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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL

USES OF ISOTOPES

(ACMUI)

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SUBCOMMITTEE ON REMOTE AFTERLOADING

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THURSDAY

SEPTEMBER 28, 1995

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ROCKVILLE, MARYLAND

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

MEMBERS PRESENT:

JUDITH ANNE STITT

ROBERT M. QUILLEN

ALSO PRESENT:

LARRY CAMPER

TRISH HOLAHAN

ROBERT AYRES

TORRE TAYLOR

SALLY MERCHANT

A G E N D A

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

(8:28 a.m.)

MR. CAMPER: Good morning. I am Larry Camper. I am the chief of the Medical Academic and Commercial Use Safety Branch, and the designated federal official. This is a subcommittee meeting of the Advisory Committee for the Medical Uses of Isotopes. This meeting was noticed; it's a matter of public record, in a Federal Register Notice published on the 21st of August, 1995.

With me here today, two members of the Advisory Committee, and Dr. Judith Stitt, who will act as the chair of the subcommittee meeting today. And Mr. Robert Quillen, who is our states representative to the Advisory Committee. Also we have Dr. Robert Ayres, who is a member of the Medical Academic and Commercial Use Safety Staff, Dr. Patricia Holahan, member of the staff; Sally Merchant, a member of the staff; as well as Torre Taylor, who also serves as the administrative coordinator for the Advisory Committee on Medical Uses of Isotopes.

This is the second subcommittee meeting in a series of three meetings. The first was held yesterday, and the purpose of the subcommittee meetings is to discuss a number of guidance modules that have been prepared by the staff to be added to the existing Regulatory Guide 10.8, which is the so called medical licensing guide.

Today we'll be discussing the guidance module entitled, Remote Afterloading Brachytherapy Module. This module is a revision to policy and guidance directive FC 86-4, which underwent substantial revision updating, following a significant medical event in Pennsylvania 1992.

This guidance document has been discussed in some form through a document identified as the brachytherapy issues paper with the Advisory Committee in total previously as well as with a number of professional societies. Currently these guidance modules are undergoing review and development, as I said for addition to 10.8 and will ultimately be included in a licensing manual, which is being prepared as part of our agency's business process reengineering initiative.

So with those comments then I would ask Dr. Stitt if she would assume the chair of the meeting and we can proceed.

MS. STITT: Good morning. How do you want to proceed?

MR. CAMPER: Go right ahead, Madam Chair.

MS. STITT: Well we have in front of us the remote afterloading brachytherapy module, and if I understand right this is somewhat informal, but we're asked not to all talk at the same time. So do you suggest we start with page 1 and keep turning?

MR. CAMPER: That's fine.

MS. STITT: And there are different colors of markers and handwritten notes on our personal copies, so I think that's what we're going to be working from.

Should we just start on page 1. And do you want to make comments about certain things you're looking at there, sir, Dr. Quillen?

MR. QUILLEN: Actually I have no comments on page 1. Those were just things to alert me and remind me of items that I needed to consider later on.

MR. AYRES: I might make a general comment, this one's a little different than any of the others in that our region and other comments just came in and have not been incorporated. So I have a folder full of comments already.

MS. STITT: Is it worth trying to bring you those up here or is that too convoluted?

MR. AYRES: They're mostly of an editorial nature. The only I guess policy issue really that's in these are some OGC stuff, which will have to start out -- is the state of Illinois comments. They're proposing much more stringent requirements on PDR than are in this module.

MR. CAMPER: What I'd like to do on that, Bob, if we could, is yesterday we also had some comments. In the meeting yesterday we discussed mobile medical imaging module and -- What was the second module we discussed yesterday?

MS. HOLAHAN: Radiopharmaceutical; radioactive

drug therapy.

MR. CAMPER: That's right. Radiopharmaceutical drug therapy.

We did have a number of comments from the regional staff on those modules, and we did share those comments with the committee members yesterday. I'd like to make sure that we also do that today; share those comments with the subcommittee members. And if the opportunity presents itself later in the day, to even perhaps take a look at any major issues, if there are -- If it's all editorial then fine, but if there are any substantial technical issues in there it would be nice if the committee could at least have an opportunity to glance through them to see if they have any thoughts about it.

MS. STITT: Well Trish, I assume you have comments you're piping up, is that right?

MS. HOLAHAN: Yes.

MS. STITT: Just in general, a lot of this -- I mean this is not particularly new material here. It seems to be a different format for some of the things that we have in Part 35 and shuffling other things around, so I'm not sure how emotional we may find some of our meeting today.

MR. AYRES: It's a rewrite of our current policy and guidance directive, with a few changes, and mostly minor, except a couple of them are relatively subtle, such as, the

bulletin had a requirement. If you'd like I can summarize the changes from --

MS. STITT: All right. Particularly those subtle ones that maybe if we haven't enough coffee we didn't catch.

MR. AYRES: From the current policy and guidance directive, one of the more subtle changes is the bulletin and the current policy and guidance directive called for the presence of the authorized user and the medical physicist or RSO. We deleted "or RSO". So we've implied that medical physicist is now required.

MS. HOLAHAN: Do we allow them to propose an acceptable --

MR. AYRES: A super alternative, and what I've provided in the way of guidance in this regard has normally been say a dosimetrist or something, similar professional that has had the specified training normal in emergency procedures on a device. For an authorized user we go along with a resident who's been trained and that sort of thing, or the next tier down in the professional level.

One of the other things I deleted because technically it's not reasonable anymore because the size of these sources have gotten so small I deleted the requirement for checking the homogeneity of the source.

MS. HOLAHAN: And that was discussed with the full ACMUI when we had the two physicists present?

MS. STITT: Right, that was our last meeting.

MR. AYRES: We had a discrepancy between 35.400 and the guidance in the bulletin on the appropriate serving instrument to use, and we decided to go with the bulletin guidance in lieu of the 35.400, so we have a licensed condition in lieu of exemption. I maintained all along that it was more appropriate to use a non-saturable iron chamber type instrument rather than a geiger saturable type instrument.

MS. STITT: And we discussed that in front of the whole committee?

MS. HOLAHAN: That's true. The one thing as Bob mentioned is, that it does a require an exemption to the regulations, currently, because we have not changed the regulations. But that can be done as part of the licensing process.

MR. AYRES: OGC's querying that, so we'll have to deal with that one.

MS. STITT: Are you dealing with that?

MR. AYRES: Well I just got these comments in the last three or four days. I got some of them yesterday, and I still haven't got these two.

MR. CAMPER: I'm sorry, Bob, help me out here. They're querying the need for the exemption?

MR. AYRES: Yes. They're querying the

need -- Well actually, Marjorie is -- querying the need for all exemptions to 35.400.

MR. CAMPER: In the sense of, are they warranted? Are they necessitated?

MR. AYRES: Well, it's just more of a question -- She's saying, well why doesn't it apply as written, and she doesn't understand the technical.

MS. STITT: They need information that they don't have?

MR. AYRES: Yes. From OGC's comments it's clear that they don't understand that technically the 35.400 requirements as written cannot be met.

MR. CAMPER: Oh, I see, okay.

MR. AYRES: I think we'll have to work that out with them.

I guess the only other significant one in here is allowing -- and Trish has written some guidance on this, and it's not incorporated in here. But allowing them to ship more activity than can be installed in the device, so that for the convenience of the vendors and the users so that they can ship 12 curies. They can ship whatever the shipping container is certified for, but can't install anymore than the safe and the device is certified for. So I think pre-ship say 12 curies and schedule the installation at the time the source reaches 10 curies.

MR. CAMPER: Bob, would you comment on the surgical intervention issue?

MR. AYRES: It hasn't really changed.

MR. CAMPER: But the point is, one of the things I want to try to make sure when we get to that point today is get some feedback from the committee, particularly from Dr. Stitt, is this idea that in doing procedures involving HDR, if you're involved in a procedure where a source could become lost in the patient's body that may necessitate surgical intervention to remove it I'd like to get some thoughts as to the way the guidance is currently structured.

Is that a reasonable requirement? Is it a situation where we're not imposing upon medical practice or problem?

MS. HOLAHAN: Okay. I just wanted to say, I don't believe at this time in the guide that we specifically say that you cannot conduct procedures unless you can do surgical intervention, and I guess the question is, is should we. Is that correct, Bob?

MR. AYRES: Well, most the licensees do, I would say, 80 percent. That's a guess. But most of the licensees; response to that requirement is, is we do not do procedures that would require surgical intervention, and they primarily predicate on that the source is always enclosed in the transfer tube applicator system. Where we of course know

there have been multiple failures of transfer tube applicator systems. So it's a little bit of a concern, but we say, okay. You say -- Unfortunately it's a little bit of that philosophy, it can't break, that contributed to the Pennsylvania incident; the source can't break. Well, basically what most of the licensees are maintaining is, the containment system, the applicator transfer tube, can't break. And we in fact know of multiple instances where they have. So we take -- we say, just plan for it, and have at least something in mind if something goes drastically wrong.

MS. STITT: And as I was reviewing this, the two aspects of an emergency -- and Trish, you addressed this in the document that you put together. The two aspects being one medical and one radiation safety. And is an institution prepared to address both those aspects.

MS. HOLAHAN: I think this comes up particularly in the cases that we talked about before with prestanding clinics and something like that. And I know the question and I've sort of tried getting again some feedback too. Even though, as Bob says, it indicates that the source is enclosed are there possibilities, for example, endobronchial, that it could actually get caught or something and no longer be enclosed, and I have gotten some indication that it is a possibility. So what is a licensee prepared to do, or what should a licensee be prepared to do in those cases?

MS. STITT: And in the draft that we're looking here, the remote afterload and brachytherapy module, there is not a statement or is it real vague?

MR. AYRES: Yes, there is.

MS. HOLAHAN: About what's required?

MS. STITT: Section F? Is that what you're referring to?

MR. CAMPER: Item f of 11.21, Emergency Procedures. There are really two things. B, is somewhat indirectly applies, but F is the more direct consideration. And as Trish pointed out, if you look at the words, it says identify the location of emergency source recovery equipment and specify what equipment may be necessary for the various equipment failures described in the procedure. At a minimum emergency equipment should include shielded storage containers, remote handling tools, and if appropriate supplies necessary to surgically remove applicators or sources from the patient, including scissors and cable cutters.

Now, that doesn't go all the way, if you will, of saying, if you're going to do a procedure in which there's a potential for the source to be lost in the patient's body you must be prepared to intervene surgically if need be. And a fundamental question for us, and it's a terribly important medical question is, if were to take a stronger posture along that line would that be acceptable to the medical community,

would be walking on the practice of medicine, or would that be a reasonable regulatory request under those circumstances?

MS. HOLAHAN: Because there is a radiation safety issue associated with it obviously.

MS. STITT: Right.

MR. AYRES: I was just going to say, the other area that's not addressed here because it gets closer to the practice medicine I guess if you will although it's a radiation safety consideration, is do they have a plan to respond to a medical emergency not related to the HDR, but involving the HDR, and that is not covered here.

MS. HOLAHAN: During patient treatments.

MS. STITT: Of course the HDR isn't the only issue. This is a remote afterloading. The more critical issue becomes HDR because of it's high doses. But this module in general applies to any remote afterloading.

MS. STITT: This section of emergency procedures covers it. It doesn't have some of the detail that you -- If you've got a true radiation safety emergency with a high dose rate source, you in theory would need to be doing a thoracotomy, or another example was the case that we've been through with the prostate implant. That was a medical emergency. Well, it was a radiation safety emergency, and that patient had a surgical removal of those seeds of radical prostatectomy within five hours or something like that. And

whether they had written procedures it described that's what they would do ahead of time. That is what they did do when the event occurred.

Some of my question has to do with how specific do we have to get in these to tell folks that you have to think about this ahead of time.

MR. AYRES: With the remote afterloading I guess part of the -- one of the considerations for leaving that out. Normally you would expect the devices to automatically retract the sources when you're responding to a medical emergency, to have a radiation emergency in conjunction with it would require a medical emergency which could do induce in equipment; kink the tube or something. But it would require that medical emergency to precipitate a failure in the device through the ability to retract the source, then creating your radiation emergency to go along with the medical emergency.

MS. STITT: A question to ask of the staff, and this comes just in the form of a clinical circumstance. If this is what we end up with, which does touch on all those aspects, although it doesn't say, give me the name of your thoracic surgeon; it doesn't get that specific. But in example, let's say a free standing clinic somewhere that's doing high dose rate endobronchial, because that's a very common procedure. It's done in lots of places. If there's a source problem, if it's one of the clinics that my institution

operates at there is no thoracic surgeon in the area. There would be within a few hours.

How much goes into this language and how much is left implied?

MS. HOLAHAN: Well let me ask you another case, because some of the responses that we had is, well a thoracic surgeon won't go into the patient if there's a source in there.

MS. STITT: That's the other response, yes.

MS. HOLAHAN: Is it sufficient to say that the authorized user would need to be able to do something in an emergency situation, or would an authorized user -- I mean could somebody other than a thoracic surgeon do the type of intervention you're talking about?

MS. STITT: No. I mean the thoracic surgeon could crack the chest and get close anatomically, and then the authorized user could fish around. It sounds bad on the record, doesn't it?

MR. CAMPER: But you're at the heart of the matter here. If you look at that what that really says in a private, free standing facility.

MS. STITT: Well it could also happen at any university hospital.

MR. CAMPER: It could, but at least in that setting you have access -- reasonable readily, you have

access --

MS. STITT: You have access. You may not have interest in --

MR. CAMPER: Right. But at least you have access to a surgical suite. Even though you don't have access to a thoracic surgeon you probably have access at lest to a general surgeon. You have a surgeon involved. But by contrast if you're in a free standing facility and you have an authorized user who is a therapist and this event unfolds you have an immediate, significant medical emergency on your hand.

So then you have to ask yourself the philosophical question. Should they be doing such a procedure? Well they might respond by saying, yes, we an do this with a high degree of confidence because we assume the potential for failure of this type is extremely small in view of the design of the equipment, the catheters in particular and so forth, therefore we have a high degree of confidence in doing the procedure.

Well that's okay, but unfortunately that one single event, even though it may be 10^{-4}, when you have that single event you've got a problem. So then the question becomes for us as regulators, to what extent should we address this in the guidance?

It would be inappropriate to impose a condition that says, thou shall be prepared to surgically intervene,

because I think that's a medical judgment call. The question -- in advice space and guidance space, to tune them to the idea that, if you're doing these types of procedures you need to be prepared to intervene surgically.

Now, we hint at it here by saying if appropriate, dah dah dah.

MS. STITT: Should you put examples? Will that clue people in?

MR. CAMPER: Well, that's a possibility.

MS. STITT: Such a case might be recovery of a source that has broken off or a source become dislodged in a lung, and you might give some examples. It doesn't mean that it's -- you're dictating what they have to have available. But you can read these things on a lot of different levels. You can think of a source in a intracavitary vaginal applicator and that's much simpler to retrieve than a small iridium source that got dislodged in the right lung somewhere.

MR. AYRES: We presume that in most vaginal cases the authorized user could easily remove the applicator.

MS. STITT: My comment about an example, would at least tip the reader off to some of the most difficult cases to try to retrieve.

To bring up another area along this same line of potential problems would be the intravascular use of high dose rate brachytherapy sources. That is HDR sources are being

used or plaque therapy in vessels --

MR. AYRES: That's an emerging field right now. We're kind of working with FDA and trying to be prepared in advance. But it's all experimental now, and the FDA's going to require IDs and the whole thing. The only one that both of us are aware of that's currently going on is at Scripps.

MS. STITT: How about Milwaukee at St. Lukes? Are they doing it? I thought they were.

MS. HOLAHAN: They are hoping to do it. I don't know if it's actually been approved for them to do it yet or not.

MR. AYRES: Well as far as FDA knows, they only --

MS. HOLAHAN: Because I spoke with the physician from there.

MS. STITT: Okay. Marcy Richards?

MS. HOLAHAN: Yes.

MR. CAMPER: We are going to explore that topic by the way.

MS. STITT: Today?

MR. CAMPER: No, at the upcoming ACMUI meeting. We're going to talk about the intravascular --

MS. STITT: Well the timing will be good because there is a subcommittee that's meeting at the ASTRO, which is the national radiation oncology group coming up shortly.

MR. AYRES: APM formed the committee also.

MS. STITT: And that's at least on the books to organize.

MR. AYRES: It's led by Coffey.

MR. QUILLEN: Joe Coffey?

MR. AYRES: Yes.

MR. QUILLEN: He was in Kentucky.

MR. AYRES: No, he's with Midwestern University, I forget which one.

MS. STITT: They're all kind of the same there.

MS. HOLAHAN: Yes, they had a workshop on that day.

MS. STITT: They have fuzzy animals that are their mascots.

MS. HOLAHAN: I was just going to go back to the advantage of putting the examples in, because that also, sort of provides -- Some of the questions that I think we've sort of all heard is, why does the authorized user have to be present because there might never be a case where -- I mean it's the physicist who would be the individual going in. For example, a vaginal applicator as a physicist is not going to want to pull that out of a patient in an emergency.

MR. AYRES: Well in an emergency --

MS. HOLAHAN: By putting examples in it helps just reemphasize the need for the authorized --

MS. STITT: And it also gives people some things that might not have thought about. They may think of what they do most frequently, but not of some other circumstances that you might get into.

MR. CAMPER: I'd even go a step further, I think physicists generally would be uncomfortable in intervening medically in any fashion. I mean the physicists, I am willing to bet, will look at their role as dealing with the radiological side, the source problem, the functioning of the unit, etc., etc., because clearly, there's a liability issue here.

MS. HOLAHAN: I was just referring to some of the comments we received.

MR. AYRES: And I think it's very appropriate because also the physician is often uncomfortable dealing at a detail level with the machine; the understanding of error messages and peculiar modes of operation and so forth. So what the whole thrust was, was to try and stay in state and regulatory language, which the authorized user and a physicist -- We want a medical expert and a machine expert there when treatment's going on. But you can't quite put it that way, in regulatory space.

MS. STITT: Why can't you?

MR. AYRES: Well you have to define, and then you'd have to define -- we'd have to go further than our

regulations currently do and define medical expert, which we really sort of do with the other end, but define machine expert. Since we're not writing new regulations we're trying to make this fit.

MS. STITT: Well the two aspects of emergency really do come down to medical and radiation safety and I don't know that you have to necessarily define, but just to make people realize and you can again use an example to indicate that. I think we could use what we've got here which is nicely stated and then refine it by using some examples.

MR. CAMPER: Okay.

MS. STITT: Those certainly were the comments that I had.

MR. CAMPER: So Item F of 11.21. We'll be looking at Item 2F of 11.21, adding some examples as a follow-on.

MS. HOLAHAN: Or possibly 2C.

MR. CAMPER: Or possibly --

MS. HOLAHAN: The last line of 2C indicates procedures should specify situations when surgical interventions may be necessary --

MR. CAMPER: Yes, you're right.

MS. HOLAHAN: -- and the steps that should be taken in the event that surgical intervention is required.

MR. CAMPER: For example, dah, dah, dah.

MS. STITT: And you could certainly go back to some of the problems that have passed through our desks as cases that have actually occurred. You don't even have to make them up; they're there.

Are there other comments on the emergency procedures section?

MR. QUILLEN: I don't have any comments on this section.

MS. STITT: You don't have any emergencies where you work.

MR. QUILLEN: That's for doctors and physicists to take care of.

MS. STITT: Any other comments on that section? How did we get to the end of the paper? Does that mean we're done?

MS. HOLAHAN: No.

MR. CAMPER: No.

MS. HOLAHAN: Sorry.

MR. AYRES: I was summarizing the changes and we of course hopped around in the various sections, and then the last one, Emergency Procedures, caught everyone's attention and we sort of dove into that one.

MS. STITT: Of all the things that I looked through it was one that I think raises a lot of questions and becomes one of the very important ones.

Well should we go back?

MR. CAMPER: That's fine. When we get to the part where we talk about the presence of the authorized user and the physicist it would be interesting to get some thoughts from the committee members as to whether or not those are in fact -- that dual requirement is in fact a reasonable an appropriate requirement. There has been some comments of a negative nature about that.

MS. STITT: Let me change text --

MR. CAMPER: But not that many.

MR. AYRES: I get an occasional call, but it's not --

MR. CAMPER: It's particularly problematic in the context of PDR, and the more criticism levied.

MS. STITT: Yes, right. And maybe that's just a whole section to itself.

Let me stop. We were at page 2, and kind of fumbling around. Everybody's been through this. Let me just go across the committee, and starting with Trisha.

Of the things you were going to look at today, name the ones that are at the high point of your list that you want to make sure we hit.

MS. HOLAHAN: Training. Probably PDR.

MS. STITT: Training, PDR.

MS. HOLAHAN: The emergency procedures, which

we've already addressed.

Was there one more, Bob? I'm trying to think. There was one other one in here.

MR. CAMPER: In your training comment, you're thinking about the physicists --

MS. HOLAHAN: Yes. Physicists, the nurses, everybody that's involved. And the QA/QC.

MS. STITT: Okay. Larry? In the whole document, what are the biggies for you?

MR. CAMPER: Well emergency procedures, of course. And the question of the mandatory presence of the authorized user and the physicist, and whether or not that is overall considered to be a reasonable request, particularly as it relates to PDR. Similarly I have some thoughts and concerns about the training. On the physicist in particular, in the sense that what we have then, is we've taken the existing teletherapy physicist in the regulations and attempted to make it fit for the use of HDR. Now I think that ultimately the way to solve that is to do a better job in the regulations of defining a medical physicist and perhaps some categories of medical physicists, specific by modality. But just some thoughts as to whether or not that approach to the training for the physicist is appropriate and reasonable.

MR. AYRES: And I don't think OGC is going to let us get away with anymore that there should be an authorized

user, medical physicist present.

MS. STITT: You mean the word "should" or what do you mean get away with anymore --

MR. AYRES: Well they're not going to allow us to say we require them to be there because that requires rulemaking.

MR. CAMPER: That's right. So anyway, those were my big picture items.

MS. STITT: Okay. The one I had to add to is fractionation. That's a bugga boo that I've -- and others you've already named.

How about you, Dr. Quillen?

MR. QUILLEN: The medical physicist qualifications is the issue that I had at the top of my list. It's 8.5.l.

MS. STITT: Okay. And did we get everything on your list, Bob?

MR. AYRES: Yes.

MS. STITT: I just want to make sure. We spent lots of time on these big issues, and if everything else is -- there will probably be some rapid page turning, but -- Because this is not new to this group; we've discussed this since I've been a member of this committee.

MS. HOLAHAN: Which is fine. It makes it a little easier.

MR. AYRES: In the comments I've received to date the only major technical -- the issue that was raised from the written comments has been by one state, thinking that the requirements on PDR should be a lot more restrictive than they are.

MS. STITT: I wonder what state that is.

MR. AYRES: Illinois.

MS. STITT: I was going to say --

MR. CAMPER: That's interesting. Well maybe when we get down to PDR it'll be kind of interesting to see what their thoughts were.

MS. STITT: And I think we're going to do PDR as a separate. Is that all right?

MR. CAMPER: However you like is fine with me.

MS. STITT: Try to break this down.

All right. I'm back on page 2 then, and I think that we just need to move through the things that seem to sit pretty well with people, and don't have to discuss each item.

MR. CAMPER: That makes sense to me.

MS. STITT: Radioactive material is Item 6.

MR. QUILLEN: I have an item at the top of page 2. And it relates to the difference in the way states operate and the NRC operates. And that is, in the top paragraph, that you're saying you cannot comply with certain of your existing regulations therefore you're providing

alternative language and license to cover those.

In our particular state as an example, if you have a regulation you cannot through a guide, which is this type of a document, change that regulation unless that guide goes through a regulatory process.

MS. HOLAHAN: Even through the exemption process?

MR. QUILLEN: They would have to ask, and you would have to play the game, where they ask for the exemption and then you grant it to them, but you cannot change the regulation through a guide, which is basically --

MR. AYRES: Well, we're not here either. What we're doing is we're providing the information that they should provide to ask for these exemptions.

MR. QUILLEN: I understand what you're saying. I understand the --

MR. AYRES: It's a fine point.

MR. QUILLEN: -- the fine point you're doing here, but I'm just saying --

MR. CAMPER: And what's happened here, Bob, is -- it's an excellent point you raise. And what's really happening here is sort of a backwards way of doing this whole process.

I mean what we have here, we have an emerging technology that's emerged since the regulations were developed in '87, then in the midst of this emerging technology we have

a serious event of consequence, patient death, subsequently followed by an effort on our part to enhance guidance and to impose through either the exemption process or the imposition of conditions what we hope is a reasonable level of regulation for this modality, which has obviously significant radiological consequences, possible.

But you're right, it's a strange way to go about it.

MR. QUILLEN: You're going about it -- In our particular state we could get challenged on doing it. I'm just telling you that.

MR. AYRES: Well, the advantage of this of course is, all of these standard licensed conditions as we call the, which are exemptions in lieu of. You go back and look on page 38, all the conditions are almost all in lieu of to change the requirements that can't be met in the existing regulations by remote afterloaders. In other words, you can't count the sources and that sort of thing.

The advantage of doing this way is we go through and this is all pre-approved by particularly OGC, so we don't have to run every time a license comes in from one of these devices this doesn't have to go over to OGS for -- These exemptions can be granted by regions without coming into headquarters and getting them approved for every license every time, again and again.

MR. CAMPER: It's interesting again your comment, in the sense that, if I look at Part 35 today and I look at brachytherapy I see really two significant flaws in regulations. One is that, we need to do some adjustment with regards to 35.400, which is brachytherapy at large. I mean, the fact that we list specific sources for example as opposed to saying, for any use which has a sealed source and device registration on record. And that's what we really should be saying.

In the second one of course is HDR. HDR is unique enough and the consequences of its use are serious enough that it warrants a separate subsection.

MR. AYRES: Actually it's in the entire remote afterloading.

MR. CAMPER: That's right. Now we have a ruling by OGC that HDR is captured under the 35.400, and we have tried to work to clarify then what we expect. But what we ultimately want to do is to make it explicit and clear in the regulations, put it through the due process and so forth.

And we were going to go down a pathway -- We had made a decision at one point to pursue specific changes to Part 35 that dealt with brachytherapy only, and we were going to go through sort of -- if such a thing exists -- an expedited rulemaking to deal with these issues. But then a decision was subsequent made to do it all as part of the major

revision to Part 35. Because, well you know we have the National Academy of Science report, and we want to take a look at that, bring that to bear. And so we're doing it all as one major effort. But I agree with you totally. I mean not the way I would prefer to do it, but given the technology and the possible consequences we had to do something.

MR. QUILLEN: Well I understand what you're doing, but I'm just saying that presents a particular problem in our state. We have a statute which says, you can't make policy through this kind of a thing, you have to go through a regulatory process.

MR. AYRES: Well, we do too in a sense, and so some of the language in there in fact has to be changed. Where there are some "shalls" or "musts" they have to be changed to --

MS. HOLAHAN: "Should".

MR. AYRES: "Shoulds".

MR. CAMPER: That's right.

MR. QUILLEN: That's what I was going to follow up on because there are shalls --

MR. AYRES: Yes, that's got to be fixed.

MR. CAMPER: And you're right, we have to clean that up. We can't use "shall" in a guidance document. We had a couple of "shalls" I think yesterday and we were focusing upon "should". Excuse me, we didn't have "shall", we had

"must"

MR. AYRES: Some of that.

MR. CAMPER: You can't use "must" either.

MS. STITT: Is that stronger than shall? I think so.

Do we need to do this line by line?

MR. AYRES: I think that sort of thing has all been well captured by OGC's comments.

MS. STITT: Does Item 7 also relate to the discussion that we're having right now, "Purposes for Which Licensed Materials Will Be Used". Is this the same problem you have within the state, that other states may also have?

Other comments on 6 or 7?

MR. QUILLEN: There's a note at the bottom of page 2. I'm not sure whether it goes to the top of page 3, but I couldn't understand --

MS. HOLAHAN: No, it's just separate.

MR. QUILLEN: At the top of page 3 it just says, on my copy, "registration certificate for the device, and/or source, period."

MS. HOLAHAN: Oh, then that is part of the note.

MR. CAMPER: It follows on from the note on the bottom of page 2.

MS. HOLAHAN: Yes, that is part of the note.

MR. QUILLEN: Okay. Is there a brachytherapy

module registration certificate?

MS. HOLAHAN: No. Where it says, RAL brachytherapy module, just that's the footnote at the bottom of each page.

The note should be three lines and the last part of it goes from "as set forth in the registration certificates."

MR. QUILLEN: Okay. I've misread it then.

MS. STITT: How about other comments you have on page 3 and page 4?

MR. QUILLEN: On the bottom of page 4, the last two sentences --

MR. AYRES: Mine's been fixed. I couldn't follow him, then I see it. I have a copy where --

MR. CAMPER: You have the only correct copy.

MR. QUILLEN: So you have the correct copy with the verbs in the sentences then, right? The last two sentences need verbs.

MS. STITT: Say that again, the last two sentences what?

MR. QUILLEN: Well for example the last sentence says, "In addition the manufacturer's name, address and telephone number for each device requested." It has to be is requested, are requested --

MS. STITT: We have an incomplete sentence,

folks.

MR. CAMPER: Okay.

MR. AYRES: Where are you at?

MR. QUILLEN: Right here.

MS. HOLAHAN: The last paragraph.

MR. CAMPER: The bottom of page 4, Bob.l

MR. QUILLEN: This one here, the change is made.

MR. AYRES: And that's actually "charged", it should "changed".

MS. STITT: Comments on Item 7? Are you ready to move to Item 7?

MR. QUILLEN: Sure.

MS. STITT: Okay. Item 7, "Purposes for Which Licensed Material Will Be Used".

You've got some copy there. Did anything come in from your associates that we need to talk about?

MR. AYRES: Minor editorial, except the OGC is again querying the basis for allowing broader use of the sources. For example on page 5, Item 7, third sentence, it says, "One of the objectives listing in the 35.400 is to ensure the sealed source is used has undergone some appropriate safety review."

What is this based on? It's not apparent in the language that the registry and so forth -- And down at the bottom they say, "The sealed source safety section concludes

the registered sources which pass testing criteria for institutional use, could be used for intercavity or topical. And again, we'll have to wrestle some of these out.

This appears to be a generic exemption, which is not permissible. We have in fact been doing this in current licensing practice, so there are some of these things that OGC is again balking on.

MS. STITT: So is that something you have to deal with outside of the subcommittee issues.

MR. QUILLEN: That was one of my questions, which is more a challenge for you people than it is for me. When you talk about intraoperative or non-human use, and in particular non-human use, you're getting into experimental procedures or animal procedures, and that certainly -- well it should be described in sufficient description detail. There's a very subtle way of saying, you've got a lot of things you need to tell us.

MR. AYRES: Yes. And I have some comments on that -- about that from a couple of the comments sheet.

One of the problems that comes up here and I was trying to address with this language, the sealed source and device of safety reviews, often separate but can be done together. In other words you can have a registration certificate on the source. You can have a registration certificate on the device. And then in some cases you have a

registration certificate on the combination of a source and device.

There's three major HDR devices used in the United States currently, and there may be some more coming which is the Omnitron and it's successor, and the Nucletron and the Gammamed.

Well the reviews have been done by multiple entities, agreement states and us. And the language in them on the use of the source varies all over. Some of the registrations state what the source can be used for, and others completely ignore it. So, to try to put some language in here that can be used in accordance with the limitations on the registration certificate doesn't work very well. And so I tried to actually say what you could use them for.

