILLIAMSON: My comment wasn't directed against that point. My comment was directed against the language which seemed to be more regressive than the currently published regulations which, to me, clearly allow a written directive to be revised at any point up until the end of -- the completion of therapy if the therapy takes a finite, non-zero amount of time.

CHAIRMAN STITT: This is actually the same wording.

MS. HANEY: We didn't make any changes in the footnote. This is the same wording as in status quo in the current rule.

MEMBER WILLIAMSON: I don't know about you, but it doesn't seem too clearly --

MS. HANEY: No, I'm not disagreeing with that by any means.

CHAIRMAN STITT: Do you think it's sufficient to have enumerated our discussions?

Okay, are you ready for a break? Anybody want to make a motion? I'll just declare a break. What is this, do we get 15 minutes for this one?

(Whereupon, the foregoing matter went off the record at 2:32 p.m. and went back on the record at 3:00 p.m.)

CHAIRMAN STITT: Go ahead.

MS. HANEY: The next topic for consideration is the radiation safety committee. And the key areas here were when -- under what conditions would a radiation safety committee be required. The working group came up with four alternatives. We're actually working group and steering group.

After we came up with the alternatives, we did go into the rule language space and make some changes there. So I would suggest that maybe we handle this area the same way as we handle the previous topic area, is go through and first decide on what's -- you know, when a safety committee is important.

And then we can look at the rule language for that particular alternative and decide if we -- if changes should be made to that text.

As far as the alternatives, one is status quo, and that's a radiation safety committee as required for all modalities in a medical institution. The second alternative, that the radiation safety committee is required for a medical institution in all modalities with the exception of the

diagnostic, low dose, sealed and unsealed byproduct material uses.

That alternative was really getting at the point of that if the modalities posed a very low risk, a radiation safety committee was not required.

The third alternative is that there -- a radiation safety committee is not required for any medical licensee. And then the fourth is that the radiation safety committee will not be required, but rather the medical licensees will be required to establish and implement a program for administrative and technical oversight of the radiation safety committee.

There is, similar to the others -- at the back of your package on page eight, there is a chart. If you want to start with that -- again, on this one, it's a little bit harder because we have more key items for consideration.

In column two, I would offer we got into having to do a double check there first with the radiation safety committee and then without the radiation safety committee. So that's why we have the X slash. And then we have alternative three and four.

And with this, I think I'll just turn it over to the committee unless you have any specific comments that you want me to make.

CHAIRMAN STITT: Anything the committee wants to direct to Cathy while she's up there? She'll be here, so we can -- we can grab her.

I think we've got the hang of what's worked for us in these other two issues, so let's just keep doing that.

Who feels strongly about radiation safety committees on this committee? I just wanted to see if I could wake up the group. Who feels strongly about radiation safety committees?

All right, so we do have some -- Jeff, don't you want to raise your hand? All right, I'm surprised.

MEMBER WILLIAMSON: I'm sure I'll think of something to say.

CHAIRMAN STITT: I'm sure you will.

Dennis, jump in here.

MEMBER SWANSON: I feel strongly that radiation safety committees are required within a medical institutional environment. I think the RSO's need the support of a radiation safety committee. I think the administration needs the support of radiation safety committees within their environment.

I think the issue, in my opinion, is not the need for a radiation safety committee, but the very prescriptive requirements that you have underneath your designation of

radiation safety committee. You don't require it for quorums, etc.

That, to me, is the issue. I think what I would like to see as an option is retention of the radiation safety committee, but allowing the institution to develop their own policies and procedures relative to how that radiation safety committee operates.

CHAIRMAN STITT: Dennis, let me ask you where your feelings would fit into the four alternatives? We're doing this a little bit differently. I guess I'd like some general comments and I'm going to direct those because there's so many individual bullets here and I'd like to get some general feelings.

So what you just expressed, does it fit into --

MEMBER SWANSON: Well, it's kind of a -- you know, it's kind of a cross between alternative one and alternative four, I believe, in that I would like to see the requirement be maintained to have a radiation safety committee.

But if you look at item number four or alternative four, it really addresses that the licensees will be required to establish and implement a program for administrative and technical oversight of the radiation safety.

Okay, the problem with number four as currently written is it says an RSC will not be required. And in my opinion, I think you need a radiation safety committee.

CHAIRMAN STITT: Okay, Cathy, go ahead.

MS. HANEY: Dennis, on page five, which is the rule text that would go along with alternative two, we made some changes from the status quo rule text to remove some of the prescriptiveness of the current rule that I think you mentioned.

What you may be looking at is something closer to the rule on page five, but with deleting a few more of these items than what the working group did as compared to being closer to alternative four.

CHAIRMAN STITT: And that's alternative two, the rule text, that you were just describing?

MS. HANEY: Right.

CHAIRMAN STITT: I might ask some of you to start --

MEMBER SWANSON: I think what I'm saying is you just -- you really need to get away from all prescriptive -- putting any kind of prescriptive requirements on how that radiation safety committee conducts its business, okay, period.

But I would strongly recommend that you retain the concept of a radiation safety committee. Again, you know,

I think a radiation safety officer needs the support of a radiation safety committee in order to ensure continued administrative support of the radiation safety program within the institution.

Conversely, I think that the administration of the institution needs the opinions of a radiation safety committee so as to ensure that these opinions are not solely the opinions of a radiation safety officer. And that's the role that I see the radiation safety committee providing to the institution.

I think it's pretty important. And I think one of the things you're going to have to define is what do you mean by medical institution, because I'm not sure that's clear to us anymore, okay -- any of us practicing today what a medical institution means, okay.

But that's a little bit of a sideline.

CHAIRMAN STITT: Well, it's possible that there's an alternative five, and I don't -- I hate to recreate things, but we were, you know, allowed to consider that. I'm not going to start suggesting that, but just to say it's possible.

I'd like to get more comments from people who have strong opinions, strong feelings.

Naomi.

DR. ALAZRAKI: What about number two, Dennis? It says that the radiation safety committee is required except

when only diagnostic low dose byproduct material is used.

MEMBER SWANSON: Well, do you want me to respond to that?

CHAIRMAN STITT: Go ahead.

MEMBER SWANSON: You know, I think in reality, if this is applicable to a medical institution, your medical institution isn't going to be limited to just provision of nuclear medicine. Okay, so it's kind of a moot point. And certainly, in my medical institution --

DR. ALAZRAKI: There are many institutions which don't have any --

MEMBER SWANSON: Well, it depends on how you define medical institution, I guess. That's the point I'm trying to make.

MS. HANEY: Yes, I can just add that the work -- yes, the working group touched on what Dennis is mentioning, that how do you define medical institution. And again, we chose not to spend too much time on that so that we could move forward.

The thought was that if it was in a hospital setting, that -- where you're getting into multi-disciplines, that's where the medical institution -- that's where you need the radiation safety committee. For the stand alone physician with a nuclear -- you don't need it.

But you're right, we would need to define better medical institution.

MEMBER SWANSON: I don't have any problems with that concept. Okay, I don't have any problems with the concept if only diagnostic nuclear medicine is the only entity in that institution. But it wouldn't make sense to me to have a radiation safety committee in an institution where you need a radiation safety committee and exclude diagnostic nuclear medicine.

That doesn't make sense to me.

MS. HANEY: No, that was not the intent of this option. It was if the facility was only licensed for, say, the current 100 and 200, they don't need a radiation safety committee.

CHAIRMAN STITT: So, just a second; let me finish with Naomi.

So the reason you said what about number two is to discuss it?

DR. ALAZRAKI: Right, but I think that number two, to me, does make sense. I think that any institution which is providing "high risk" procedures using radioactive materials or radiation delivery needs a radiation safety committee.

And to support -- for all the reasons that Dennis said, to support the radiation safety officer, to be sure that

there is a level of awareness on the part of the administration and on the part of physicians practicing in the institution about radiation safety.

So I think number two sounds to me very reasonable.

CHAIRMAN STITT: It would be hard to believe that this group could hone in on something that quickly.

Barry's jumping up and down, and then Dan.

DR. SIEGEL: I'm not jumping up. Just a point of -- I think Naomi's picked up on it. As it came across in this version, option two is not worded correctly because it implies that the committee doesn't have purview over 35.100 and 35.200 activities.

When in fact, what it means to say is that you don't need a committee if the only thing you're licensed to do is 35.100 and 35.200. If you're licensed to do other things, then all of it comes under the purview of a committee. And I also, just for the record, support the concept of radiation safety committees for all the reasons Dennis said.

CHAIRMAN STITT: Barry, what you were just referring to when you look at our page eight, alternative two, with radiation safety committee/without radiation safety committee, is that what you're referring to?

DR. SIEGEL: No, I'm -- look on page five.

CHAIRMAN STITT: Okay.

DR. SIEGEL: And right at the beginning of the draft rule text where it says each medical institution licensee shall establish a radiation safety committee to oversee the use of byproduct material, with the exception of diagnostic low dose, sealed and unsealed byproduct material use.

That implies that the committee wouldn't look at that stuff. That's not what's meant. At least I don't think that's what's meant.

MS. HANEY: It was not what was meant.

MEMBER NELP: That's the exception of institution use only.

DR. SIEGEL: That's correct. And there are some of those. And those small, 20 bed hospitals that only have diagnostic nuclear medicine don't need to be burdened with a radiation safety committee.

CHAIRMAN STITT: Let me ask Cathy then to explain to me the -- in the matrix on page eight, the slashes. So you're saying if it's the small group that Barry just referred to, the other side of the slash refers to them?

MS. HANEY: Correct.

MEMBER WILLIAMSON: It seems maybe one way to address the question is not should there be a radiation safety committee. I think that's sort of like asking should there be motherhood and apple pie and stuff like that. But are -- is

basically the current mode of medical practice such that we need a federal law to keep this check in place with a high level of confidence?

I guess that's, to me, sort of the John Graham test here, if I could call it that.

CHAIRMAN STITT: Go ahead, the John Graham test.

MEMBER GRAHAM: I think with the clarification of alternative two that we've discussed, that, as I understand it, means there would be a radiation safety committee in organizations that covers diagnostic materials as well.

