UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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SUBCOMMITTEE ON MANUAL BRACHYTHERAPY, TELETHERAPY

AND GAMMA STEREOTACTIC RADIOSURGERY

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FRIDAY

SEPTEMBER 29, 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.

COMMITTEE MEMBERS:

JUDITH ANNE STITT Chairman

ROBERT M. QUILLIN Member

DANIEL F. FLYNN Member

ALSO PRESENT:

Larry Camper

Trish Holahan

Torre Taylor

Penny Lanzisera

Neelan Bhalla

Jim Smith

I N D E X

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

(8:13 a.m.)

MR. CAMPER: Good morning, ladies and gentleman. I'm Larry Camper. I'm the Chief of the Medical Academic and Commercial Use Safety Branch. I am the designated federal official for this public meeting, which was announced in the Federal Register on the 21st of August 1995. This is a meeting of subcommittee of the Advisory Committee on the Medical Uses of Isotopes.

Today is day three in a series of discussions dealing with guidance modules that are to be included into Regulatory Guide 10.8, and then subsequently included within a licensing manual that is currently under development through our business process reengineering process. At this point, the subcommittee has discussed mobile medical services, radioactive drug therapy, remote afterloading.

And today, we will discuss modules dealing with manual brachytherapy, teletherapy, and gamma stereotactic radiosurgery. With that background then, I would ask Dr. Judith Stitt, who is chairing the subcommittee, to proceed for us.

CHAIRPERSON STITT: Let's follow the format that we worked over yesterday, which really is going through the module page by page. But, as we started off yesterday, I'd ask folks to -- you can tell I'm from the midwest; folks is how we talk there -- I'd ask folks to give me issues that they felt strongly about or needed special attention.

And I think possibly the remote section, because it's a bit newer technology, had some more areas of intense interest than the manual might. The other thing I'd like to ask, Trish, since you were the one who had passed out the comments that you had gotten back -- as we get on the page by page, if you'll interject the appropriate comment that we need to look at.

Dr. Flynn or Quillin, are there areas that are -- this particular document that are particularly troublesome or need more indepth review -- anything that we -- make sure we focus on?

MEMBER FLYNN: I just would ask that if we can go through -- for example, one section that always concerned me was the training of nursing staff for the manual brachytherapy, because we have an instance where, in a radiation oncology department, where we have individuals -- physicians like ourselves who have many years of training who are on site with physicists with many years of training, who are on site with technologists who go through an extensive training during the day hours.

And then during the evening and weekend hours, the nursing staff are at somewhat of a disadvantage being up on the hospital floor with perhaps one hour of training a year or even less who then are responsible for taking care of the medical needs and the nursing needs of many patients on the floor. Their training has always been focused on that, and then they -- an incident occurs involving a brachytherapy patient.

Sometimes the incident is handled well, and sometimes it's not handled well. But I think that we have to provide the guidance to the medical community in terms of the level of training and retraining that the nurses should get if they're especially -- the nurses that are on the brachytherapy floor taking care of these kinds of patients.

I just -- I'm looking at two incidents right now, Region 1, right now. It was just given to me less than a month ago. Again, with this large source that a nurse taped to the face of the patient -- this is another incident. And another incident that occurred in Region 1 where a source fell out of an ovoid again. This has happened a number of times.

It went unrecognized by those who were applying the source, but it was recognized by a nurse nine hours later. And the licensee reported that with the inverse square law that the dose to the patient's skin was very low. And I've discovered they made an error in their assumption. I reinterviewed the nurse by phone and that the source wasn't 12 centimeters away, but in contact with the skin.

So the dose was much higher. So that's all going to be reworked, and I've confirmed that. And so, it's one area that always concerned me, because going -- when the patient is in the hospital from 7:00 to 6:00 or 8:00 to 5:00 is virtually an army of heavily trained people to take care of a problem that occurs. And then from 6:00 at night until 7:00 in the morning, that's not the case for an inpatient.