MR. CAMPER: Bob, I have two questions for you. Help me out here with something. I haven't looked at this for a long time. But I'm struck by a couple things. The last two sentences of the first paragraph.

MR. AYRES: Which page?

MR. CAMPER: Of page, of item 7 on page 5. We say, if you intend to use a source for purposes other than specified in 35400, you should request and receive an exemption to the regulation prior to use.

Now, they may also choose to go the route of having the source or device reviewed and approved. And I

believe the material that you submit is set forth in 32.210, is that correct?

But, in reading this, it's not as clear to me that the reader would understand that you have an avenue available to you. If a manufacturer has chosen not to have the source or device reviewed and approved for a particular use, that the licensee can also submit the same kind of information, go through the same process that a manufacturer.

MR. AYRES: If you look at the first paragraph, page 2, I refer them to the guide for Preparation of Application for Radiation Safety Evaluation Registration of Sealed Sources Containing -- which is what they would follow to do this.

And there's an error there which I'll correct. I refer to both guides as 10:11. One's 10:10, one's 10:11.

MR. CAMPER: Let me see, where were you?

MR. AYRES: Item 6, first paragraph, on page 2.

What I do is, I talk about the radiation safety evaluation and I cite the guidance for having that done. I could go back to the section that you're referring to and re-cite it. That's where the process for --

MR. CAMPER: Oh, okay. Maybe what you might do right there is insert a sentence that would remind them of that. Because if they're reading that and they think, well I've got to go the exemption route, well that's not the only

way. Okay?

Although, I guess that would ultimately result in an exemption too.

MS. HOLAHAN: They'd still have to get an exemption.

MR. CAMPER: There would still be an exemption, but it's a little bit different, I think, than we set forth.

MR. AYRES: Yes.

MR. CAMPER: Then, in the final sentence -- and again - help me out with this, I just can't recall. Medical broadscope licensees are not limited to the conditions that you specify in 35400. But even a broad can only use it, can they not, for a use that's been reviewed and approved?

MR. AYRES: According to Steve, sealed source devices -- I didn't think this case -- I was trying to clarify that. My understanding is a broad can design their machine and not have to have it reviewed.

MR. CAMPER: Okay. I understand that and I think I've heard that too. It would be interesting for me --

MR. AYRES: That came up with intravascular about device review for these --

MR. CAMPER: Well, it would be worthwhile to fully understand or revisit why it is that even a broadscope could do it absent that particular device or source being reviewed for such use. Clearly broad scope institutions have

a higher level of sophistication and can probably use these things safely. But it would be interesting to know the intricacies of the regulatory basis for that to occur.

MR. AYRES: Yeah, I don't fully understand that either. In fact I know there are some exceptions. Like one broad scope licensee recently discontinued -- built their own HDR. And in fact it had a custom review, Howard.

MS. STITT: Howard University.

MR. CAMPER: That's interesting.

I'm not saying that's not acceptable. I'm just saying I'm a little bit perplexed as I sit here remembering all the intricacies of just how that happens and what the regulatory mechanism is that allows it to happen.

It's something that I would like to take a look at, at some point.

MR. AYRES: Well, OGC has competence in this area.

MR. CAMPER: That's interesting. Okay.

MS. STITT: So, then, how are we doing on item 7? Did we go through the issues you had?

MR. QUILLEN: Have you had any veterinary schools apply for this.

MR. AYRES: Yes. Well, I'm not sure we have. I know Sealed Source and Devices got involved in the approval of what they call the pig wire which was a HDR source intended

for experimental use on the intravascular area with pigs.

Whether we -- a number of veterinary licensees are very small. Whether any of them are using ACR, I don't know.

MS. HOLAHAN: Most of it's broadscopes that are doing the veterinary work.

MR. AYRES: A broadscope could be doing it and we wouldn't know about it.

MS. STITT: That's probably the places that would be doing it.

MR. QUILLEN: Well, it's not a medical broadscope, it's a university broadscope.

MR. AYRES: Yeah.

MS. HOLAHAN: Well, many of our broadscopes are university broadscope which would be broad research and broad medical.

MR. QUILLEN: The reason I say this is because our veterinary school has their own linear accelerator and they do their own --

MR. AYRES: Oh, yeah. We clearly have veterinary teletherapy installations. I know that. But I'm personally unaware of many veterinary applications of HDR by our licensees.

MR. CAMPER: Similarly, I'm unaware of any.

MS. HOLAHAN: Does CSU have one?

MR. QUILLEN: CSU has a linear accelerator. So, I'm just assuming that the next thing they'll want --

MS. STITT: The next step is HDR. Well, our vet school has our old cobalt unit. But if it's going to happen, it's going to happen in his state. If HDR is used at the vets, that's where it will start.

Other issues on item 7? Trish, no?

MR. QUILLEN: None here.

MS. STITT: Bob?

MR. AYRES: No.

MS. STITT: Everybody's happy. Are we ready to move to item 8, authorized users?

I'm getting a couple of shakes over there.

Let's see, am I right. Is this part of our intense area of concern list?

MS. HOLAHAN: Yes. Now let me -- what I wanted to say is there are some issues that are applicable to all of the modules that are being developed that have actually been moved up into the body of 10.8. So if you notice under authorized users, there is no physician authorized users, that is because that is dealt with in the body of reg 10.8. Because it is the regulations, per se.

MR. CAMPER: Why don't you just expand on that a little bit, so that Bob and Judith would fully know how the staff is doing that.

MS. HOLAHAN: Okay. As part of the overall effort we are revising what is currently 10.8. Sort of updating it now. At this point we haven't updated the appendices and I think that is something that we'll explore a little further. Then it will all be tied in and folded in to the business process re-engineering licensing manual.

But what we have done with developing these licensing modules, is take out those items that are applicable to all modules. For example, who do you submit your license to? Basically, training for authorized users, waste management, certain types of equipment are addressed up in the body.

And that's why, in some ways, as you go through you may feel that there are things that are missing. They might be missing from the module, but not up front.

MS. STITT: Got it. So, at item 8 under authorized users we're looking at physicists, authorized afterloading physicists and that's the substance for section 8.

MR. AYRES: Yeah, that's correct.

MS. STITT: Okeydoke. Let's jump into commentary then. The section that follows that is training which is another high-priority topic.

Trish, you spent a lot of time on this. Why don't you summarize the issues that are your areas of concern and

any feedback that you've gotten.

MS. HOLAHAN: Okay. And maybe I'll let Bob address the physicists first and then I'll get into the nursing staff.

MS. STITT: Okay.

MS. HOLAHAN: Bob, do you want to focus on the comments that --

MS. STITT: The comments that you've been getting.

MR. AYRES: Not really very many. This is one of those areas that I think we are certainly headed for in general with part 35, if we ever get there.

I think the feeling from the committee and all the input I get, and of course, from some physics professional societies, of course, is that a medical physicist is a necessity for a brachytherapy program in general, but a high dose rate in particular. Obviously we agree with that position with relationship to the high dose rate program.

The problem becomes, again, this regulatory -- making it fit. We don't have a description for other than a teletherapy physicist. So what we've done in this is tried to expand on that a little bit and define what we mean by brachytherapy physicist. Without saying -- we'd be very happy to have you substitute brachytherapy experience for teletherapy experience, et cetera.

MS. HOLAHAN: And that, again, if you recall, was one of the issues we discussed, should they have specific experience with HDR. Currently, the way the regulations are written for a teletherapy physicist, is they must have experience with a teletherapy unit and they must understand the teletherapy regulations.

Well, again, as Bob says there is no regulatory basis for the brachytherapy physicist, but we feel that it's important that they have HDR experience. So if they've come in and said no, we haven't done teletherapy but we've done all this brachytherapy HDR work and we'd like to be licensed as a HDR physicist, then we are considering that as equivalent experience.

MR. AYRES: And we conclude with the fact that we made need to bring some of these to the committee.

MS. HOLAHAN: Right.

MS. STITT: Well, you've used the phrase here, experience. And one of the things that I've kind of groused about in the past was terms that were sort of made-up terms.

Granted, teletherapy physicist has been in there for a while, but the physics community doesn't have specific licensure any more than the medical community does for a brachytherapy physician. I mean that's not a board certification. It's not even a certificate type of thing.

But that's not to say that experience in

teletherapy or experience in brachytherapy can't be -- I think those are different sort of things. It may not sound that way but I think that the way that the community actually works, they are different.

MS. HOLAHAN: Yes.

MS. STITT: In the other issue -- and as you read through this, it's relatively mild mannered -- the issue of remote afterloading which is what this module is. When you move to high dose rate remote afterloading is really one of intensity, not only the source, but the involvement.

I think probably some of the comments that you get Bob, have to do with communities where the physics support is by contract and somebody comes by and looks at your cesium stock and reviews your plans. And that's very different from being there on site when you're using a high dose rate source.

I think that's really where the problems can really develop so far as administering therapy. Can we, can the NRC address that. We'll get to that when we get to the presence of authorized users.

MR. AYRES: -- Was in fact one of the things we were trying to change. Because the practice was, in fact, in many licensees, continuing. The physicist was a contract physicist who dropped by occasionally and was not necessarily or often was no present during treatment.

MS. STITT: Right.

MR. AYRES: Or even during the treatment planning, in some instances.

MS. STITT: And that's probably an adequate mode of function, under some circumstances. When you change that remote afterloading from low dose rate to high dose rate, I don't think it is.

MR. AYRES: No.

MS. STITT: What are you getting from your feedback? How does the committee review this particular issue -- I guess we've sort of already moved on to the presence of the authorized user.

MR. AYRES: Well, the only formal input we've got on this, of course, is from one of the physics professional societies who think part 35 should be changed to require medical physicists for all brachytherapy.

MS. STITT: For all brachytherapy?

MR. AYRES: Yes.

MS. STITT: Gee, do you think they have anything to gain by this?

MR. AYRES: But, in particular in remote afterloading in high dose.

MS. STITT: I guess I've strayed. I've moved on before the a descriptive --

MR. CAMPER: I've got a couple

MS. STITT: To get us back on track here.

MR. CAMPER: I had a couple of comments here on the physicist training.

Let me just sensitize the committee members to a couple of things about the dilemma that we find ourselves in today. And again, this sort of gets back to what Bob pointed out, Bob Quillen pointed out earlier this morning. Kind of where we are and how we are approaching this thing.

You know, we refer here in the guide to the training specified in 35.961. Well, if you go look at the training in 35.961, you'll find again, as in all of our training requirements, we've got the certification route and certain board certifications are identified. And then we have the so-called "or" pathway which is a degree of some type of academic training and some specified and specific experience.

Well, there are two things that we need to do when we start the revision of part 35 to really tackle these issues. One is -- first of all 35.961 is teletherapy physicists only. What we need to do is explore with the medical physics community what we should do. Should there be a medical physicist identified in the regulations and in certain subparts that are identifying teletherapy physicists or brachytherapy physicists or whatever. But we can't solve that now, but must bear in mind for the future.

The second thing really is that we accept certain certifications. For example, we accept certification from

the American Board of Radiology in therapeutic radiologic physics; Roentgen ray and gamma ray physics, x-ray and radium physics or radiological physics. Then the question that we will have to re-explore is are those board certifications addressing the question of brachytherapy, remote afterloading being required in training programs that often lead to studying for the certification examination

For years, the agency has relied upon -- every time you see a board certification or regulation, the process that has been gone through historically is we have talked with the boards and determined what they are actually requiring of their residency certification programs, and then we ultimately bring that board certification to the advisory committee on the medical use of isotopes and they say, yes, this would seem to be adequate and you may list it in the regulations as being acceptable.

Well, there's been some criticism in recent times about whether those boards are or are not requiring training that we think is appropriate. And perhaps maybe we have even been mislead to some degree. Or what we were once told as a commitment is in fact not going on today.

And I'm not saying that's either true or not true. I'm just saying it is something that we will have to explore when we revise part 35 and see what board certifications really mean.

The other thing that comes to mind is, if I look at this training experience -- and this is just so you'll have a real world understanding of what we've run up against. You go to the "or" pathway, it identifies certain masters or doctorate level degrees in physics, biophysics, radiological physics or health physics that has completed one year of full time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of a teletherapy physicist.

Now, that poses a couple of problems for us. One is that we get people who come in with degrees, for example, with backgrounds in engineering. But yet they have had work experience and training in the medical physics arena. So then the question becomes is that an equivalent academic preparation comparable to a degree or masters degree in health physics?

And then the idea that if one looks as the regulations literally, why do I have to get one year of supervision under a teletherapy physicist? What if I've been working for one year under a brachytherapy physicist, particularly one dealing with HDR. Now, obviously that's more apropos if you are trying to do HDR.

But it is a problem with some of the existing regulatory language.

So what we've tried to do then, having said all

that, is on page 6, item 1, bring to bear the fact that we're looking for experience in HDR or PDR sources. But most of the time, we can work our way through it when we get these unusual outlyers. We were about to bring an engineer who wanted to do HDR brachytherapy but then we pressured that there wasn't enough experience and they withdrew the request. And he's getting more experience.

MR. AYRES: We're processing one now.

MR. CAMPER: I share that with the committee to kind of sensitize you to a couple of the problems that we see. I recognize that eventually we will have to do something about it in the regulations.

But with those kinds of problems and issues in mind, does it seem that we have put forth the best possible effort at this time under 8.5.1, items 1, 2? To capture pertinent HDR or PDR experience.

MR. AYRES: Item 2 is a policy issue that Janet raised and I don't know if it's been resolved.

MS. HOLAHAN: Not yet.

MR. AYRES: Apparently, it's in the old reg guide but it's not really in part 35 about whether we accept equivalency from NRC.

MR. CAMPER: We have not resolved that yet.

MS. STITT: Do the attorneys have something to say about that or is that not their area?

MR. AYRES: It's not a -- it's not provided for in the present part 35 is my understanding, as one of the acceptable certification methods.

MS. HOLAHAN: It's listed as a --

MR. AYRES: Licensee.

MS. HOLAHAN: licensee or user.

MR. QUILLEN: Well, my comments include that particular issue, but they also because -- you've defined teletherapy physicist which you have in the existing regulations, now you've got a brachytherapy or medical physicist which is not in the existing regulations.

MR. AYRES: Right.

MR. QUILLEN: And not in this guide, either, as a definition. So you've got two terms here that are undefined.

MR. CAMPER: Those two terms being what, Bob, I'm sorry. Teletherapy physicist.

MR. QUILLEN: Teletherapy physicist or medical physicist.

MS. HOLAHAN: And I think our interactions to date with the community have indicated that we should, to include the ACMUI, that we should go the direction of looking to have a broad medical physicist with specific, you know, requirements underneath, depending on what they're going to be doing. If it's other than board certification.

MR. AYRES: If we actually formally include one

or both of these revisions of part 35 they would clearly need to go into this definition part, 35.2 is it?

MS. HOLAHAN: Right. Correct.

So, are you suggesting that it should go into the glossary?

MR. QUILLEN: Yes, if you are going to use the terms.

MS. HOLAHAN: Okay. Maybe use one, but not both.

MR. QUILLEN: Medical physicist is sufficient, I think.

MS. STITT: Right. Could we just use medical physicist? I think it leaves plenty of leeway. It may be easier to --

MR. AYRES: That's what I used if you notice the first sentence.

MS. HOLAHAN: Except that the title calls it an authorized RAL physicist and I think we're getting into confusing --

MR. AYRES: I was making an attempt here, and of course one has to do the dance with OGC on this whole area. But making an attempt here to use medical physicist and then sub divide down below that. You want experience in the areas in which they're applying to do work, of course.

MR. CAMPER: Yeah, I think medical physicist would be the more commonly accepted term.

MR. AYRES: It is within the industry, is my understanding.

MS. STITT: Right, it certainly is. And it means you don't have to come up with definitions that are viewed as being artificial by the industry.

MR. AYRES: It's a case here that I think the way that part 35 was structured, that teletherapy, being the older technology had the bad accidents first and got this area addressed in the detail that we're now --

MR. QUILLEN: Can I ask a broader question here? The guide pertains to not just high dose brachytherapy or pulse dose rate brachytherapy. It also says it applies on page 1 to low dose rate and if you ever have it, a medium dose rate.

If I read the guide, it says here, I could read it to say that if I have a low dose rate facility I wouldn't need a brachytherapy medical physicist's qualifications because they're not covered in this section.

MR. AYRES: Right. It says for HDR and/or PDR. That's where we feel a physicist is essential at this point. We're not imposing it on LDR.

MR. QUILLEN: That was intentionally?

MR. AYRES: And it goes along with an argument which I agree with. And until we change part 35 if we wish to address it then, it's correct. I think it is a very cognizant

argument that if we impose any additional requirements beyond those that we really, really feel are necessary on low dose RAL, remote afterloading, we discriminate against an advantageous ALARA procedure as opposed to conventional remote afterloading brachytherapy.

So, any additional requirement that we put on LDR just discriminates against that technology. Because the hazard level other than a mechanical failure, at least on dose rate-wise, is no different than conventional brachytherapy.

MS. HOLAHAN: And we haven't been specific and we'll discuss that tomorrow in the manual in terms of the requirements for a physicist, except generally along with other medical support staff; a dosemetrist, etc.

MR. AYRES: That's the way I've treated LDR in here. To try to not impose anything above and beyond what we impose upon conventional brachytherapy. Except those things that are appropriate because the quality controls on the device and that sort of thing. And in lieu ofs for inventory and sources and so forth.

MR. QUILLEN: What if somebody came into you with an application that said my experience is in low dose rate remote afterloading technology and now I want to use high dose rate?

MR. AYRES: You mean a physicist?

MR. QUILLEN: Yes.

MS. HOLAHAN: Who was not board certi -- who did not have any of the certifications in the regulations.

MR. QUILLEN: It says in here that you don't have to provide that information, specifically.

MR. CAMPER: Where Bob?

MR. QUILLEN: In 1.

MR. CAMPER: Now, for HDR they do.

MR. QUILLEN: I know. But I said what if somebody has that kind of experience and comes in?

MR. CAMPER: Well, if you go down to 1 though, it says include information on the individual's experience in the use of HDR, PDR, RAL, brachytherapy and use of dosimetry systems used to perform the calibration measurements of HDR.

If someone came in with only LDR experience they would not be satisfying the criteria they were asking for in item 1.

MR. AYRES: And there certainly does -- the calibration of the sources between LDR and HDR are substantially different.

MS. STITT: What comments have you been getting? I mean this has been out for a while.

MR. AYRES: Very, very little. Almost nothing on the physicist. What we -- the comments generally come in two classes; and they've been very small across the board.

It started with process with bulletin which is

where most of this originated. And the comments have been from a few physicians like how dare you tell me I have to be there to take care of my patient.

The physics side has been really quiet except the professional organizations and almost all medical physicists are --

MS. STITT: Very supportive.

MR. AYRES: All lined up right behind the other in support of it.

MS. STITT: What a surprise.

MR. CAMPER: Well, they tend to favor board certification.

MS. HOLAHAN: That's right. They would prefer that we only had board certification.

MR. CAMPER: But, again, we can't only rely on board certification.

MR. AYRES: The other general comments we heard mostly from the committee were mostly from the economic side of this issue.

MS. STITT: The other aspect of economics is when you don't do it correctly. It becomes very expensive.

MS. HOLAHAN: Very economically --

MS. STITT: So, I think this is not an issue -- well, I think this is an issue that many people would agree with and we're happy with the way it reads.

MR. AYRES: I guess my personal position is here a little bit, if we require it, it sort of levels the economics a little bit.

MS. STITT: How do you mean?

MR. AYRES: That doesn't give an institution the option of not having a medical physicist and trying to compete with an institution that does in a more thorough manner with trained professionals.

MR. CAMPER: Bob, let me ask you a question.

MR. AYRES: Yeah.

MR. CAMPER: Are we exploring with OGC at this point? Or Trish, have we been exploring this question of recognition of physicists named on a state license?

MS. HOLAHAN: I need to follow that up with Janet because she had --

MR. AYRES: That was one that Janet was going to take on.

MS. HOLAHAN: I haven't had a chance to discuss with here.

MR. AYRES: Well, it replies to authorized users, too.

MR. CAMPER: No, authorized users is addressed in 35.2. Definition of authorized users in 35.2 points out that agreements state if your named on an agreement state license it's acceptable.

MR. AYRES: Okay.

MR. CAMPER: Yes. If you go back and look at authorized users, then it goes on to say, identifies an authorized user on a permit issued by a commissioner agreement state specific license of broadscope is authorized to permit the use of byproduct material. Identifies and authorizes users --

But it doesn't say that for the teletherapy physicist, and of course it is silent on the term medical physicist
or HDR physicist.

MR. AYRES: Right.

MR. CAMPER: That is interesting. I think from an operating perspective I would like to see the agency be able to accept the physicists that have been reviewed and approved by an agreement state, but you're right. That is an interesting policy.

MR. AYRES: Well, Janet's position was to bring it to your attention as a management issue.

MR. CAMPER: Well, it has my attention.

(LAUGHTER)

MS. STITT: Trish, I have a question. On the physician, granted about physicists, but we've made some statements here about physicists being present. In 10.8 does it say physician as the authorized user or the authorized user

must be present for -- is there a corollary somewhere?

MS. HOLAHAN: It says -- we address that further down within the guide.

MS. STITT: Okay, keep going.

MS. HOLAHAN: It's in item 10 in that we say that the authorized user must be physically present.

MS. STITT: That does appear in this document then.

MS. HOLAHAN: It does.

MR. AYRES: We're just -- I'm just completing the second or third round on the bulletin where essentially we have all of our licensees committed to that authorized physicist user presence with perhaps some RSOs.

MR. QUILLEN: Let me interject something here on subparagraph 1.

I understand what you're saying here, but from experience I've had in looking at some applications, this is really kind of vague, what you're asking for here. If I could suggest some additional language between individuals and experience if you could put in specific experience?

MR. AYRES: yeah.

MR. CAMPER: Bob, in your situation, do you expect to see or ask for number of cases involved?

MR. QUILLEN: Well, the one case we had to deal with was actually not in the area but in the gamma knife area.

MR. CAMPER: Right.

MR. QUILLEN: At the time we had to deal with it there was no guidance for gamma knife. In retrospect we didn't do a very good job of it because the person involved claimed experience, which in latter viewpoint,we couldn't document.

And that's why I was trying to tighten up some of the language you have here.

MR. CAMPER: Was there a falsification of records?

MR. QUILLEN: It wasn't a falsification. It was just, you talk about experience, yes, I was there.

MR. CAMPER: Oh, I see.

MR. AYRES: I know of the gamma knife it's an apprentice-type system.

MS. STITT: Isn't that what medicine is?

MR. AYRES: Well, for both the physicist and the authorized user.

MS. STITT: You got it.

Well, I have to put in a plug, not that this group's going to go out and sign up, but I think, as probably many of you are aware, that it's been many years in coming, but the American Brachytherapy Society has developed a school of brachytherapy and we're having our first school this December.

And the school of brachytherapy is a 14-module course that will be given over time. This year we're only going to be able to do three modules. GYN is a whole day session. Half day of intraluminal specifically, lung, GI sites. And then a half day of systemic isotopes, P32, strontium.

And different physicians and physicists in the field have put together these teaching courses. I'm running the GYN course.

My point is that we will have experience that folks can decide to take or not to take. Institutions can pay the $1,000.00 to attend the session and this may start showing up as the trail that you see on qualifications.

We're actually, in the GYN section, doing four hours of lecture and then four hours of hands-on with phantoms where we can do insertions of applicators, perineal needle insertions and case discussions.

So it's the first organized attempt that the medical community has been able to put together. It's really on-going education in brachytherapy, and it will be all forms of dose rates.

It's exciting for me to be involved with because it is something I've been hoping to do for years. And at least gives some focus so that if you want to be a brachytherapy physicist, whether we call it that name or not,

there at least is some formal education.

MR. AYRES: Are these courses oriented toward the authorized user, the physicist or both?

MS. STITT: Both. The course that I'm in charge of has myself for high dose GYN, Patty Eifel whose well known in low dose rate, Beth Erickson is known for her work in interstitial, and Bruce Thomadsen who is one of the physicists that was submitted.

So, our goal is to track physicians and physicists.

MS. HOLAHAN: It's being given in conjunction with the ABS meeting?

MS. STITT: Yes. This year the meeting comes first and then the school is Monday and Tuesday. And then on subsequent years, the annual meeting is going to be six months off. So that the school is going to be given every December and the meeting is actually going to be in the Spring.

MS. HOLAHAN: Oh, they're moving?

MS. STITT: Yeah, moving the meeting. But that means that folks can come, get training in brachytherapy in great detail. And it will be a combination of medical and physics. In fact Bert Speiser is putting on one of his emergency procedure sessions where you have an emergency and proceed.

So, I think it's going to help the community a

great deal.

MR. CAMPER: That's good news.

MS. STITT: And we're here to help you.

MR. CAMPER: That's right, you are.

MS. STITT: Trying to make your life easier.

MR. CAMPER: We're all for that.

MS. STITT: On item 8, other comments there?

MR. AYRES: I added the "specific". I liked that comment.

MR. CAMPER: I do too, and I would only take it one step further, Bob.

MS. HOLAHAN: Give examples.

MR. CAMPER: And I'm wondering if we should be requesting the number or types of cases?

MR. QUILLEN: This is the next thing I was going to say.

MR. AYRES: The only question I have do we do that for the teletherapy?

MS. STITT: Do you have to?

MR. AYRES: Under training and experience I think you sometimes get it on the certification.

MR. CAMPER: Well, what the regulation says, and I'd really have to take a look at the teletherapy guide to give you an explicit answer. But on a regulatory basis what we're looking for is the academic course, one year full time

training in therapeutic radiologic physics, which is fairly explicit, and an additional year of full time work experience under the supervision of a teletherapy physicist that includes the tasks included in 35.59, 35.632, 35.634, 35.641, which all deal with evaluating the beam, the various checks and so forth.

MR. AYRES: Well, having looked at some of these, that's a fairly typical thing to be put down going this route for an authorized user. But I don't recall seeing it for the teletherapy physicist.

MS. HOLAHAN: The other thing is you are asking for the number of cases and types of uses does not address the quality control checks that they are required to do which is what the teletherapy, I think, is getting at.

MR. AYRES: That tends to be more like the current one that we have pending that Torre has on the authorized physicist.

MR. CAMPER: If you were to do it, your sentence -- what you do is you put a parenthetical "e.g." following brachytherapy where it says include information on the individual's specific experience on the use of HDR, PDR, RAL, brachytherapy. For example, numbers and types of cases.

And then go on to say and the use of dosemetry systems because Trish, your point is well made, it's not just about the clinical involvement. That doesn't satisfy the idea

of knowing the dosemetry systems and so forth.

MR. AYRES: Yeah, I've also got some comments on some of the other material that I might need to factor in here. It includes also, of course, what Trish already mentioned, experience in the QC procedures related to these devices.

MR. CAMPER: What is the thought of the committee members? Is there any value in getting that or not? Or do you think just the insertion of the term "specific" before experience, is that enough?

MS. STITT: I think specific certainly helps. I think you can ask. You don't have to say you must have *x*-many, but you could ask for a listing.

Are physicists accustomed to that? Physicians certainly are. Essentially all board certification requires you to list the number of laparoscopies that you've done by patient identifier.

MR. AYRES: I'm speculating, but I don't think so. Most of the applications I've seen for physicists don't tend to put that kind of information in.

MR. CAMPER: See, what you had --

MS. STITT: Process rather than the case.

MR. CAMPER: If you were to do it, and I'm not necessarily advocating that we do do it, I think the term "specific" inserted is a very good suggestion.

But, what I'd like to think would ultimately happen, again, in rule space, is that we'll work with the physics community to define some appropriate levels of training.

We'll revisit what we have for teletherapist, we'll talk about medical physicist and they'll help us in developing specific words for requirements. And that may or may not include some clear identification of cases.

MR. AYRES: It's clearly worth exploring revision of part 35.

MR. CAMPER: So, I think what I'm hearing, for now, just the insertion of the word "specific" might be enough.

MS. STITT: Well, and the other thing just to keep in the back of your mind is certainly, any brachytherapy but particularly high dose rate is really an episodic sort of thing, even involving the dosemetry and the QC sort of thing.

So, if at some point of time, the listing of cases is important, rather than the teletherapy which goes on all the time, all the time, all the time, but brachytherapy is a scheduled event and it wouldn't be unreasonable to say, show me the number of cases and what they involved.

But right now may not be the time.

MR. AYRES: Yeah, I am aware that some high dose rate programs have very low treatment, a frequency of one of

two a month.

MS. STITT: Oh, right. And that's the other reason you may want to be specific about that, because brachytherapy is less than 5 per cent of radiation oncology. Many places it is zero per cent because it is too expensive and too high risk.

Even with low dose rate sources, not worth the effort.

MS. HOLAHAN: So, they could come in and say they've done a year of experience but only have done six cases.

MS. STITT: That's right. And that's why the teletherapy is so different than brachytherapy and I don't think it is unreasonable to hold brachytherapy to some different standards.

MR. QUILLEN: We had a facility that lost their therapist, their oncologist and did contract work for about a year.

And during that time the HDR unit just sat there; never was used.

MR. CAMPER: Let me ask again. I think I'm hearing -- Judith, I think you're comments just now were a fairly compelling argument for asking for the number of cases. Because you are right; one year's experience might be two episodes.

MS. STITT: Right. But you might have seen them from the back of the room with 23 people standing in front of you. So that's some of the other quality issues that this has brought up.

But I don't think this is -- I'm not picking on physics at all. This is the same for physicians. It is also an area where you can be very quantitative about and --

MR. CAMPER: Well, I think what I would suggest then, barring any strong objections, that we would insert say a parenthetical "e.g." following brachytherapy where we say number and type of cases actually involved with.

MR. QUILLEN: I think that's a very good idea.

MS. STITT: You could put list the number and types.

MR. CAMPER: Or we could be even more specific. List the number and types of cases. That would be even stronger.

MS. STITT: Because that data is easily available.

MR. AYRES: I think of the two, numbers is more important than types. Now, that does raise a problem. Because then, if you are the reviewer in the region and you look at this, the question then becomes, what is enough?

MS. STITT: Right, aren't we avoiding that for the time being?

MR. AYRES: Well, we are, yeah.

MS. STITT: I think we have to.

MR. QUILLEN: At least it gives them something to work with. Because when you come into the ACMUI, the ACMUI at least then knows if the person has done one case or a hundred cases.

MR. CAMPER: Right. And I think that's what I would do. At some point there will be notes inserted in here for the reviewers, under the SRP approach.

And I think that's what we can tell them. If there some question as to whether or not there seems to be an adequate number of cases presented, and not specify a number, then refer that to the advisory committee.

MS. STITT: I think that you can be a medical physicist or a radiation oncologist and you don't have to link other terms to that, i.e. brachytherapy physicist, et cetera. You can be a medical physicist with a list of procedures and it tells your colleagues, it tells your regulatory agency, it defines your practice. So, I think it works together well.

MR. CAMPER: Okay.

MS. STITT: Back to the physicians. Are we requiring this?

MS. HOLAHAN: Actually, that was going to be my next question. Because I'd mentioned to you that it was up front, but it is very general in terms of just reciting the

requirements in part 35.