Yes, I'm saying in this -- this is one of those rare situations where I would say there's a federal regulation that would retain a radiation safety committee for all the reasons that have been discussed. And that's from someone who literally spends time every couple months evaluating what hospital committees we could kill.

This is not one of them.

CHAIRMAN STITT: Would the group like to focus on alterative two as far as the subcomponents?

All right, you going to go along with that for now, Lou? Okay, all right.

MEMBER FLYNN: Are we going to make a resolution that we accept two or not?

CHAIRMAN STITT: Yes, please do that.

Dan.

MEMBER FLYNN: I make a --

CHAIRMAN STITT: Do you want John to speak for you?

MEMBER FLYNN: I make a motion that we support alterative number two with the modification that institutions who exclusively have diagnostic low dose, sealed and unsealed byproduct use do not need to have a radiation safety committee. But otherwise, they would fall under the purview of a radiation safety committee in other circumstances.

CHAIRMAN STITT: All right, discussion.

Lou.

MEMBER WAGNER: I think I agree with it in principle, but I'd like to extend it a little bit to say diagnostic low dose sealed is -- excludes the potential for the same facility to be able to treat hyperthyroidism. And that can be done on an outpatient basis.

And I personally would like to see that also included because there's lots of small facilities that will do the majority of diagnostic, but they'll have a few patients that they treat too, and that's all on an outpatient basis.

They have a radiation safety officer that oversees the issues. They have a physician that oversees the issues. They have a technologist there. It's an outpatient basis. I'd like to see that included in the definition here.

MEMBER NELP: Of exceptions?

MEMBER WAGNER: Yes, the exception of diagnostic low dose, sealed and unsealed byproduct material uses. And I'd also like to include in that the outpatient treatment of hyperthyroidism.

CHAIRMAN STITT: Dennis and then Naomi.

MEMBER SWANSON: I have a problem with that in that now you're going from something that's clearly low risk to something of a different level of risk, and then we're going to have to make that determination for every other procedure that we do.

Clearly, the NRC has recognized diagnostic nuclear medicine as low risk. Let's leave it like it is and not try to confuse it with that issue.

CHAIRMAN STITT: Naomi.

DR. ALAZRAKI: I think what Dennis -- I'm not sure that I understood what you just said, Dennis, but I think that if you're using therapeutic doses of I-131, that you really do need the radiation safety committee to support the RSO and to also raise the awareness of the administration about the issues of radiation safety.

Because you are dealing with doses which -- of I-131 which fall into the category of they need special attention, I think.

MEMBER WAGNER: I have personal experience with it since I run such an institution. And it's very small in

terms of a lot of its procedures. There's basically only three people involved, the technologist, myself and the physician.

And we never have any problems, and I never have any problem getting support from administration. And whenever we meet, we meet as a group. We meet as a group or three people. We meet as a group and we go over all the issues. We address all those things.

I don't understand -- yes, but here you're getting into this rule about the committee meeting, and then you're going to fall under all the other prescriptive elements of the committee.

MEMBER SWANSON: But that's what we're talking -- that's what they need to take out.

DR. ALAZRAKI: Yes, the committee could be adjusted for the type of situation that you're talking about.

MEMBER WAGNER: And then also -- well, okay.

I can see your point. If the size of the committee could be adjusted for that, that's one issue.

But I just don't want to see facilities that are just limited by that to be hampered by having requirements for another committee which has so many X members, and have such a size, and meet on a formal basis, and that take minutes for a quorum and all that other stuff, which simply is unnecessary.

CHAIRMAN STITT: Go ahead, Ruth.

MS. McBURNEY: Yeah, I think it's important for those facilities to still have a radiation safety committee if they're doing therapeutic -- using any therapeutic levels of material.

In the situation you were talking about, Lou, it's probably more important that we have more flexibility in the make up and membership of the committee, especially if it's a radiation safety officer that's off site in these small facilities that's not on site all the time or physicist or whatever to get together periodically to discuss matters, but may not need to be made up of all these other representatives.

CHAIRMAN STITT: Just a comment.

We have a motion that we will vote on, and then I think to follow what we've been doing on other sections, then we should go through the draft text point by point.

Okay, Dan, we'll let you make this motion. Do you want to repeat it?

MEMBER FLYNN: I make a motion that we accept alternative two with clarification that the institutions with only diagnostic, low dose, sealed and unsealed byproduct materials do not have to have a radiation safety committee.

CHAIRMAN STITT: Okay.

All those in favor? All those opposed?

And the good news is, if we continue to chug along at this rate, we're going to take some of tomorrow's

agenda and put it today. That's to spur you on. I don't know if you view that as good news or bad news.

In fact, Cathy's gone out to see if she can hustle some -- let's turn to page five. If I've got it correct, that is alternative two, which we just voted in favor of. And some of this gets into the specifics that I think a number of the committee members brought up.

Let's start discussing the draft rule text for alternative two.

Dennis, go ahead.

MEMBER SWANSON: For alternative two, you know, to get rid of the very prescriptive requirements here, I would suggest that you look at alterative four now, okay.

And if you go to page seven under draft rule text at the bottom of the page, you would have something like to oversee the use of licensed material, the licensee must establish a radiation safety committee or policies and procedures relative to the operation of the radiation safety committee that will do the following.

Okay, and those are the general performance type of criteria without getting into anything prescriptive.

CHAIRMAN STITT: We may want to end up with a motion on this because this gets a little more specific than -- we were making commentary on the previous section.

MEMBER SWANSON: So moved.

MEMBER NELP: Second.

CHAIRMAN STITT: All right, we've got a motion and we've got a second. And the motion is for us to turn to page seven.

MEMBER WILLIAMSON: Do we need to vote on this before we turn to page seven?

(Laughter.)

CHAIRMAN STITT: Well, the intent of the motion was to turn to page seven. Let's discuss page seven, draft rule text.

Dennis, why don't you just walk us through it. You're the guys that have to use this, so talk to us about this.

MEMBER SWANSON: I would say that draft rule text, which now would come under option two, --

CHAIRMAN STITT: Right.

MEMBER SWANSON: -- okay, would say to oversee the use of licensed material, the licensee must establish policies and procedures relative to the operations of the radiation safety committee that will do the following.

And really, those are pretty performance-based as they're written there. I don't really have a whole lot of problems with those.

DR. SIEGEL: Except paragraph E because E is -- if you look at E on page seven, E is develop a mechanism for communication.

MEMBER SWANSON: That is the mechanism. You're right.

DR. SIEGEL: But the committee is the mechanism.

MEMBER WILLIAMSON: So would the proposal be to take on page seven A and B and substitute it for B(1) through B(5) on page five? Is that the idea?

MEMBER SWANSON: Yes, it would be basically taking A through E and -- excuse me, A through D and substituting it for everything that's currently under A and B on page five.

CHAIRMAN STITT: The motion we're dealing with was -- I mean, if we stick with your motion, that's effectively what the trade off is. The motion kind of directs us to the stuff on page seven.

All right, let's keep on discussing this.

MEMBER WILLIAMSON: Well, I think then it's not clear what the definition of radiation safety committee is.

I would think one might want to keep the bit there where it says that the membership -- you know, basically should be a representative cross section of the primary users and authorized users within the institution and include some connection to management and the radiation safety officer and

so on because that's the reason that was -- that we put forth for having the radiation safety committee in the first place.

Otherwise, it doesn't seem that there is any difference between alterative four and alternative two if you don't keep the definition of the concept of radiation safety committee intact in some form. Otherwise then radiation safety committee can be whatever the institution specifies it to be and we're back to alternative four.

CHAIRMAN STITT: Any rebuttal?

MEMBER FLYNN: I agree with that. I think you could be a little bit more specific about the safety committee. For a small institution, if it's a representative from each modality, if there's one modality, there's one member. Bigger institution, therapy, nuclear medicine and other areas, there would be more representation to the committee if there was nuclear cardiology and other people.

But a small institution, the committee would be, by definition, small. So it shouldn't be too burdensome. I find it's also -- is there something missing intentionally in this? Since I'm a new RSO, I see there's something missing here that we have to discuss every meeting, and that is I don't see where it says review quarterly the exposure records and review annually the ALARA program.

That was sort of, you know, carved in stone as to something we do. Is that intentionally out of --

CHAIRMAN STITT: Cathy has a comment.

MS. HANEY: Yes, it was intentionally taken out thinking that the requirements in Part 20 to have an ALARA program and periodically review your program cover those. And we were going in with the philosophy that if there's a requirement in Part 35 that is required -- also required in 20, that we would let 20 take care of it and take it out of 35.

MEMBER FLYNN: Okay, because -- I mean, I've discovered problems with some exposure records and then we've taken actions. But that wouldn't happen then. It's probably not necessary. These are not major problems. They're -- you know, they're --

MS. HANEY: Well, the intent again would be is that yes, that review would still take place, but it would be --

MEMBER FLYNN: By who?

MS. HANEY: By the radiation safety committee or whoever is reviewing the ALARA program at the facility. And I mean, I need Part 20 to give you the exact quote for you. But there is a requirement for the annual audit of the program in Part 20. And as part of reviewing that, one would look at the film badge records, the dosimetry records.

And that's not necessarily being required under a 35 requirement, but would fall under a 20. Again, it was

giving the licensee a little bit more flexibility in how they do these things. And we just thought the Part 20 requirement covered it.

You know, if you want to put it back in, we can certainly put it back in. But it wasn't --

MEMBER FLYNN: I'm not sure if it should be back in or not. I just wondered if it's not there -- I mean, if you don't want it, keep it out. But do you think that the licensees will pick up on the fact that they need to do it?

I mean, who's going to know if the safety committee doesn't know that they should do it?

MS. HANEY: Well, I guess --

MEMBER FLYNN: How does that happen in a small institution that they just say well, if they just don't do it, they don't feel it's required anymore so they stop doing it?

MS. HANEY: We would still have in guidance space when we're discussing radiation safety committee -- we'll probably still have some references to Part 20 requirements. That, you know, in addition, you know, Part 20 says you ought to be doing this.

So it's not -- the guidance wouldn't be meant to be just solely Part 35. I guess the other is that the licensee should be familiar with Part 29 and what they should be doing under Part 20.