And we really have to address that. There are many issues that we hope don't occur, but brachytherapy patients have medical emergencies too, whether it might be difficulty breathing because of emphysema or there may be -- they're technically an older patient, so they can have a heart condition, severe chest pain, something happens that they're unstable that blood work needs to be drawn.

And so, other health care providers must get to the room, and the patient who has a brachytherapy implant and do medical kinds of things. And sometimes there's a delay or a hesitancy to do the things they need to do because of a concern about the radiation aspects.

If the nurses are well trained, they can act initially until the medical staff arrive on site as the medical health care providers who are in charge to help give guidance to those who don't have the training who need to draw blood or take an EKG or do suctioning on the patient -- breathing difficulties.

So, I just want to make sure that 9.1.1.1 training for nursing staff gets a lot of attention.

CHAIRPERSON STITT: The training section yesterday was the subject of a fair amount of discussion. I think the issues with remote, however, are different than with manual. So that's probably going to be a high level of attention area. Bob, areas that you -- what should we focus on?

MEMBER QUILLIN: Well, the only issue in this particular document that is a higher priority for me is the issue under permanent implants, 11.19.2, about how you handle the source that becomes dislodged after a patient has left the hospital. The instructions that are in the document here I think are wishy-washy, I guess is the best way to put it.

CHAIRPERSON STITT: Okay, we'll make sure and touch on that. How about to my left? Any high risk, high frequency kind of problems?

MS. HOLAHAN: Okay, I guess the one question that I would put on the table is similar to what we had yesterday for the manual is currently -- if you notice, the document you have in front of you doesn't have anything specific for item eight, which is training for authorized users.

A similar question to what we had yesterday, should we include the section to say that a physician that isn't board certified should have -- you know, should provide demonstration of experience with brachytherapy as -- or is that not as critical in terms of the experience?

And then the other question, although there is no specific training for physicists and we don't require a physicist for manual, should we address the fact that there are no specific requirements in Part 35 for physicists, or just remain silent on it?

CHAIRPERSON STITT: We'll get there, won't we? I'll put that in my notes. All right, let's start with the page one and page two of this draft. And Dan, what we've been doing is literally going page by page and paragraph by paragraph. And folks

who have comments that they've reviewed it would just kind of bring them up in order and graze through it, look at it section by section and keep going.

MR. CAMPER: Judith, let me interject a general concern. Also from the standpoint of training, Dan's points -- an observation that I've made about training is if I look at the regulations today on the training that is supposed to be provided to nurses in the brachytherapy arena, it's pretty comprehensive. But yet we still continue to get some of the events like you were just describing where the nurse tapes it to the face of the patient and this type of thing.

I don't know why that continues to happen. I don't know if it's a problem associated with are all shifts being instructed. Because I think certainly the requirements seem to be comprehensive enough, but something's not working, and that concerns me. And the other one is, in looking through the glossary, there's some terms in there where we define interstitial, intraluminal, intracavitary, topical, etc., etc.

I want to make sure that we've captured those definitions adequately from a medical perspective or that we haven't gone too far -- that they seem to be acceptable to you.

CHAIRPERSON STITT: Other comments on items six, seven? Seven includes interstitial treatment and lists sources; and 7.1.1 has -- relates to eye plaque brachytherapy.

MS. HOLAHAN: Okay, I just want to address a couple of the comments that I had made -- I received on item seven as -- one of the comments I had got was that we have listed gold-198 for interstitial. Somebody said nobody uses that anymore. However, I think we have seen cases in which gold is still being used, so we are not -- I mean, it is in the regulations, so we have not removed it.

And I guess I just wanted confirmation that gold is still being used periodically.

MEMBER FLYNN: Yeah, but it's -- that's right, you have to include it even if a few licensees still use it.

MS. HOLAHAN: Right, but it is still being used, even if it is rare. Also I-125 -- I think Dr. Flynn made the comment is available as ribbons as addition to seeds. And what we have cited here is what's in the regulations. This was a comment Larry had made yesterday about 35.400 has very specific listings.