Now, in part 35 it does have specific, obviously, board certifications that you can be an authorized user. Also, there is an "or" category in the clinical experience for which you must have three years of supervised, clinical experience. Examining individuals, reviewing case histories to determine their suitability for brachytherapy treatment, selecting proper brachytherapy sources.

But there is nothing specific as to having HDR experience. And I know we did explore this with the ACMUI in May. And I think, at that time, it was a good idea to have the HDR experience.

Should we bring back into this a specific section to focus on the experience required for an authorized user.

And Bob, maybe you can address as to whether that has been considered.

MR. AYRES: Well, I'm not sure we've discussed it a lot.

My understanding, one agreement state requires specific HDR experience for physicians. In particular, my understanding is that the emphasis is they at least want the physicians to understand that this treatment, in most cases, must be fractionated and cannot be given in one fraction. And that's the state of New York.

I haven't seen a copy of their requirements, but

I have heard they have some specific requirements for authorized users in HDR above and beyond the normal certification requirements that we have.

MS. STITT: I think I would be enraged if I were a physicist to see that you were putting some things in the statement about me but colleague the physician has a different standard.

The way I understand it, we're not saying you must do *x*-number. We're just saying, list.

MR. CAMPER: Right.

MS. STITT: And I think that's very acceptable and gives a feel.

MR. AYRES: Well, one controversial thing that I have heard more adverse comments about is further down in the training. We do require the physicians to be trained on the device on normal and emergency procedures along with the physicist.

MS. STITT: You're getting some heat about that?

MR. AYRES: Yeah.

MS. HOLAHAN: So, I think from what I'm hearing, we should probably include a section in here on the authorized users. And if they are not board certified -- and again I think Larry has pointed out that this is one of the questions -- how do board certification programs address HDR?

MR. AYRES: My understanding from earlier

information from Dr. Flynn is that they don't. On HDR.

MS. STITT: It depends on the program.

MR. AYRES: You can't be assured of it.

MS. STITT: No.

MR. CAMPER: We're headed for some sit-down specific discussions with the boards and so forth and so on, somewhere along the line as we revise part 35 and get an understanding of what they're doing and not doing. And see if we can come together and make it work.

For now, maybe what Trish is suggesting is the idea, here under authorized users, we would insert a section with physicians and we could draw their attention to the requirements and the regulations under 35.940.

But, it probably would be worthwhile to make a comment or two in there where it talks about the 500 hour supervised work experience, it talks about emergency procedures, it talks about the three years of supervised clinical experience that we would expect a demonstration of experience with HDR specifically.

MS. HOLAHAN: Or PDRs.

MR. CAMPER: Or PDRs.

MS. STITT: All radiation oncology residents have to keep a list of all patients, no matter what kind of therapy is being used. Brachytherapy, teletherapy, so, physicians are accustomed to listing and I don't think it will be out of the

ordinary of what they've seen before.

MS. HOLAHAN: It shouldn't be a problem.

MS. STITT: It may be a problem, it's just not out of the ordinary for what's expected of them.

MS. HOLAHAN: Okay.

MR. CAMPER: So, that approach seems reasonable?

MS. STITT: Are they talking us into something here?

MR. QUILLEN: Yeah, I think so.

MR. CAMPER: Well, it is a fairly significant movement. I think it's a reasonable one.

MS. STITT: But it's a big difference in what we've said and making the statement that we, and when I say we I'm talking about NRC, requires *x*-number of cases.

That's very different from saying, "list".

MR. CAMPER: That's correct.

MS. HOLAHAN: And I don't think we're saying --

MR. CAMPER: We would be saying that we expect to see specific experience in HDR embodied within these broader guidelines of the numbers of years of clinical experience. As opposed to saying that we expect, as you just said, *x*-number of cases.

MR. AYRES: I thought I'd captured that to some degree with the training requirements for authorized users. They receive eight hours training on the device.

MS. STITT: Now, is that in the section we're looking at?

MS. HOLAHAN: Where is that? I was having trouble finding that.

MR. AYRES: Ah --

MS. HOLAHAN: The normal and emergency operation?

MR. AYRES: Yes.

MS. HOLAHAN: That's actually, and that was another question, it's under the section for training for the medical physics staff which doesn't include the authorized user.

And I noticed that one of the comments that we received was that we should require the same training for the authorized user.

MR. AYRES: Yeah, it says authorized users in this section.

MS. HOLAHAN: Where?

MR. AYRES: The licensee authorizes physician users, physicists.

MS. HOLAHAN: Oh, okay. You're right. Maybe we need to modify that title the same we modified if for yesterday.

MR. AYRES: Well, if we put in an extra one for authorized user under 851. We didn't have one for authorized users where we had the section for physicist, so I didn't have

a place to put it.

MS. HOLAHAN: Yeah, but we don't want that in there because that's what training experience that they have to demonstrate to us.

What this is is what annual and refresher training. So I think we just need to modify this section as well.

You're right, it does say authorized user; maybe it just needs retitling.

MR. AYRES: Oh, the title looks okay to me. The general title is --

MS. HOLAHAN: The subsection you've got it under says, "Training for Medical Physics Staff". And I think yesterday in the discussion on radioactive drug therapy we changed the title of that section to "Training for Staff Directly Involved in Administration and Monitoring of Patients Undergoing Remote Afterloading Therapy".

MR. AYRES: Oh, okay. Right.

MS. HOLAHAN: Rather voluminous title.

MS. STITT: A much longer title.

MS. HOLAHAN: That's right. But I think the question was who is actually considered medical physics staff.

MR. AYRES: Yeah.

MS. HOLAHAN: And so I think we can --

MR. CAMPER: Yeah, if you make it clear that they

are involved in the administration or the monitoring of --

MR. AYRES: Well, we might need to move that one. Maybe move it over under --

MS. HOLAHAN: Under the general title, perhaps, even. Up front.

MR. AYRES: Normal and Emergency Operation of -- under general training.

MS. HOLAHAN: Right.

MR. CAMPER: I'll have to look at that. It's a good point.

MS. HOLAHAN: Okay.

MS. STITT: Are we working item 9 then?

MS. HOLAHAN: Yeah. Does anybody have anything else on --

MR. AYRES: I have a real good comment that I want to introduce from region three on nine on training and it deals with nurses training and other staff.

I'll just present it for comments.

"We suggest, in addition of a descriptive sentence to the text in either the nurses' training section or as a definition in the glossary to better emphasize that all care givers need appropriate training to participate in RAL therapy. Especially low dose rate and pulse dose rate.

The new sentence reminds licensees and applicants that the term 'nurses' includes registered nurses, licensed

practical nurses, nurses aids and supervisor head nurses, any and all of whom may care for RAL patients and need the training specific in that module.

We suggest this because we have occasionally observed licensees who directly train only registered nurses or head nurses in brachytherapy therapy radiation safety procedures, while licensed practical nurses and nurses' aids actually render the bedside care for the patients.

The trained nurses are then expected to train the bedside care giving nurses in a pyramid manner and this training style may not be as comprehensive or effective as the direct training provided by the qualified instructors."

MS. HOLAHAN: I think that sets up the point that Dr. Flynn has raised at several meetings in terms of the nurse training.

And I just wanted to give as a lead-in to that, this list we had included in the module that

was discussed at the last ACMUI meeting for the manual brachytherapy therapy and we did get comments back from Dr. Flynn.

Now I think we have expanded or modified it and tried to address it to remote afterloading. I guess the question is, is everything included for remote afterloading that we would need for manual.

MR. AYRES: Well, I guess the short version is they want us to make it clear that training the head nurse or the RN is insufficient if they are using LPNs and nurses' aids to actually provide the hands-on care. We would expect them to receive the training first hand from the trainer.

MS. STITT: Well, when you read through various appendices that the NRC staff sends out several times a year regarding low dose rate, be it manual or remote, it's commonly nursing staff or ancillary staff that's involved in a slipsource or an applicator that's on the floor. So it's clear that the system is not working. Or it's so diffuse that it's hard to get everyone trained at the same level.

And the head nurse is not making rounds on these patients; she's making schedules.

MR. AYRES: Right. I think this point is well taken, and I intend to incorporate it.

MR. CAMPER: Yeah, that's right

MS. HOLAHAN: Basically, that all nurses should receive direct --

MR. AYRES: All nurses who provide any patient care whatsoever.

MS. STITT: Caregiver is the term that was used. And that's kind of a catch phrase, but it describes that lots of care is given by lots of different named individuals.

Well, we've got a lot on item 9 to slog through

here.

Do you want to take a break?

MR. CAMPER: Yeah, 10 - 15 minutes.

MS. STITT: Yeah, we're a small group. We can rely upon ourselves to get back here in some orderly fashion.

(Whereupon, the meeting recessed at 10:08 a.m.)

CHAIRMAN STITT: Back on the record, then, and we left on Item 9 and we've been discussing training, so, let's jump back in.

Is that where we left?

MR. AYRES: Yes. We're on Item 9, yes.

CHAIRMAN STITT: And, there's lots of pages of training. So --

MS. HOLAHAN: Okay, I just want to, unless somebody has some comment specifically on the first 9.1.1, I just wanted to make a comment that came out of yesterday's --

CHAIRMAN STITT: Okay.

MS. HOLAHAN: Okay. Again, yesterday, they were talking about the radioactive drug therapy module and one of the recommendations was in terms of training for nursing staff to retitle that.

And, again, that gets somewhat back at -- it's called training program for professional staff responsible for the care of patients undergoing H or remote afterloading therapy rather than specifically nursing staff.

CHAIRMAN STITT: I agree and it relates to the comment you made --

MS. HOLAHAN: And, I think they also wanted to highlight the fact that the training should be commensurate with their duties because the comment was that there was a lot of detail training in here.

And, there may be some nurses or caregivers that don't necessarily need the level of -- another comment, and I just wanted to outline what they had addressed in modifying these, because what many of the modules had very similar training programs in was the basic radiation biology.

They felt it was more important that it was a basic radiation effects. That they didn't necessarily need to know radiation biology per se.

MR. AYRES: You'll notice the second sentence in the first paragraph it says that individuals should be instructed in the following topics commensurate with their duties.

MS. HOLAHAN: Yeah. They just wanted that bolded and underlined and I don't know what this subcommittee's thoughts are as to whether or not we should emphasize that or not.

CHAIRMAN STITT: Well, in a clinical fashion I feel that that's exactly the issue. If you're talking about nursing staff there on the night shift with a patient with

sources in place, they don't necessarily need a lot of detail but they certainly need to know what applicators look like and isotopes look like and specific hands-on what do I do if this event occurs.

And, this is a very awe inspiring list of general training topics. And, I like the idea of bolding the commensurate with their duties.

And, again, you could also use examples if you wanted to do that. Not to be all inclusive but what should the caregiving staff that's making rounds on the patient what should they be looking for.

That might get into too much detail. Yeah, here's something. Number 18. Dose to embryo/fetus limits.

Which people need to know what things. So, we'll leave it up to the institution commensurate with the duties.

MS. HOLAHAN: Yes, and I think, generally, in terms of the reg guide that is out on the instructions to prenatal workers, they also recommend that all, not all staff, but at least all supervisors and all female staff should receive that instruction before they actually become pregnant.

CHAIRMAN STITT: Um-hm.

MS. HOLAHAN: So, sort of up front.

CHAIRMAN STITT: Right.

MS. HOLAHAN: So, there is guidance. And, I think the other document actually referenced the Reg Guides'

specific that could be used for some of these instructions.

The only other comment that they made yesterday was they took out the last two items. What's here is 25 and 26.

MR. QUILLEN: I was going to recommend you take out the last item, too.

MS. HOLAHAN: The questions and answers?

MR. QUILLEN: Yes.

MS. HOLAHAN: Okay.

MR. QUILLEN: I wasn't sure how you instruct somebody in questions and answers.

CHAIRMAN STITT: The issue about previous incidents, why did they want that out?

MS. HOLAHAN: Sally, do you want to address that? Sally?

MR. AYRES: I don't think it should go. I think that's all from valuable lessons learned.

CHAIRMAN STITT: I agree.

MS. MERCHANT: That was one of the suggestions that it be changed to say lessons learned. They did not want that to be interpreted by some applicant slash licensee to mean that you had to provide your history to the -- in the training session even though it must be available.

Legally, it must be available to the staff. That doesn't mean you have to stand up there and beat your breast

and say we had incidents --

CHAIRMAN STITT: Um-hm.

MS. MERCHANT: -- and we were involved and --

CHAIRMAN STITT: Or, you could take it to mean you have to have an incident before you can --

MS. MERCHANT: -- they said does that mean that anyone who did not have any kind of incident, who had a perfectly clean record, should not have to address that point.

In other words, it's a question of how's that going to be interpreted.

MS. HOLAHAN: Okay. Because we weren't necessarily meaning it to be incidents at that facility.

MR. AYRES: I've got a comment on that.

MS. MERCHANT: Well, that came up.

MR. AYRES: It's very good.

MS. MERCHANT: That came up. So, the feeling was that most lecturers are going to use anecdotes.

CHAIRMAN STITT: Right.

MS. MERCHANT: And, that it would be something that would happen anyway. But, if it was going to stay in, they would have preferred it to say lessons learned rather than give anyone an impression, because keep in mind, as we had discussed earlier, it is guidance.

These are not regulatory requirements and, unfortunately, people follow these as though they are gospel.

CHAIRMAN STITT: Well, the phrase examples can be very instructive and it doesn't imply that it's a previous incident.

It could be an example from other incidents and, you know, that are in print or something you've just made up because folks learn best from example or -- what was the phrase you used?

MS. MERCHANT: Anecdotes?

CHAIRMAN STITT: Anecdotes. But, examples of circumstances or examples of situations.

MR. AYRES: I have a comment here I'm trying to find. It addressed it very well.

CHAIRMAN STITT: Yes, Bob.

MS. HOLAHAN: Okay, the other point is, I mean, there is one information notice that's out in terms of some of these types of incidents and, you know, that would probably be made available anyway but not necessarily to new staff coming in.

MR. QUILLEN: One of the things you want to get across here is the fact that there have been incidents.

MS. HOLAHAN: Um-hm. I think that was the intent of putting it in.

MR. QUILLEN: Right. And, but the way this is phrased it could be interpreted as there was an incident at this

facility.

MS. HOLAHAN: So, examples of -- would you say examples of situations?

MR. AYRES: This one is very nice. Let me read it to you. It's a good comment.

It says please confirm that for all workers and authorized users refresher training will include components that will serve to maintain an awareness of radiation safety with respect to changes in license, changes in regulatory requirements, and lessons learned, experiences derived from NRC information notices, NRC/NMSS newsletters, and NRC inspection findings at your own institution.

MS. MERCHANT: I don't think they're required to give inspection findings from their own institution unless there's -- I mean it's got to be available.

But, I don't think that they should have to interpret this as you have to include your inspection findings in your training.

MR. AYRES: Well, this is a for example list but --

CHAIRMAN STITT: How about something that says examples of clinical circumstances, clinical cases, clinical situations, any of those phrases?

I mean a lot of times I will lecture and I just make up a case.

MS. HOLAHAN: Examples of clinical situations.

CHAIRMAN STITT: Combine several things that will make several -- the teaching points that you've been through.

So --

MS. HOLAHAN: Examples of clinical situations and lessons learned?

CHAIRMAN STITT: Um-hm.

MS. MERCHANT: Sounds good.

CHAIRMAN STITT: Okay. Let's keep talking about this section on training. Let's ignore, for the time being, PDR devices.

Well, I guess we -- if I ignore it for the time, where does that take us? Is 9.1.1.2 for the PDR?

MR. AYRES: Yes.

MS. HOLAHAN: No.

CHAIRMAN STITT: No? Well --

MR. AYRES: No. All right. I had to reread it myself. Okay.

CHAIRMAN STITT: The only reason I was trying to separate that out is PDR's got some issues that --

MR. AYRES: What I tried to do here, and maybe not entirely successfully, this was a change from policy and guidance directive.

Policy and guidance directive just, more or less, went down the topics serially and then had a license

reviewer's guide that said this one applied to this and this one applied to that, a check list.

This one, because it's more of an outline format, I tried to sub-index, LDR, HDR, and PDR, as appropriate and anything that didn't specify one or the other specifically was intended to apply to all.

And, like I said, I may not be totally successful. It's tough writing this for all of the remote afterloading modalities because they converge and a section will apply to all.

Then, it will apply to a sub-set. Then, it will come together again and apply to all. And, then, another sub-set has to be broken out because --

CHAIRMAN STITT: Will this be understandable to those who have to use it?

MR. AYRES: Well, that's what I'm saying --

CHAIRMAN STITT: Because if we're confused at all here --

MR. AYRES: -- it's tough to --

CHAIRMAN STITT: -- I suspect that they are.

MR. AYRES: I think the intent is to provide -- is add a check list to this in the future?

MS. HOLAHAN: For the license reviewers --

MR. AYRES: Yes.

MS. HOLAHAN: -- there will be check list. But,

again, this will be going out to licensees and, I guess the question is is it confusing -- should PDR be dealt with at the bottom of the section on training?

Should we go through possibly considering the training programs?

CHAIRMAN STITT: I'm just -- as I look at the format -- I'm having format problems and maybe content problems.

But, definitely, format. On page 8, there's general training. On page 11, there's general training.

And, I'm not sure what they refer to.

MR. AYRES: Well, that's because this is the nursing staff which we're changing to professionals responsible, on page 8 through 10.

On 11, we start medical physics staff. It's smaller.

CHAIRMAN STITT: Okay. So, it may just be the way that it's -- okay. I'm having trouble with the dots and the one's.

But, again, I think it's more of a format problem. Now that I understand how it's laid out it's easier to --

Tell me your major sections. Let me start from page 7. The major sections are what?

MR. AYRES: It's easiest when you look at the

index and where they're indented.

MS. HOLAHAN: Actually, the first section we probably need the 9.1.1 because that's general under the training program and we can just start, then, the nursing staff as 9.1.1, I think.

That may make -- at least get one set of numbers out.

MR. AYRES: Yes.

MS. HOLAHAN: So, if we took out that training program for individuals responsible for remote afterloading the personnel should be instructed in, that first section is your general introduction.

CHAIRMAN STITT: Okay. I'm with you now.

MS. HOLAHAN: Okay.

CHAIRMAN STITT: And, then, we --

MS. HOLAHAN: Then, the next section could be 9.1.1. Take out one set of one's here.

MR. AYRES: Yes, just all the way through.

MS. HOLAHAN: Yeah. And, then, training for caregivers responsible, whatever the wording was that I coined before, then, under that training for caregivers, you'd have general training, normal and emergency operation, and, then, specific for PDR.

Then, your next section would be 9.1.2.

CHAIRMAN STITT: Which was medical physics? Is

that right?

MS. HOLAHAN: Right.

MR. AYRES: Yes.

CHAIRMAN STITT: Okay.

MR. AYRES: One general style comment here. I got some comments on -- there's people -- and the cover letter didn't address it, I think, adequately, but these are not, as you've obviously noticed by now, sequential numbering.

And, in the main items, as well as in the sub-items, and that's because overall in the entire Reg Guide 10.8 they are sequential.

But, the holes, like we go from Item -- under Item 9 we go from 9.1 to 9.3. 9.2 isn't there.

That's something that doesn't apply in this module but is -- well, I'd have to have the whole outline for 10.8 to tell you why, what it is, and why it's missing.

CHAIRMAN STITT: All right. I think I understand. So, they should have, within each section, some similar format.

MR. AYRES: Yeah. In other words, if you go to mobile diagnostic, Item 9 will be the same --

MS. HOLAHAN: Right.

MR. AYRES: -- it'll be training for individuals, but there will be other items that are in that are in that that are not in this one and vice versa.

MS. HOLAHAN: Right. Now, the question is does that get confusing going from the module back to the body back to the module is you are either a license applicant or a reviewer?

MR. AYRES: If you have the entire Reg Guide 10.8 it shouldn't be nearly as confusing but --

MR. CAMPER: Well, what's going to have to be -- I mean, obviously, the plan has been that the licensee can read the general stuff.

They can go specifically to that module most applicable to them and the idea was that that would make it easier.

Now, the point been made that you've got to go back and forth but have we've been as clear as we could be in the module that cross-referencing will have to occur?

MS. HOLAHAN: No.

MR. AYRES: No.

MR. CAMPER: Well, maybe that's --

MR. AYRES: I presume that would be taken care of in the Reg Guide, the first section.

CHAIRMAN STITT: This is something that we need to --

MR. CAMPER: Well, I think the Reg Guide should say that. No question. But, what I'm thinking is I can certainly see a scenario where someone who's trying to put

together an application would go to this module.

And, I think it needs to be in both places.

MR. AYRES: Well, I don't understand how we're doing this for sure. I thought it was only going to be available as the entire Reg Guide.

In other words, you couldn't write and ask us for a module. You'd get the Reg Guide. It's a published, bound --

MR. CAMPER: Well, yeah. But, is someone -- well, eventually 10.8, the plan is that it would be revised.

It would have all of these modules. If someone wanted 10.8, they would get the whole general text and they would get all the modules.

MR. AYRES: Yeah.

MR. CAMPER: But, if someone came in and said hey, send me the module on teletherapy, for example, they would get that and the general text of 10.8.

They would not get all the modules.

MR. AYRES: That's what I didn't understand.

MR. CAMPER: But, here's the problem. I mean I can certainly see how a module, though, could become separated out in the field.

CHAIRMAN STITT: It will be.

MR. CAMPER: It will be. And, so, I think what we need to do is make sure that the main body of 10.8 draws

attention to specific modules.

But, also, in the lead-in section of each module, remind them that they're going to need the main body of 10.8 and will have to cross-reference as they step through requirements outline in the module.

CHAIRMAN STITT: It goes back to the thing I keep harping on. In the training section, there's nothing about physician training here because it is --

MR. AYRES: There's nothing unique here.

CHAIRMAN STITT: Okay.

MS. HOLAHAN: Well --

MR. AYRES: Except we've now discussed that item.

MS. HOLAHAN: No, I think that in Item 9 is, and that was what the discussion we'd had earlier, what is currently on page 11 is 9.1.1.2.

But, we could change -- with the renumbering it would become 9.1.2, okay? Where it says training for the medical physics staff?

CHAIRMAN STITT: Um-hm.

MS. HOLAHAN: Everything under there is also applicable to the authorized users. So, if we retitle that as training for staff directly involved in administration and monitoring of patients undergoing remote afterloading therapy, then, all that information is also applicable.

And, even though an authorized user has specific

training and experience to be listed as an authorized user, they must also received all this training.

CHAIRMAN STITT: Right. I think that's -- you have a way of putting -- linking more together but it's more --

MS. HOLAHAN: But, I think when you see it, it will make sense.

MR. CAMPER: And, the other thing, too. There's some words that go under the heading 9.1.1.1.

MS. HOLAHAN: Well, we'll renumber that.

MR. CAMPER: Training for everybody. But, that paragraph becomes, what is it? It's training commensurate with --

MS. HOLAHAN: It is in here and we're just going to bold it.

MR. CAMPER: Yeah. Commensurate with your responsibilities and so forth.

MS. HOLAHAN: Right.

MR. CAMPER: Obviously, a physician doesn't need to know a lot about basic radiation biology and so forth and so on.

MS. HOLAHAN: We hope they know that.

MR. CAMPER: Some of the other topics it would because they already have had that, obviously.

MS. HOLAHAN: Right.

CHAIRMAN STITT: All right. So, I think we've got the outline. The structure there has cleared that up for me.

MS. HOLAHAN: Yes. So, basically, the two sections would be one is caring for the patient either while -- and the other one is actually an administering and caring. So --

CHAIRMAN STITT: So, within those, are there comments about normal and emergency operations, the low dose rate device?

That appears under the -- it appears at the bottom of page 9. We been through the previous section.

MS. HOLAHAN: Should that be -- are you saying should that be repeated in the second section?

CHAIRMAN STITT: Uh --

MS. HOLAHAN: The one that's for training for nursing?

CHAIRMAN STITT: Actually, I'm just asking if there're comments. Anybody have comments on the emergency operation section for the caregivers.

Let's go ahead and jump in with PDR because this is the caregiver section. Do you have comments that have come in, Bob Ayres, regarding the PDR?

MR. AYRES: Yeah, a lot. One from an agreement state.

CHAIRMAN STITT: Do you want to jump into those or how does the staff feel? Trish, how do you view this section as it reads currently?

Is this a compromise? Is this workable? This really states some of the things that we've been through.

At least, this discussion is pretty straightforward in outlining what the dilemma.

MS. HOLAHAN: Yes, it's outlining the dilemma and I think it's addressing some of the proposals that we have had come in as an acceptable alternate.

CHAIRMAN STITT: Um-hm.

MS. HOLAHAN: Is that correct, Bob?

MR. AYRES: I'm sorry.

MS. HOLAHAN: This is taking into account the proposals that we have had in as an acceptable alternate for PDR.

MR. AYRES: Right. It incorporates presentation on behalf on AAPM at the ACMUI as well as a site visit.

MS. HOLAHAN: In the ACR proposal?

MR. AYRES: And, the one licensee we did have for PDR and the site visit included discussions between NRC, the licensee and the manufacturer.

All sitting together. The region representative, myself and Jeff Williamson and Steve Teague.

CHAIRMAN STITT: So, then, are we happy with it

the way it is? It certainly represents a small fraction of what's going on.

Ironically, it's probably the best way to do brachytherapy just from a biologic standpoint. But, it's probably the most difficult way to do it from a safety standpoint and patient safety.

MR. AYRES: The comments I've gotten on this and, again, some of these are agreement state specific problems like you brought up and running into problems with state law, that sort of thing.

MS. HOLAHAN: I'm getting a copy made of the state comments that you're looking at.

MR. AYRES: Okay. One of them is that the module indicates that NRC will consider trained nursing staff to qualify as device operators.

It's actually nursing staff and therapists. They go on to comment the department rules prohibit a non-certified individual from administering radiation to humans and it is not likely that nurses will qualify.

Well, I think there's a little misunderstanding there. They're not doing an administration per se.

They're watching --

MR. QUILLEN: Monitoring.

MR. AYRES: -- monitoring the administration which was, in fact, was prescribed and started by the

physician authorized user.

So, I'm not sure about the validity of that comment.

MR. QUILLEN: That's what my linear accelerator operator does.

CHAIRMAN STITT: Right. Carry out the orders.

MR. AYRES: Yes. In teletherapy, it's the -- the therapists all the time are even more so involved in the administration than is the case for HDR.

They made another minor comment on the training where we -- the module indicates that both practical and written exams should be administered.

And, they think we should require that copies of the exams and answer key with a specified minimum passing criteria be submitted as part of the license application.

That's maybe -- I'm not sure if we wanted to get involved at that level of detail. Where they get into problems with the HDR, it does not adequately address the use of PDR's they say.

The module indicates a more sophisticated alarm system. Sensors lack of constant surveillance. And, it says the alarm system is not defined.

I think they have a misunderstanding there and we could probably discuss that a little bit. I need to rewrite that for a little better clarity based on the comments.

In doing electrical engineering work in the past, I took some liberties on understanding that obviously, not everyone caught.

The section implies that what -- their main thrust is that the patient remains attached to the device during non-treatment times and they object to that.

They say if you're going to leave the patient attached to the device, you have constant surveillance. Otherwise, you disconnect.

And, that's certainly contrary to the philosophy in which these devices were developed to be operated.

And, I'm not sure I go along with that. But, that's their central thrust. If the patient is connected to the device, you have constant surveillance.

If the patient is not -- otherwise, disconnect the patient from the device. And, they go into various examples, too, like visitors and so forth.

That's the real thrust. What the special alarm system is, and maybe I should just explain it up front as the wording doesn't do adequately.

But, what we felt was, and this is being done in, I understand, Arizona, they have a facility where they have this type of alarms, is that if the machine fails, and the definition of failure would be that you have what I call a wire, well, and it really is, a logical "and", that requires

that if the device is not in the safe, the room monitor must be going.

Okay? That is the function check and if that doesn't happen, the device is supposed to generate an error, retracts the source.

In other words, it indicates that the room monitor, the prime alert, what have you, has failed. It generates an error.

Retracts the source. And, required operator intervention to correct the problem before the source can be -- treatment can be restarted.

The real alarm condition, and in this case we specify an audible alarm because it's not under constant supervision and it may be 30 feet down the hall from the nurses' station, is if the device says the source is safe, retracted, and the room monitor is alarming, then, a significant non-silenceable audible alarm is generated until the problem is corrected.

That's a special alarm system. We tie the radiation monitor into the interlock alarm system and in two ways to generate an alarm and to run a self-test, if you will, on its function.

In other words, if the device says the source is out, the alarm better be going. If the device says the source is in, the alarm better not be going.

MR. CAMPER: This is an Arizona requirement.

MR. AYRES: Yes.

MR. CAMPER: Are any of the agreement states doing that?

MR. AYRES: I have no knowledge.

MR. CAMPER: Is Colorado doing that?

MR. QUILLEN: No.

CHAIRMAN STITT: Who's actually doing PDR?

MR. AYRES: There's very few of them. None anymore in our states and --

MS. HOLAHAN: Is there one in Arizona?

MR. AYRES: There is certainly one in Arizona.

CHAIRMAN STITT: Who is it? Do you know?

MR. AYRES: Who?

CHAIRMAN STITT: What institution?

MR. AYRES: No, I don't. I have a list. I could find it. I could find that out.

CHAIRMAN STITT: There can't be more than a couple of places that even do brachytherapy to any degree.

MS. HOLAHAN: I know UCSF has a program.

MR. AYRES: Yes, yes. They have one.

MR. CAMPER: Who does it?

MS. HOLAHAN: UCSF. San Francisco. And, then, I know there's some research on-going in Michigan.

MR. AYRES: Yes. The philosophy applied to this

was recognizing that the level of risk was one tenth of HDR but substantially more than LDR.

It's a 1 Curie source max. So, that -- translate that into that you have 10 times more response time than you would with a comparable accident with HDR with everything else being equal.

MR. CAMPBELL: What about when everything else is not equal? Treatment duration is not equal.

MR. AYRES: Well, the actual --

MR. CAMPBELL: It's several hours or days.

MR. AYRES: Well, it's 70 -- it's a typical LDR. Overall treatment period, the actual source exposure time, is comparable.

In other words, the source may be out 5 minutes. And, everybody agrees that this is an experimental modality in that all the evidence suggests that you get the equivalent of LDR tissue response by pulsing the source.

It depends on the source strength. If its a full 1 Curie, you may be treating 5 minutes of every hour.

If it's a half a Curie, you have 10 minutes. If it's a quarter, you have 20 minutes of every hour until you reach source exchange.

The advantages of it are is, of course, it apparently produces the identical tissue response to that of LDR.

It allows nursing care without interfering with the treatment in any manner what so ever unless there's an emergency because the nursing care can be scheduled for the off time.

Obviously, you could schedule visits, too, if you wish. The one thing I've talked to to the people at Mallinckrodt that were using it, the other touted advantage of it, apparently, isn't, or at least at that institution and, as far as I know, not very much used, is the ability to shape the field by the stepping -- varying the dwell times.

It would have, I guess, an advantage over conventional LDR. With a smaller source, you could probably treat some areas that might be more difficult to treat with a large manual afterloading.

CHAIRMAN STITT: So, what do we need -- do we have what we need here, for the time being? I mean I think PDR is probably the most ethereal of all the things we're discussing because it's the least established due to all the pluses and minuses that you just elucidated.

I think one of the issues that's bothersome to me and also to the NRC is that there may be a one tenth of the level of problem if a source is stuck in place.