CHAIRMAN STITT: I'd like to get the committee back to the items that are listed on page 7. I want to just continue discussing these. There has been the issue brought up that there potentially needs to be an addition, as long as we're focusing on this group, because that's what the motion has led us to focus on. But one of the comments that came up was we may need to add some segment that talks about the composition of the committee.

MEMBER SWANSON: I have no problem with including a segment that addresses the composition of the committee. However, I don't think that segment should include specific requirements for specific individuals. So I would recommend if you're going to do that that you would include a statement, something like, "Membership must reflect the scope of operations respective to the use of byproduct materials within the institution and include the radiation safety officer and a representative of management."

CHAIRMAN STITT: Do you have that written down?

MEMBER SWANSON: I do have that written down.

CHAIRMAN STITT: Okay. Because we need to -- I'll make a note that it must reflect the composition.

Okay. Let's continue to discuss page 7, A through E, and there is a potential F that Dennis just described.

MEMBER SWANSON: Probably be A.

MEMBER WILLIAMSON: Well --

CHAIRMAN STITT: Oh, yes, Jeff. Okay.

MEMBER WILLIAMSON: Well, on page 7 under A, maybe teletherapy physicist might be kind of an outmoded requirement as --

CHAIRMAN STITT: Yes.

MEMBER WILLIAMSON: -- a category.

CHAIRMAN STITT: Go ahead, Cathy. I think we've discussed this before.

MS. HANEY: This is something that I think will get refined further on down the line as we work with it. Some thoughts were given to, you know, in this case just defining a physicist, that we would not -- you know, do we need to define a teletherapy physicist, an HDR physicist, gamma stereotactic? You know, do we want to get at that level of wordiness and definition space, or can we just say "physicist for the modality."

So whatever and wherever we end up on those particular items, you'd have to make the corresponding change here. But that was an item that has been brought to our attention.

CHAIRMAN STITT: Okay. Good comment. Any other commentary on the bullets that are in front of us?

MEMBER NELP: I think it's pretty good. Simplified, but it's the same.

CHAIRMAN STITT: Do we want to go as far as making a motion? This is fairly --

MEMBER GRAHAM: We have one on the table.

CHAIRMAN STITT: That's true. I'm sorry. We --

MEMBER WILLIAMSON: That was to turn to page 7, right?

(Laughter.)

CHAIRMAN STITT: We have a motion to turn to page 7. Right. It was a little -- it was more eloquent. It was more eloquently stated than that. Dennis, give us your --

MEMBER SWANSON: I recommend that under option 2 we replace Sections A and B with the draft rule language that appears under alternative 4, A through D, plus an additional statement E that would include, "Membership must reflect the scope of operations respective to the use of byproduct materials within the institution, and include the radiation safety officer and a representative of management other than the radiation safety officer," which is the standard wording.

CHAIRMAN STITT: Okay.

MEMBER WAGNER: Second.

CHAIRMAN STITT: All right. So that was the motion. It has been seconded. We have had some discussion. Go ahead.

MS. McBURNEY: Would you still have the introductory statement in 2, but changing the wording to

reflect, "Each medical institution licensee shall establish a radiation safety committee to oversee the use of byproduct material, with the exception of institutional licensees that use only diagnostic and low dose and then seal"?

CHAIRMAN STITT: Yes. That was the first motion that we voted on, so that's still -- that's intact. Now we're just discussing the text, the draft rule text.

Everybody ready? More comments? John?

MEMBER GRAHAM: Well, I think the only comment for the record is that with the motion that we're about to vote on, there clearly is a committee stating that there is no need for a prescriptive rule on a quorum, or how often that committee is meeting, or how they are maintaining records.

CHAIRMAN STITT: And the record should show all of these people are shaking their heads up and down.

(Laughter.)

They're too tired to speak up.

All right. That's in the minutes. All right. Let's vote on this.

DR. SIEGEL: You are, in a way, saying that the committee has to meet at least annually, because option D says, "Review annually, with the assistance of the RSO, the radiation safety program."

CHAIRMAN STITT: I suspect John, in his axing of hospital committees, if you're committee didn't meet annually, you would be on the list to be axed. So --

Any other comments? All right. Let's vote.

Those in favor of this recommendation, including the additional proviso that reflected composition, raise your hands.

Those opposed?

We are on a roll.

Now we are at the free association part of the meeting, because we're an hour and a half ahead of time.

Here's what the plan is. We're going to turn to tomorrow, 4:15. We're going to start with the University of Cincinnati. I'm hoping that radiopharmacy guidance and carbon-14, which are supposedly being in preparation somewhere upstairs, may be able to float down here.

There is a suggestion we could start on training and experience, but the cardiologist is gone for the afternoon. He will be back tomorrow morning. There is going to be a lot of discussion on patient notification. We have to discuss definition of reportable events, and I think that is going to take a fair amount of -- either one of those alone is going to take some time. Well, at least reportable events are.

So we've got a fair amount of material that I think we ought to keep using until at least 5:00 today, because we really break down and get tired when tomorrow gets here.

MEMBER NELP: We could discuss training and experience with the exception of nuclear cardiology, which is sort of a -- but there is a lot of other material there to discuss. And then Manny -- we could save that segment perhaps for when he returns tomorrow.

CHAIRMAN STITT: I think anything we can get started on today is going to be a help.

MS. HANEY: -- the radiation safety officer aspect of that package. The package you have has several pages of training and experience for the authorized user, and then you go ahead and interpret the experience for the RSO. So maybe we, again, can start on that. We will have copies of the viewgraphs made for you. But that, like you said, we could at least do some preliminary discussions on.

DR. ALZARAKI: What about the University of Cincinnati?

MS. HANEY: That's what I'm doing now.

DR. ALZARAKI: Oh, that's what you're doing now. Okay.

CHAIRMAN STITT: Do we have handouts on that, or is that --

MS. HANEY: Well, I'll have handouts for you. I'll have them available for you.

Also, I didn't get the opportunity to study up on this subject, so you'll have to bear with me.

CHAIRMAN STITT: We'll learn with you.

MS. HANEY: We'll learn --

CHAIRMAN STITT: This is all new to us, too.

MS. HANEY: All right. And I can't get -- I tried to move this up. We can't do it.

All right. Let me go ahead. Basically, this started back in 1996 when NRC received a petition from the University of Cincinnati. They asked that we amend 20.1301, which is the dose limits for the public, to authorize that specified visitors of hospitalized therapy patients that are currently considered members of the public be allowed to have their dose limits go up to 500 millirem. This was really intended for individuals that would provide support, direct support/comfort to the patients.

We noticed that receipt of the petition in the Federal Register and asked for comments on it. Then, their next step was to prepare a draft rulemaking plan. This was forwarded to the agreement states for their review and comment, which is along with our standard for how we address petitions.

There were revisions made to this plan, and it was forwarded to the Commission for their approval in August of last year.

The proposed rulemaking plan -- these were the elements that were listed that would allow an authorized user physician the discretion to permit consenting adult family members to receive up to 500 millirem annually from exposure to the patients. We would then have to amend 35.315 and 35.415 to require licensees to obtain and document voluntary informed consent from the family members if they would be going over 100.

The licensees would be required to provide ALARA guidance to these visitors, and then we'd amend 20.1003 to include a definition of a family member.

Some of those things changed, so don't get too -- don't focus too much on what is up there. You've got to wait until the last two slides.

Okay. The Commission approved the rulemaking plan, and we just recently received this. And they asked in the proposed rule that would go out that we would justify, on a public health and safety basis, the requirement for the licensee documentation that the family members provide informed consent to receive up to the 500 millirem and that they receive the ALARA instructions.

They said that any of the recordkeeping requirements needed to be discussed in the Federal Register. And the third one, we should coordinate with ACMUI to draft a plain English informed consent form, some of why we're here, but you may not need to do that. And that they also wanted us to make a very clear statement in the Federal Register notice that it may be possible for some individuals to receive up to one rem exposure under this.

The thinking there is that more than likely, the primary caregiver, after the patient is released from the hospital, who can now get 500, is going to be the same person that is going to be the specified visitor in the hospital; and, therefore, they get another 500, and you add 500 and 500 and you get 1,000.

Okay. Here is what staff is proposing to -- how to address the Commission's direction. We propose eliminating the licensee's requirement to document the informed consent and the ALARA guidance. We felt that it would impose an unnecessary burden and cost upon the licensee, and that it can't be sufficiently justified on the basis of health and safety.

Then we would revise Sections 1301, 315, and 415 -- and I have the rule language for you -- and then we would add in the Federal Register notice about the one rem.

Okay. 1301 would be revised to indicate that if an authorized user determines that it's appropriate in accordance with Part 35, the authorized user may permit a radiation dose up to .5 rem.

And then, in 315 and 415 -- it would be good if I can get these up there -- just add the statements that on a case-by-case basis, with the approval of the authorized user and in consultation with the radiation safety officer, the 500 millirem.

So I bring this to you as a status report, but also from the standpoint of looking -- this is -- you're the first group that has seen this rule language. This was developed I think on Wednesday morning. So it's a very good time now for you to make comments on it from the standpoint of rule language or a decision to not go ahead with the informed consent and the documentation of that, and any other items that would be associated with this.

MEMBER NELP: I'd like to make a comment.

MS. HANEY: Oh. And let me add one more thing before you open it up. We recognize that this is a revision to Part 35, and at the same time we have this major revision to Part 35 going on. But the Commission direction was such that we would move ahead with this rulemaking, so there was a decision made to go forward with this.

CHAIRMAN STITT: Wil?

MEMBER NELP: I've been very heavily involved with the ethics and principles of informed consent over the years in other areas at our university. And I think your recommendations that it not be a requirement in writing are excellent.

MS. HANEY: Okay.

MEMBER NELP: What you've recommended there I think is very reasonable.

MS. HANEY: Okay.

CHAIRMAN STITT: Other comments from the crowd that is familiar with this? Naomi?

DR. ALZARAKI: Well, I think the whole thing is very reasonable. I think it should be done.

CHAIRMAN STITT: It's getting scary.

(Laughter.)

Dan?

MEMBER FLYNN: I can remember we had a few low dose rate gynecology brachytherapy cases, and the dose rate of the meter could be 30 milliremkins an hour, or .03. And then you have these very elderly patients, you know, and the -- you know, the husband who is 75 years old would like to spend time with his wife. And these terrible restrictions, asking him to be 20 feet away against the wall, it just seems bizarre for a 75-year old man not to be able to get a few hundred millirem

if the need be, you know? Because there is no harm or danger to that individual.