And so, what we have repeated here is the listings, and I don't know how to address the additional uses that is is being -- it does -- is shipped in seeds -- or in ribbons, I apologize.

MR. CAMPER: No, I think you've done all that you can do at this point in terms of the regulatory authorizations. That is what we have to work with for now. That needs to be fixed, as we've discussed. It really ought to be -- as I said I think yesterday, that any source for any approved use for which the source and device has undergone review.

But until we can fix that, I think this is about the best we can do.

CHAIRPERSON STITT: Any other comments on 7.1?

MR. CAMPER: No, I had a couple of editorial things within item seven itself, --

CHAIRPERSON STITT: Okay.

MR. CAMPER: -- but I can share those with Trish. The main thing really is that I thought the sentence that reads "it is not the intent of 10 CFR Part 35 to prohibit appropriate medical practices" would be better served by moving it in the paragraph a bit up to the next page. The sentence reads "when the manufacturer or

end user requests that a safety review be performed for a proposed type of use, the integrity of the source is tested against the criteria for the type of use requested," so forth and so on.

And I think at the end of that sentence is a better place to insert it is not the intent of Part 35. Another alternative place might be just before the sentence that commences "medical broad scope licenses are not limited," blah, blah, blah. It certainly could be little bit better fix, but it's editorial.

CHAIRPERSON STITT: Sounds fine. We take editorial comments here. Let's look over eye plaque brachytherapy. Comments?

MS. HOLAHAN: What I'd like to -- and let me just perhaps go -- repeat what I had said yesterday for Dr. Flynn's benefit -- is when we have developed these modules, we're also making revisions to the body of Reg. Guide 10.8. And so, there is some items that apply across the board to all modules that are addressed up front in the body.

There are some obviously that are specific to manual that we have tried to focus in here. That was the first point I wanted to make. The second point is when we were developing these modules, previously there had been Reg. Guides that were put out for licensee use, and then there was the standard review plans that were used by licensing reviewers, which often included reviewer's comments specific.

When we were doing these modules in the revision of 10.8, a decision was made that actually in many cases the reviewer's comments were also helpful to the licensees to understand the processes and where we were going. And this is one of those cases. In terms of the eye plaques, there was a description of the eye plaque not so much telling licensees what it is, because we assume if they're

coming in that they understand that; but that would also be provided to the license reviewers so that they have an awareness.

CHAIRPERSON STITT: But it's nicely set up as far as describing how this thing works, the comments about why it is interstitial or considered to be interstitial rather than topical.

MR. CAMPER: Is that all that is reasonable as an explanation?

CHAIRPERSON STITT: I think it is.

MEMBER FLYNN: Yes.

MS. HOLAHAN: Because this has been a question that has come up is whether or not it's interstitial versus topical. And so, if -- you know, if you feel that it is not interstitial, then we'd appreciate your comments.

MEMBER FLYNN: I could see it both ways.

CHAIRPERSON STITT: What?

MEMBER FLYNN: Sometimes you consider it both ways.

CHAIRPERSON STITT: Yeah. I mean, I think it -- the arguments support calling this interstitial the way it's been set out. It's clearly not the use of a surface applicator. I mean, that is kind of --

MEMBER FLYNN: Okay.

CHAIRPERSON STITT: -- in its own little category, which is why it's got its own little category. Other comments? Dr. Quillin? Okay, no blue stuff on that?

MEMBER QUILLIN: No.

CHAIRPERSON STITT: Okay, all right. 7.2 is intracavitary describing cobalt and cesium.

MR. CAMPER: I had a question about that one for the committee. Down toward the end of the paragraph, we make the statement that "This exemption

will be granted with no additional safety procedures or commitments. In addition, for purposes of NRC's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary," -- no problems with that medically that --

MEMBER FLYNN: Right.

MR. CAMPER: Okay.

CHAIRPERSON STITT: I agree.

MR. CAMPER: Wonderful.

CHAIRPERSON STITT: Does that help you?

MR. CAMPER: It does.