However, if you don't know that that source is stuck in place --

MR. AYRES: Right.

CHAIRMAN STITT: -- one tenth doesn't matter a wit.

MR. CAMPER: That's the point I was getting at. You know, you have a monitoring problem --

MS. HOLAHAN: Yes.

MR. CAMPER: -- that you don't have with HDR treatment.

MR. AYRES: Yes.

MR. CAMPER: You've got a duration problem.

MS. HOLAHAN: Right.

MR. CAMPER: You have the question of availability of the right staff all the time. There are some problems like that.

MS. HOLAHAN: We've tried to get around that and we have gotten around it with HDR saying the authorized user and the medical physicist have to be present.

MR. AYRES: What the components here are, besides the special alarm system, which is, if you will, in lieu of somebody sitting there watching there all the time.

Maybe that's not adequate. The other one is that the people that do watch it or who are available to respond immediately, that is, within a minute or less.

Well, we really don't specify that. But, they'd be specially trained in all the normal and emergency operations.

They have to prove their competence by practical exam. There's another stipulation in there that they need to be retrained twice a year because one makes the assumption that these individuals do not have the repetitive hands on experience that the physician and physicist does.

You know, In other words, they'll be on shifts. And, there will be shifts that there'll be treatment going on and they won't be there and so forth.

And, so, we put in a double the training refresher requirement and there is a requirement in here that the ROS/physicist/physician be available in, I'd have to look it up, in some minimum amount of time to respond to a page, be it home or wherever.

And, now, whether this aggregate set of requirements is sufficient is what's on the table.

CHAIRMAN STITT: Does the issue of emergency -- when we jumped into our discussions this morning, we actually starting talking about emergency --

MS. HOLAHAN: Procedures.

CHAIRMAN STITT: -- management of HDR sources. Where did I loose that section to?

MS. HOLAHAN: That was around page 34 or 33.

CHAIRMAN STITT: And, that is in which -- what is section 11.2 called?

MS. HOLAHAN: Section 11 is called radiation

safety program.

CHAIRMAN STITT: Okay. So, then what we discussed as far as this section that we've discussed should also relate to PDR.

Is that correct? That is, as far as retrieving.

MS. HOLAHAN: Yes. Now, again, that raises a question of the surgical intervention, yes --

CHAIRMAN STITT: Right. But, if you're looking at the document --

MS. HOLAHAN: -- which we don't specifically address.

CHAIRMAN STITT: -- and contemplating PDR, this emergencies procedures also relates to it. It doesn't have to be repeated anywhere.

MR. AYRES: Right.

CHAIRMAN STITT: Okay.

MS. HOLAHAN: Right.

MS. HOLAHAN: All right, so, back to your question, which is the right one. Do we have what we need in this section for the time being?

I guess just in general I think this is probably as good as we can do when you realize that this is not as highly developed, it may not be because of the constraints, but at least it makes some statements that we haven't made before.

CHAIRMAN STITT: Okay.

MR. CAMPER: I suspect you're right.

CHAIRMAN STITT: So, then, PDR was turned into something fairly easy.

MR. AYRES: Well, we wrestled quite a bit and lots of discussions occurred between what's put down here and --

CHAIRMAN STITT: That's why it looks so well done because you've done all the homework to set it up for us.

Well, then, let's move on to --

MR. QUILLEN: I'm not finished with that section, yet.

CHAIRMAN STITT: You're not? You've got to speak up, sir.

MR. QUILLEN: You have the new title of the device monitor slash operator, okay? And, later on, you use the title device operator.

And, then, later on further, you use the title device monitor. At first, I thought you were talking about one person.

Then, I think you're talking about two different people. What are you talking about?

CHAIRMAN STITT: Sounds like something that's out of the nuclear reactor industry, doesn't it?

MR. CAMPER: What's the second one?

MR. HOLAHAN: We say device operator on 11, device monitor operator on page 10 and where -- do we say device monitor alone somewhere?

MR. QUILLEN: Yes, back -- let's see. Let me find it. It's on page 28 under 11. And certified.

There we have a specially trained and certified device monitor.

MR. AYRES: Where is that? Page 20?

MR. QUILLEN: 28.

MR. AYRES: I think there may be a real reason for that one. Let me get there and see.

MR. CAMPER: We have device operator up on 10.

MR. QUILLEN: Okay.

MR. CAMPER: And we have -- where's your trained?

MR. QUILLEN: Device operator slash -- monitor slash operator. The next page talks about the device operator.

MR. CAMPER: Yeah, I have those two. Device operator.

MR. QUILLEN: On page 28, under 11 --

MR. HOLAHAN: Okay. That's referring to PDR there.

MR. AYRES: PDR where we have those extra requirements for the monitor. So, I did that with some deliberation, but maybe it's not clear at that point.

CHAIRMAN STITT: Is a certified device monitor a gizmo or a person?

MR. AYRES: Person.

MS. HOLAHAN: Is that the same as the device monitor operator that's referred to on page 10, I think, is the question, isn't it?

Because it'd talk about only -- we have a primary device monitor operator --

MR. AYRES: Yeah, it is. They're both under the PDR section.

MS. HOLAHAN: Yeah. But, I guess we need to be consistent and decide what we want to call them.

MR. AYRES: Yeah, yeah.

MR. QUILLEN: Be consistent on what you're going to call them.

MR. AYRES: And, maybe -- it looks like --

MR. CAMPER: Why is it just the device operator, Bob?

MR. AYRES: Well, because under PDR the nurses or the specially trained nurses or therapists aren't operating the device.

They're just --

MR. CAMPER: Right. They're more monitoring.

MS. HOLAHAN: So, could we take out operator on

page 10, then, the slash operator?

MR. AYRES: Probably. I need to look at those.

MS. HOLAHAN: I mean for PDR, could it just be -- I mean that's a possibility. For PDR, it could be a monitor and, then, the operator is the person who actually pushes the button.

MR. QUILLEN: Because on the next page you have device operator which is somebody, it appears, that's under the physics staff.

MR. AYRES: Yes, that's correct. That was the intent. What we have for LDR and PDR, we have the people who watch over it are not the operators, not the ones who program it, not the ones who initiate the treatment.

MR. CAMPER: A question for you, Bob. If I read 9.1.1.2.2 or 1 the list there it says an outline of initial training provided by the device manufacturer or individual, so forth and so on, the licensee gives to the authorized user physicists and/or RSO and device operators.

What device operator is there that isn't an authorized user, a physicist, and/or an RSO?

MS. HOLAHAN: Therapist.

MR. AYRES: Therapist.

MR. CAMPER: That's an authorized user.

MS. HOLAHAN: No, no. A tech.

MR. CAMPER: Oh, okay.

MS. HOLAHAN: Formerly a technologist, now a therapist.

MR. AYRES: A lot of times, even with our requirements that the physicists and the authorized user be there, they are often there but actually somebody else, a therapist, is actually manipulating the device.

MR. CAMPER: Then, why don't you say therapist --

MS. HOLAHAN: Some states will only allow -- won't allow the physicist to operate it.

MR. AYRES: It could be a dosimeterist.

CHAIRMAN STITT: Does device operator get a definition somewhere? Is it supposed to?

MR. AYRES: Well, that what I thinking about. With all these things we're talking about maybe these should go in the glossary.

MS. HOLAHAN: Yeah, we could define it. Yeah.

MR. AYRES: We'd get them straightened out and put them in the glossary.

MR. CAMPER: Well, it's either that or you might be a little more clear by saying or others. See, an AU, a physicist or an RSO is a device operator, may be a device operator.

MS. HOLAHAN: Can be, yeah.

MR. CAMPER: Then, you can say or other device operators for example, technologists or dosimeterists.

MS. HOLAHAN: We've got that idea of the general category on the top of the page where basically -- right there.

That's listing sort of who all the general folks are that we're talking about except there again --

MR. CAMPER: Well, then, you ought to draw a distinction to device operator, then.

MS. HOLAHAN: Well --

MR. CAMPER: You see, once again you have a device operator as a line item.

MR. AYRES: Well, I see something else here, too. I should delete and/or RSO because you made the decision towards the end to delete and/or RSO out of the required people and this is a place that I didn't -- I missed getting back --

MS. HOLAHAN: Well, we could include RSO as possibly needing that though, as well, right? Because --

MR. AYRES: Well, the reason it was in there was because that was in lieu of the physicist if they didn't have one.

And, I wouldn't think the RSO would need the training unless he was going to be a device operator or something like that.

MR. CAMPER: And, now we require them to have the physicist.

MR. AYRES: Yeah.

MR. CAMPER: You're right. That's a good catch.

CHAIRMAN STITT: Well, I do like what Larry suggested in defining -- that the device operator has an explanation or an explanation just by that comma which could include a dosimeterist or RTT.

MS. HOLAHAN: Could we say, up at the top of that page, in the 9. --

CHAIRMAN STITT: At the top, yeah.

MS. HOLAHAN: -- that that would include and that should actually be including authorized user, physicist, therapist, dosimeterist or other device operators, just in case.

MR. AYRES: I was just going to say or other device operators.

MS. HOLAHAN: Right. Just in case we missed somebody.

MR. AYRES: And, then, we define in the glossary, put in the glossary, device operators and device monitors, and/or other device operators.

MS. HOLAHAN: Bob, let me ask you a question. Up there is you've got the authorized user only for HDR and PDR treatments.

Shouldn't the authorized user receive all that other general training, too?

CHAIRMAN STITT: I thought it stated that it did.

MS. HOLAHAN: The way that it's worded is only the normal and emergency operation.

MR. AYRES: Well, that wasn't my intent. That goes beyond, I think, what we need. Again, Dr. Stitt can very well address this but, I think, with LDR the authorized user is not necessarily even there when treatment is initiated.

They may or may not be depending on the institution and the individual physician but requiring them to have training on the device, I think, would be clearly appropriate if they are the primary responder to a difficulty with the device.

But, if they aren't --

MS. HOLAHAN: Yes, but, if you look under the general training, it isn't really the -- well, the operating instructions, but it gets into the appropriate radiation surveys, the source inventory controls, source leak testing.

Particularly, if others are all doing it under the supervision of the authorized user, I don't see, and let me ask --

CHAIRMAN STITT: Oh, I agree with that.

MS. HOLAHAN: -- Dr. Stitt, again, should that be included as part of the authorized user training as well?

CHAIRMAN STITT: Yes. As far as I'm concerned, it should be. I mean, actually, this is all material -- this

would be training that if the authorized user is the physician, they would have been trained on during their residency or hopefully --

MS. HOLAHAN: So, then, they may not need the --

MR. CAMPER: I do have a question, though, about one of those. Number 2. What do we mean by source inventory control?

MS. HOLAHAN: What source is in storage and what source is in the unit. Well, and then, don't forget, this encompasses remote afterloading or LDR as well.

MR. CAMPER: LDR. Oh, yes. That's right. Okay.

CHAIRMAN STITT: Yes.

MR. CAMPER: That's it.

MR. AYRES: You might say the Indiana, Pennsylvania had a poor inventory control on the source.

MR. CAMPER: Well, it's up to you but I might argue that point.

MS. HOLAHAN: Actually, one of the conditions is in lieu of the 35.406 which is the source inventory, so --

MR. CAMPER: Well, I was thinking, obviously, of more classical inventory as in LDR.

MR. AYRES: I forgot or didn't capture well what were we changing this title to 9.1.1 to which is going to become 9.1.2 which is train for medical physics staff?

It was going to be training --

MS. HOLAHAN: Okay. I can give it -- well, training for professional staff responsible for the care of patients undergoing remote afterloading.

And, then, 9.1.2 becomes training for staff directly involved in planning, administration and monitoring of patients undergoing.

MR. CAMPER: That's consistent with our approach yesterday, right?

MS. HOLAHAN: Right.

MR. AYRES: I may get together with you.

MR. HOLAHAN: Yeah.

MR. CAMPER: Yeah, you didn't have the benefit of the discussion yesterday. If you had been there, it would have helped a lot but we can --

MR. HOLAHAN: Plus I have Sally right here in front of me.

MR. CAMPER: -- get together on that.

CHAIRMAN STITT: Bob Quillen, do have other comments?

MR. QUILLEN: A couple editorial comments.

MR. AYRES: Okay.

MR. QUILLEN: On number 3, at the top of page 11. I think that should be a separate paragraph because the lead into that is how we're to act in this capacity as individuals who meet the following minimum training requirements and 3 is

not a training requirement.

MS. HOLAHAN: Where? I'm sorry.

MR. AYRES: Oh, I think I have a comment on that, also, from another source. Same thing, yeah.

MR. CAMPER: It's number 3.

MR. AYRES: It's not a sub-set. It's a separate paragraph.

MS. HOLAHAN: Oh, okay.

MR. AYRES: There's a couple places where that occurs.

MR. QUILLEN: I'm next down to 9.1.1.2.2.

CHAIRMAN STITT: The bottom of the paragraph on page 11.

MR. QUILLEN: Yes. And, this is another editorial one. You have a sentence here. It has almost 70 words in it and the verb is the last word in the sentence.

It would be helpful --

MR. HOLAHAN: In number 1?

MR. QUILLEN: Yes.

MR. CAMPER: Our old English teachers would have found this intolerable, right?

MR. QUILLEN: I would just put the verb up here in front of the sentence.

MR. HOLAHAN: We need to find on old English teacher to fix that section, right? This is what's called a

run on sentence.

MR. AYRES: Well, it hasn't gone through our technical editor. I don't know whether this documents going to go through our tech editor.

MS. HOLAHAN: I don't know if the licensing manual will.

CHAIRMAN STITT: I can see where a well-placed period would help that out.

MR. CAMPER: Yeah, that's right. We don't want 70 words in a sentence.

CHAIRMAN STITT: We can get that fixed for you, doc.

MR. CAMPER: Even a bureaucrat shouldn't do that.

MR. AYRES: Sneak one in.

MR. QUILLEN: That's all I have.

CHAIRMAN STITT: All right. If we fix that on page 11, that'll make him happy. How about page 12?

It's still -- now, we're at normal and emergency operation at HGR remote afterloading devices.

MS. HOLAHAN: I'm sorry. Where are you?

CHAIRMAN STITT: 12.

MS. HOLAHAN: Okay.

CHAIRMAN STITT: Any comments on 12?

MS. HOLAHAN: I'd like to make -- are we on the section for training for ancillary?

CHAIRMAN STITT: Let me just -- hang onto that thought.

MS. HOLAHAN: Okay.

CHAIRMAN STITT: And, let's see if anybody else has other comments that relate to normal and emergency operation of HGR remote afterloading devices, editorial or otherwise.

MR. QUILLEN: On number 2, it wasn't clear to me what you were looking for with respect to affiliation.

MR. AYRES: Well, often time, it's a vendor. Other times, it might be a consulting firm or in house.

MR. QUILLEN: What you're really looking for is the qualifications, isn't it?

MR. AYRES: Yeah.

MR. QUILLEN: Rather than the affiliation?

MR. AYRES: Well, yeah. Is there an advantage to knowing where they're from, I guess, is the question.

MR. CAMPER: What's the yardstick to judge?

MR. AYRES: Yeah.

MR. CAMPER: I don't think there is one. It's really about their qualifications.

MR. AYRES: Yeah.

MR. CAMPER: Who. Who did it. And, are they qualified. I think Bob has got a good point there. I would suggest deleting the word affiliation unless somebody has a

compelling reason why we shouldn't.

Yes. I guess the only advantage to affiliation of the vendor providing it, sometimes confer upon them expert status, maybe appropriately, maybe not.

CHAIRMAN STITT: I suspect you're going to be given an affiliation anyway.

MEMBER QUILLEN: Yes. I would expect so, too.

MR. AYRES: Yes. I think you will be, too.

MEMBER QUILLEN: It will be in their CV.

CHAIRMAN STITT: Anything else that you want to discuss on normal and emergency operation, HDR devices? Mr. Ayres?

MR. AYRES: I'm sorry?

CHAIRMAN STITT: Anything else on that section?

MR. AYRES: I don't have anything.

MEMBER QUILLEN: I don't have anything either.

CHAIRMAN STITT: All right.

MR. AYRES: Not here.

CHAIRMAN STITT: Dr. Holahan, do you want to move on to 9.1.1.3, "Training - Ancillary."

DR. HOLAHAN: Which is now 9.1.3.

CHAIRMAN STITT: Which is now. I'll get that down. "Training for Ancillary Personnel (Housekeeping, Dietary services, Security)." Do we have a new name for that section?

DR. HOLAHAN: No.

CHAIRMAN STITT: No? Oh.

DR. HOLAHAN: But I did want to address -- and because this went out later, I wasn't able to provide this to Bob yet -- that the other modules we have revised.

Part 19.12 was revised this summer. And so it has now been that -- it used to be that anybody going into a restricted area need training. Now the revised language that we will revise this to read is, "Individuals whose assigned activities during normal and abnormal situations are likely to result in a dose in excess of 100 millirem must receive instruction commensurate with potential radiological health protection problems in the workplace."

So basically if you've just got a visitor walking through, they don't necessarily need instructions or if you've got somebody who's just walking, an ancillary person just walking through, unless you feel they are likely a normal or abnormal situation.

So that will be revised to read I think --

CHAIRMAN STITT: What you just read.

DR. HOLAHAN: -- the new language.

CHAIRMAN STITT: Will that also include some examples like you just gave or are those sort of off the cuff?

DR. HOLAHAN: I think the examples are still going to be the same. Particularly with HDR is that if

there's an abnormal situation, an individual if they are in a room with an HDR are likely to receive in excess of 100, so I think in many situations.

Now, the point is -- and that's made at the bottom -- that "Licensees may choose to prohibit ancillary personnel from entering restricted areas."

CHAIRMAN STITT: Okay.

DR. HOLAHAN: But they would still need to provide some training. Basically "Don't go in this room when this sign is up."

MR. CAMPER: And what document were you reading from?

DR. HOLAHAN: Oh, this was out of the radioactive drug therapy module since we already made that change.

MR. CAMPER: Okay.

CHAIRMAN STITT: What do Number 1 and Number 2 relate to? I mean, I know what they are, but they're kind of hanging out there, "Posting," and "Labeling." Is this training they're supposed to have on posting and labeling or is there more information we need to hear? Posting --

MR. AYRES: "Individuals will be instructed in the following topics," and those are the two topics.

CHAIRMAN STITT: Okay.

MR. AYRES: This parenthetical statement probably should be moved. It gets a little bit in the way of

understanding that. It should be moved up ahead of that.

MR. CAMPER: Bob, help me out a minute.

MR. AYRES: Yes.

MR. CAMPER: For ancillary personnel, housekeeping, et cetera, posting is clear. Labeling is what? Labeling on the device itself?

MR. AYRES: Yes, for example. You can have the room posted or you can have --

DR. HOLAHAN: You could have a label. I mean, if --

MR. AYRES: "Radioactive material. Do not disturb" or something like that on a safe or --

DR. HOLAHAN: Right. "Don't pick up something marked with a label on it that says 'Radioactive material.'"

MR. CAMPER: Well, that's supportable here because we might have a lead container sitting around or a source that fell out.

DR. HOLAHAN: Right, source.

MR. AYRES: Or a new source yet to be installed.

MR. CAMPER: Right. Okay. Just an editorial comment about the paragraph, though, a few lines up, where it says, "10 CFR 19.12." "10" can't stand alone at the end of the sentence, as in "10 CFR 19.12."

MR. AYRES: No. That --

MR. CAMPER: Just a minor editorial comment.

DR. HOLAHAN: It will be probably be moved anyway --

MR. CAMPER: Yes. I'm sure it will.

DR. HOLAHAN: -- some when we revise it.

MR. CAMPER: I'm sure.

MEMBER QUILLEN: One of the problems of the way this is stated is that what ancillary people need to be trained in is what is the meaning of labels --

DR. HOLAHAN: Right.

MEMBER QUILLEN: -- and signs. They don't do posting themselves.

DR. HOLAHAN: No. Oh, okay.

CHAIRMAN STITT: I guess that's the problem I had with it. Thank you. When I see those two words there, in fact, I would suggest that we need a -- if you're going to keep that first paragraph, then let's make a second paragraph that says, "Individuals will be instructed in the following topics." It lists them.

MR. AYRES: Yes. That sentence has got to be moved that follows that.

CHAIRMAN STITT: Yes. But I agree with Bob's comment.

MR. CAMPER: The meaning of.

CHAIRMAN STITT: The meaning of. There you go.

MR. CAMPER: Yes.

CHAIRMAN STITT: Posting. The meaning of labeling, which I had to ask myself.

MR. AYRES: Or you could put it in a sentence, "The meaning of the following topics" or "understanding of" or something like that.

MR. CAMPER: Yes.

MR. AYRES: It could be adjusted either place, but yes.

DR. HOLAHAN: The other -- and, again, I don't mean to refer continually back to the other module. But the other point that was in there that raised a question as to whether or not it should be included as radiation protection to include concept of time, distance, and shielding.

CHAIRMAN STITT: There you go. Concept of. I mean, okay.

DR. HOLAHAN: And we could include that as well, as opposed to meaning of posting and labeling and precautions.

CHAIRMAN STITT: Right, right.

MR. CAMPER: Similarly, I would be specific about what you mean by "precautions." You mean precautions when in rooms where remote brachytherapy is occurring; right?

DR. HOLAHAN: Right. It's even if they're going into a PDR room with --

MR. CAMPER: Right. I think we should be specific about what we mean by "precaution."

CHAIRMAN STITT: And, Trish, you keep bringing it up. We need to make these things as homogeneous as we can, where they should be, so that it doesn't appear that we're making up new issues under training just because the isotope may have changed or the use is changed. And where it makes sense we have to, but we need some continuity. It sounds like you're responsibility for bringing us up on that.

MEMBER QUILLEN: One of the problems that you get into -- and I'll give you some experience to illustrate this -- is that when I was in Ohio, both the NRC and the State of Ohio had an ongoing set of issues with Western Reserve University and University Hospital. And when I asked the University Hospital what was the primary language of their ancillary staff, their janitorial staff, they said, "Polish."

So they could not read instructions. I mean, they needed to be instructed in Polish basically what signs meant, what labels meant, what they were supposed to do. But you couldn't post instructions in English on the wall and expect them to understand what they were supposed to do.

MR. CAMPER: Yes. So you might modify your sentence, then, where it says "Individuals will be instructed in the following topics," "in a manner that ensures that they understand the subject matter," something to that effect.

MEMBER QUILLEN: That's right. You need to get something across that these people have to understand these

issues, rather than just be able to --

MR. CAMPER: If you say something like what I just said, I think you're making the point without that treading on thin ice in that you begin to sound discriminatory.

MEMBER QUILLEN: That's right. And I know in our area it's Hispanics.

DR. HOLAHAN: I know. I was down in Texas. And many of the signs were posted in both English and Spanish.

MEMBER QUILLEN: Right, but this is one of the things I noticed at University Hospital in Cleveland. You had many ancillary people who just didn't know. I mean, they just did what they were told, and that was it --

MR. CAMPER: Right.

MEMBER QUILLEN: -- because they couldn't read the signs.

CHAIRMAN STITT: And we do need to address that in some tasteful fashion.

MEMBER QUILLEN: Well put.

CHAIRMAN STITT: Well, I was having the same problem. What's posting? And what's labeling?

DR. HOLAHAN: So if we say "meaning of posting and labeling" and then "necessary precautions," would that be --

MR. CAMPER: Well, again, I think the point that

I was making was it's necessary precautions when and areas where LDR or PDR or HDR is occurring. I mean, that's --

DR. HOLAHAN: When in a restricted area?

MR. CAMPER: Well, see, you could be in a restricted area for some reason other than where LDR, HDR, or PDR is going on. I mean, the bottom line is you want them to know when they're going in a room where --

DR. HOLAHAN: Yes. But, again, if we're saying this is commensurate. Okay.

MR. CAMPER: Well, "precautions" is not nearly descript enough.

MEMBER QUILLEN: You know, this is too --

DR. HOLAHAN: Right. But the language is going -- that is currently in Part 19 says --

CHAIRMAN STITT: It depends on what kind of precautions you're concerned about.

DR. HOLAHAN: Well, it says "commensurate with potential radiological health protection problems present in the workplace" in Part 19 now. So I think that will address that to some degree.

MEMBER QUILLEN: Well, the other issue I have is the situation we see periodically and I think other people see periodically is that janitorial staff does not follow the work rules associated with working in a medical environment. They get bags mixed up. So they put yellow bags up in magenta bags

and vice versa and white bags.

And so there's an issue here that they understand whatever the -- not just the precautions, but the -- I hate to use the word "work rules," but something like that associated with the environment.

DR. HOLAHAN: Well, would it be typical for many of the remote afterloading cases that ancillary staff would just be told not to go into the room?

CHAIRMAN STITT: Yes, that's very typical because of what you're describing.

MR. AYRES: And there isn't really a bag problem with remote afterloading.

DR. HOLAHAN: No.

MR. AYRES: There isn't radioactive waste associated with it.

MEMBER QUILLEN: I know. But I'm just saying that that's what happens.

MR. AYRES: I understand your point and --

MEMBER QUILLEN: I don't know how many times in my life I've had to deal with that issue of putting --

CHAIRMAN STITT: Why don't you take the parentheses out of "Licensees may choose to prohibit"? I mean, I only say that in a --

DR. HOLAHAN: That could actually be moved up, too.

CHAIRMAN STITT: It sounds like --

MR. AYRES: That's in error. That sentence needs to be made a separate sentence that starts ahead of "Individuals." Yes. That one I've already noted.

CHAIRMAN STITT: Okay. It makes it sound like "Oh, by the way" when, actually, a lot of people choose that route because --

MR. AYRES: That will be made a stand-alone sentence between "review" and "Individuals."

CHAIRMAN STITT: Good. And we're going to try to flesh out "Posting/Labeling," "Precautions" to include the things that we just brought up, then.

"Training for Contractors." "Contractors" refer to what?

DR. HOLAHAN: Anybody.

MR. AYRES: Anybody, including physicists, nurses. It just says everything that applies to your own people applies to contractors.

CHAIRMAN STITT: Okay.

MR. CAMPER: Wy don't you just --

CHAIRMAN STITT: Give examples.

MR. CAMPER: -- embody that term or that concept earlier when you're talking about who's being trained?

DR. HOLAHAN: Because --

MR. CAMPER: Why do you need a separate section?

DR. HOLAHAN: Because we felt it was significant enough to bring it to light. We didn't want it lost in the body as you're just sort of scanning through to have contractors --

CHAIRMAN STITT: I can see that.

DR. HOLAHAN: We wanted to make sure that people were aware that contractors working for the licensee are still working on that license.

CHAIRMAN STITT: Would you describe who contractors might potentially be? And that will just catch people's eyes. We all know it, but I had to ask a question to be sure.

DR. HOLAHAN: Okay. I mean, in our --

CHAIRMAN STITT: Contract nursing staff are involved in this. And I think it's a potential risky area. But, nonetheless --

MR. AYRES: It covers a huge spectrum. I mean, it could --

CHAIRMAN STITT: Well, give some examples.

DR. HOLAHAN: Give some examples.

MR. AYRES: It could even be construction folks become ancillary personnel at that point.

CHAIRMAN STITT: Well, somebody might say, "Yes. That involves the contract that we have for physics," but not realize that in some hospitals the folks who are writing the

license may not realize that nursing staff, particularly on certain shifts, are all contractual and are brought in from outside agencies for short.

MR. AYRES: Yes. That's always a problem with overlooking particularly contract nursing personnel.

MR. CAMPER: You could have a consultant physicist, too; correct?

MR. AYRES: Oh, sure. I mentioned that.

CHAIRMAN STITT: Some examples.

MEMBER QUILLEN: Operator, slash operator.

DR. HOLAHAN: Yes. I think you do have temp services for therapist, too. So if you brought in a --

CHAIRMAN STITT: Some examples would say "This means you."

MR. AYRES: Yes. We have visiting authorized users.

CHAIRMAN STITT: True.

MR. CAMPER: No longer.

CHAIRMAN STITT: No longer?

MR. CAMPER: Not after the radiopharmacy rule. The term authorized --

CHAIRMAN STITT: They can come in?

MR. CAMPER: Visiting authorized user no longer exists in our regulations after the radiopharmacy rule, which became effective in January. Remember that now they may, the

licensees may, authorize an authorized user provided they have certain board certifications and then subsequently notify us within 30 days of having done so. So the term --

DR. HOLAHAN: So locum tenants would be included under that? Locum tenants would be included that they would just let us know if they are coming in?

MR. CAMPER: As long as they're Board-certified. Now, if they're not Board-certified, they still have to seek an amendment. But you will not find the term "visiting authorized user" in the regulations today.

MR. CAMPER: Oh, okay. Off track.

CHAIRMAN STITT: So that doesn't really relate to the mobile HDR units? Those aren't visiting authorized users. Those are authorized users.

MR. CAMPER: That's right. They're a use. That's correct.

MR. AYRES: Which, by the way, mobile HDR is not in here whatsoever.

CHAIRMAN STITT: That was meant to be off -- not off the record, but -- right. We've had enough difficulties.

MR. AYRES: It was in the -- I guess it wasn't in the cover letter. The reason is we have yet to receive an application for mobile HDR.

MR. CAMPER: Two reasons, actually. That is correct. We have not yet received, although we anticipate

receiving in the near future. But literally today Part 35 prohibits --

MR. AYRES: Yes.

MR. CAMPER: -- licensing of a mobile HDR. If we were going to license one, we would have to grant it by exemption --

MR. AYRES: That's correct.

MR. CAMPER: -- to Part 35. Now, as Bob said, we've never had to do that yet. We did meet with an organization this summer that was going to submit an application. They have not as of yet.

The State of California has a license to mobile HDR; in fact, to this very same organization.

MR. AYRES: Yes. And I understand they're actively advertising at this point. We've been getting a bunch of telephone inquiries in the last couple of weeks about mobile HDR from agreement states, in particular, but also some of our regions.

I understand that also applies -- since it's not authorized, that applies to reciprocity also at this point.

CHAIRMAN STITT: Have there been any misadventures from the California unit yet?

MR. AYRES: One misadministration.

MR. CAMPER: Your comment about reciprocity is correct. One-fifty states that we will recognize under

reciprocity those things which the agreement states have authorized their licensee to do unless it is contrary to our regulations, --

MR. AYRES: Which it currently is.

MR. CAMPER: -- which it currently would be. That's right.

MR. CAMPER: Are we losing you in that regulatory jargon?

CHAIRMAN STITT: I was thinking what I wanted to have for lunch.

MR. AYRES: In other words, right now we have no licensed mobile HDR. And we would not grant it under reciprocity.

CHAIRMAN STITT: That will be a separate subcommittee meeting.

MR. CAMPER: Yes, it will.

CHAIRMAN STITT: "Records," 9.3.

DR. HOLAHAN: It just says you have to keep them.

CHAIRMAN STITT: What?

DR. HOLAHAN: It just says you have to keep them.

MR. AYRES: For three years on your training records.

CHAIRMAN STITT: Training records. All right.

MR. AYRES: That's under 9. So it's training.

CHAIRMAN STITT: Right. Item 10, "Facilities and

Equipment." So 10.1 is really what it looks like?

DR. HOLAHAN: Yes.

CHAIRMAN STITT: Okay. How about 10.1.1 and thereafter?

DR. HOLAHAN: Yes. 10.1 is general. Then you've got either the pulsed or then 10.1.2 is the low-dose rate, which is why it's broken down like that.