CHAIRMAN STITT: Barry?

DR. SIEGEL: The only thing I am not sure about is why the after-consultation with the RSO is a condition of this. If we believe that the authorized user has the radiation safety training necessary to administer 35.300 and 35.400 things, why does the RSO have to be in the loop? It's just one more bureaucratic complication of a medically sensible rule. So I'd recommend deleting that phrase.

MEMBER FLYNN: I would also, because the -- in some institutions the RSO is not a physician. I think this is really a medical judgment here and not about a specific individual case.

CHAIRMAN STITT: John?

MEMBER GRAHAM: I think we can formalize this and summarize the discussion. I'd recommend that the ACMUI recommend the adoption of the rule as proposed with the revision to 315 and 415, removing the requirement for consultation with the radiation safety officer.

MEMBER NELP: Amen.

CHAIRMAN STITT: Was an amen the same as a second?

(Laughter.)

Discussion? Dennis?

MEMBER SWANSON: The only reason why I could see that would be there on a practical basis is because the radiation safety officer is typically the person that monitors dose rates, okay, and would set the time limitations. At least that's the way it is in our institution. So, you know, I think in reality that is what takes place. I can see why you might want to take it out, but --

CHAIRMAN STITT: Ruth and then Jeff.

MS. McBURNEY: Also, what is the entry to 35.315? Who is authorizing the case by case?

DR. SIEGEL: The licensee.

MS. HANEY: The licensee is theoretically authorizing it, but it is really being done by the authorized user.

MS. McBURNEY: Okay. So, I mean, there if the licensee is authorizing that, I would think that the radiation safety officer would need to be involved, and also, to help verify the dose to those members of the public and visitors.

MEMBER NELP: I'm going to comment on that. You do have to keep a -- if you release these people, you do have to make a record of it. You have to make a notation of it. And on a case in point, I will monitor these patients myself if the RSO isn't immediately available. It's just much more convenient.

And I think to make them beat the individual isn't necessary. I think the licensee is capable of doing monitoring. I'm quite sure he would be.

CHAIRMAN STITT: Lou and then Jeff.

MEMBER WAGNER: I think the offensive word here is the approval. We have a --

(Laughter.)

I think the approval is the word that is the difficulty. So now you can advise the RSO. I don't care. Go ahead and advise the RSO that you are doing this, but you don't have to seek approval from the RSO.

DR. SIEGEL: It doesn't say that.

MS. HANEY: No, it's approval of the authorized user after the authorized user has consulted with the RSO.

MEMBER WAGNER: I'm sorry. I misread that.

DR. SIEGEL: But if the RSO says no, what happens?

MS. HANEY: It doesn't happen. I mean, you can't allow the person to get 500, the way it's worded now.

DR. SIEGEL: And so do we really want the RSO to be able to overrule the physician's judgment that the dose will be within the prescribed limit and that it's appropriate for this adult visitor to be with that patient?

CHAIRMAN STITT: Jeff and then Naomi.

MEMBER WILLIAMSON: What was the rulewriter's motivation for including this qualification in here, Cathy?

MS. HANEY: Really for the same reasons I think Dennis brought up and -- or at least I heard a little bit of. It's just that the radiation safety officer would bring to the decision process some of the radiation safety aspects that the authorized user may not be keying in on.

I can tell you that it was not a "must be in there." There was not a lot of discussion on including it, so I think if the committee wanted it excluded there would be a very good chance that it could come out. This was -- you know, strawman language went up.

MEMBER WILLIAMSON: It seems very paternal. Let me put it that way. You make the presumption that, you know, if it's not exactly specified how to do it in the regulation that the authorized user will behave in an irresponsible fashion. So I think that, you know, the law is there and the institution should have the flexibility to figure out how to follow it.

CHAIRMAN STITT: Right.

Naomi, you had a --

DR. ALZARAKI: Yes. Since we have a definite dose limit there, I would hope that we wouldn't require the institution to be badging people for this, and I was just wondering whether it shouldn't, instead of being a definite

limit, say approximately or something like that. Just because I don't -- you know, it's a legal requirement here, and if they start badging people and going to that expense, in terms of the interpretation, in terms of enforcement, how this will be read.

MS. HANEY: I think it would be read that the licensee would not have to badge, but the licensee would be able to have some type of program or procedure or something in place that they could show that they have made a decision that, you know, this person has not received greater than 500.

It would be very unlikely that we would put approximate 500. We usually go -- you know, we go for a number in the rule. But the licensee would have the flexibility of meeting this. I would expect that when the statements of consideration get written for the rule that it would bring up those things that I just said that the licensee would -- you know, it's up to the licensee to set a program.

And when an inspector came out, they would probably say, you know, "Are you allowing visitors to come up to 500?" You know, "What is your -- how is this individual specified? And how are you making sure that they stay under 500?" And then they would stop at that point.

CHAIRMAN STITT: Dan?

MEMBER FLYNN: Are we talking other than low dose rate brachytherapy patients who were admitted to a hospital?

Is there someone else that we're talking about? I've had 131 cases admitted to a hospital.

Well, you know, what happens is what is posted on the door, because I do it -- you know, the dose rate at two feet, the dose rate at a meter, the dose rate at the doorway. You still have those things posted.

MS. HANEY: Right.

MEMBER FLYNN: That doesn't change that. But for that specific case-by-case basis, you say, "Mr. Smith, you can stay there and hold your wife's hand for two hours," but it can't be more than eight hours in a day or for the time, you know. You give the time limit. It's going to be 30 -- whatever the dose rate is at three feet, you just tell him how long he can be there. I mean, that's what we do with everybody else.

You don't badge everybody. You note the dose with a geigercounter, and you measure what the dose rate is at two feet and at one meter, at the bedside and at one meter, and then you -- that's posted and you advise the -- the nurses have training. You just multiply the dose rate times the hours, what your limit is. You know, that's all you need to do.

CHAIRMAN STITT: Any other comments? Lou?

MEMBER WAGNER: I'd just like to finalize on this. I commend the NRC for coming up with such a sensible

rule that is non-prescriptive and is really getting to the point. I can only request, and my personal opinion would be it really is unnecessary to have the after-consultation with the radiation safety officer. And I would recommend that it would be even better if that were removed.

MEMBER GRAHAM: That's part of the motion on the floor.

CHAIRMAN STITT: So let's vote.

All those in favor -- do we want to repeat the motion? It was to accept with --

MEMBER GRAHAM: With the amendment that it would delete clause under 315 and 415, with after-consultation with the radiation safety officer.

CHAIRMAN STITT: Okay. Those in favor, raise your hand.

Those opposed?

We're doing well.

Are you able to go on?

MS. HANEY: I will try radiopharmacy, with the understanding that if there are questions that I cannot answer that we'll -- I'll get those for you tomorrow.

As most of you are aware, there were three guides that went out relative to the radiopharmacy rule. They went out in the March time period. The comment period is closing

in the very near future. On that, we have received some comments on it -- on the documents.

Our plan is to -- obviously, to review all of the comments, we'll need to address them, and we'll move forward to finalizing the guides. We are hoping in the November timeframe to have a meeting with the organizations, the appropriate organizations that were involved with commenting and development of the reg. guides, where we would bring out some of the issues and concerns in finalizing the document.

The document would probably -- that meeting would not take place until the November timeframe, and then we would be working toward finalizing the document. It would probably be in early -- in spring of next year is probably what I would guess at this point, as far as final documents being out.

We are running into some concerns, because some of the items in these reg. guides -- in the reg. guides were merely -- the reg. guides in the one case, that was an Appendix to 10.8. There are some things in there that are very specific and tied to Part 35 revision that we're doing right now.

So we may not be able to do all of the changes that some of the individuals wanted, the commenters wanted, made now in light of what is going on in 35, and with the guidance development going on there because it would be -- we'd be coming out with one thing, and then the rule is going

to be changing right away, and we'd be getting in. So we may not be able to address all of those comments.

That's where we are. And as I said, I mean, if you have specific questions, I'll try to answer them.

CHAIRMAN STITT: Go ahead. Dennis? Naomi?

MEMBER SWANSON: No. I think that my concerns, and I think the concern of the nuclear pharmacy community, is that there are several problems with the guidance document as written. We have repeatedly been offered the opportunity to meet with the NRC to discuss those problems, and I think that is what we're looking for at this point in time is the opportunity to meet with the NRC to discuss this problem.

MS. HANEY: Okay. Actually, they are in my viewgraphs, so let me see if I -- how well I covered everything I was supposed to say.

Okay. I covered everything.

(Laughter.)

My staff can brief me very well.

CHAIRMAN STITT: Any other comments to Cathy from the nuclear pharmacy group, nuclear medicine group area? Okay.

MS. HANEY: Let me go ahead with the C-14.

CHAIRMAN STITT: All right.

MS. HANEY: We spent I think a considerable amount of time at the last meeting discussing this. The

proposed rule was published on June 16, 1997. The comment period ended on July 16th. Right now we are resolving those comments. I do not think we received very many comments on the particular -- the proposed rule.

The document right now is on its way to the Commission for final blessing, and at that point it will be published for a final rule.

Good enough?

CHAIRMAN STITT: Comments to Cathy? Dennis?

MEMBER SWANSON: I think one of the main comments that I've heard regarding that rule dealt with there are provisions in that rule that addressed modification of that capsule for research purposes that basically prohibited use of the C-14 urea in any other dosage form other than the capsule. Okay? And there was concern because now we're back into, you know, restricting the practice of medicine and practice of pharmacy as to what might be done with that particular agent.

Now I'm guessing -- and correct me if I'm wrong -- that the reason for that is because this addresses exempt distribution to general licensees.

MS. HANEY: Correct.

MEMBER SWANSON: And personally speaking, I'm not sure I want general licensees to be modifying those capsules. Is that -- I think that that's --

DR. SIEGEL: But, in fact, it's not really to any individual, because it's a legend drug which means that you need a prescription to get it in the United States.

MS. HANEY: Right.

DR. SIEGEL: So you didn't have to put that in your rule, but that is, in fact, what will happen.

Isn't there a provision, though, that says that if you are going to use the capsule, if the individual is going to use the capsule for research, then the individual has to be a Part 35 licensee?

MS. HANEY: Right. And it would fall under 35.6.

MEMBER SWANSON: And I wasn't totally sure I understood why you said that -- I mean, why a gastroenterologist who was doing a study of the treatment of ulcer disease couldn't use this tool as part of his research in his office if he chose to conduct that research.

I wasn't sure where that came from, because the risk certainly isn't any higher when it's used in the research mode, as it exists, than it would be used in the clinical mode.

MS. HANEY: Donna-Beth, can you -- this is what -- you know, I was not prepared to do this today.

DR. HOWE: Since we haven't seen the Commission's approval on it yet, we don't know exactly what the statements of consideration will say in that particular area. But right

now, the statements of consideration say that in order to -- because it comes under research, in order to protect the human subject certain basic rights, then it would have to come under 35.6, and that is not based on risk, nor did the health and human services regulations, uniform regulations on protection of human subjects base it on risk.

There was a comment on the health and human service uniform policy that said it should be based on risk, but they did not adopt that comment. They did not respond to it. It is independent of risk.

DR. SIEGEL: There is no problem with that. Nothing in allowing the distribution of one microcurie C-14 capsules relieves the end user from requirements with the uniform federal policy on human subject proportion. That would be my spin on it.

DR. HOWE: That's true.

DR. SIEGEL: And since the people you're releasing it to aren't your licensees, they are not really bound by any further regulations from the NRC anyway.

MEMBER SWANSON: They're held to a different set of regulations.

DR. SIEGEL: They're held to a different set of regulations by a different standard altogether, not really linked to the -- once that capsule leaves -- if I understand

it, once that capsule leaves the manufacturer, it is out of NRC purview at that point.

DR. HOWE: It is the same as a smoke detector. As long as the smoke detector is being used as a smoke detector, it is under exempt distribution. If the smoke detector were taken apart, and the source put into something else or used for some other purpose, then it would no longer be exempt distribution.

So the capsule is for diagnostic test and not for research. If it were to be used for research, it would then come under 35. We haven't seen the final Commission decision on that comment.

MEMBER SWANSON: Certainly, if anybody was intending to use it in research where they were going to modify the capsule or the dosage form, okay, I would want that to be governed under Part 35. However, if somebody is just going to use that capsule in the current dosage form as part of the research study, okay, it ought not have to come under Part 35. It is a prescription drug, I think is basically what we're saying.

DR. HOWE: But it will come under Part 35 because of 35.6, and that there are --

MEMBER SWANSON: But we're saying it's not appropriate.

DR. HOWE: -- protections under --

MEMBER SWANSON: Okay.

MS. HANEY: Dennis, if we can -- maybe we can, you know, do some more research between now and tomorrow. If we can find out something that would help provide a better reason for you, we'll let you know tomorrow, if that would be okay.

MEMBER SWANSON: Okay. But I think you need to understand that that person using that capsule and that dosage form in research, you know, the obligations of that research project are covered by another set of regulations. Okay. You don't need to codify that in your regulations. I think, in fact, that codification is inappropriate.

MS. HANEY: Okay. We'll take that under advisement, and we'll also look and see what we can find out between now and tomorrow.

I guess the last topic that was under 4:15 tomorrow was the discussion on Part 33 rulemaking. And when I gave you the status this morning on your previous recommendations I covered that, so I don't think I need to go back over that, unless you have specific questions.

CHAIRMAN STITT: Good. I think we've taken care of the 4:15 to 5:00 slot.

We've got an hour left. I want to use it for something. There are a couple of possibilities. I think we

can't be as formal, but we could start discussion of training and experience. That's a very hot topic.

There's another thing on my mind which we could do. It has to do with the handout. I got it by e-mail yesterday, and then there is a handout threshold of reportable events. We could at least discuss reportable/recordable. We could discuss these definitions -- the old misadministration -- and not start making motions and recommendations, but there is going to be some need to at least get up to the same level of discussion.

Jeff is nodding his head. That's about all it is going to take for me to want to pursue this, quite frankly.

MEMBER NELP: Is that the 12:30 topic?

CHAIRMAN STITT: This is the 12:30 topic. What I would like to do -- and, Cathy, I don't know if you -- I don't want to put you on the spot, but if you can -- you seem to be able to help lead us into discussions. Would you look at recommendations for threshold of reportable events? I don't want to start identifying those alternatives that we like or don't like, because we'll have to do that. There is a member of the public who will be here tomorrow, but I think we need to be saying similar things to one another.

As to our level of understanding, the status quo recordable/status quote reportable, which was referred to as a misadministration still is. We had one last week.

Wait a minute. I flagged it here. Another option is raising these thresholds to the level of NRC abnormal occurrence in reporting criteria. That's a whole different set of topics -- well, not topics, but of thresholds. So unless somebody boos me and pulls me off the stage, I'd like to at least get us talking about what these numbers are, what your feelings are, so then we can start looking at the alternatives tomorrow.

Jeff, you and I agreed, let's do it. All right.

Cathy, do you want to try to introduce the subjects?

MS. HANEY: This is going to give me a free night tonight, because now I don't have to study for my presentation tomorrow.

CHAIRMAN STITT: There you go. Well, I think this will help us at least start to hone in on the alternatives, if we can have this discussion now.

MS. HANEY: Well, let me tell you what got us to this point. I went to the first working group meeting in August. This paper was not developed. When we got to the steering group point and we started talking about patient notification, we started to -- we really got into the point of, well, the notification issue is so closely tied to what is the reporting threshold and the recording threshold that we need to start looking at this.

Also, from Don Cool having done some presentations to the professional societies where he was able to, on a cursory level, start talking about what the different alternatives were, again, he was getting asked questions like, well, what is the threshold for reporting? In other words, you know, at what point do I need to be concerned about telling you different things?

The other thing that was driving this in coming up with alternatives was the SRM again. It said that we should come up with a way to identify precursor events, and I probably -- I don't have here the exact quote from the SRM for you, but it's back at my desk. I'll get that -- I mean, back at my seat. I can get that for you.

So we were trying to somehow come up with a way of capturing these precursor events. When the working group sat down to do it, we first -- we came up with a term for discussing these precursor events that went something along the line of, if there is anything else you think we ought to know, then tell us. And that wasn't going to work in regulatory space.

(Laughter.)

So at that point we said, well, you know, we've got a week and a half until the ACMUI meeting. We have to get this out of here, so why don't we put forth what our intent is to capture, and then have you help us develop what the exact

rule language would be for -- or not the exact rule, but a strawman rule language for what is this precursor event and what we're trying to get at.

That is really what this note 2 is directed at, and it's probably worthwhile taking a minute or two to read this note 2, because this is what we're looking for as far as the precursors go.

Again, as with QM, it was being taken as a given that we needed to identify precursor events, and that's why, through all five of these alternatives, you will note that we have precursor event in there.

The alternatives that we came up with for the status quo plus the precursor -- status quo meaning that you keep the current definition for misadministration and you keep the current definition for recordable event. Those currently appear in the definitions of Part 35.

The thinking is that no matter how we end up defining these terms, coming out with these thresholds, they probably will no longer appear in the definition because they don't -- it's not really appropriate to have them in the definition section. We will probably end up throwing them back into some type of rule text, with a reference from the definitions section, back to the rule text. But again, that's three or four months down the line.

The next alternative that we came up with is that we would raise the reportable to the AO criteria, and then still have that precursor in there. The AO criteria, if you look on page -- I guess the best place to see that is on page 7. I want to make sure I get you to the right -- yes, page 7 at the bottom, A and B. The reason for going to that is it's a dose base, and trying to get into a dose base space there.

We would still keep the recordable, but we would raise the recordable to the current reportable level, or, in other words, the current level for misadministrations.

The third alternative gets rid of recordable events and just has the reportable at the AO criteria.

The fourth one is to -- that the reportable would be lowered to the recordable. This gets very confusing.

(Laughter.)

It was very hard at the working group level, and from listening to myself now it is even still confusing.

But in other words, four is a lowering of the current threshold, is what it really means.

Five is a combination of, you know, pick 1, 2, 3, or 4, but rather than having a requirement for the reporting of these voluntary -- for the reporting of the precursors, there would be a voluntary reporting of precursors, and we would, at that point, be looking to some of the other federal agencies where there is voluntary reporting to see how it is.

And I think -- if you will give me a second, I think in order to evaluate this I do need to read the page from the SRM for you.

Okay. What I'm going back to is under the SRM on DSI-7. It's under your tab on update or revision of Part 35. Item 3 -- and this is very key to this presentation -- is that the staff should address how best to capture not only relevant safety significant events, but also precursor events. And that -- so during your deliberations on this, the bottom line is we need to be able to capture some of these precursor events, and that's why it appears throughout this whole document.

The other thing to keep in mind in reviewing this is that we have a requirement to report to Congress AOs. So you can almost take the AO threshold as the highest level. That's a fixed level at this point with Congress, so that's your high. And then your low point is that we need to be able to capture the precursor events.

And with that, I'll just open it up to discussion.

CHAIRMAN STITT: Cathy, let me hone in on that and just ask you a question. Because the QMP supposedly had as one of its interests precursor events, but that seemed to -- precursors were supposedly to be picked up by a certain threshold that if you exceeded was reported, and, therefore,

could identify precursors, and that doesn't seem to work at all. How would this be different in identifying precursors?

MS. HANEY: Well, I guess let me say, first of all, the concept of these thresholds would come into play in several places in the rule. It might go back in -- however a QMP ends up being -- you know, there may be a touch on these reportable/recordable, using the new definition in that rule text. It would also come about in patient notification. Do you notify the patient at recordable/reportable? So this subject has -- touches several aspects of Part 35.

As far as -- I think what you're saying is since QMP didn't capture precursor events, what makes us think that this will? Is that pretty much --

CHAIRMAN STITT: That's the short way of putting it, yes.

MS. HANEY: Okay. I think we're recognizing that QMP didn't capture precursor. The Commission has said, "Staff, go out and capture these precursor events," and now we're trying to come up with a way of doing that. And that is what gets us back to where I said we started out trying to define precursor and we couldn't get there.