CHAIRMAN STITT: Okay.

MR. AYRES: Yes. We treat pulsed, medium, and high the same as far as shielding goes. And there are no mediums. And for biological response reasons, I would not anticipate any.

CHAIRMAN STITT: Are there any comments that you've received about these sections?

MR. AYRES: Not any -- again, across all sections are minor editorial corrections. There was something about monitors. I'm trying to remember.

CHAIRMAN STITT: In the "Monitor" section, are we trying to be inclusive of pulse? It looks like we are.

MR. AYRES: Well, this is the room monitor. Without having had a chance to collate these, if you will, it will be a little tougher.

CHAIRMAN STITT: Under --

MR. AYRES: Oh, I remember. The comment was relating to training and that we needed to explicitly address

the use of surveys meters and room monitors and interpretation thereof under "Training." I knew there was one comment in about that, having it in the wrong section.

CHAIRMAN STITT: There is a separate section, 116, regarding pulse, dose, rate, and devices and more sophisticated alarm system.

Bob Quillen, do you have comments in this section or is it --

MEMBER QUILLEN: No.

CHAIRMAN STITT: It's fairly straightforward. Nobody has -- it probably doesn't have changes in it, in particular, does it, from other past versions or --

MR. AYRES: Yes. It's 10.1.1.4.2 on Page 16 I'm going to have to just clarify a little bit. Most people didn't understand why I "anded" and why I "orred."

MEMBER QUILLEN: Neither did I.

MR. AYRES: That's logical "and," logical "or." Like I said, my electrical engineering background came through there and got everybody.

DR. HOLAHAN: Logical to you, Bob, but not to the non-engineers.

MR. AYRES: I can draw a little integrated circle.

MR. CAMPER: We physicists say you have to keep an eye on those engineers. You've got to watch those guys.

No. We understand what you're saying, Bob.

MR. AYRES: I could do "this," instead of "and" or "or."

CHAIRMAN STITT: That would help a lot.

MR. CAMPER: Surrogate symbols.

DR. HOLAHAN: Let me ask, Bob, because I think I know. I recall this. Do we specifically address that we will not allow portable shields for HDR; correct?

MR. CAMPER: That's correct.

CHAIRMAN STITT: Where is that? Because that's one of the things I was looking for. Is that in this section?

MR. AYRES: Yes. It certainly is.

CHAIRMAN STITT: That's why I was looking --

MR. AYRES: Now you're asking me to find it.

CHAIRMAN STITT: Oh, "Adequacy of Shielding for HDR Devices," I guess. I'm on 19.

DR. HOLAHAN: It should be under the facility diagram, I think.

MR. CAMPER: The facility diagram.

MR. CAMPER: No.

CHAIRMAN STITT: Wait a minute. "For the PDR licensees specify." Well, we all feel that way if we can find it.

MR. AYRES: Low dose rate. "Low-dose rate I explicitly allowed. And that's on Page 10.

DR. HOLAHAN: Ten?

MR. AYRES: Or Page 18, second paragraph down. That's portable or allows it for low-dose rate. Adequacy of Shielding for HDR."

DR. HOLAHAN: I guess because the question has been raised about whether or not it should be allowed for PDR, I think.

MR. CAMPER: It has been raised.

DR. HOLAHAN: Yes.

MR. CAMPER: We have had a technical assistant's request on that.

DR. HOLAHAN: For PDR?

MR. AYRES: Not for PDR. For HDR. And we're treating PDR the same as HDR.

MR. CAMPER: Right.

DR. HOLAHAN: Here we have on Page 20 in terms of for PDR afterloading devices, the licensee should specify the configuration of portable shields, if applicable." That's Item Number 2. But that PDR doesn't address --

MR. CAMPER: But do you know what? I don't think we say under this category entitled "Adequacy of" --

DR. HOLAHAN: Right, that they cannot.

MR. CAMPER: -- that you can't use a portable shield.

CHAIRMAN STITT: Then we need to add it.

MR. CAMPER: Yes, we do. I could have sworn we addressed that someplace.

CHAIRMAN STITT: We certainly talked about it enough.

MR. CAMPER: Maybe I'm recalling the technical assistance response in which we said you couldn't use it for HDR.

MR. AYRES: Oh, I did lie. Under 2 on Page 20, I said, "For PDR" --

DR. HOLAHAN: Yes.

MR. AYRES: -- "afterloading devices, the licensee should specify the configuration of portable shields."

MR. CAMPER: You covered LDR and PDR well. But we haven't --

CHAIRMAN STITT: Well, that might be a place to stick the next number in there and --

DR. HOLAHAN: Put it in that same paragraph?

CHAIRMAN STITT: -- exclude it from HDR as a separate number, I would think.

DR. HOLAHAN: If that's the case, then that second --

MR. AYRES: Well, I could try to just put it as an additional sentence in 2 that portable shields are not allowed in a little --

DR. HOLAHAN: Do you think it's significant enough that it should be called out separately as a separate line item?

CHAIRMAN STITT: How often do you get questions about it?

MR. AYRES: We just don't.

MR. CAMPER: Well, we had had one. We had one technical assistance request that I recall. Is that the only one?

MR. AYRES: Well, we have had one, yes, which we did the TAR on. And then I think there's been a couple since that I just referred the regions to the TAR.

CHAIRMAN STITT: I'd make it a separate number, just make it a single -- you know, if it just needs one or maybe two sentences, but it would be very easy to see as you're running through this.

MR. AYRES: Okay. It's something our license reviewers are very much attuned to.

MR. CAMPER: Correct, but if someone were coming into the world of HDR new as a business venture or whatever, it would be good to know that you can't.

CHAIRMAN STITT: Right. You don't have to even look for it.

DR. HOLAHAN: That would be HDR and MDR, wouldn't it? Would it be HDR and MDR?

MR. AYRES: Yes. For shielding purposes, yes.

DR. HOLAHAN: Okay. But just for PDR, we would allow it.

MR. AYRES: Well, I put that in there. I guess that's on the table.

MR. CAMPER: Well, you have, what, one-tenth of the source strength.

MR. AYRES: Yes.

DR. HOLAHAN: I think, too, with PDR it would be looking at going into where it would be conducted. Would it be necessary to have portable shields or it wouldn't --

MR. AYRES: Well, they clearly -- most of the institutions I'm aware of tend to use PDR a lot like they use LDR.

MR. CAMPER: Absent shielding.

MR. AYRES: Well, except with shielding LDR for --

MR. CAMPER: Oh, they are using?

MR. AYRES: Oh, yes. That --

MR. CAMPER: Portable? Portable shielding?

MR. AYRES: Yes. That one-curie source mandates that. They can't meet the unrestricted area under restricted area limits otherwise unless they don't use adjacent rooms or restrict --

MR. CAMPER: You mean at the boundary of the --

it depends on how big the room is.

MR. AYRES: Yes. They normally do it in -- what the normal situation --

MR. CAMPER: Actually, you're referring to the two mr per hour?

MR. AYRES: Yes.

MR. CAMPER: That's at the boundary of the unrestricted area?

MR. AYRES: Yes.

MR. CAMPER: And all I'm saying is that would be a function of the size of the room.

MR. AYRES: Yes. But what they normally do is roll in a PDR in a standard manual low-dose patient treatment room.

MR. CAMPER: Yes. I understand. I understand what you're saying. I think to get to the crux of your concern, I think your statement in Item 2, your last sentence, I think you've captured it well, "For PDR afterloading devices, the licensee should specify the configuration of portable shields, if applicable, used for each set of calculations." It seems pretty --

MR. AYRES: The tendency I see with the people who want to use portable shields for HDR are those who try to put them in --

MR. CAMPER: Nonexisting --

MR. AYRES: -- an orthotherapy --

MR. CAMPER: Right. That's right.

MR. AYRES: -- room or simulator room.

MR. CAMPER: That's right.

CHAIRMAN STITT: Or to turn a room that really isn't adequate into something that will pass.

MR. AYRES: Yes.

CHAIRMAN STITT: All right. In another --

MR. CAMPER: It is typically in a transition, too, that they're wanting to do that.

MR. AYRES: Well, the one I did the TAR one, they wanted to do it permanently.

MR. CAMPER: That's right. they wanted to mount it in the floor. That's right. They wanted to use a portable shield and mount it in the floor.

MR. AYRES: And one hanging over the patient.

MR. CAMPER: That's right.

DR. HOLAHAN: Now there's a pretty scary thought.

CHAIRMAN STITT: Other comments on the section that we're working on, "Shielding"?

MR. AYRES: Here I thought I had addressed that, and it isn't explicit.

CHAIRMAN STITT: That's why we have these meetings.

MR. AYRES: That's right.

CHAIRMAN STITT: Bob Quillen, anything here?

MEMBER QUILLEN: No. The only item I had was on Page 20. And it was Item 4, on "Calculations to determine the dose." This is both HDR and PDR. And with PDR you'll have to explain to me how often, on what periodicity, I should say, these things operate? Which do you have them on, how many hours per day, or --

CHAIRMAN STITT: Well, several minutes an hour.

MEMBER QUILLEN: Several minutes an --

MR. AYRES: To upwards of an half an hour out of an hour.

MEMBER QUILLEN: Half an hour of an hour over what period? All day long?

MR. AYRES: For three days, three-four days.

MEMBER QUILLEN: Three or four days. If you use a continuance occupancy factor of one, you would be doing a calculation based upon a total day's exposure, then, as if somebody was there 24 hours a day.

MR. AYRES: Which a patient in an adjacent room may be.

MEMBER QUILLEN: Well, but for a worker probably is not going to be.

MR. CAMPER: It wouldn't be, would not be.

MEMBER QUILLEN: They would not be.

MR. CAMPER: If you have someone sitting at a

desk or standing in one place all the time.

MEMBER QUILLEN: Well, I would say continuance occupancy factor of one would be based upon somebody who is not an occupational worker, not a worker in the petroleum. You're making a possible worst-case scenario for a facility where --

MR. AYRES: Well, this is unrestricted areas where we're considering the public.

MEMBER QUILLEN: I know.

CHAIRMAN STITT: And I think he --

MR. CAMPER: Yes. But you still should use a realistic occupancy factor.

MR. AYRES: Well, we said --

MR. CAMPER: That's what you were saying. Right, Bob?

MEMBER QUILLEN: Yes. I think this is for one case it's reasonable. In one case it's not reasonable.

DR. HOLAHAN: But I think the argument --

MR. AYRES: We say we will accept less, but you've got to at least show us it's reasonable. And if you don't want to actually demonstrate what the occupancy factor is, then one is a conservative way to go.

MR. CAMPER: No question.

MEMBER QUILLEN: Yes. But you use the term "compelling."

MR. AYRES: Well, "compelling" might be --

DR. HOLAHAN: I think we have --

MR. CAMPER: The fact that we have someone in that station 25 percent of the time and using a quarter occupancy in and of itself is legitimate rationale.

MR. AYRES: Yes, yes.

MR. CAMPER: I don't know if that's compelling or not, but it's legitimate.

DR. HOLAHAN: But I think it depends on what the unrestricted area is because, again, as Bob said, if it's a patient room next door, then you may well have a patient in there full time.

Also in some cases we've had licensees come back and tell us, "Well, it's just a stairwell in there" or something.

And we say, "Yes. But just make sure. How are you going to verify?" And there have been some cases where you've got people residing --

CHAIRMAN STITT: In the stairwell?

DR. HOLAHAN: Well, or in a closet or things, homeless.

CHAIRMAN STITT: Only in D.C.

MEMBER QUILLEN: If I were writing this, I would have said, "should consider an occupancy, a factor appropriate for the use of the adjacent area."

MR. CAMPER: I think that makes sense, Bob. I mean, that principle holds true whether you're developing, designing an X-ray suite or a therapy suite. I mean, that's a truism. Use the occupancy factor that is appropriate and design your shielding and your distance accordingly.

DR. HOLAHAN: But that also means you need to tell us what the adjacent areas area.

MR. CAMPER: Sure. That's --

CHAIRMAN STITT: And explain it.

MR. CAMPER: And explain it.

MR. AYRES: I think it should stay in there, though. Absent any information, it will be presumed to be one. I mean, all I'm saying is that one is the default valve.

MR. CAMPER: Well, wait a second. If you put some words in like Bob is suggesting, Bob Quillen is suggesting, say "Calculations to determine the dose received by individuals present in unrestricted areas should consider occupancy factors appropriate to or consistent with the actual use of the actual presence in adjacent areas."

DR. HOLAHAN: "Possible use."

MR. CAMPER: In the case of a patient in an adjacent room, the occupancy factor would be assumed to be one.

MEMBER QUILLEN: Yes. You can put that in. I mean, that's --

MR. CAMPER: See, the way you've got it now, it really leads them with a bridle on to one. And that's a little strong.

MR. AYRES: Yes.

MR. CAMPER: I understand your conservatism. And that's a legitimate concern. But I think that if you capture words such as Bob was suggesting and then call out the point that if it's a patient --

MR. AYRES: All I want to do is -- you know, I think, yes, it needs to be changed and say, you know, "Provide us the information. But absent the information, we will assume one."

MR. CAMPER: Well, you could say that specifically.

MR. AYRES: Yes, yes.

MR. CAMPER: Okay.

MEMBER QUILLEN: That was my only comment on Page 20.

MR. CAMPER: But let me just give you the argument to that. One could argue that, "Absent that information, you should ask."

MR. AYRES: Well, if they want to take the most conservative number, why ask?

MR. CAMPER: No. We would be taking the most conservative number.

MR. AYRES: Right.

MR. CAMPER: the way you structure that comment, we would be taking --

MR. AYRES: Right.

MR. CAMPER: "If you don't give it to us, we will assume one."

MR. AYRES: Yes. Well, why should we ask if they don't want to provide it and just presume one or they just presume one themselves?

MR. CAMPER: I'm just saying there are two ways you can -- two ways we could take that. One would be if it's not specified, you could specifically ask so that you would be getting the best data possible or you can take the conservative approach, "We will assume one."

MR. AYRES: Yes.

MR. CAMPER: And as long as we alert them to that, I mean, that's reasonable.

MR. AYRES: Well, actually we shouldn't have to alert them because that should be in their calculations. They've got to presume an occupancy factor in the calculations or --

MR. CAMPER: Well, again, I think if we structure it the way --

MR. AYRES: Okay. Yes. I'll revisit that one. It needs a little --

MR. CAMPER: It should work.

DR. HOLAHAN: You should also maybe indicate that they should -- remind them to describe what the adjacent areas are.

MR. AYRES: Yes.

MR. CAMPER: Are we clear about that point in the facility diagram?

MEMBER QUILLEN: Yes, you are.

DR. HOLAHAN: Are we?

MR. AYRES: One of the problems that assuming one takes care of and using a specific value doesn't if the use of the room changes. Then one would need to put some language in here that they will have to amend their licensee with new calculations if the room usage changes; in other words, they convert the room from a treatment planning room to a patient room or whatever.

MR. CAMPER: I had a comment now that we've gotten back into that section. Under 10.1.2.1, "Facility Diagram," we have a sentence there which I know why you have it in there, but I must tell you it's a little troubling as I read it. It says, "The patient room should be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care."

DR. HOLAHAN: I think we also said that in the --

MR. CAMPER: Well, what bails us out of that

sentence is "as is consistent with good medical care." In other words, I could readily see why one would want to develop a room in which it was very close to a nursing station because of the fact that this procedure is ongoing for a long period of time and you want to be able to have good monitoring.

The reason you've done this, of course, is because of exposure rate. But, you know, you can design to exposure rate. Page 18.

MR. AYRES: Yes.

DR. HOLAHAN: We use that same language in the manual, "brachytherapy module," as well, basically to --

CHAIRMAN STITT: Which module?

DR. HOLAHAN: Manual brachytherapy, one we'll discuss tomorrow.

CHAIRMAN STITT: And this was the fire language. Is that right? Is that somewhere?

MR. CAMPER: I mean, couldn't you modify? Instead of saying that the room should be as far away from the nursing station, couldn't you say something along the lines of "The room should" -- let me give you the thought. The room that is used should be consistent with providing good medical care while considering a means to reduce the exposure.

MEMBER QUILLEN: It uses its own ALARA concept, basically.

DR. HOLAHAN: Yes. It's the ALARA

considerations. And I think that --

MEMBER QUILLEN: You've got good medical care and ALARA combined. And you have to balance the two.

DR. HOLAHAN: Right.

CHAIRMAN STITT: So maybe you should make that statement, instead of saying --

MR. CAMPER: That's what I -- well, yes, but --

CHAIRMAN STITT: -- where the room should be located.

MR. CAMPER: That's right. I mean, the idea of saying the room should be --

CHAIRMAN STITT: Just say put it where.

MR. CAMPER: -- far away from the nursing station is a little troubling.

CHAIRMAN STITT: Yes.

MR. CAMPER: You should say that the placement of the patient room should bear in mind principles of ALARA and good medical care.

CHAIRMAN STITT: I've actually worked in institutions where they were right next to the nursing station --

MR. CAMPER: Absolutely.

CHAIRMAN STITT: -- for that very reason.

MR. CAMPER: Absolutely. You design it accordingly. That's what lead in the wall is for.

DR. HOLAHAN: Currently in the --

MR. CAMPER: There are Pb-lined glass windows and so forth.

DR. HOLAHAN: That language came out of Appendix R of the existing Reg. Guide 10.8.

MR. AYRES: Yes.

DR. HOLAHAN: It says, "The patient's room will be as far away from the nursing station and heavy traffic hallways as consistent. It will be a private room unless the dose rate at one meter meets requirements in 20.105(a) and" --

MR. CAMPER: Well, I understand.

DR. HOLAHAN: Okay.

MR. CAMPER: And I still have the same problem with it as a matter of principle, though. I'm not saying it's poor, inadequate. I'm just saying there's a better way to say it.

I mean, what you're really getting at is what Bob is raising. It's really about ALARA and at the same time good medical care. And you place your room with those things in mind or you design your room accordingly.

DR. HOLAHAN: So you're saying to revise it to say something about it should be located to take into consideration both ALARA considerations and good medical care. The problem is then people come back and say, "Okay. What do you mean?"

MEMBER QUILLEN: That's their problem.

DR. HOLAHAN: They can figure it out; right?

MR. CAMPER: I think health physicists understand. Physicists understand that concept.

DR. HOLAHAN: You're assuming again that everybody has a physicist on staff.

CHAIRMAN STITT: This is pretty high level stuff. I mean, they're either going to have a good contractor or they're going to have a physicist on the staff. I don't think it's the same as talking to the housekeeping people.

DR. HOLAHAN: Okay.

MEMBER QUILLEN: No.

CHAIRMAN STITT: He says it's not. I mean, here you're saying it should be far away. I think you should not tell them where it should be but tell them that the issues you're dealing with are ALARA and medical care and let them figure out where it should be because it's going to be different in different facilities.

MR. CAMPER: See, actually you have three things. You have ALARA, good medical care. You have exposure limits, the boundary of unrestricted areas. I mean, those are the three things you've got to consider.

CHAIRMAN STITT: I want to make you folks work through the end of the item that we're on. So --

MR. CAMPER: What a taskmaster.

CHAIRMAN STITT: I know. Well, I was trying to figure out if we could get through Item 11, but I don't think it's going to work.

MR. AYRES: We don't have very -- short trip, short trip.

DR. HOLAHAN: Item 11 is pretty much all left, that is left.

MR. AYRES: It's huge.

DR. HOLAHAN: Item 11 is the rest of it. Okay?

CHAIRMAN STITT: Well, you can't go to 11 until you finish what we're working on.

DR. HOLAHAN: Item 10.

CHAIRMAN STITT: So just tighten those sphincters. I shouldn't say these things. I need to practice. All right.

MEMBER QUILLEN: Can I just ask a question for clarification? Because on top of Page 18, the first line there, my copy is such that I can't read. It says "general information." Then the next word I can't read.

CHAIRMAN STITT: Mine says "described previously."

MR. CAMPER: We did that on your copy on purpose, Bob.

DR. HOLAHAN: What? Wait a minute. What? Can you start with the beginning of the sentence because I think I

--

MEMBER QUILLEN: "In addition to the general information."

MR. AYRES: "In addition to the general" -- it's on Page 17 on my copy.

DR. HOLAHAN: Okay. Thank you.

MR. AYRES: "Described previously in this guide."

MEMBER QUILLEN: "Described." Okay.

DR. HOLAHAN: Okay.

MR. CAMPER: Just as a matter of record, you and Bob are working from a different copy than we are?

DR. HOLAHAN: I just put it straight up. And I think it's the difference in the type that was done. Yours is somewhat smaller type.

MR. AYRES: Yes, yes.

DR. HOLAHAN: And I don't know how it came out differently, but it did.

MR. AYRES: Yes. I just printed a fresh one, too.

DR. HOLAHAN: It's only shifted by a line or two, but it's enough that we're scurrying every time you --

MR. AYRES: Well, I have a copy of that. I sometimes go back to those.

DR. HOLAHAN: Yes. OGC's comments are the --

MR. AYRES: Yes. We have, it looks like, 10 and

12-point pitch type.

DR. HOLAHAN: Yes. Okay.

MEMBER QUILLEN: Well, going back to that paragraph, then --

CHAIRMAN STITT: We're under "Facility Diagram." Is that correct?

MEMBER QUILLEN: "Facility Diagram."

CHAIRMAN STITT: 10.1.2.1.

MEMBER QUILLEN: "In addition to the general information described previously in this guide, provide a description of any additional shielding of proposed patient rooms used for implant therapy." What does that have to do with facility diagram? It has to do with additional shielding requirements. Isn't it?

CHAIRMAN STITT: Does that refer to temporary shields?

MEMBER QUILLEN: And then you go to "consistent with good medical care," which is really -- the paragraph heading doesn't describe what's in your paragraph is what I'm saying.

DR. HOLAHAN: Well, except the facility -- your location of your patient room -- again changing it in light of what we just discussed with the ALARA and the good medical care, that is part of the facility diagram where you can actually locate it.

And then I think your shielding would be part of your facility diagram. You're using additional shielding.

MEMBER QUILLEN: Well, it talks about portable shields, too.

DR. HOLAHAN: But those would also be part of what you're using in your facility to comply with --

MR. AYRES: If your permanent shielding isn't adequate from your facility diagram, you're going to have to address that issue.

MEMBER QUILLEN: I just found the paragraph heading to be not descriptive of what information you were searching for in the paragraph.

MR. AYRES: Okay.

DR. HOLAHAN: Oh, okay. Well, yes because, actually, 10.1 is entitled "Facility Diagram," too. And this is like a subheading of a subheading.

MR. AYRES: This is specific to low-dose rate devices.

DR. HOLAHAN: Yes, but on Page 13, the overall topic is "Facility Diagram."

MR. AYRES: Yes.

DR. HOLAHAN: Then we go into HDRs. Then we go into LDR. So I think we need to --

MR. AYRES: Yes. Okay. I see. It needs to be reexamined.

CHAIRMAN STITT: Or retitled. Is she complaining?

DR. HOLAHAN: No. She was just asking where.

MR. CAMPER: Simon Legree has us moving to this part.

CHAIRMAN STITT: All right. So we like what it says, but we'd like to call it something else?

DR. HOLAHAN: We'd like to call it something different.

CHAIRMAN STITT: Would that be right, Bob?

MEMBER QUILLEN: Yes.

CHAIRMAN STITT: Okay. It's not the content as much as --

MEMBER QUILLEN: Yes. It's not the content. The content just doesn't follow the --

MR. CAMPER: Right, right.

MR. AYRES: I'll play with that.

CHAIRMAN STITT: So we'll find some other way to describe that.

All right. "Viewing and Intercom Systems," "Warning Systems and Access Control."

DR. HOLAHAN: How about "Diagrams"? That's what it's called under the HDR section.

CHAIRMAN STITT: What's it called?

DR. HOLAHAN: "Diagrams."

CHAIRMAN STITT: That's what it is. You're asking for diagrams in Paragraph 1 and 2.

MR. AYRES: Okay. So noted.

CHAIRMAN STITT: How about "Viewing and Intercom Systems" as well as "Warning Systems and Access Control"?

MR. CAMPER: Again, we're only under LDR here.

CHAIRMAN STITT: Remote LDR. Is that right?

MR. AYRES: Yes, remote afterloading.

DR. HOLAHAN: Yes.

CHAIRMAN STITT: Right.

DR. HOLAHAN: Manual will be dealt with tomorrow.

CHAIRMAN STITT: Okay. There's no issue on remote low-dose rate that comes up in the high-dose rate regarding moving the devices? Is that correct? Are we happier with relocating LDR devices than we are with relocating HDR devices?

MR. AYRES: Right. Just recently I've addressed this issue with some guidance to the regions. And our current position as set forth in that is you can't move them. We grandfathered those that we're permitted to.

CHAIRMAN STITT: LDRs we're talking about?

MR. AYRES: HDRs.

CHAIRMAN STITT: HDRs. All right.

MR. AYRES: But we won't consider it unless the devices meet the new requirements for transportability for

future licenses.

CHAIRMAN STITT: But LDRs, that's not one of the issues that --

MR. AYRES: Not one of the issues.

CHAIRMAN STITT: So this is all looking fine. How about in the last paragraph on 18, "Warning Systems and Access Control," specifically in regards to relocating? Everybody's happy with that?

I'm not questioning. I just want to discuss it.

DR. HOLAHAN: Right.

MR. AYRES: Yes. The only special thing in there is when they move it, they reconnect whatever interlock protective systems they have, they be tested before they begin treatment.

MR. CAMPER: Bob, a question for you.

MR. AYRES: Yes?

MR. CAMPER: Bob Ayres, on Page 19, under 10.2, "Survey Instruments," is this clearing up that confusion that exists on 35?

MR. AYRES: No. This goes with the existing requirements because this is LDR.

DR. HOLAHAN: Well, actually, no. The survey instruments, that's just what you must have. And that goes back to 420. That's not use of survey instruments. Isn't that under operating procedures?

MR. AYRES: Yes. See, this requires both here. It says you've got to have both of them.

DR. HOLAHAN: Okay. This is a --

MR. AYRES: That's just reiterating, if you will, 35.420.

MR. CAMPER: No, no. How do you get to both of them? Where do you see that?

DR. HOLAHAN: Because 420 --

MR. AYRES: "Licensee shall confirm the possession and availability of a portable radiation detection survey instrument and a portable radiation measurement survey instrument." That's both of them.

DR. HOLAHAN: It's under operating procedure is the question you're asking?

MR. CAMPER: What's the national dose rate from the LDR?

MR. AYRES: Same as conventional low dose. What? Twenty r per hour or something like that?

MR. CAMPER: Why do you want somebody to have a survey measurement instrument capable of a range up to 1,000 millirem per hour?

DR. HOLAHAN: Because 420 --

MR. AYRES: Well, I didn't see any particular reason in granting any -- I mean, that's what's required for conventional manual afterloading brachytherapy and --

MR. CAMPER: Well, that's true. I mean, that's a regulation problem.

MR. AYRES: That's a regulation problem.

DR. HOLAHAN: Section 10.2 applies to both HDR and LDR remote afterloaders, that section you're reading on survey instruments.

MR. AYRES: Yes, it does. It's now out of --

DR. HOLAHAN: Now, I'll switch from --

MR. CAMPER: No.

DR. HOLAHAN: No.

MR. AYRES: Yes, it does.

DR. HOLAHAN: It dropped from 10.1. Anything with a 10.1.2 addresses low-dose rate.

MR. AYRES: Yes.

DR. HOLAHAN: Then once you get to 10.2, you're into a new section.

MR. AYRES: Yes. You can keep track of things better by always referring to the indented.

MR. CAMPER: I see. Well, that's not easy to follow.

MR. AYRES: Well, that's the structure of the document.

DR. HOLAHAN: That's the structure of the way the Reg. Guide is written, and all Reg. Guides are written into --

MR. CAMPER: Yes, yes. Okay. I see what the

problem is. Also, frankly, 35.420 as currently written could be improved.

DR. HOLAHAN: Correct.

MR. AYRES: Right.

DR. HOLAHAN: Hopefully we can deal with that as we revise Part 35.

MR. CAMPER: Yes. Okay. I see the problem. Okay.

MR. AYRES: If you promise to sit on OGC, I'll approve it.

MEMBER QUILLEN: I'll just for the record make a comment that when we adopted our version of Part 35, that medical physics consultants came to me and said, "Look, there's no good one instrument that will do this."

So what we wrote our regulation to say is, "You will have survey capability between these two ranges. And I don't care whether you use one instrument or two instruments or three instruments."

MR. CAMPER: You're saying to go from .1 to 1,000?

MEMBER QUILLEN: Yes.

MR. AYRES: I understand there are instruments available now that will cover that range.

MEMBER QUILLEN: Well, that's what the manufacturer is saying. People who practice in the field say

no.

MR. AYRES: Maybe.

MR. CAMPER: Okay.

CHAIRMAN STITT: All right. Any other comments on this? We're winding up through this section here? Bob Quillen, other things you have to comment on?

MEMBER QUILLEN: No. I think I've made all my comments.

MR. AYRES: One little sneaky thing I put in here just looking ahead, just a comment the reason of it, on Page 20, on Item 5, I put "units of rem or millisieverts." The reason for that is at least in Russia and maybe some other places in Europe and maybe -- I'm unaware of in the U.S., but there are some RAL procedures, at least being used and investigated using neutron sources; in particular, Californium 252. So I was just anticipating.

MR. CAMPER: Bob, I noticed here on Page 21 -- and you may have done this. I just haven't thought about it before now. In Item 6(b), where we're saying a "dose within 0.5 rem (5 millisieverts)," have we used English and standard international units throughout? I would double-check that, but --

MR. AYRES: I tried to.

MR. CAMPER: Okay.

MEMBER QUILLEN: That's an editorial --

MR. CAMPER: As we move towards complete implementation of our metrification program, we should make sure we're doing that. And perhaps you have. It's just a thought.

MR. AYRES: I think the latest comments I got from our tech editor is -- I may need to change this. Anyway I think now we've done the switch and metric goes first.

DR. HOLAHAN: Yes.

MR. CAMPER: I thought it was the other way around.

MR. AYRES: Well, it used to be. I think it's now we've -- I'll check that.

DR. HOLAHAN: It's -- yes.

MR. CAMPER: Okay. Whatever is consistent with the agency policy.

DR. HOLAHAN: The only point that I just wanted to make quickly -- and I just wanted to raise it on the table -- is on Page 19 under "Security of RAL Devices," one of the questions that has been posed to me when I have been talking to individuals is: For security of the device, if you shut it off with the keys and everything else, there does -- how far away does an individual have to be to take the key with them? And what is unattended? And I don't know. Do we need to spell that out any further?

Because there's been a question, "Look, I've done

all my warm-up and everything else, and I'm going off to do this. But I don't want to shut the whole unit down to take the keys out."

CHAIRMAN STITT: What are the possible actions that would be acceptable or not acceptable?

DR. HOLAHAN: I don't know. I just wanted to raise it because it --

MR. CAMPER: Why would I not want to take the key with me if it was unattended?

DR. HOLAHAN: Because I'm only going down the hall to my office.

CHAIRMAN STITT: Maybe it depends on what unattended means.

MR. AYRES: Well, device is --

DR. HOLAHAN: Well, I guess that's --

MR. CAMPER: Still, at that point it is unattended. It is not being monitored. It is not in use.

CHAIRMAN STITT: But you've just done your warm-up procedures?