CHAIRMAN STITT: Well, let me throw something out about that, and then I would be interested to hear opinions. As you probably know, my institution is doing a fair amount of

research on human factors, human error, and precursor events, and it's usually a research topic.

One of my concerns, and certainly my question, is is this something that can be identified in a standard practice? I mean, just in the practice of medicine, the procedural aspects that institutions would even understand are precursors to something that is eventually going to -- might happen or might be caught as a near miss and then corrected.

My concern is that this is easily a research topic. I don't know if it lends itself, at least through any of the measurements that we have, to identifying this in the routine course of practice. I'm not sure if we can get precursor data through any type of regulatory process.

Dennis and then Jeff?

MEMBER SWANSON: Is it possible to address this through a performance-based requirement, something along the lines that the licensee shall establish policies and procedures for reporting and evaluating precursor events, and then allow them to come up with their internal policies and procedures? And would that meet the NRC's requirement in that you would have access to this information through your inspection process?

In other words -- let me give you an example. I mean, you know, we have policies and procedures in our institution where we -- you know, we record and evaluate any

-- where we exceed the dose of a radiopharmaceutical, a diagnostic agent, by more than 10 percent, because we consider that the standard of practice, plus or minus 10 percent. Okay? Can we leave some flexibility for the institution to develop their own policies and procedures for capturing these events?

MS. HANEY: I think we can leave some flexibility. However, we need a certain amount of uniformity across licensees. And without defining a precursor event, I don't think you would have -- we would not have the assurance that we were getting the uniformity that we need.

MEMBER SWANSON: The problem that you have in defining precursor events, though, is, you know, you can actually limit the information you get, which is what we've seen from the past. Okay? And if your goal is to truly evaluate these events for the purpose of, why did they happen and what improvements, you don't want to limit the information that you get. Okay? And I think that -- I've said it many times. That was the problem with the previous reporting program.

So there's kind of a tradeoff there I think in what you're looking for and what the goals of this program is.

CHAIRMAN STITT: Jeff?

MEMBER WILLIAMSON: Yes. I guess I have a couple of comments on this. I think the first is to amplify I think

on what has just been said by Judy. It is kind of in a research area, what the significance of these things are, and I think there are several implications of that.

First of all, I don't know that it is possible at this point to give an objective criterion so that any event X is a precursor event, if and only if the following conditions apply. You can characterize but not define, and use clinical judgement to make an assessment of whether a given deviation from the norm has potential for more -- under some slightly different scenario for the possibility of an unsafe situation; and, therefore, you know, requires some kind of corrective action, or is of interest to others.

So I think, you know, there is going to be sort of a level of fuzziness that you'll have to accept that we deal with every day as clinicians. And if you're going to sort of be like clinicians, you've got to kind of accept, you know, the way the world is, I would argue.

Secondly, I am not clear what the -- you've got this directive to create precursor events. Do you know why you want the precursor events and what you're going to do with them? Are you going to use this as sort of a method of meting out more punitive actions and punishing licensees? Are you just collecting the data for research? I think this is really important.

You should be addressing, in a clear fashion, some perceived public health hazard. And, you know, the purpose for -- you know, will dictate the method you use to collect the data and what you do with it. And if you sort of start out, well, we're just going to have precursor events, you know, I think you understand what I'm getting at.

MS. HANEY: Let me read you two sentences from the note at the bottom of the page that I think starts to get at what you've asked -- that the requirement would be intended to identify events, incidents, and situations which have implications for that facility or implications for similar facilities, generic incidents that may adversely affect the dose to the patient or the public.

The objective of this requirement is to identify information that would be useful to avoid potentially significant problems and to improve the radiation safety program at licensed facilities.

CHAIRMAN STITT: There are a couple of comments down here. I just wanted to add, before I let this side talk, that, again, as I remember several presentations about QMP, I could swear that a variety of things that had to be documented in the QMP had to do with a fishing expedition, that the NRC was looking -- was going to look at all of the stuff that was turned back in to see if there was something that maybe made a picture, made a drawing or a diagram.

Studying this as I do with a whole group of people who are from all sorts of walks of life on our campus, this is a very difficult topic, and I just am concerned that it's another fishing expedition that is not very well defined by those few groups of people in the country, where you've even looked to people who you're spending a lot of money contracting to. And they don't know what they're doing.

So it concerns me that we're turning it into a regulation and asking people who are practicing medicine to determine what precursor events are on what I view is another fishing expedition.

Naomi?

DR. ALZARAKI: I presume, although I don't know that it was -- I see it written anyway -- and maybe this is a wrong presumption -- that we're talking about -- as reportable events, we are applying this only to therapeutic procedures or utilizations of radioactive iodine which exceed whatever the threshold is -- 30 micro --

MS. HANEY: You have a combination of both there. If you go with the status quo, you go a little bit -- you are in that space of the therapeutic. If you go with the report with -- that the AO criteria, since that is a dose based, if you meant to administer a diagnostic dose, and instead you administered a therapeutic dose, you could kick into this. So

that is why I can't give you a definite yes or no to your question.

DR. ALZARAKI: 2 and 3 would almost -- at least by 3 definition -- yes, they both use the abnormal occurrence.

MS. HANEY: Yes. As long as you're using the AO criteria, you are at a dose base, so it's not a differentiation between diagnostic and therapeutic, although it almost falls into that.

Now, in 2, where you do keep the option of reportable and recordable, the recordable, when it becomes the current misadministration, again, is still -- it is still the big things like the therapy.

DR. ALZARAKI: Okay. Well, you know, taking that into consideration and the discussion about whether this is a large research project being conducted by NRC which is not well spelled out and being financed by users, you know, I think alternative 3 of the options we have makes the most sense.

CHAIRMAN STITT: Barry, you had a comment?

DR. SIEGEL: Yes, two. One, in partial answer to what you just said, Naomi, currently misadministration reporting captures some, but a very tiny number, of diagnostic misadministrations if those dose thresholds are exceed -- the five rem EDE and the 50 rem organ -- and it almost never happens. That's number 1.

Number 2, I just now realized, Cathy, that actually the way this is structured you have left out one option. As much as I hate to say it, you've left out status quo reportable/delete recordable, because you have that parallel structure and all of the others --

MS. HANEY: Yes, that's true.

DR. SIEGEL: So you actually need a new number 2, and then 2 would become 3, 3 would become 4, 4 would become 5, and 5 would be alternatives 1, 2, 3, 4, or 5.

MEMBER NELP: Where are you reading from?

DR. SIEGEL: The voluntary report. I'm just saying that --

MS. HANEY: But you're right. Yes, because that gets back to this morning's discussion on whether we even need the recordable --

DR. SIEGEL: Correct.

MS. HANEY: -- aspect.

Can I recognize Don?

CHAIRMAN STITT: Yes, you can.

MS. HANEY: Don?

MR. COOL: I wanted to try and address, for just a moment, several of the things that have been said around the table about how any of us got into the issue of precursor, because I think perhaps understanding a little bit of the context might help just a little bit.

First of all, let me say, Dr. Stitt, that you may well be right in terms of whether or not we are going fishing, and whether or not, in fact, the type of fishing is actually in terms of trolling, or wandering around hoping that we will snag something with a long line off the back of the boat.

The historical background -- the Commission has been interested in precursor events -- put that in your quotes -- in all of its programs, as a general way of expressing that from a regulatory standpoint, but more importantly from a how can we improve overall performance within the community that is regulated and for which we are held responsible by our friends down on Capitol Hill, by seeing if there are ways to identify things which didn't quite go bad enough wrong for us to get called down on the Hill on the carpet, and which would lead someone, maybe the same institution, maybe other institutions or programs or activities, to look at and think about whether or not the same sort of thing might go wrong there, and, therefore, lead you to think about whether or not you might want to do or change something within the program or the way in which you conducted business, so as to avoid that.

The examples that tend to get tossed around when you're in Commission meetings and discussions generally don't come from the medical community. They are things like, well, you know, once upon a time, such and such facility bulged a UF6 cylinder. That really was a precursor to the fact that

some other facility two years later did the exact same scenario, except that they succeeded in rupturing the cylinder. And had somebody sort of thought about that, then maybe they wouldn't have gone and done the same sort of thing by not weighing the cylinder, and, therefore, have avoided the particular event.

The reason I think that it is, and probably always would be to some extent, a fishing or a research expedition is the very nature of the fact that a priori I can't sit here, and I think what I'm hearing you say you can't sit here, and write A, B, C, D, and E forms the explicit, complete, universal set corresponding to precursor, all of the possibilities that go wrong.

What the Commission has asked us to do is to attempt to find ways to capture those things, and this is why we wrote the note on the bottom here and why we are really not so much in text space that we have alternatives, but rather looking for your suggestions as to how to draft text that might assist in having people understand that what we are looking for is, in fact, things which would tell us that there is something within the programs that other people would benefit from knowing about.

And a priori I would have guessed that the agency's approach to such data might be to publish an information notice or put into the newsletter that thus and so

happened and that people might want to be alert for similar sorts of things, and see what sort of implication it has for your program. Thank you very much. End of discussion.

Now, with that as background, I don't know whether you can then come back and say, "But that's why, in fact, you see things like voluntary reporting, and why you see things like can you define a sort of generalized methodology that would have people thinking in the same lines and being alert to the same issues."

Quite frankly, I don't think the Commission was necessarily thinking about a punitive detailed structure of saying that identifying a precursor event threw you into violation space. In fact, the whole point of this is not necessarily to get in that mode, but rather to be able to identify and to have someone else be able to do something about it before you got into that kind of mode of operation.

CHAIRMAN STITT: A couple of comments, and then I'll let the committee speak.

When devices have problems there is a reporting mechanism through the FDA. Accelerators commonly end up on that list, and some of that can be thought of as precursor. What strikes me, both in my practice and also reading this, is that over the past few years the things that have happened in therapeutic radiology is the advent of remote afterloading, both low dose rate and high dose rate, which is a mechanical,

computerized -- it's got hardware, software -- infinitely more procedural as far as various steps that certain people have to coordinate. And it's one of the better models for looking at precursors.

Low dose rate or manual remote afterloading is probably at the far end of the spectrum and is why it makes it very difficult to do precursor for that. And all you've got, unless your source falls out of the bucket or the bucket falls off, is basically sequences of human error.