DR. HOLAHAN: You've done your warm-up procedures. You've done your dosimetry. The patient isn't there -- or no. You haven't done your dosimetry. You've done your warm-up procedures and everything else.

The patient isn't there yet. You're leaving it for 20 minutes until the patient gets there. But you don't

want to sit and watch it, sit beside it while you're waiting for that patient to come down.

MR. AYRES: My personal reply to that would be if I were asked that question, "Well, okay. Make the access door to the treatment facility lockable and that be locked." Then the keys are not accessible. The console key is not accessible.

MR. CAMPER: That's not a healthy situation to have. It's just not.

DR. HOLAHAN: Okay. I'm just raising it because the question has been raised, and I just wanted to put it on the table to see if there is, you know --

MR. AYRES: That's done. You know, it's not locked during treatment, of course, but if you had your door to your treatment room lockable, then you could leave the device in and power it up because you've --

DR. HOLAHAN: But the console is outside. So it's not.

CHAIRMAN STITT: Consoles aren't necessarily in secured areas.

DR. HOLAHAN: Right.

MR. AYRES: Right.

CHAIRMAN STITT: The machines are, but the consoles aren't.

MR. AYRES: But if the source was under a locked

shield, which we would by locking the treatment room door, somebody runs out, so what, I mean?

MEMBER QUILLEN: Well, there's another thing you could put in here. You could say it's not in use or is unattended and not under observation because sometimes when you mean attended, you mean somebody is standing there. In other cases something's unattended, but it's under observation.

MR. CAMPER: Right.

MR. AYRES: Again, it's a bit of a definition thing, I guess, you know.

MR. CAMPER: Well, you could, but you could put an "i.e." after "unattended." Where it says "unattended," there is not not under observation -- or you could say "not being directly observed" or something to that effect.

MEMBER QUILLEN: We've come into this same question with linear accelerators, where they say, "Look, there's nobody standing at the control panel."

MR. CAMPER: Yes. "We're fired up, keeping warmed up."

MEMBER QUILLEN: "And we're going to keep it on," but it's under observation.

CHAIRMAN STITT: That's acceptable.

MEMBER QUILLEN: Yes.

CHAIRMAN STITT: I think we ought to be specific

because this is a common, ordinary household problem. Not in use or unattended. You can read it to mean "It's Tuesday. We don't do these procedures on Tuesdays." Yet, that's different than "We've got it warmed up. We're waiting for the patient." It's not in use, but it would still be under observation.

MR. CAMPER: Well, you see --

CHAIRMAN STITT: Do you want to --

MR. CAMPER: See, someone might argue "If I'm warming it up, it is, in fact, in use."

MR. AYRES: Yes. That's a legitimate argument.

MR. CAMPER: There are different types of in use.

MR. AYRES: Yes.

MR. CAMPER: Irradiating the patient. That's another type of in use. I'm preparing it for irradiation. That's also.

MR. AYRES: The observation is one method of ensuring the console keys are inaccessible to authorized persons.

DR. HOLAHAN: Unauthorized persons.

MR. CAMPER: Unauthorized, right.

MR. AYRES: That's what I said, "unauthorized persons."

CHAIRMAN STITT: What's the circumstance where a patient has got an applicator in place, films have been done, the nurse is in the room with the patient, the console is

outside, and then the team that's just taken the films and done the planning has gone off to the --

MR. AYRES: Then they had better take the keys with them.

DR. HOLAHAN: They can't.

MR. CAMPER: No, they can't.

CHAIRMAN STITT: But that would fit this definition of not --

MR. CAMPER: That's right.

DR. HOLAHAN: Not attended.

MR. CAMPER: So under that circumstance you would want it to be under observation.

MR. AYRES: Yes.

CHAIRMAN STITT: Because it would be under observation is a --

MR. AYRES: You're really self-explanatory. That's one method of assuring that the keys are inaccessible to unauthorized persons. One method is that whenever the keys are in the console, they're under constant observation. The console is under constant observation. That's a method.

CHAIRMAN STITT: There are a lot of fine points when it comes down to how you really clinically use these things people are either going to achieve or not achieve depending on how you use this and also what your intent is.

When I read that, my mind thought "Oh, this is

when the machine is not being used at all."

MR. AYRES: Well, that's certainly included, yes.

CHAIRMAN STITT: Well, that's easy. That means they shouldn't be in the --

DR. HOLAHAN: They shouldn't be.

CHAIRMAN STITT: Like in the copier. The keys to the copier are always in the door by the copier. But that's a black and white. And I think the operating circumstance is the gray. And that's a lot more common. Well, it's a problem area. And you could get partly through that if you used observation.

MR. AYRES: Yes. I don't think things like this should be too specific because there are a lot of ways --

MR. CAMPER: Furthermore, the keys should always be inaccessible to unauthorized individuals.

MR. AYRES: Well, of course.

MR. CAMPER: Always. Maybe the sentence --

MR. AYRES: Well, this is presuming that they're inaccessible when you're actually operating the machine because you're going to fight them.

MR. CAMPER: Well, what I'm trying to say is --

DR. HOLAHAN: Just say "This should include the methods for use to ensure that the console keys will be inaccessible to unauthorized persons."

MR. CAMPER: That's right.

MEMBER QUILLEN: That's your goal, yes.
MR. CAMPER: That's the goal right there.
DR. HOLAHAN: And just take out that --
MR. CAMPER: Yes. I thought about --
DR. HOLAHAN: -- parenthetical phrase.
MR. AYRES: Yes.
MR. CAMPER: Yes, yes. I mean, that's the goal. You want the keys to make --
DR. HOLAHAN: You don't want somebody who shouldn't have the keys wandering around the hospital with them.
CHAIRMAN STITT: Right.
MR. CAMPER: Right.
DR. HOLAHAN: Because whether it's in use or unattended or not, they shouldn't have them.
CHAIRMAN STITT: Right. And we're making it simpler, instead of more complicated. Is everybody else happy with that?
MR. CAMPER: Yes. I think that will work.
CHAIRMAN STITT: Okay. We're talking about "Adequacy of Shielding for HDR and PDR Devices."
MR. AYRES: Yes.
CHAIRMAN STITT: We've been through that.
MR. AYRES: Yes, we've been through that.
CHAIRMAN STITT: I knew that looked familiar.

MEMBER QUILLEN: One last comment on Page 18. The last sentence on Page 18, at least my Page 18, which ends in "should be described," I had to read that sentence three times to understand it because of where the verb is placed.

DR. HOLAHAN: But saying "Describe restricted area controls."

MEMBER QUILLEN: Yes.

DR. HOLAHAN: "Describe your restricted area controls."

MEMBER QUILLEN: Right.

DR. HOLAHAN: Make it "active."

CHAIRMAN STITT: You'd make a good journal referee.

MR. CAMPER: Mrs. Earl would be proud of you.

CHAIRMAN STITT: Very good.

MEMBER QUILLEN: You don't want to get the people frustrated when they read something like that.

CHAIRMAN STITT: That's true. Absolutely.

MEMBER QUILLEN: They get frustrated because "What do these people want me to do? I don't" --

CHAIRMAN STITT: Start with an --

MEMBER QUILLEN: -- "understand what they want me to do."

CHAIRMAN STITT: People are happy. Right. "Here's what you're supposed to do." All right. So we like a

shielding section. That's 10.6. Have we been through all of 10.6 that we need to discuss, including the words on Page 21? Got anything on your page? No?

MEMBER QUILLEN: No. I'm ready for 11.

CHAIRMAN STITT: Okay. Bob Ayres, are you ready for 11 or lunch, whichever comes first?

MR. AYRES: Lunch.

CHAIRMAN STITT: Folks to my left?

MR. CAMPER: Lunch.

CHAIRMAN STITT: Okay. Good. Can we be back at 1:00?

(Whereupon, a luncheon recess was taken at 12:19 p.m.)

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

(1:16 p.m.)

MS. MERCHANT: Okay. We're back on the record.

CHAIRPERSON STITT: All right. Page 21, item 11. I believe all we have left is item 11, is that correct?

MS. HOLAHAN: Well, there's a small 12.

MR. AYRES: Very small.

MS. HOLAHAN: Yes.

CHAIRPERSON STITT: But half of the document is yet to go. So radiation safety program, leak tests, a lot of blue lining over here. Why don't we have you lead off here?

MEMBER QUILLEN: Well, the only comment I had was on the next page there.

CHAIRPERSON STITT: Okay.

MEMBER QUILLEN: On page 22, that refers to Appendix L that I didn't have, so I couldn't review that.

MR. AYRES: That refers to Reg. Guide 10.8, which is a leak test procedure, and I don't know if that's getting any change or not.

MEMBER QUILLEN: It says here it's personnel external exposure program.

MS. HOLAHAN: Oh, you're on personnel monitoring.

MR. AYRES: Oh, I was reading -- okay. It's the same thing.

MS. HOLAHAN: Currently, there have been no

changes made to those, but I think that's something that we were going to look at and see if there were changes that need to be made.

MR. AYRES: Yeah.

MS. HOLAHAN: But they are the appendices from the existing Reg. Guide 10.8, as it stands today.

MR. AYRES: This is written with -- in view of the fact that this will be one chapter in that Reg. Guide, so --

MEMBER QUILLEN: Okay. It talks about calibration pocket dosimeters also, and I have yet to see a pocket dosimeter that could be calibrated. I can see where you can shut the calibration on it, but I can't see how you could calibrate one.

CHAIRPERSON STITT: So you're suggesting that calibration ought to come out of that sentence, procedures?

MEMBER QUILLEN: All I'm doing is -- frequency for calibration checking of pocket dosimeters.

CHAIRPERSON STITT: Does anybody have 20.1501(b)?

MS. HOLAHAN: Yes.

CHAIRPERSON STITT: Does it talk about calibration of pocket dosimeters? I don't --

MS. HOLAHAN: 1501 was it?

MEMBER QUILLEN: 1501(b).

MS. HOLAHAN: Okay. 1501(b) says, "The licensee

shall ensure that instruments and equipment used for quantitative radiation measurements are calibrated periodically for the radiation measured."

MR. AYRES: Yeah. What this --

MS. HOLAHAN: And (c) is all personnel dosimeters.

MR. AYRES: Right. What this sentence, just covers that eventuality. If you use pocket dosimeters to monitor personnel exposure, not that -- that's when you've got to calibrate them. And so if you can't calibrate them, you can't use them for that purpose. So this covers that --

CHAIRPERSON STITT: What comments do you have?

MEMBER QUILLEN: Well, I've never seen a pocket dosimeter that you could calibrate. You can check the calibration on it, but you certainly can't calibrate.

MR. AYRES: But then, have you seen these dosimeters used in lieu of film badges, for example?

MEMBER QUILLEN: Well, I haven't been in practice for a long time, but at one time, yes.

CHAIRPERSON STITT: Yeah, I have, too.

MEMBER QUILLEN: Many years ago.

(Laughter.)

MR. AYRES: Yeah, it's a back-handed exclusionary statement, I guess. It says if you can't calibrate them, you can't use them for this purpose.

MEMBER QUILLEN: Okay.

CHAIRPERSON STITT: Are you going to let it go, or do you want to -- you want "calibration" taken out of there?

MEMBER QUILLEN: I'd just --

MR. AYRES: I might -- one suggestion. As the primary means of monitoring personnel exposures.

MEMBER QUILLEN: Where would you put that in?

MR. AYRES: If you use pocket dosimeters to monitor and change to monitor as the primary means of monitoring personnel exposures.

MEMBER QUILLEN: Yes, I can understand that. That would help.

CHAIRPERSON STITT: Would it still be okay to say "frequency for calibration and maintenance, as required"?

MR. AYRES: Primary method, then.

CHAIRPERSON STITT: The next sentence.

MS. HOLAHAN: What was your first fix, Bob?

MR. AYRES: What?

MS. HOLAHAN: What was your first fix?

MR. AYRES: Well, that was it. It was --

MS. HOLAHAN: I missed it.

MR. AYRES: If you use a pocket dosimeter as the primary method of monitoring personnel exposures.

MS. HOLAHAN: Okay.

MEMBER QUILLEN: What are you doing about electronic dosimeters?

MR. AYRES: How about either use pocket or electronic?

MEMBER QUILLEN: Okay.

MS. HOLAHAN: So do you think that's still a problem, having it in as -- having "calibration" in there?

MEMBER QUILLEN: Well, I would take --

MS. HOLAHAN: Or are we taking "calibration" out now?

MEMBER QUILLEN: I'd take "a pocket" because now you've added electronics, so I'd say "such dosimeters," or whatever.

MR. AYRES: Just if you use electronic dosimeters?

MEMBER QUILLEN: Yes.

MR. AYRES: Okay.

MS. HOLAHAN: Okay.

MEMBER QUILLEN: That's --

MS. HOLAHAN: If you use electronic dosimeters, okay.

MR. AYRES: As the primary method of --

MS. HOLAHAN: It should provide the useful range and procedure --

MR. AYRES: -- monitoring personnel exposures.

MS. HOLAHAN: Okay. By the way, just as a correction, I just as I was looking it up, it's Appendix D, not Appendix L that is the personnel monitoring. That was just a --

MR. AYRES: Oh. Changed L to D?

MS. HOLAHAN: Change L to D.

MEMBER QUILLEN: Okay. That's the only comment I had on that page.

CHAIRPERSON STITT: Any other comments? Bob Ayres?

MR. AYRES: No.

CHAIRPERSON STITT: Okay. Implant source record and inventory, 11.14. This looks very straightforward. I don't --

MEMBER QUILLEN: One of the things that I thought would be helpful in here, and a lot of my highlights refers to records that you're supposed to keep, as if you had some place where there was a summary of all of the records that you had to keep.

CHAIRPERSON STITT: That's a good point, where it just lists --

MR. AYRES: Yeah. We actually generated a document, but now the NUREG -- I think it was the NUREG that listed all of the recordkeeper environments throughout our regulations. It was kind of interesting.

MEMBER QUILLEN: Because of -- for example, this record of inventory has to be kept for five years. Most of the other records have to be kept for three years.

MR. AYRES: That's right. And a few, like the calibration of teletherapy units, have to be kept as long as you have the device.

CHAIRPERSON STITT: Well, at the end, we have a glossary. Why don't we fix up something that would fit into this section, maybe at the end of the section or adjacent to the glossary and refer to it, and just list what's required.

MR. AYRES: I would think this would need to be run up the -- discussed a little more widely. If we do something like this here, I think it applies to everything.

MS. HOLAHAN: It would impact all of the modules. So the question is, do we want to have that sort of up front as a separate, stand-alone, all of the records that are required for each area? Or each -- if we have it for this module, we should have it in each of the modules as to what are the records, and what are the record protection requirements.

CHAIRPERSON STITT: I think it would make a lot of people's lives, including the NRC's life, easier. And it's not creating anything new. It's abstracting and making a list.

MR. AYRES: Yeah, I think that's one that maybe

we make a note on.

MS. HOLAHAN: Right.

MR. AYRES: It's broader than just this module, by far.

MS. HOLAHAN: Right.

MEMBER QUILLEN: But it just impressed me all of the records you were going to have to keep based upon this section, and that there were some small differences in the length of time the records were going to be kept. But it would be helpful for the users to have a list to say, "Gosh, I know I have to keep all of these records."

CHAIRPERSON STITT: So a list for the record and the duration?

MEMBER QUILLEN: Yes.

CHAIRPERSON STITT: And we could do it for all of the sections.

MS. HOLAHAN: Yes. Bob, let me just -- because I just have a small question. Were we going to spell -- I notice you've got "referred to the standard license conditions." Were you going to spell out any more in the body as to what that included, or did you just --

MR. AYRES: I'm not sure what you're talking about.

MS. HOLAHAN: For the source inventory. You don't describe the alternative method. You just say it's

included in one of the standard license conditions. Well, the standard license conditions don't go to a licensee. Do we need to spell it out in the Reg. Guide?

MR. AYRES: We do. They're attached here.

MS. HOLAHAN: Will they be when it goes out to the licensees?

MR. AYRES: That's the intent. So it's --

MS. HOLAHAN: Because we don't -- we're not doing it with any of the other modules, to put the standard licensing --

MR. AYRES: Well, Janet agreed that it was unique here because we had to do these "in lieu of's" all over the place, because 35.400 couldn't apply, or wouldn't apply. There was no way you could apply it.

MS. HOLAHAN: Okay.

MR. AYRES: And we had a unique situation here and, you know, you -- with remote afterloaders, no way to meet the requirements for manual --

MS. HOLAHAN: Okay.

MR. AYRES: -- which is all that 35.400 addresses.

MEMBER QUILLEN: Okay. That's one of the questions I was going to ask later on, because I wasn't sure whether the standard license conditions were going to be attached to this module.

MR. AYRES: That at least was the decision going in here after discussing it with Janet, and we removed attachment from them. They're just part of --

MS. HOLAHAN: Okay.

MEMBER QUILLEN: Well, the thing says "in the attached sample license condition," which is --

MR. AYRES: Yeah, but it's not an attachment with an attachment number, and that sort of thing.

MEMBER QUILLEN: Okay. So it's not attached anymore. It's --

MR. AYRES: Yeah, because -- and these were really attachments to Reg. Guide 10.8. So if we made them attachments, they're attachments to attachments, and it got a little out of hand.

MS. HOLAHAN: Were these only the standard license conditions that were in the P&GD --

MR. AYRES: Yeah, that's correct.

MS. HOLAHAN: -- or did you expand them to include the new ones that we're going to need?

MR. AYRES: No, just the ones that were needed to get around 35.400, primarily.

MS. HOLAHAN: Okay. No, I'm just thinking that that -- probably we need to consider either have them all in or because the thing -- it would be a standard license condition requiring the physical presence of the authorized

user and medical physicist. And so that's how it --

MR. AYRES: Well, then, I called them sample license conditions here.

MS. HOLAHAN: Yeah, okay.

MEMBER QUILLEN: Okay. If you're going to be doing that, this is another editorial comment, and that is the sample license conditions should have some sort of numbering system. So if you're going to cross reference the page 22 to the license conditions, you know exactly which one you're referring to.

MR. AYRES: Just editorial -- that's a different way of doing things, but I'm not going to say it's precluded.

MEMBER QUILLEN: I'm just trying to make it easier for the people to use this, so they don't go through here and wonder which one you're talking about.

CHAIRPERSON STITT: Is that doable? It would certainly make it easier for the folks that are trying to understand how to use it.

MS. HOLAHAN: Yes.

CHAIRPERSON STITT: You had some of the same comments, then, Dr. Quillen, in your blue marker, all referring to required forms and duration.

MEMBER QUILLEN: Right.

CHAIRPERSON STITT: You've got that throughout your document, right?

MEMBER QUILLEN: Right.

CHAIRPERSON STITT: So we're talking about implant source record inventory and area survey, and let's include LDR devices.

MEMBER QUILLEN: One of the questions I had really goes over to the next page, page 24, item 4. It says, "Record of survey results will be maintained for inspection by the Commission for the duration of the license." All of the other records are being kept for three years, five years, etcetera.

MR. AYRES: That, again, is in 35.

MEMBER QUILLEN: Yeah. Well, I just wondered, does that mean at the end of -- when your license is terminated, you can throw away all of the survey records, even if they're not three years old or five years old?

MR. AYRES: Not the way I would read it. Once we release a facility as -- or return to unrestricted public use, we're done.

MEMBER QUILLEN: Well, the reason I'm saying is --

MS. HOLAHAN: Plus, it would be all part of the -- I mean, the termination of the license, there would be certain things that would have to be demonstrated --

MR. AYRES: Decommissioning.

MS. HOLAHAN: -- in terms of -- yeah,

decommissioning and bringing it down to acceptable levels. So there are several license conditions that we use beyond what we use here that are required to be kept for the duration of the license.

MEMBER QUILLEN: If I were a licensee, there were some of these records I'd like to keep myself.

MR. AYRES: Well, there's certainly nothing wrong with keeping records above and beyond our requirements for other reasons.

CHAIRPERSON STITT: Yeah, and I don't think this implies that you have to destroy them at all.

MR. AYRES: Not at all.

MS. HOLAHAN: Yeah, you're not precluded from keeping them.

CHAIRPERSON STITT: No.

MS. HOLAHAN: You're just not being required to maintain them.

MR. AYRES: By us. You may be required by somebody else.

MS. HOLAHAN: Yeah.

MR. AYRES: Hospital accreditation organizations, or professional accreditation organizations, or IRS, or whatever.

CHAIRPERSON STITT: Bob, do you have other comments on page 23 or page 24?

MEMBER QUILLEN: That's all I have.

CHAIRPERSON STITT: Trish? Page 25 is operating and calibration procedures.

MS. HOLAHAN: Before we go back to -- on 27, can I go back?

CHAIRPERSON STITT: You can go wherever you want to go.

MS. HOLAHAN: I'm sorry.

CHAIRPERSON STITT: Which page? You have to tell us where you are, though.

MS. HOLAHAN: Page 24.

CHAIRPERSON STITT: Okay. I was going to say, we can't go --

MS. HOLAHAN: And it corresponds to the license condition on page 38. It's regarding the survey for HDR, and it's just an issue that has been raised in the sense that for LDR, for the survey required, in terms of 35.404, you only need to keep the initials of the individual who performed the survey. We specified the name of the individual making the survey for HDR. Can we just have that as initials, too? I mean, I know the issue has come up.

MR. AYRES: Yeah. Well, it's currently a TAR, so I guess we need to see how that comes out.

MS. HOLAHAN: Okay. But we accept the -- we do accept initials as a signature.

MR. AYRES: Well, what I did -- and I'll tell you how I got where I got -- and I'm willing to go back to the full thing, it's knowing these -- it's "in lieu of," it's the inventory thing, or who was authorized to get brachytherapy sources out of inventory.

MS. HOLAHAN: By the way, for clarification, it's the second condition on page 38, the one that starts "in lieu of the source inventory."

MR. AYRES: Yeah.

CHAIRPERSON STITT: Well, I've got a -- my 38 is the glossary. That's part of --

MS. HOLAHAN: Oops. Then, it's the one that starts -- is titled "Standard License Conditions."

CHAIRPERSON STITT: Okay.

MS. HOLAHAN: Sorry.

CHAIRPERSON STITT: In lieu of?

MS. HOLAHAN: Yeah, the second one.

CHAIRPERSON STITT: I'm with you now. Go ahead, Bob.

MR. AYRES: What -- okay. Yeah, the second one, in lieu of 10 CFR 35.406. What 35.406 requires is a listing of who is authorized to do this, by name, and then when they do the inventory, they're to initial the inventory as having been completed.

What I did was I -- when I did the "in lieu of,"

I said, let's see,

MS. HOLAHAN: It's the second condition.

MR. AYRES: (c), item (c), make a record of the survey, giving time, date, and name of the individual making the survey, which meets the name requirements of the existing 35.406.

MS. HOLAHAN: So the existing 406 requires the name of who is doing the survey?

MR. AYRES: That's correct.

MS. HOLAHAN: Okay.

MR. AYRES: It requires name and initial. It requires an authorized list.

MR. CAMPER: 406, what?

MR. AYRES: 35.406.

MR. CAMPER: No, no, I know that. 406 --

MS. HOLAHAN: (b), is it?

MR. CAMPER: (b), (1) -- that's --

MEMBER QUILLEN: (2) -- (b)(2).

MR. CAMPER: Yes.

MEMBER QUILLEN: And (b)(3) also.

MR. CAMPER: And the initials --

MS. HOLAHAN: Yeah, but that doesn't require the name --

MR. AYRES: Or it's the initials of the individual who removes the --

MS. HOLAHAN: Oh, the names of the individuals permitted to handle the sources.

MR. AYRES: Right.

MS. HOLAHAN: And I guess the question is, could we do a similar thing with HDR, have the names of the individuals who are permitted to do the survey, and then they could just initial it at the time of their survey.

MR. AYRES: Sure.

MS. HOLAHAN: Okay.

MR. AYRES: Or what I did was try to reach a compromise, just put down the name and --

MS. HOLAHAN: Okay.

MR. AYRES: -- instead of the name and initials.

MS. HOLAHAN: But that doesn't -- actually, that doesn't include an initial, does it?

MR. AYRES: No.

MS. HOLAHAN: So they're not really signing off that they've done it, so we may be better off to try and parallel what's currently required for the inventory, have a list of the names and then have them initial.

MR. AYRES: Yeah, they could have it preprinted on the form or something, the survey form.

MS. HOLAHAN: Or a listing over the AU -- I mean, if you've got a list of authorized users, or authorized physicists, or whatever, who would do the surveys, you could

just maintain a list of that.

MR. CAMPER: Yeah. It says that they shall make a record of brachytherapy source use. Now, I would imagine you could go about creating some ongoing record, wherein you would identify individuals for the record. But then you -- and their initials parenthetically, for example, I think if you use their initials.

Now, we had a TAR also --

MS. HOLAHAN: Yeah, and this is what were just referring to is there was a TAR in-house that people didn't want to put down their full name each time they did a survey. They just wanted to say, "Okay, this is who I am," and just initial off every time they --

CHAIRPERSON STITT: So to keep the record like we talked about before, with -- of the individuals, plus their initials, and if we parallel the two systems, then we --

MS. HOLAHAN: Right.

CHAIRPERSON STITT: -- are working in concert of prior --

MR. AYRES: Yeah. What I did was make it a little bit shorter and not require the names and initial, but just the name -- enter their sign and ended up with both a name --

MR. CAMPER: But they're all supposed to be consistent, aren't they?

MS. HOLAHAN: Yes, because, actually, we don't require an initial or a signature currently. Okay.

MR. CAMPER: Well, I also got the impression in one place we're requiring initials and in one place we're requiring a name. Is that correct?

MR. AYRES: Well, the reason the name came in is this is this -- 406 is rather unique in having a specific requirement for the name to be listed.

MS. HOLAHAN: And basically, it's because it's a list of the people authorized to --

MR. AYRES: It's an authorization.

MS. HOLAHAN: Yeah. Okay.

MR. AYRES: It's kind of a "no, never mind" almost.

CHAIRPERSON STITT: So does that address the point you wanted to bring up, Trisha?

MS. HOLAHAN: Yeah, I think we just needed to address it and perhaps make them consistent between the two, I think.

MEMBER QUILLEN: Well, my --

MS. HOLAHAN: I mean, if it is something that comes in --

MEMBER QUILLEN: -- my intent on this one was to wait until the TAR gets all signed off and then we'll see where that one stands.

MS. HOLAHAN: Yeah. Okay.

MR. AYRES: I knew this one was, in fact, going through the technical systems request process with all concurrence. And once that one is reached, I figured to adjust this --

MS. HOLAHAN: That we can adjust this, yeah.

MR. AYRES: -- appropriately.

MS. HOLAHAN: Yeah, that could be done.

CHAIRPERSON STITT: All right. But let's do it the same across the board.

All right. So that's 24, then. Other issues on 24? We were looking at 25. 25? 26? We're just listing page after page of a variety of issues relating to safety, the safety program.

Bob, what do you have there?

MEMBER QUILLEN: This gets back to -- and I think we discussed this earlier on the approved alternate.

MR. AYRES: Yeah, okay.

MEMBER QUILLEN: On page 27.

CHAIRPERSON STITT: Okay, right.

MEMBER QUILLEN: 27, okay. That's not back.

CHAIRPERSON STITT: And so how do you want that?

MEMBER QUILLEN: I just wondered what you had in mind as to who would be approvable as an alternate?

MR. AYRES: Well, rather than being restrictive,

I was hoping to get away with a general comment here. The way we've been dealing with this pretty much is on a case-by-case basis through a TAR process, or whatever, and I recently put out some, I guess, instructions on the bulletin guidance to the regions, listing those, at least to date, we had approved.

And I -- I'm not sure I have -- I remember that all-inclusively. But, for example, for the authorized user, it would be a resident properly trained in the use of the device, working under -- or anybody working under the supervision of the authorized -- other physician working under the supervision of the authorized user.

CHAIRPERSON STITT: Would that be preferable than an approved alternate?

MR. AYRES: Well, then we restrict it to those, I guess, few cases that --

MS. HOLAHAN: Or could we use it as an example, I guess.

MR. AYRES: And a trained dosimetrist we have permitted in --

CHAIRPERSON STITT: Maybe we should strike "approved alternate," because that implies that there is a form to fill out and an approval process to go through, and I'm not sure that that's what we're trying to say.

MEMBER QUILLEN: That's what the -- well, the first thing as I read it and I thought it's -- who is making

the approval here? Because I wasn't sure who was making the approval, which is --

CHAIRPERSON STITT: Yes.

MEMBER QUILLEN: The second point is, I read it to mean that the authorized user had to be there, and then either the medical physicist or radiation safety officer or an approved alternate.

MR. AYRES: Yeah. The radiation safety officer has got to go, too.

MR. CAMPER: That's right. We were just --

MR. AYRES: I fixed it in the one place that it was mentioned, and it -- you've got to look around through the document.

MEMBER QUILLEN: So I didn't read this to mean that the authorized user would have an alternate --

MR. AYRES: I agree, if everybody else does. Just get rid of "approved alternate" and you're back into the space of exemption requests that we typically are on this kind of --

MS. HOLAHAN: Well, should we address the fact that licensees may come in to request, and that -- to propose an alternate, such as a physician under the supervision of, or a specially trained dosimetrist?

MR. AYRES: My intent here was more with that statement as guidance to our license reviewers, who have been

provided -- who we -- who are the approved alternates through out technical assistance request and other correspondence. But since this goes to perspective licensees also, that could be confusing at that point. For the license reviewer, it makes more sense, because they know who we've approved.

MEMBER QUILLEN: I'd take out the "approved alternate" and do what was suggested, which is say that the applicant can suggest alternate --

MR. AYRES: The typical situation we run into where they request some relief is the facility which is very common that only has one medical physicist, and they don't want to suspend treatment when this individual is on vacation.

MR. CAMPER: Well, the approved alternate statement --

MR. AYRES: Yeah.

MR. CAMPER: -- is consistent, though, isn't it, with the earlier point, which I do believe is made in the document, that under -- well, that was under PDR, though, we would consider an alternative. We have never, until this point, indicated that we would accept an alternative to --

MR. AYRES: Right.

MR. CAMPER: -- the AU or the --

MR. AYRES: Except in other documents.

MR. CAMPER: Right. I mean, I'm talking in this document.

MR. AYRES: In this document, that's correct.

MR. CAMPER: Well, I guess the -- and I guess that's the next comment. I mean, should we? And then, the other comment is it seems to me that it's worthy of a couple of words being inserted that a physician working under the supervision of an authorized user, e.g. a resident, is acceptable.

MR. AYRES: Well, in all of our other documents, we also say "with the specified device training."

MS. HOLAHAN: But that goes without -- because that's up front, that anybody who is involved with it must have --

MR. AYRES: But it says "the authorized user." It doesn't say "approved alternate" in that section, or anything like that.

MR. CAMPER: Well, we've got to be careful about this, because clearly residents, I mean, can do this and should be able to do this.

MS. HOLAHAN: Without having to come in here.

MR. CAMPER: I mean, you don't see a problem with that, do you?

CHAIRPERSON STITT: No. No.

MR. CAMPER: So --

MS. HOLAHAN: And we can maybe just expand --

MR. CAMPER: We may need to do it in both places.

MS. HOLAHAN: Right.

MR. CAMPER: To make it clear, I mean, specifically that residents who are operating under the supervision of an authorized user can do this, provided that they have obtained the device-specific training. That's really the issue, right?

MS. HOLAHAN: Yes.