So I think that with remote afterloading of all dose rates with the stereotactic, because they are all procedural and gizmo related, that those factors make precursor research more possible.

Certainly, what I would like to recommend and have the committee support me entirely on is lots of money being given to my institution from your institution.

(Laughter.)

We have little bits of money that are coming that way, but I think I'd like to see you make that motion and everybody support that we continue our research.

All right. Let me open it up. Jeff had his hand up.

MEMBER WILLIAMSON: Well, I think it's all fine and well to collect such information and become a clearinghouse for it and see if you can see a pattern. But I

think if you are going to include it in Part 35, which is regulatory space and potentially punitive if you, you know, don't play along according to the proper tune, you should, one, clarify explicitly this is not, you know, going to lead to -- lead an institution into punishment space as you put it for complying with the request. And secondly, it should be voluntary. And thirdly, the criteria, since you accept that they are inherently fuzzy given our level of knowledge of human errors and factors analysis, you know, should explicitly recognize the necessity to exercise clinical judgment in identifying these events.

CHAIRMAN STITT: I'm going to go around the table for any other comments along this line, and then I have one final task this group has to do before we quit today.

Anybody else over here? You'll be next after Dennis.

MEMBER SWANSON: You know, in listening to this, my personal feelings about this is I think it's important to report directly to the NRC events that meet the abnormal occurrence threshold. I would also think it's important that somewhere in -- you know, what I get concerned about is what about the events between that threshold and unintended deviations from whatever is planned.

I don't want institutions -- and there ought to be something in the regulations that address the requirement

for the institutions to look at those events, okay, and that's what I'm getting back to is there probably ought to be some performance requirement for them to look at those events as part of their quality improvement program.

Again, let me emphasize, though, I wouldn't put specific numbers on those. I would leave that up to them to determine in their policies and procedures, and then I would see a voluntary reporting of that information to the NRC.

CHAIRMAN STITT: Wil?

MEMBER NELP: I had a question to you. If I have a reportable event, I fill out a form to report it to you that -- you have made up the form that you've sent to me, is that correct? You give me a method of reporting and you ask me to fill out the blanks?

MR. COOL: The present process doesn't necessarily have a form. The rule says that if you have X type of event -- and right now it's expressed as percentages plus or minus on the dose, then you need to call the operations center within X number of hours and provide the following kinds of information.

The fact of the matter is that my friends who are on the fourth floor here in the operations center have a little form and they're going to ask you the things so that they can check out the little boxes and enter it into the system.

MEMBER NELP: So why wouldn't you say, "Thank you, Dr. Nelp, for telling me about this. Now I'm going to send you another form, and I'd like you to list -- answer these questions and see if there are any things that led up to this that we should be aware of, because we're compiling this information."

There were precursor events, but the term is very glitzy. It's an in word. If you go out to Walla Walla, Washington, and ask physicians about their precursor events, they're not going to know what the heck you're talking about. Or they may think you're being rude.

(Laughter.)

I agree with Judith that we want to -- there are simple ways of policy you can gather the information. But let's keep it out of the regs. I think it should not be in the regulations at all.

CHAIRMAN STITT: Rude or maybe even kinky.

MEMBER NELP: Kinky, yes.

CHAIRMAN STITT: All right. We'll say that you're first in line on this side. Just this once.

DR. SIEGEL: Precursor events I think, having discussed this previously with some members of the staff here, I think if you try to define that in the regulations you're going to go back to the other thing I used to joke about with this -- operators are standing by -- because you're likely to

have it so vague that people are going to be so confused about what they have to report that you're either going to be buried in paper or buried in phone calls.

And that is why I really strongly support a voluntary reporting mechanism, which you don't even have to take responsibility for. You could work out a deal with the United States Pharmacopeia and let them be the clearinghouse for your voluntary reports, much the same way that they are for drug and device reports, those that are not -- the device reports that are not mandatorily reported to the FDA.

That's a way to let people who have something that occurred that is bothering them let people know and start investigating it if they choose to. It is a very non-judgmental mechanism. And frankly, based on the things that I've seen the USP do with the data and what they transmit on to the FDA, I think it has worked very, very effectively. And so it could be completely out of Part 35 space and still accomplish what the Commission wanted to accomplish. So that's what I would argue for.

CHAIRMAN STITT: Good comment. Keep on going.

Andrew?

MEMBER KANG: Yes. I have just one comment, or the question is that I -- I fully understand the NRC's deep concern about the radiation safety in this precursor event. But I am not sure that -- and precursor means, by definition,

it is an event happening prior to a main event. Without that main event happening, how do you define the precursor?

You know, again, all of the potential precursor events doesn't necessarily lead to accidents. So again, it is very vague terminology there, the precursor. We can say that that is precursor, but it is very difficult to assess, even if you collect all of the precursor event data.

So I think what I would think is more appropriate is that when you collect any real incident report, then you can -- may perhaps collect at the same time what the user think that might have been happening prior to the incident. Only you can collect the data when radioactivity event happened. Then you can probably collect some precursor event.

CHAIRMAN STITT: John?

MEMBER GRAHAM: There have been a number of comments that we should go on the record to recommend that the collection of information on precursor events is a great, good, and wonderful thing as long as it's kept on a voluntary level. As I think we discussed at length in the April meeting, the problem is that you cannot collect this information. You cannot analyze this information without committing resources to do just that.

And I don't know -- and from the tone of your comments -- for the Nuclear Regulatory Commission to go out in search of precursor events that might avoid a Three Mile

Island accident, I understand that it wouldn't take me very long to get to a very strong cost-benefit analysis of doing that.

But at the level that we're talking, with the millions of procedures that we're talking about, to come up with a national database to try to track medical precursor events that may or may not, after a litany of esoteric research, result in a change in the system or procedure, I would not recommend even a voluntary system moving forward if it's going to have significant cost.

So I think the issue is that the staff has been charged to address how to capture precursor events. Fine. I think the staff could recommend a voluntary program and throw the charge back on professional societies and groups that already exist to identify the best, most effective way to voluntarily review those activities. You can't do this -- and the USP was discussed at length last time as a voluntary program and is still the best model I think any of us have heard of.

And I would go on record that I think we ought to -- and as the other component, move towards option 3, which is a reportable event is raised to the AO criteria.

CHAIRMAN STITT: I want to get to that in a minute. It costs money to use the --

MEMBER GRAHAM: Nothing is free.

MEMBER FLYNN: I just also believe that it should be voluntary, and there is other ways to get at it, quite frankly. For example, if someone had all of the minutes of all of the radiation safety committees that have met say in the last five years, you could read through minutes -- you read through minutes. I have read through the minutes of other hospitals. You come across incidents happening, things that happen that they discuss during the meeting briefly. It's not a reportable event. It's not a recordable event. It's just something that someone brought up at the meeting.

And you'll find that things come up that could have led to something that could have been a problem but it was, you know, caught right away or something. It was taken care of. Those would be, in my view, precursor events and they -- you find them in the minutes of radiation safety committee meetings.

The other thing that -- I think that anyone who voluntarily reports has to understand that there is no enforcement side to whatever this event was. So I think it has to be voluntary. When inspectors come around, they can ask that this is now -- part of inspection is voluntary. If there are any things that have come up, it's not enforceable. It's not -- there is no -- if there is anything unusual happening during any of the plants that we should know about in order to -- you're laughing.

If it's voluntary, you know --

CHAIRMAN STITT: How are you going to make me believe that there is no punishment?

Naomi, let's go on to you.

MEMBER FLYNN: Well, if you haven't violated any --

CHAIRMAN STITT: Right. I don't think that's the culture we've worked on under -- for so long that it would be very difficult to start --

MEMBER FLYNN: Well, anyway, if you look at all of the misadministrations that I guess the NRC is trying to put together a database on right now, there are things that have happened quite commonly in radiation oncology. At least in the 50 or 60 I've looked at there have been three different things that have happened multiple times, and I --

CHAIRMAN STITT: Let's keep going. Naomi, I'm going to go to you, and then I have another --

DR. ALZARAKI: Again, some variation on the same theme, and that would be that if the NRC really wants to collect this data, if they have the funds to support contracting with one or two professional societies to collect it for them on a voluntary basis from their constituents, you might be able to collect something over some period of time.

But I've got a project on breast cancer that I'd love for you to put in the regs. to collect data for me.

(Laughter.)

CHAIRMAN STITT: Well, tomorrow we will address alternatives 1 through 5. It would not be beyond my summary of what I've been hearing today to think that although each of these includes that we should address precursor events in all of these alternatives, I think we could end up in trouble if we try to come up with an alternative and also hook on the statement about precursor. They may end up needing to be different statements.

Jeff, I want to move on. Can I?

MEMBER WILLIAMSON: Yes. I was going to ask if I could ask a question about a different aspect of this presentation, but perhaps this is not the one you intend to move on to.

CHAIRMAN STITT: Well, here is what I want to do, and we're getting down to 20 minutes. Again, this is to bring us hopefully together so that we're using the same terms. I would like to review, in the document that we have, the old recordable event, the old misadministration, the status quo recordable, the status quo reportable, and AO. So I'm looking at page 3, looking at --

MEMBER WILLIAMSON: Could I ask a question about AO?

CHAIRMAN STITT: Yes. Let's just talk about what AO -- because when we get to the alternatives tomorrow, if we

understand what terminology we're using, I think we won't have to have that discussion again.

Tell us about AO, then.

MEMBER WILLIAMSON: Well, you know, what AO looks like to me is that it is an event that must satisfy two criteria. It has to deliver doses, you know, to organs or bone marrow or something that exceed a certain threshold which is specified here in Part A, and then it must satisfy a bunch of conditions which are the same form -- have the same form as the current definition of misadministration.

So it seems to me like what the intent is is to rule out a certain set of procedures that, you know, do not have the potential for giving dose that exceed these thresholds. My concern about this is that it does not address one of the major glaring deficiencies of the current misadministration definition, which is there is no threshold for wrong site.

So I would like to ask, if I -- if we were doing an intracavitary implant in a patient that gave more than 1,000 centigray to the target organ, and the resident, say, is removing the sources at the end of the implant, and he or she fumbles and drops the source on the bed for two seconds, and gives a microsievert extra to the thigh of a patient, that, under current terminology, I think would be a

misadministration, because there is no lower dose threshold for wrong site criterion of the misadministration definition.