MR. AYRES: Well, then, you give the one specific approved alternate. That's for an authorized user, you know.

MR. CAMPER: Well, the medical physicist is a problem.

MR. AYRES: What we have approved is a dosimetrist.

MR. CAMPER: Well, let me ask you this, then. What would you do -- would you -- that raises an interesting question. If one looks at the requirements in 961 about the experience that's required to become a teletherapy physicist or a brachytherapy physicist, if you will, could a physicist in training during that one year -- could that physicist in training for that year function in the role of the medical physicist in this instance? Or could it be only an identified and approved physicist on the license?

MS. HOLAHAN: Similar to the way a resident --

MR. CAMPER: Similar to the way a resident --

MS. HOLAHAN: -- fill in as an authorized user.

MR. CAMPER: Yeah, right. What about that? Any thoughts?

CHAIRPERSON STITT: It seems like it would work. I mean, is that -- the way things are written --

MR. CAMPER: It's certainly treating -- it's treating a physicist in training in a parallel fashion to a physician in training.

MS. HOLAHAN: That would still, though, probably wouldn't it have to come in on a case-by-case basis, though, still for an exemption, because whereas we have defined training and experience for authorized users and residents in training --

MR. CAMPER: Do you mean defined it in the regulations?

MS. HOLAHAN: We don't have defined regulation yet for a medical physicist, except for teletherapy physicist --

MR. AYRES: Except our linkage to teletherapy --

MS. HOLAHAN: That's right.

MR. AYRES: -- equivalent.

MS. HOLAHAN: So it's not quite as clean-cut as with the resident physician.

MR. CAMPER: Well, that's certainly true. In pure regulatory-ese, you're right. But certainly, we are imposing a regulatory requirement --

MS. HOLAHAN: Yes.

MR. CAMPER: -- via the current mechanism that we're using, because we're asking for specific things in guidance space, and then we're using --

MS. HOLAHAN: That's true.

MR. CAMPER: -- conditions. I mean, the net impact is a regulatory requirement.

MR. AYRES: Yeah. And OGC is kind of dragging their heels on this one. I'm not sure how it --

MR. CAMPER: You know what I'd like to do? I'd really like to explore that particular question with the ACMUI. Maybe we can add that as a squeeze-in agenda item. We'd have to notice it, though, wouldn't we, Torre? If we were to explore this one specific question, the concept of a physicist in training, while obtaining their experience as delineated in Part 35, to become a brachytherapy physicist --

MS. TAYLOR: We can add -- we'll have to amend the Federal Register. So I just need to know --

MR. CAMPER: Do we still have time to do that?

MS. TAYLOR: We're past the 15 days. But with good reason, we can always do another one, and we'll need to put in a reason.

MR. CAMPER: If we could do it, it would be nice to take advantage of the fact that the committee is going to be meeting very quickly, and I think we can address the issue

in probably 20 minutes to half an hour.

MS. HOLAHAN: Trish, I wasn't listening, if you would write the question out and get with me later.

MS. TAYLOR: Okay.

MR. CAMPER: That's a good way to make sure we explore it thoroughly.

CHAIRPERSON STITT: Except there won't be any physicists at that meeting.

MS. HOLAHAN: Yeah, that's -- the only question is we don't have a physicist at the next ACMUI meeting. Do we want to --

MR. CAMPER: Well, we would have Dr. Wagner, but you're right. He's not the right type of physicist, yeah.

Now, we're in an effort to reinstate the second physicist position, which may or may not be in place by the meeting next spring. Yeah, that's a good point. We probably -- well, we could certainly get a sense from the committee in terms of -- but it wouldn't be the same as having a physicist there.

Well, for purposes now, let's ponder whether that makes sense or not.

MS. HOLAHAN: Should we put in a statement at this point in time saying that licensees can propose alternatives on a case-by-case basis until we --

MR. CAMPER: I think what I would do is, yeah,

try to capture a sentence in there that points out to them that physicians operating under the supervision of -- provided they have obtained the instrument-specific training, and so forth, and then see if you can't come up with a sentence that says, "Licensees may propose alternatives which will be evaluated on a case-by-case basis." That leaves the door open if someone wants to call us up and say, "Let me talk to you about this possible scenario."

But that concept of a physicist in training, in parallel fashion to a physician in training, is something we ought to explore at some point with the committee.

MS. HOLAHAN: I just wanted to make sure that, in my mind, that everybody here is comfortable with taking out the "or radiation safety officer."

CHAIRPERSON STITT: I am.

MS. HOLAHAN: Okay. Then, let me go back up to number 8. Should "radiation safety officer" then come out of that last sentence in item 8? If it's going to be the requirement --

MR. AYRES: No, this one is more -- this one is intended to be more a review of the procedures, and I think the RSO is playing an appropriate role there. It's a commitment, a license commitment, that when -- says, "shall not commit any treatment with which a decoupling -- not removed -- decoupled or jammed source cannot be removed

expeditiously in the patient, as determined by the authorized user with consultation."

And the RSO has a responsibility in this area. This is like a preparation of the application.

MS. HOLAHAN: Could I, then, propose that we say the RSO and medical physicist?

MR. AYRES: I'd say "and/or."

MR. CAMPER: Well, a question, Bob. In the case at hand, in item 8, when the source becomes decoupled or jammed, cannot be removed expeditiously from the patient. That's a medical issue. That's a pure medical problem. I mean, what is an RSO really going to do at that point?

MS. HOLAHAN: They may have the physicist in there trying to --

MR. AYRES: And placed in a shielded container. It's --

MS. HOLAHAN: I wasn't saying --

MR. CAMPER: Yeah, but I'm focusing on what -- it's inside the patient.

MEMBER QUILLEN: You've got a good point.

MR. AYRES: Well, I guess I was looking ahead that often the authorized user is not the author of the license application. As a matter of fact, I think more often the case than not he is not involved in preparing the license application.

MR. CAMPER: You know, you realize that this gets us back to that central question that we were exploring early in the game today under emergency procedure.

CHAIRPERSON STITT: Right.

MR. CAMPER: I mean, for example, if you were to -- if you took the statement and truncated it at the point -- for the period after container, or for that matter after patient, I mean, that's -- that's really the question that we were dealing with this morning. Do you state it that explicitly? And we somewhat shied away from that explicit statement, as I recall, didn't we?

MR. AYRES: Well, this is pretty explicit, but it's --

MR. CAMPER: Well, that's my point.

MR. AYRES: It's a judgment or a -- we're asking for a commitment from the licensee they won't do this, and that's -- that commitment is predicated on the judgment of the individuals involved.

MS. HOLAHAN: In a way, this is almost saying that you must commit that if you're doing something that is going to require surgical intervention and you can't do it, then you're going to tell us that you won't do it.

MR. CAMPER: Well, let me spend my --

MR. AYRES: I'm saying, what the normal response is is they're saying it's going to be contained; and,

therefore, there won't be a --

MR. CAMPER: Let me spin my point differently, then. In the case at hand in item 8, we are soliciting a commitment from the licensee that it shall not conduct any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded container. Now, then you can go on and on with whom this consultation is being derived.

But is that statement to that point consistent with what we were saying under emergency procedures in item 11.21?

CHAIRPERSON STITT: I thought it was. It's a different way of saying what we talked about earlier this morning. It really doesn't matter who you confer with. The statement stands as it is. Put a period after "container."

MR. CAMPER: Well, what I'm getting at is we are --

MS. HOLAHAN: Oh, don't even have the last part of the sentence?

MR. CAMPER: Well, what I'm saying is if you read that -- the emergency procedure, where it says, "If appropriate, supplies necessary to surgically remove applicator or sources from the patient, including scissors, capable cutters." Does that coincide with or work for the fact that you have previously, on page 27 under item 8,

solicited a commitment from the licensee that they will not do it?

MS. HOLAHAN: No, because --

MR. AYRES: No. It says they won't do it if they can't --

MS. HOLAHAN: Right.

MR. AYRES: -- if they can't expeditiously remove it.

MS. HOLAHAN: So if they can expeditiously remove it surgically --

MR. CAMPER: So now they've committed that they will expeditiously remove it.

MR. AYRES: And then, this is going on on technique.

MR. CAMPER: Okay. No, no, I understand. So stay with me. So they commit that they can expeditiously remove it.

MR. AYRES: Yeah.

MR. CAMPER: All right. Then, you go over there to your emergency procedures and you say, "If appropriate, supplies necessary to surgically remove." You've already committed to doing it.

MS. HOLAHAN: No. They may --

MR. AYRES: No. You may have committed to not doing the procedures which -- well, restricting yourself,

which some have, to only doing those procedures which would not require surgical removal.

MR. CAMPER: I know. But let's say they make the commitment, under item number 8, that they will not do it unless they can remove expeditiously from the patient and place it in a shielded container. Make a commitment to do that.

MR. AYRES: Right. Which may or may not involve surgical procedures. If it's a --

MR. CAMPER: Okay.

MR. AYRES: -- Fletcher suit, it's not going to, or a tandem.

MR. CAMPER: Well, let's say, for example, that they commit to doing it, and they commit to doing bronchial procedures.

MS. HOLAHAN: Then, they would have to --

MR. CAMPER: Then, under item F, on emergency procedures, we would expect to see, wouldn't we?

MR. AYRES: Yeah, exactly.

MS. HOLAHAN: Then, it is appropriate.

MR. AYRES: Then, it is appropriate.

MR. CAMPER: Well, is that clear to our reviewers?

MR. AYRES: Well, I would certainly think so.

MR. CAMPER: Is it clear?

MS. HOLAHAN: I think it is.

MR. CAMPER: Okay.

MS. HOLAHAN: I mean --

MR. AYRES: Yeah, I --

MS. HOLAHAN: Because I think if appropriate says if you're going to be doing things that you might need them, then, yes, you've got to have those. But if you're not going to, then you don't have to have those. If you're --

MR. AYRES: Yeah. Someone --

MS. HOLAHAN: -- you're not going to do those, then you don't have to have them.

MR. AYRES: Some licensees have stated on their application that they were only going to do OB/GYN-type procedures or a select list that didn't involve anything that would require surgical, and then they didn't address these issues.

MS. HOLAHAN: Templates are sutured in, aren't they?

CHAIRPERSON STITT: Say that again?

MS. HOLAHAN: Templates. You know, they would be sutured in, wouldn't they? So that would --

MR. AYRES: Well, I don't know whether you define cutting a suture a surgical procedure or not, pulling a template out. I --

CHAIRPERSON STITT: It's possible that a needle

could get stuck inside the patient or -- so you'd have to go after it surgically.

MR. AYRES: Yeah. We had the case in, what, Keesler, where the needle got bent and --

CHAIRPERSON STITT: I don't see the same problem. I am having somnolence from lunch, and you guys are on a high from it. But, to me, we're saying the same thing.

My only problem with number 8 is that I don't know what the consultation with any of these people has to do with the fact you either commit to do the procedure or you commit not to do it. I don't -- I think that the consultation aspect of it is sort of fabrication.

MS. HOLAHAN: So you would propose to end it after "container"?

MEMBER QUILLEN: That's what I would --

CHAIRPERSON STITT: Yeah. I mean, I don't see how consultation either before or after the license is written, or during a procedure, changes whether or not you've made this commitment that you can or cannot do X, Y, or Z procedures.

MR. AYRES: Yeah, right.

CHAIRPERSON STITT: So I'm sort of looking at it differently than --

MR. AYRES: Okay.

CHAIRPERSON STITT: But the three of you go

ahead, and we'll just take a nap and let us know when we're supposed to get --

MR. AYRES: You didn't have the chili.

(Laughter.)

CHAIRPERSON STITT: That's right. The rest of you did.

(Laughter.)

Are you happy yet? Okay. Eight?

MR. AYRES: Yeah, okay.

CHAIRPERSON STITT: Took care of 9. Trisha, you were kind of going backwards. What else do we need to review that you caught that we need to smooth over?

MS. HOLAHAN: I think you've addressed it by taking out those last two -- that last sentence, so it's gone, so --

CHAIRPERSON STITT: All right. So points number 4, 5, 6, 7, 8, 9, are there any more issues, just on the two pages we have in front of us? How about for you, Trish?

MS. HOLAHAN: I'm just going to raise a question that was discussed yesterday in item number 3. And, I'm sorry, I did tell you I wasn't going backwards.

CHAIRPERSON STITT: Where?

MS. HOLAHAN: Item number 3.

CHAIRPERSON STITT: Oh, I'm sorry, you can't because I only said 4, 5, 6 --

(Laughter.)

All right.

MS. HOLAHAN: Yesterday discussing, again, the radioactive module, and when we were discussing instructions for nursing personnel, the issue came up as to what instructions of the authorized user should we as a main -- should we require nursing personnel to follow the authorized users instructions regarding care to be provided, medical care. Or is that another -- I mean, regarding care with respect to radiation safety aspects.

MR. AYRES: Oh, you went way back. Oh, okay.

MS. HOLAHAN: Yeah, I'm sorry.

CHAIRPERSON STITT: Just say it again. Let me listen to it another time.

MEMBER QUILLEN: You're qualifying care, in other words. You're trying to qualify it?

MS. HOLAHAN: I'm asking, should we?

MEMBER QUILLEN: Medical care, which is radiation --

MS. HOLAHAN: Or is it sufficient the way it is written?

CHAIRPERSON STITT: What would be the alternative to the way it's written?

MS. HOLAHAN: The question that had come up yesterday was, should NRC be putting in their guidance that

the nursing personnel are required to follow the authorized users instructions, which would include medical care.

CHAIRPERSON STITT: I don't think the NRC can require medical care.

MS. HOLAHAN: No. But the way it is written, does this read as though it is only the care in terms of the radiation safety aspects?

CHAIRPERSON STITT: Oh.

MEMBER QUILLEN: That's the way I read it.

CHAIRPERSON STITT: That's the way I read it, too. But then, it was kind of set up, because it's got RSO and because it's an NRC document.

MEMBER QUILLEN: I didn't read it that you were requiring --

MS. HOLAHAN: Well, I'm not, and I just wanted to make sure that that was clear.

MR. AYRES: One of the things I had in mind here, of course, is the typical thing I would expect is where it says pulsed dose rate is care -- normal care should be restricted between the 30 minutes to the hour, if we -- which the authorized user would issue because that's when the sources would not be out. That sort of thing.

CHAIRPERSON STITT: Did yesterday's isotope group want to see a change of any sort, or was it just an area they were discussing?

MS. HOLAHAN: They just -- it was just an area that they were discussing, in terms of the instructions when you're talking about following the instructions of the authorized user. We were clarifying it specific to the radiation safety aspects.

CHAIRPERSON STITT: That's how I read it.

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: Because they are also expected to follow medical orders that are written regarding --

MS. HOLAHAN: Right.

CHAIRPERSON STITT: I guess I'd focus that it was --

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: -- really relating to radiation safety issues.

MR. AYRES: I guess I took it that everybody -- most of us are taking that as implied.

MS. HOLAHAN: Okay.

MR. CAMPER: Can I raise something again? Can I take you back to page 27, item 8, again, for a moment?

CHAIRPERSON STITT: That's forward.

MR. CAMPER: Oh, I'm sorry.

MS. HOLAHAN: Yeah, we jumped forward now.

CHAIRPERSON STITT: Better ask Trisha if she has

anything on 2 that she wants to --

MR. CAMPER: We go forward from our last backward spin.

CHAIRPERSON STITT: Right.

MR. AYRES: You are now on page 25, right?

CHAIRPERSON STITT: Well, but now --

MS. HOLAHAN: Now we're back up to 27.

MR. AYRES: Now, we're back to 27? Okay.

MR. CAMPER: For item number 8, I'm still a little troubled by item number 8, and let me try to articulate it a little bit differently this time. In item number 8, I would prefer if there was some way to put a positive spin on it. As I read it now, you're asking a licensee to commit that they won't do certain procedures. Could you change it and say, "A commitment from the licensee that it shall only perform procedures" --

MS. HOLAHAN: Yes.

MR. CAMPER: -- "treatment procedures for which a decoupled or jammed source" --

MS. HOLAHAN: Can be --

MR. CAMPER: -- "can be removed."

CHAIRPERSON STITT: And I think we'd make it a lot more understandable as to what it was I was committing to do.

MR. CAMPER: And the second part of that I would

then suggest, if you go over to page 34, item F, where it says, in the emergency procedures, "if appropriate." I would put a parenthetical "refer to" --

MS. HOLAHAN: Right.

MR. CAMPER: -- "commitment" in item 8 under whatever part this is.

MS. HOLAHAN: Right.

MR. CAMPER: Then, I think it's very clear to the licensee that, guess what? You made a commitment back earlier that you were only going to do procedures if, and this is where "if" comes to bear.

MR. AYRES: Where are you at?

MR. CAMPER: I'm saying on page 27, item --

MR. AYRES: No, I got that.

MR. CAMPER: Okay. Go over to the emergency procedures, item F, on page 34. Okay? Item F, page 34, Bob.

MR. AYRES: Okay.

MR. CAMPER: And the sentence in there where it says, "And, if appropriate," and I would parenthetically insert "refer to commitment of item 8" --

MS. HOLAHAN: 11.201(b)(8).

MR. CAMPER: Right.

MR. AYRES: I'm glad you --

MR. CAMPER: Very good.

CHAIRPERSON STITT: That's a special test they

take before they --

MR. CAMPER: And then, I think that the licensee, at that point, could put a positive spin on what they're committing to, and it's clear to them that, yeah, you'd better go back and look at what you said, because this is where surgical procedures come to bear. And I think it puts us in a pretty good comfort zone at that point.

MEMBER QUILLEN: Yeah.

CHAIRPERSON STITT: I do, too.

MR. CAMPER: Without causing -- without making them do it, right?

CHAIRPERSON STITT: I'm surprised you didn't catch that, because you're the -- this is actually a grammar, or not a grammar but an editorial construction sort of thing.

MR. AYRES: Linkage.

MEMBER QUILLEN: I get tired of being --

CHAIRPERSON STITT: The only responsible individual.

MR. CAMPER: He didn't have the chili. That's what it was.

CHAIRPERSON STITT: All right. I like that. I think it makes -- and it relates those two, which is also very important, that all of this material relates to one another.

Well, Trish, you have the option of going backwards or forwards.

MS. HOLAHAN: This is just a simplification, I'm hoping.

CHAIRPERSON STITT: Okay.

MS. HOLAHAN: Okay? Because of the item 11.201(b)(8) --

MR. AYRES: Whatever --

MS. HOLAHAN: -- just a question, Bob. Under that 11.20, can we not take out those initial numbers and just have that as a --

MR. AYRES: Where is 11.20 at?

MS. HOLAHAN: Page 24.

MR. AYRES: Oh, that's back.

MS. HOLAHAN: I was afraid to say that, because I knew that was backwards.

MR. AYRES: Yes, it is.

CHAIRPERSON STITT: I haven't done my job very well.

MR. AYRES: What about 11.20 now?

MS. HOLAHAN: Okay. Taking out those initial numbers, because that could be a new paragraph just to say the licensee should provide a copy of operating procedures, again, I was trying to simplify the number of numbers that we have in here.

MR. AYRES: Oh, okay. Fine.

MS. HOLAHAN: And then, (a) and (b) could be --

stay as (a) and (b) and then --

MR. AYRES: Well, they could be (1) and (2), then.

MS. HOLAHAN: Yeah, and the same thing for -- on page 28.

MEMBER QUILLEN: Why is it that in this you go 11.20, and then (1), but in your regulations you go 35.404, and (a)?

MS. HOLAHAN: But we're taking out the (1).

MR. CAMPER: Well, I think the answer is it's guide format, right?

MS. HOLAHAN: Well, I think partly as some of this came from the P&GD, putting it into that format, whereas we have some of these 1's and 2's. But you're right, it is guide format that we have numbers. I don't know why.

CHAIRPERSON STITT: Because. Because it's made that way.

MS. HOLAHAN: That's right.

MEMBER QUILLEN: I was wondering why it's inconsistent. That's all.

MR. AYRES: Even more, it doesn't follow standard outlining format, which would be Roman numerals followed by capital letters, followed by --

CHAIRPERSON STITT: I imagine there's a whole agency that knows about those things, though.

MS. HOLAHAN: Anyways, I've finished going backwards now. I'm up to 27 again.

CHAIRPERSON STITT: Are you sure? You lied before.

MR. AYRES: You could petition for rulemaking on changing the guide format.

(Laughter.)

CHAIRPERSON STITT: So let's just flip through from page 23, or wherever we -- we're probably up to 28, aren't we?

MR. AYRES: We're somewhere around 28 or 29.

CHAIRPERSON STITT: We think that 23 to 28, 29 is looking okay.

MEMBER QUILLEN: 11 is the one I discussed before.

MR. CAMPER: Right.

MEMBER QUILLEN: I hope you've got the comments I had about --

MR. CAMPER: Your operator device monitor.

MEMBER QUILLEN: Certified --

MR. CAMPER: Right.

CHAIRPERSON STITT: Certified device monitor, which I thought was a gizmo, but I'm told was a person. So we're going to -- how did we resolve that?

MS. HOLAHAN: We're going to --

MR. CAMPER: We're supposed to make it consistent throughout, aren't we?

MR. AYRES: Well, yeah. It ran two things -- you're actually putting a certified with the wrong thing in a sense. We're required -- it goes back to the training for these, and under training it said that they should be both trained and certified -- in other words, tested. But it's probably confusing on this, where it's used here. That's how come it got in there.

MS. HOLAHAN: Because actually, the reference to 9.1.1.3 refers them back to the training and certification.

MR. AYRES: Training and certification, yeah. But it may be a little confusing --

MR. CAMPER: Could you imagine someone reading this transcript? Someone reading this transcript, can you imagine?

(Laughter.)

I don't know if I could follow that 11.2.3(b). It does get cumbersome, doesn't it?

CHAIRPERSON STITT: Is point 11 satisfactory with whatever changes, and what are the changes?

MR. AYRES: Yeah, I will readdress it.

CHAIRPERSON STITT: You'll fix that for us?

MR. AYRES: The intent was clear. The way it came out isn't so clear.

CHAIRPERSON STITT: All right. So you're going to fix that one up. All right.

MS. HOLAHAN: And with that one --

MR. AYRES: I'll probably just get rid of the "trained and certified."

MS. HOLAHAN: -- for the PDR, and that item 11, as we say "the medical physicist or radiation safety officer," is that what we're looking at?

MR. AYRES: Okay.

MS. HOLAHAN: Or is that going to --

MR. AYRES: I got this decision right at the end, and I made the one change in the license conditions. And, yeah, radiation safety officer is history.

MS. HOLAHAN: Okay. But for LDR, the radiation safety officer is acceptable, item 10.

MR. AYRES: Item 10 doesn't deal with LDR.

MS. HOLAHAN: Yes, it does.

MR. AYRES: Oh, wait a minute. I'm reading item 11. Where is item -- oh, yeah.

CHAIRPERSON STITT: The one before.

MR. AYRES: Yeah, yeah, right. Item 10, it's appropriate.

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: So we are allowing RSOs for LDR but not for PDR.

MS. HOLAHAN: Or HDR.

CHAIRPERSON STITT: Or HDR, right. And all of the folks that use those devices know that and have been through this discussion and practice.

MR. AYRES: Yeah. Often, a radiation safety officer sets -- establishes the procedures sometimes in an LDR.

MS. HOLAHAN: Right. But is that the case as much for HDR and PDR? It would be primarily the physicist, wouldn't it?

CHAIRPERSON STITT: No. They don't have any -- they basically have nothing to do with HDR and PDR.

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: All right. So we're consistent. Thank you for catching those, though.

All right. I think we're at the bottom of 28, and we're looking at 29.

MR. AYRES: Yeah. It starts with the daily checks.

CHAIRPERSON STITT: And we are discussing all remote afterloading.

MEMBER QUILLEN: A couple of questions on 2, which starts on the bottom of page 28 and goes over to the top of page 30. It wasn't clear to me -- this is editorial again -- why you had a colon at the end of the paragraph on page 28.

MR. AYRES: Yeah, that's inconsistent. I should have semi-colons after all of the 1, 2, 3's, then, if I did that. I can get rid of the colon and make it a period.

MEMBER QUILLEN: Okay. On --

MR. AYRES: It's a case of moving this. Some of this was written from scratch, and others was imported from the policy and guidance directive, which left dangling artifacts.

MEMBER QUILLEN: On the list of things you're supposed to be doing, as far as daily checks, at the end of number 5 it says you're supposed to keep a result of this test, with the initials. And then, in 7, it says again you're supposed to be keeping a record of these tests, with the initials. Either that's redundant or whether -- I'm not sure whether 7 applies to all of the above six or only -- which one.

MR. CAMPER: Okay. Well, 7 -- right, 7 should be the catch-all for all of the above.

MEMBER QUILLEN: Yeah, that's what I thought it was, but then --

MR. CAMPER: Right.

MEMBER QUILLEN: -- because you had --

MR. CAMPER: It is redundant. You're right.

MR. AYRES: Yeah, I'll take care of that.

MR. CAMPER: So we should just strike it from

item --

MEMBER QUILLEN: 5.

MR. CAMPER: -- 5, right.

MR. AYRES: And as normally mentioned, normally -- or 7 will become not 7, but become a paragraph because it's a recordkeeping requirement as opposed to a test.

MR. CAMPER: right.

MEMBER QUILLEN: Right. That was my next comment.

CHAIRPERSON STITT: Okay.

MR. AYRES: I got so I like these numbers so much I just kept going.

(Laughter.)

CHAIRPERSON STITT: Bob Quillen, what do you have next?

MEMBER QUILLEN: Next is item 3. The first sentence says, "Prior to use, the following checks will be performed in accordance with the manufacturer's instructions within the preceding 30 days." Now --

MR. AYRES: Again, we'll get rid of the colon, I guess, and go to a period there.

MEMBER QUILLEN: Well, it wasn't clear to me, prior to initial use, or prior to every use, or --

CHAIRPERSON STITT: Is this acceptance testing?

MEMBER QUILLEN: Or what is it? I wasn't clear

as to what use we were talking about here.

MR. AYRES: That prior use, yeah, makes it awkward. This is a 30-day -- the monthly checks, and --

MEMBER QUILLEN: So are you talking about monthly checks?

MR. AYRES: Yes.

MEMBER QUILLEN: Okay. Then, why don't you say something --

CHAIRPERSON STITT: Monthly checks will include, or will --

MR. AYRES: Well, I was trying to do a little something different here, but it didn't work out well. What I was trying to say was that you need to do these checks every 30 days, if you're using a machine.

CHAIRPERSON STITT: Why don't you say that?

MR. CAMPER: Yeah, really.

CHAIRPERSON STITT: Seriously, it's very straightforward, and then it's got some records that have to be kept and some lengths of time which end up in the other document that we're talking about.

MR. CAMPER: And also, if you want it done every 30 days, Bob, just say at intervals not to exceed 30 days. If the device is used, at intervals not to exceed 30 days --

MR. AYRES: That needs a little work.

MR. CAMPER: -- then you shall do certain things.

MEMBER QUILLEN: And you need to separate (e) out like you have --

MR. AYRES: Yeah. That's a standard correction. Yeah, the intent was there is -- storage closet, no --

CHAIRPERSON STITT: So 3 has to do with monthly checks. Number 4 is?

MR. AYRES: Calibration.

CHAIRPERSON STITT: Calibration. Bob Quillen, what do you have to say about calibration?

MR. AYRES: I have some comments on that.

MS. HOLAHAN: Would it be clearer to have subheadings under there?

CHAIRPERSON STITT: Under the calibration section?

MS. HOLAHAN: Well, yeah, to have a subheading on monthly checks, a subheading on calibration.

CHAIRPERSON STITT: It would make it easier --

MS. HOLAHAN: Yeah.

CHAIRPERSON STITT: -- for the users to use.

You've got comments about the calibration from the field?

MR. AYRES: Yeah, something, you know, looking -- I can't remember who made it.

CHAIRPERSON STITT: Do you have anything, Dr. Quillen?

MEMBER QUILLEN: I was trying to remember what the --

MR. AYRES: Oh, from Region 1, we should clarify who is authorized to perform calibrations. We asked for physicists to perform the calibration but imply that someone besides the physicist can calibrate the unit. That comes out of the teletherapy where the -- somebody else can perform the calibration, but the physicist has to review it.

CHAIRPERSON STITT: So that's 4(a)?

MR. AYRES: Yeah, 4(a). We should clearly specify if someone under the supervision of the physicist can calibrate the unit to be consistent with the requirements of teletherapy. We should require that the calibrations are performed by a medical physicist authorized on the license.

One of the comments -- and I think maybe I missed -- I've got to go back. I don't think I missed it; I think the commenter did. But I think it's pretty clear here that a medical physicist has to be a named individual on the license. If it isn't, it should be. Yeah, but that comes under the fact that it's listed under authorized users, authorized RAL physicists.

MS. HOLAHAN: Should be named on the license.

MR. AYRES: For programs using HDR, PDR, RAL therapy and medical physicist experience, should be named on license. So it's there. They missed it in -- when they got

over here in the calibration and said, "Well, gee, how about naming the physicist."

MS. HOLAHAN: They are named.

MR. AYRES: And they are named. I thought it was.

MR. CAMPER: Okay. It's named on the license, right?

MS. HOLAHAN: Yes.

MEMBER QUILLEN: I know what it was. Paragraph (c) doesn't have a verb in the first sentence.

MR. AYRES: Oh, yeah.

MS. HOLAHAN: Should be maintained.

MR. AYRES: Shall be maintained, yeah.

CHAIRPERSON STITT: Shall include or will --

MR. AYRES: Should. Yeah, you can't put "shall" in here.

CHAIRPERSON STITT: -- to maintain, okay. That comes -- that goes under your list of required recordkeeping?

MR. AYRES: If we do it, yeah.

CHAIRPERSON STITT: If we do it.

(Laughter.)

MS. HOLAHAN: Well, actually, should that be records of maintenance?

MR. AYRES: Yeah.

CHAIRPERSON STITT: Records of maintenance

requirements.

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: On 4(a), do we want to -- sentence 1 plus sentence 2? Or who can calibrate -- promote afterloading device sources?

MR. AYRES: That was the issue that was brought up. What we do under teletherapy, we allow an individual under the supervision of the authorized physicist to perform the calculations. He is supervised by an authorized physicist. Should we or shouldn't we, I guess is the question.

CHAIRPERSON STITT: Who is that likely to be?

MR. AYRES: It could be anybody. The authorized physicist develops a calibration procedure and reviews the --

MR. CAMPER: Well, you get back to this physicist in training, for example.

MR. AYRES: Or a dosimetrist or a technologist.

MR. CAMPER: Right, or a technologist, or the physicist himself, of course.

MR. AYRES: Yeah. Or the physicist himself, yes.

MR. CAMPER: Right.

CHAIRPERSON STITT: But one of the problems with brachytherapy versus teletherapy is teletherapy is very stable as a rule. It should be.

MR. CAMPER: Right.

CHAIRPERSON STITT: And we're talking about sources that are coming and going here, potentially. I mean, this is a high dose rate iridium. I'm just a little -- I'm more reluctant to allow some of this to be done --

MR. AYRES: Well, we've now got two situations.

MR. CAMPER: So you're saying the second sentence should be explicit that only the physicist can do the --

CHAIRPERSON STITT: That's a question that I have.

MR. AYRES: Well, we also have two situations now. We have the Farmer chamber type calibrations, which require more precision and care, and, of course, source to detector distances are very critical because of the lower strength of the source and the non-uniform field that you have with regard to teletherapy.

On the other hand, a lot of facilities are going over to the small well ion chamber, which calibration almost becomes trivial except checking the math for the --

CHAIRPERSON STITT: That's true.

MR. AYRES: -- for those that are non-pressurized air chambers for the appropriate corrections for air density and temperature, etcetera. So you have one that's a real easy calibration procedure, technically, or at least in form you run the -- if you've got a proper jig, you program the source to go out to the middle of the chamber and take a reading, and

that's it. The other one is -- requires more care.

CHAIRPERSON STITT: So, I mean, in that sense, it reads perfectly well and is practiced that way.

MR. AYRES: Yeah, by many -- more and more are going to the well chamber for these devices.

CHAIRPERSON STITT: Well, and, of course, the issue is whether or not the authorized physicist checks their own work or somebody that they're supervising. If they don't check it, you're going to have a mistake like you --

MR. AYRES: Well, they are required to --

CHAIRPERSON STITT: -- the high dose rate prostate implant. I mean, that didn't get checked. And a regulation change wouldn't have made that any different. It was a practice --

MR. AYRES: Let me clarify here a little bit and make sure it actually --

CHAIRPERSON STITT: So I think I'm satisfied with it, unless you folks feel strongly.

Other issues under Section 4 about calibration? Bob Quillen, did you have other things on that section? Or other comments from the --

MEMBER QUILLEN: I have to look at 30.59.

CHAIRPERSON STITT: -- outlying areas?

MR. AYRES: I recently on this dosimetry system and the AAPM certified lab calibration got a question, and my

response was on that -- that they -- one manufacturer makes these well chambers as an integral unit. Electronics chamber and everything, it's all one -- like a dose calibrator. It's a black box.

And they pointed out that this was extremely difficult and expensive to ship, and so on and so forth, because it was a whole package, and wanted exemption from the calibration every two years. But they had committed already to calibrating their Farmer chamber, which they use for this and other things, every two years. So I said, "No problem. You calibrate your Farmer chamber every two years, and you transfer the calibration to your well chamber."

In other words, as soon as you get your calibrated Farmer chamber back, you calibrate your fresh HDR source, and then transfer that calibration to the ion chamber, and you've accomplished the same thing without sending the ion chamber. It's a transfer calibration to the AA -- ADCL is what they're called -- laboratory.

MEMBER QUILLEN: I didn't have any more comments on this.

CHAIRPERSON STITT: On that section, for calibration? Does that bring us to 5, then, methods used for -- obtain compliance with --

MR. AYRES: The requirement in --

CHAIRPERSON STITT: All right.

MR. AYRES: -- 10 CFR 59.

CHAIRPERSON STITT: Trish, anything you have from here backwards?

MS. HOLAHAN: Wow, I'm getting a reputation here.

CHAIRPERSON STITT: No, you're not. That's why we work together on this.

(Laughter.)

MR. AYRES: Brake or reverse shift lever.

(Laughter.)

CHAIRPERSON STITT: That way we know we have truly reviewed. Everybody happy with it at this point, or are we willing to keep moving forward? Because if there are some other things that you are kind of sitting there dwelling on, we ought to review them. Larry?

MR. CAMPER: No, I think I'm okay.

CHAIRPERSON STITT: Bob Quillen?

MEMBER QUILLEN: I'm okay.

CHAIRPERSON STITT: All right. That brings us to emergency procedures, which I think I've heard about before.

MR. CAMPER: Yes, I think we have.

CHAIRPERSON STITT: Do you think we've had enough emergency procedures?

MR. CAMPER: I think so.

CHAIRPERSON STITT: Okay. Maintenance. Maintenance of remote afterloading.

MEMBER QUILLEN: I have a question on maintenance.

CHAIRPERSON STITT: Yes, sir.

MEMBER QUILLEN: It's more how the NRC does things, which is do you require or expect that a person performing maintenance on these devices do a reciprocity request when they go into another jurisdiction?

MR. AYRES: Definitely.

MR. CAMPER: Sure.

MEMBER QUILLEN: We had to tell Nucletron that they had to do that, because they weren't doing it.

MR. AYRES: They got a civil penalty for not doing it in our -- they are now licensed.

MR. CAMPER: Be careful to the degree to which we discuss names.

MR. AYRES: Oh, okay.

MR. CAMPER: Particularly if there is some ongoing action.

MR. AYRES: This is not. This is several years old.

MR. CAMPER: But even there, I think I would make that point without referencing any --

MR. AYRES: Since it was public document I -- but yeah, they now handle -- one way of handling it is to become licensed in the state, or the other way is to do reciprocity.

And if a company does a lot of repair work, it's probably to their advantage to get licensed in the location where they do the repair work rather than --

MR. CAMPER: But this point, though, that I think that Bob is getting at is the point that I raised yesterday when we were talking about mobile nuclear medicine, and that is yesterday I wanted to have some words put in that reminded people in doing mobile nuclear medicine, if you're crossing out of NRC jurisdiction, going into an agreement state, then there is the question of reciprocity, and do we need to contact the agreement state, because the reciprocity requirements vary from state to state.

And imagine a scenario where you have an NRC license, and you're operating from southern Virginia, and you want to go across the border into North Carolina. You can't just do that.

Well, similarly, it might be worthy if we could find some words to put in here to point out that reciprocity may be a consideration when using companies for purposes of calibration, and that there is a need to ensure that reciprocity requirements, as they relate specifically to the states involved, are met.

MS. HOLAHAN: But is that incumbent on the licensee or the manufacturer?

MR. CAMPER: Well, it's incumbent upon the

servicer, the company.

MR. AYRES: Actually, there is three scenarios -- agreement state, one agreement state into another, from an NRC state into agreement state, and from an agreement state into an NRC state. There is all --

MR. CAMPER: Well, I -- but, you know, it does -- certainly, the responsibility for the reciprocity is with the service organization. I guess the question is, should --

MR. AYRES: Should the licensee check --

MR. CAMPER: Well, or should the licensee at least be aware --

CHAIRPERSON STITT: Should be aware, right.

MR. CAMPER: -- that reciprocity, when you're dealing with companies that are calibrating or, excuse me, doing maintenance on your remote afterloading device, you know, you probably would be wanting one that has gone through --

MEMBER QUILLEN: Right.

MR. CAMPER: -- whatever appropriate reciprocity is.

MR. AYRES: Well, I guess the only problem there there isn't an incentive or disincentive, and there is no penalty accrued to the licensee if repair is being done by a maintenance or vendor organization that doesn't have reciprocity. The --

MR. CAMPER: Well, no, but wait a second. Actually, no. The licensee shall confirm that only personnel who are licensed by the Commission or an agreement state to perform such services will perform maintenance. You --

MR. AYRES: But that doesn't have anything to do with reciprocity.

MR. CAMPER: Well, certainly, it does. No, absolutely, it does. I would submit to you that if you're an NRC licensee in an NRC state, and you're using a company that's licensed by an agreement state, and reciprocity has not occurred as required under 150.20, that company is not licensed by the Commission in that case to do it.

MR. AYRES: Yeah. You're getting to a point that the --

MR. CAMPER: Or an agreement state, and then the process involves reciprocity.

MR. AYRES: The way the situation is now you go read any vendor or service organization license, and you'll see that they are licensed to service machine X, Y, A, B, C, or what have you, which as I read this would satisfy that requirement. Now, I admit that the company hasn't satisfied their own requirement if they don't apply for reciprocity.

Right now, in any case I'm aware of, the fault is attributed to the service organization, never to the licensee.

MR. CAMPER: Well, there is no question about that.

MR. AYRES: -- require reciprocity.

MR. CAMPER: And then, this is --

MR. AYRES: I'm just saying --

MR. CAMPER: It's an informational point.

MR. AYRES: Yeah.

MR. CAMPER: The licensee should -- is there any value, or is it appropriate for licensees to be aware that when dealing with organizations that are licensed by the Commission agreement state, and are crossing state lines, that there is a reciprocity process involved? I mean, is there any value in them knowing that?

MEMBER QUILLEN: See, here's the problem we face in an agreement state. I have -- company A comes in from another agreement state, or from the NRC, for that matter, and does maintenance. They have not filed a reciprocity with me. They leave. The only person I have jurisdiction over is the licensee.

I don't have jurisdiction over that company that came in under reciprocity once they're gone, because I have no jurisdiction outside my state --

MR. AYRES: I guess that's where we differ --

MEMBER QUILLEN: Yeah.

MR. AYRES: -- with you.

MEMBER QUILLEN: And I can't do anything about it. The only thing I can do is go hassle my licensee at the -- you used a company that was --

MR. AYRES: This sounds like a much broader issue. It sounds like it deals more like a problem with 150 part than it does here. What we're trying to do is -- it sounds to me --

MR. CAMPER: Well, as you know -- you are correct. I agree. We have a memo with research to do a revision to 150.

MR. AYRES: But it -- reminding licensee that their service organization should do something, which if they don't bother to check, isn't going to cost them anything anyway. It probably would not be too --

MEMBER QUILLEN: Well, it is going to cost them, because it's going to --

MR. AYRES: Okay. I guess in our states, it wouldn't.

MEMBER QUILLEN: I mean, it's going to cost them that we're going to hassle them.

MR. AYRES: Well, they're the only people we can hassle.

MEMBER QUILLEN: Oh, well, we would hassle the vendor or the service organization.

MR. AYRES: Well, yes, but the vendor was in an

agreement state. How are you going to hassle them then?

MEMBER QUILLEN: We have that provision in our -- in 150.

MS. HOLAHAN: So do we want to put a statement in here just saying that --

MR. AYRES: I guess you always do have some authority. You can always bar the vendor from -- an individual agreement state could take some sort of regulatory action to bar the vendor from working in the state, or assess a civil penalty that they can't work in the state again until they pay. I would think you would have some sort of authority.

CHAIRPERSON STITT: Is it appropriate to put a helpful tip in this section of an NRC document on a --

MS. HOLAHAN: Where we remind the licensee that it's the vendor's responsibility, but the vendor would --

MR. CAMPER: Well, if we were going to do something about it, in terms of information, it would be something along the lines of a sentence that said, in essence, the following. If we have a sentence that says, "The licensee should confirm that only persons who are licensed by the Commission or agreement state to perform such services," blah, blah, blah.

Please note that a service company licensed by -- remember now, we're talking NRC licensees -- licensed by an

agreement state will be required to file for reciprocity within -- by -- with the NRC in order to perform this service.

CHAIRPERSON STITT: Bob Quillen, is that helpful?

MEMBER QUILLEN: Yes.

CHAIRPERSON STITT: Let's put that in. It's easy to read, it's a helpful hint, and there is no paper that has to be kept for three years.

MEMBER QUILLEN: Right.

CHAIRPERSON STITT: We've done them a favor. Okay. Let's keep going with maintenance. Bob, what else do you have?

MEMBER QUILLEN: That's all I have.

CHAIRPERSON STITT: Are you sure?

MEMBER QUILLEN: That was my last item.

CHAIRPERSON STITT: Okay. Trisha?

MEMBER QUILLEN: I had one grammatical thing.

CHAIRPERSON STITT: One grammatical thing. One editorial comment? All right.

MEMBER QUILLEN: Under waste management, which is the next page. Go up to 12 -- let me --

CHAIRPERSON STITT: No, I'm not going to let you go on to 12, not yet. Save it.

Any other issues on maintenance, Section 11? Trisha?

MS. HOLAHAN: No.

MR. AYRES: Yeah. One of the items is buried in here. I'll just mention it. It also arose out of the mobile unit is -- is the source replacement issue, and in here is a requirement that they -- it either be done by the vendor or somebody certified -- trained and certified by the vendor to do those source exchanges.

CHAIRPERSON STITT: Which section is that, or which --

MR. AYRES: This is the one we did, 11.22.1.

CHAIRPERSON STITT: 1, okay, all right. Anything else?

MR. CAMPER: Nothing here.

CHAIRPERSON STITT: Okay. 12, radioactive waste management.

MEMBER QUILLEN: Okay. My comment on radioactive waste management is that what you're referring to here is not -- it's unclear because you've got two situations. You've got a situation you're talking about where you're returning material to the vendor, which I think is the typical situation.

MR. AYRES: The normal, yeah.

MEMBER QUILLEN: Okay? Which is not radioactive waste management. The second situation is where the licensee actually does dispose of the sources. So you're mixing two different situations here.

Now, in the first situation where you're returning the material to the vendor, it has been my experience the vendor comes in, packages the material in their shipping container, and then does the paperwork while the licensee sort of stands by the sidelines and watches.

MR. AYRES: Some do and some provide the container with instructions.

MEMBER QUILLEN: Yeah. Well --

MR. CAMPER: Is anybody getting rid of the sources, other than that way? And, if so, why would they?

CHAIRPERSON STITT: Other than what?

MR. CAMPER: Returning it to the vendor.

CHAIRPERSON STITT: Iridium-192 we returned, not the high dose rate sources, but LDR sources we returned. How did this --

MR. CAMPER: You return them to the vendor, right.

CHAIRPERSON STITT: How did this come up in regard to yesterday's discussion? Do they return sources, or do they use them up and just --

MR. CAMPER: Yesterday was radiopharmaceutical therapy.

MS. HOLAHAN: So we'll be discussing it tomorrow.

CHAIRPERSON STITT: Radioactive waste management, then?

MR. CAMPER: We'll discuss it tomorrow. But it's all liquid.

MR. AYRES: And you can see this is 12.3. 12.1 and 2, obviously, deal with the other more normal disposal method.

MS. HOLAHAN: In the Reg. Guide -- you see, the item is listed the way the license application is listed. Item 12 is considered waste management, which is, you know --

CHAIRPERSON STITT: So do you --

MS. HOLAHAN: -- disposal of sources would be more --

CHAIRPERSON STITT: Bob Quillen's point about is waste management returning sources to vendors, or is that --

MR. AYRES: That's one form of --

CHAIRPERSON STITT: Is it?

MR. AYRES: -- managing the waste disposal.

MEMBER QUILLEN: The transfer is not a waste disposal, because if you do ship it as waste, it becomes waste. But if you ship it back to the manufacturer, it is still material. It's a very crucial point in waste management that --

MR. CAMPER: Yeah. And my point was that I would be surprised if anybody is doing anything but that.

MR. AYRES: For these type of sources, yeah.

MR. CAMPER: What?

MR. AYRES: For these type of sources.

MR. CAMPER: Exactly.

MS. HOLAHAN: Because even the cesium sources found there are returned.

CHAIRPERSON STITT: So do we just -- is our problem here the label isn't quite right? Radioactive waste management is not the label we want? Item 12 is returning sources.

MR. AYRES: Well, I think this is a broader question for 10.8, because I think that's the number for 10 --

MS. HOLAHAN: You see, it's -- the title relates to the Form 313 on your license application. Now, the question is, where else would you address it if it was not waste management, because it is returning sources? And that's why we created a separate category. As Bob mentioned, 12.1 is waste disposal. Yeah, 12.2 is other waste disposal. And then, 12.3 is returning sources.

CHAIRPERSON STITT: Okay. So it's just under the Section 12.

MR. CAMPER: Well, where are the words for that?

MS. HOLAHAN: For what?

MR. CAMPER: This is in --

MS. HOLAHAN: This is in the body of Reg. Guide 10.8.

MR. CAMPER: Yeah, 10.8. Okay.

MS. HOLAHAN: And that's why -- and then, if you look at the actual Form 313, which you submit with your license, this item is classified as waste management.

MR. AYRES: Yeah, it isn't exactly a perfect fit, but it's making --

MR. CAMPER: Right.

MR. AYRES: -- putting a slightly round peg in a square hole.

MS. HOLAHAN: Right.

MR. CAMPER: Well, another question on that, what do you mean by the first sentence? "Most RAL brachytherapy sources are reused for therapy," what does that mean?

MR. AYRES: Well, there are some that aren't.

MR. CAMPER: Well, what do you mean, they are reused for therapy?

MR. AYRES: Well, mobile treatments or before the sources --

MS. HOLAHAN: More than one --

MR. CAMPER: Oh, no, I understand that. But what does that have to do with the returning sources?

MR. AYRES: It just says that they aren't -- well, okay. It says unlike other -- an example where it isn't would be the Nucletron low dose unit, where they custom cut iridium ribbons and load them into a safe for remote afterloading.

MR. CAMPER: Right.

MR. AYRES: That's a one-shot deal and then the sources are replaced. They're custom assembled for --

MR. CAMPER: No, I understand.

MR. AYRES: They're iridium seeds.

MR. CAMPER: No, no, I understand that. But the category is returning sources.

CHAIRPERSON STITT: Well, you could just say when sources --

MR. CAMPER: When the useful source --

MR. AYRES: You could delete that sentence. It wouldn't hurt anything.

MR. CAMPER: -- is reached, or when the useful life of the source is reached, it will be necessary to replace it, and they should be returned to the vendor or other authorized recipient.

MR. AYRES: I guess a source expires for three reasons. It's permanently implanted, which is obvious. It is customized, such as an iridium ribbon that is ordered and cut to length for a particular one-time treatment.

MR. CAMPER: Right.

MR. AYRES: And/or its half-life.

MR. CAMPER: Right.

MR. AYRES: I mean, there is three reasons for replacing a brachytherapy source.

MR. CAMPER: The third is just -- it has gone through its decay cycle.

MR. AYRES: Yeah. That's one of the -- I mean, the first sentence doesn't really add anything.

MR. CAMPER: I don't think it does either. I mean, I think it --

MR. AYRES: Yeah.

MR. CAMPER: -- it isn't wrong, but it isn't --

CHAIRPERSON STITT: You could say when remote afterloading brachytherapy sources are replaced, they should be returned to the vendor or other authorized recipient.

MS. HOLAHAN: I think, too, is this was -- again, we were trying to keep modules consistent, and the manual brachytherapy may need to be changed when we discuss it tomorrow.

MR. AYRES: Yeah.

MS. HOLAHAN: It starts off saying --

MR. AYRES: About the same thing.

MS. HOLAHAN: -- many brachytherapy sources may be reused for therapy. Whenever possible, used sources that will not be reused should be returned to the vendor for disposal. As opposed to indefinite storage at licensee's facility. So that's, you know --

MR. AYRES: That's a little bit of trying to keep things in similar --

MS. HOLAHAN: Yeah. So -- and, again, why is it in that one?

CHAIRPERSON STITT: Items 1, 2, 3, 4, and 5, are those lining up? Is everybody happy with those? Packaging, surveys, labeling, etcetera. Bob Quillen?

MEMBER QUILLEN: I'd have to go back to the licensing guide. But, obviously, all of these things that refer back to 49 CFR --

MR. AYRES: Yes.

MEMBER QUILLEN: -- and so what you're doing is saying, in accordance with 49 CFR, you want to assure that you do these --

MR. AYRES: And/or 10 CFR 171 or --

MR. CAMPER: No. Isn't it CFR 170? Isn't it?

MR. AYRES: Yeah, 170. I should refer to --

CHAIRPERSON STITT: Are there any more issues on that section? Item 12? Are you ready to go to the glossary, folks?

MR. CAMPER: Yeah, that's all I have.

CHAIRPERSON STITT: I looked at the glossary. Who wants to complain about the glossary?

(Laughter.)

MR. CAMPER: Who wants to complain?

CHAIRPERSON STITT: I mean, I've been through it. I think it's helpful. It's fine. It's brief. It's to the

point.

MR. CAMPER: There's a couple of terms that we've discussed today that should be added, aren't there?

CHAIRPERSON STITT: Yes, that's right.

MEMBER QUILLEN: Yeah, that's right. That's my only comment.

CHAIRPERSON STITT: And what are those terms?

MR. AYRES: I had one comment here that -- on interluminal -- maybe suggest an additional definition as with the inner space of a tubular organ. But in lumen, it -- lumen of a tube is sort of a gratuitous definition, I guess.

MS. HOLAHAN: I think it came out of Steadman's.

MR. CAMPER: Well, were you going to put in medical physicist?

MR. AYRES: Yeah, that --

MR. CAMPER: Were you going to put in operator?

MR. AYRES: Certified or --

MS. HOLAHAN: Do we want to have certified --

MR. CAMPER: What does "certified" mean? Certified by whom?

MR. AYRES: By the definition in this document.

CHAIRPERSON STITT: But if we can define it in that document.

MS. HOLAHAN: But do we need to put that --

MR. AYRES: I look at that issue and --

MS. HOLAHAN: Yeah.

MR. CAMPER: What does one need to do to become certified? Demonstrate competence, and certification is tested --

MR. AYRES: A written and practical test demonstrating competence in the --

CHAIRPERSON STITT: Does it say that?

MR. AYRES: Yes, it does.

MR. CAMPER: Where do you get all of that? Where does it say that?

MR. AYRES: It's in the training.

MS. HOLAHAN: Bob, for the purposes of --

MR. CAMPER: Is that a matter of record, though, in --

MR. AYRES: Yeah, they've got to keep records of that.

MS. HOLAHAN: For the purpose of the glossary, though, could we define device monitor and device operator? And then, in the training we would say that they would need to be trained and certified, rather than calling them a certified device monitor.

MR. AYRES: Yeah. I think the certified may go away, yeah.

CHAIRPERSON STITT: It's a catch-phrase that brings up a lot of bells that we'd have to support, and we

can't. And I think it would just be easiest to leave it.

MS. HOLAHAN: The only term I think might be difficult to define here is medical physicist, because we're going to define medical physicist as it applies to this module.

MR. CAMPER: Well, the definitions are always -- the definitions here would be germane to this module.

MS. HOLAHAN: Right. But then the question is -- because the comment is also being raised, do we define a medical physicist when we use the term in --

MR. AYRES: Yeah. I don't really use "certified" in the training. I say, "Upon completion of this training, competence should be demonstrated by both practical and written examinations."

CHAIRPERSON STITT: But there was a phrase in there that -- at one point, that Quillen found that said certified device operator.

MR. AYRES: Well, yeah, I read that.

CHAIRPERSON STITT: We need to strike the "certified" in that.

MR. AYRES: Yeah. Got to get rid of that. It relates back to this, and I just called it certified competence demonstration. Wrong way to go. Okay.

MS. HOLAHAN: Are there any other terms that you think should be included?

MEMBER QUILLEN: None that I have.

CHAIRPERSON STITT: I don't remember reading through anything that was out of --

MR. CAMPER: No. I think those are the ones that we've stirred up along the way.

MEMBER QUILLEN: Yeah, I think we should have W-I-R-E, O-R underlined, hyphen E-D.

CHAIRPERSON STITT: Where are you, Dr. Quillen?

MR. AYRES: Oh, I'm going to readjust that. I -- that wired or/wired and.

MEMBER QUILLEN: For us non-electrical engineers.

MR. AYRES: I will rephrase that, those two. I'll just say logical or/logical and.

CHAIRPERSON STITT: Okay. Other comments on the brachytherapy glossary? Yes? No? Everybody happy with that? Okay.

Now, the standard license conditions. Is this new? Yeah, I guess it is, isn't it? We put things together -- pulsed, medium, high dose rate -- so we need to review these pages like the others or --

MS. HOLAHAN: These were what --

MR. AYRES: We bounced into and out of them as we went through the document already.

MS. HOLAHAN: Right.

MR. AYRES: We certainly discussed this source

inventory one, I think, quite a bit.

CHAIRPERSON STITT: How about the first sentence? Is this -- can we use the term "always"? Is that all right in this case? We can use that term?

MS. HOLAHAN: They don't apply to anything other than remote afterloading devices.

MR. AYRES: Right.

CHAIRPERSON STITT: Only apply to the use of -- are we going to get grief over always, shall, should?

MS. HOLAHAN: Yeah, because some of them don't apply to all. Is that --

MR. AYRES: Right. I have them generally apply to all, pulsed, and medium, and high.

MR. CAMPER: Yeah, he has segregated them by --

MS. HOLAHAN: Do we need the word "always"? Can we just say, "The following license conditions apply to use"?

MR. AYRES: It's probably a little over it. I wonder if --

MR. CAMPER: I'd strike "always."

MR. AYRES: Should I get rid of "standard"? I refer to them in the text as sample.

MS. HOLAHAN: You've got them both ways in the text.

MR. AYRES: Yeah, I --

MS. HOLAHAN: Standard and sample.

MR. AYRES: Yeah. Need to be consistent. I don't know which way to --

MR. CAMPER: Well, standard is our --

MR. AYRES: Okay.

MR. CAMPER: -- nomenclature.

MR. AYRES: That's what I --

CHAIRPERSON STITT: Okay.

MEMBER QUILLEN: I have a comment on (b) at the bottom of page 39.

CHAIRPERSON STITT: Okay.

MEMBER QUILLEN: You refer to item 9 sub-items.

CHAIRPERSON STITT: You're wondering where that is, huh?

MEMBER QUILLEN: Let's see, this says, "The following shall" -- I would opt for putting them in, all of them, so that they can --

MS. HOLAHAN: And then we do -- we would be --

MR. AYRES: Okay. If that's the case, I'll take care of that. That will come out of -- that one I missed that came out of the old policy and guidance directives. That's item 9.

MS. HOLAHAN: Which one was that?

CHAIRPERSON STITT: Paragraph (b), page 39, listed in item 9.

MR. CAMPER: Let me ask the group a question.

Trish and I were having a sideline discussion here. You're saying in this case now, on page 39 and 40, you're saying standard license conditions that are being used for RAL, for brachytherapy, okay?

Now, the other modalities, the other issues for which we also developed modules also carry with them certain standard conditions. Those other modules, unlike this one, do not have in them, at the end, those standard conditions. They are in this particular one because, again, this is part of this fallout that I alluded to earlier today, in that we had been doing a lot of the current level of regulation of HDRs through license conditions, just as time as we modernized the regulations, if you will.

Now, the question really is, a) what is your impression of having the standard license conditions included in the guidance document? Do you think that is of utility to the licensee, to the applicant? Or could it be jettisoned? Or -- and secondly, if we do keep it in this one, if we think it has value, should we be putting standard license conditions that apply to the other modalities in those guidance documents as well? Do you have any impressions about that?

MR. AYRES: One thing I mentioned that -- that part of the reason, too, is we needed a lot of these "in lieu of's" --

MR. CAMPER: Right.

MR. AYRES: -- type of standard license conditions.

CHAIRPERSON STITT: Say that again. What are you referring to?

MR. AYRES: Because we had to provide an alternative to the current regulations that didn't -- for manual brachytherapy for -- that just can't be applied to a remote afterloading device.

MEMBER QUILLEN: Well, I liked having them in here. The only thing that -- I was confused for a while, and it just dawned on me why I was confused, and that was that page 39 and 41 are in different print than pages 40 and 42.

(Laughter.)

And part of -- and when you printed it, part of it got carried over to one page, so --

CHAIRPERSON STITT: Somebody summarize for me what this is, because all of the points here are in the larger document. So it's a distillation of the essence that the --

MS. HOLAHAN: No, these are actually what get put on the license. When you come in and you get an approved license, then attached to your license are all of these conditions that you have committed to. It says, "This is what you're going to do."

CHAIRPERSON STITT: And then, the body that we just went through is a discussion in more detail of some of

the conditions --

MS. HOLAHAN: That's correct.

CHAIRPERSON STITT: -- or how you reach --

MR. AYRES: Yeah. In the body, sometimes I just referred to these standard licenses.

CHAIRPERSON STITT: So in that sense, I think it would be very helpful, because it's a place where you start, and then, like Trisha, work backwards.

(Laughter.)

MS. HOLAHAN: And I guess, then, the question is, would that then be helpful? Should -- this goes back to your consistency question of modules. If we're going to include it in one, should we include them in --

CHAIRPERSON STITT: Well, I think so.

MS. HOLAHAN: -- all of them? Now, this list would be expanded, because there would be more conditions that we don't have in here yet.

MR. AYRES: It may. Yeah, I think so.

MS. HOLAHAN: Again, as I mentioned, the one that comes to mind is the physical presence of the physician and the authorized user. That would become a license condition.

MR. CAMPER: The thing I'm struck by when I think about it is if I kind of look at this across the board, I would think that there is value in an applicant seeing in front of them the kinds of conditions that will ultimately be

imposed upon them in their license as a result of their application and the commitments they are making, whether it's for, in this case, RALs, for that medical use at large in the medical licensing guide. Is there some value in, again, seeing the conditions that will ultimately be imposed upon your license?

MEMBER QUILLEN: I think it would.

MR. CAMPER: Would that help you better understand what the licensing process is all about?

CHAIRPERSON STITT: Exactly. And how to go through that process.

MR. CAMPER: Because, you know, there are those who say the licensees don't do a terrible good job of reading their licenses once they get them. But they, in theory, you would think, would be looking to a guidance document as they're applying to get it and trying to submit the right kinds of things.

MS. HOLAHAN: That's one thing that I wanted to add, too, is in developing these modules, previously what had happened is the Reg. Guides that went out to licensees contained certain information. Then, we had what was called a standard review plan for license reviewers that would often include reviewers' notes.

Well, as part of this overall module effort, it came to our attention that often those reviewers' notes were

also helpful to licensees, and so what we have done now is this would be the document that would be used by both the licensees and the licensing reviewer.

So we have included anything that previously might have been considered a reviewer note into the body of the module. And then, the only thing that the reviewers would have additional would be a checklist as they would go down looking at a license application.

MR. AYRES: And perhaps related technical assistance requests, the sort of thing that come after the document.

MS. HOLAHAN: That's right. But it wouldn't come -- I mean, not as they would use as the body, but that's one of the things we have tried to do is incorporate many of the reviewers' notes in so that everybody is working, knows where everybody is.

MR. CAMPER: You know, the idea is that truth-in-lending. You know, if our reviewers need to see that, why shouldn't applicants be aware that the reviewers are seeing that and focusing upon it? And that's a legitimate and reasonable approach.

MEMBER QUILLEN: I wasn't here for your discussions yesterday, but I certainly would think that they should have access to that.

MR. CAMPER: Yeah, I think that makes sense also.

MS. HOLAHAN: Just as a note, we can pull out the old Part 20 references on the --

MR. AYRES: Oh, I already noted that. That was in --

MS. HOLAHAN: Okay.

MR. AYRES: -- importing this stuff over from --

(Laughter.)

That has already been duly noted in --

MS. HOLAHAN: Oh, okay.

CHAIRPERSON STITT: What other business do we want to do today?

MR. AYRES: That's all for today.

MS. TAYLOR: That's all we can do today.

MR. CAMPER: That's all we do today, because the schedule for the other topics are in the --

CHAIRPERSON STITT: Tomorrow we'll do manual brachytherapy, teletherapy, and gamma -- same fashion that we worked today.

MS. HOLAHAN: A lot of the issues that we discussed in remote are also applicable to manual, so hopefully some of those won't take quite as long.

MR. AYRES: Actually, we did this review the reverse of the way they were written. Manual was written before --

MS. HOLAHAN: That's true. We wrote manual, and

then we wrote remote.

CHAIRPERSON STITT: Well, the remote is the harder of the whole group, isn't it?

MR. CAMPER: I think so.

CHAIRPERSON STITT: I would think so.

MR. AYRES: It's certainly more complex, I guess, because of the multitude of different types of devices.

CHAIRPERSON STITT: So we'll start off with manual first thing in the morning.

MR. AYRES: Okay. That will work.

MR. CAMPER: Okay. Are we in closure for the day, then? That's it.

(Whereupon, at 2:55 p.m., the subcommittee meeting was concluded.)