Would this be also an abnormal occurrence? We have delivered, let's say, one milliremkin of radiation to some unintended site, which is a very tiny fraction of the dose that would be there anyway from inverse square law falloff of the implant as prescribed.

MS. HANEY: I think in that case for it to be an AO you'd also have to meet the criteria of A, if you reference page 3. You would have met it under B. Under B, it would have been an AO criteria. But if you didn't exceed the dose thresholds in A, it would not have been an AO.

MEMBER WILLIAMSON: Well, I guess the question is, does the dose levels in A -- are they unintended doses, incremental doses added on top of the doses that are supposed to be there? Or are those the doses that would be there if you correctly executed the procedure? So in other words, I thought the --

MS. HANEY: These are incorrect.

MEMBER WILLIAMSON: So the intent of the AO definition is that these doses are due to some kind of an avoidable error on the part of the caregiver, and they are not due at all -- these are on top of the doses that would have been delivered if the implant had gone off as prescribed. Is that correct?

MS. HANEY: Yes, that's --

MEMBER WILLIAMSON: Because I did not get that impression from, you know, my discussions with Dr. Siegel about this issue.

CHAIRMAN STITT: Well, we could make a statement as we address this in more detail about the wrong site, that it keeps coming up, particularly, again, with the remote afterloaders, because I think you just are able to more define certain occurrences. In the past, it was a little bit magical.

MS. HANEY: Also, I guess a couple of things to know -- when we reference up there the -- like on 2, 3, and 4, where we're raising something to the current misadministration criteria, if there are problems with the misadministration criteria like, for example, the wrong site, the changes could be made in the rule text at that point. This was more a conceptual change as compared to the nitty-gritty items.

MEMBER WILLIAMSON: Well, you know, it's just I think -- I want to underscore again, I think one of the most kind of destructive influences of the current misadministration definition and associated reporting rules, you know, is that it lets a whole bunch of -- it treats a whole bunch of cases of small errors, most of which probably fall under the wrong site in some sort of trivial way, but then are treated by the agency as if they involved, you know,

some real injury or some event of medical significance to the patient, and you have to go through and notify the patient and the referring physician, get everybody alarmed, and it sort of creates -- and then also subject the institution to punitive measures -- all over something that by definition, you know, is presumed to have medical significance and involve potential harm to the patient, but in reality doesn't. And so I really think this is an important issue.

CHAIRMAN STITT: I also want to refer the group back to the discussion we had today and didn't complete -- licensee is required to maintain reportable events, recordable events, abnormal occurrence events. So that discussion has to be held tomorrow. And there are some levels that --

MEMBER NELP: It can be either/or.

CHAIRMAN STITT: Well, it could be any of the above. Remember, we said we need to -- the feeling was we probably needed to maintain some sort of record. What will it be?

MS. HANEY: The other thing, when I got back to my desk I realized this morning when I spoke about the one SRM where the Commission had given the SRM to the ACMUI, there were two more questions that had to do with events that I was going to table until this discussion. Would you like me to put those up just so people can be thinking about them?

CHAIRMAN STITT: We can be thinking about them tonight, right.

Does everybody feel comfortable -- I don't know if comfortable is the right word -- are we making the same -- are we working under the same understanding that misadministration, according to 35.2, and all of the points that are listed here on 35, everybody now knows what abnormal occurrence event criteria are?

MEMBER NELP: I'm confused whether we're talking about having to report only one series of events that are "mistakes" or "misadministrations," and they would follow the definition of what is called an abnormal occurrence. And those are the events that we would report, or we would report events other than that as also being misadministrations.

CHAIRMAN STITT: I think that's what we will be discussing.

MS. HANEY: Yes. It really depends upon the option that you choose.

MEMBER NELP: So we could choose just one event will be reportable, and it can have this definition or some other definition.

MS. HANEY: Right. But then you also have to come to grips with this precursor event.

MEMBER NELP: Well, I think we've come to grips with that. I think that's very --

MS. HANEY: Okay.

MEMBER NELP: I don't think that's --

MEMBER GRAHAM: Just one question on that before we leave it. The definition of abnormal occurrence that is published here on page 7 that you had introduced as a required data element that you, the NRC, has to report to Congress?

MS. HANEY: Yes.

MEMBER GRAHAM: Is that Congress' definition of an abnormal occurrence?

MS. HANEY: No. That's --

MEMBER GRAHAM: Is that staff's recommended definition?

MS. HANEY: It is --

MEMBER GRAHAM: Could this committee throw it out and propose something else?

MS. HANEY: Well, yes, I guess is the answer. This is the definition that NRC has gone to Congress with and said, "This is what we will report to you at this level." Now --

MEMBER GRAHAM: So any change in it you would have to take back to Congress.

MS. HANEY: If we change the AO criteria -- now recognize that this group can change those numbers for the purpose of Part 35. Where I run into a problem is if you raise the Part 35 reporting higher than the AO criteria, then

I can no longer -- we can no longer meet the statutory requirement to tell Congress.

So you have the -- well, you have -- I mean, if you want to make it 30 versus 50, I mean, that flexibility is in there. You can even come up with other thresholds. These were just ones that the working group came up with.

MEMBER GRAHAM: Okay. But to clarify, we can make it lower, but we couldn't make it higher without the NRC having a requirement of going back to Congress.

MS. HANEY: Yes.

MEMBER GRAHAM: So --

MEMBER NELP: And this is the current requirement.

MS. HANEY: This is the current requirements for the AO criteria. Also, realize that this is -- there are several other requirements for reporting to Congress. This is only a small portion of the AO criteria, and I only picked the ones that were specific to misadministrations. There are ones that are just specific to fuel cycle, to reactor site, things like that. But this was the only section that was appropriate.

MEMBER WILLIAMSON: Could you supply us tomorrow with a more complete definition, and if you have any, you know, useful regulatory guide or other associated document that helps you interpret this to --

MS. HANEY: The AO criteria?

MEMBER WILLIAMSON: Yes. To give us --

MS. HANEY: Sure.

MEMBER WILLIAMSON: It's totally new to me, and I must confess I find the wording of it very ambiguous. And maybe this is just sort of a very brief summary of a longer, more extended definition.

CHAIRMAN STITT: You know, Cathy, a question along that similar line, you report to Congress, then, under Section B -- represents either B2, treatment delivered to the wrong treatment site. So Congress just heard about you have dropped the source on the patient's thigh?

MS. HANEY: No. No, because in this case it's an A and B. So if he dropped the --

CHAIRMAN STITT: I got you.

MS. HANEY: -- source on the patient's site, and the dose exceeded A --

CHAIRMAN STITT: Okay.

MS. HANEY: -- then we would have to tell Congress.

CHAIRMAN STITT: Thank you.

MEMBER NELP: Did you, in fact, report any AOs to Congress last year from the arena of medical usage?

MS. HANEY: Yes, we did.

MEMBER NELP: Do you know how many?

MS. HANEY: How many? About 12.

MEMBER NELP: Thank you.

MEMBER SWANSON: This is an attempt to establish consistency between the Part 20 AO requirements, right? Don't they appear in Part 20?

MS. HANEY: No. AO criteria is a management -- an NRC document, a management directive, internal staff document.

MR. COOL: What you will find is that the AO criteria in general are at least a factor of five larger than any of the actual dose criteria. So if you're looking at Part 20 dose limits, the AO criteria are generally five times the limit in Part 20. So in general, the AO criteria are a set of numbers which are substantially above that which requires reporting in the regulation itself, and is the cut set that the Commission has currently given to Congress.

And Congress, by not disagreeing, coming back and saying, "We want to hear about -- more or less has accepted with regards to what we will tell them about really significant events under their particular act and oversight actions." The agency, in fact, just in the last year or two did a revision of the criteria, and there were some changes. And, in fact, the present set that is represented here in the medical arena is a set which results in there being fewer AOs

identified in this arena than there was previously by about a factor of two.

CHAIRMAN STITT: Go ahead, Cathy.

MS. HANEY: Yes. As I mentioned, in the SRM that went directly to the ACMUI there were four questions. Two we discussed this morning. These are the last two, and they are event related. So we can maybe come up with answers for these during tomorrow's discussion.

The third question that was in considering various events, misadministrations, equipment failures, and procedural errors, what criteria should the NRC use to determine that a particular event is isolated rather than having program implications for that licensee or generic implications for other medical licensees, and what is the best process for the reporting of events to ensure that the NRC is aware of potentially generic issues.

And then the last question is, in evaluating errors, should a threshold be established beneath which corrective action is not required? And how would such a threshold be set, and how would it be implemented? So those are things that are very key to this discussion of precursor events.

MEMBER FLYNN: Are we discussing this again tomorrow?

MS. HANEY: I'm closing it up. I'm closing up shop.

MEMBER FLYNN: Good.

(Laughter.)

MS. HANEY: Well, that's -- no, it's --

CHAIRMAN STITT: Yes, this has all been background for tomorrow. I think we have had quite a discussion, however, on precursor events.

Don't leave yet. You're not excused. You have to ask permission.

Any other comments before we close down for today? Take this section home, make sure you're comfortable with it, so we don't have to spend a lot of time going through definitions tomorrow again.

MEMBER FLYNN: I think looking at these incidents, I mean, I think that -- I think -- is it Dennis Serig who is compiling a lot of this database? And I think if an incident comes up, like in radiation oncology, I think the staff could ask, you know, members of this committee, together with NRC staff, who have been collecting a database, to determine whether this is something that they need to pursue or not.

Then you've got -- you know, if it's a nuclear medicine problem, then you've got several nuclear medicine people here, plus you've got staff like Mr. Serig, who is

collecting a database over the years with these abnormal occurrence events and misadministrations and other things, to determine whether this happened before, whatever it is that has happened, and whether anything needs to be pursued on that or not. I think it has to be a case-by-case basis.

CHAIRMAN STITT: Any other comments? Looks like we wore out that side of the room. Okay. 8:00 tomorrow morning then.

See you then.

(Whereupon, at 4:55 p.m., the proceedings in the foregoing matter went off the record.)

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