MS. HOLAHAN: Well, just one thing. Again, something that has come up as a question, and we just sort of want a confirmation in the direction that we were going.

MEMBER FLYNN: I always thought of intraluminal and intracavitary as being identical. It's in a -- it's not implanted in terms of violating tissue. It's in an existing cavity or tube that's anatomically there. And you're not going into the tissue or doing anything surgically or embedding anything into the body. You're in a cavity.

MS. HOLAHAN: Okay, because I think one of the problems is in 35.400 again. There is no such thing as intraluminal.

CHAIRPERSON STITT: It just doesn't address it.

MS. HOLAHAN: Right.

CHAIRPERSON STITT: Yeah, to me it's kind of a subcategory of intracavitary. That is, just a specialized version of intracavitary. All right, isn't this wonderful when it's just so simple to do this?

MR. CAMPER: It's just --

CHAIRPERSON STITT: But we have been doing manual brachytherapy since Madame Curie, so we probably ought to have some experience in how to issue --

MEMBER FLYNN: When I was looking at this the other night, when you put 7.2 and sub (a), cesium-137 and cobalt-60, was did there used to be a sub (b), and you need to have a point (a) there? Or did you mean to have (a) cesium, and (b) cobalt?

MS. HOLAHAN: Now again, what that is is taken straight from 35.400. And it is listed because we had done it in other section 7.1 -- we'd had (a), (b), (c). 7.2 only had one listing as to what is approved for intracavitary. So there was no (b) or (c).

CHAIRPERSON STITT: You'll also find, Dan, that there's some places where there seems to be items missing or portions of items missing, and we're not looking at the complete -- well, we're not looking at all of the document. We're looking at --

MEMBER FLYNN: Like Section H?

CHAIRPERSON STITT: Yeah. So you'll find some things that -- this is not a stand alone document. Topical applications?

MS. HOLAHAN: Let me ask one quick question on eye plaques. And I do apologize for going backwards again.

CHAIRPERSON STITT: That's fine.

MS. HOLAHAN: A comment was made that cobalt-60 is also used in eye plaques.

CHAIRPERSON STITT: Right.

MS. HOLAHAN: Is that correct? We have not addressed that in here, and I was wondering again if --

CHAIRPERSON STITT: No, I think it is, isn't it, Dan?

MEMBER FLYNN: I'm not sure if it's still being used or not. I have never done any eye plaques. As a matter of fact, a lot of centers don't do eye plaques. There's a certain limited number of centers. They're usually associated with a large ophthalmological hospital and they get large numbers of cases and they do them extremely frequently than most other centers -- or many other centers never do them at all.

CHAIRPERSON STITT: Now cobalt-60 is used, because we use it either experimentally -- I know we use it for animal research for eye melanoma.

MS. HOLAHAN: Okay, is that -- that's in what form? Because again, I'm looking now at what we have in 35.400, is it doesn't list cobalt-60 as seeds. Whether or not --

CHAIRPERSON STITT: Oh, no; we need to ask a physicist.

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: Or I can call you back with that information. How do you want to handle it?

MR. CAMPER: Would you mind doing that?

CHAIRPERSON STITT: No problem. I'll E-mail you.

MS. HOLAHAN: All right.

CHAIRPERSON STITT: That way I don't have to -- I love E-mail, yeah. If you're not on E-mail, you're left out. All right, I will get the information on eye plaque cobalt and E-mail you.

MS. HOLAHAN: Okay, yes, please.

MEMBER FLYNN: I think large numbers like at certain centers like Hahnemann in Philadelphia and certain centers have been doing them for years. So they will -- some of these people who are doing them every week will be able to answer our questions.

CHAIRPERSON STITT: Are there other comments on the ocular or intracavitary, and let's include topical? Dan, does topical read right to you? Is that how you use the phrase? I always referred to surface applications, but I'm not hung up on that at all. Does NRC -- has topical been the catch phrase for years?

MS. HOLAHAN: Again, that's the use in 35.400 currently.

CHAIRPERSON STITT: Okay, I'm easy, flexible.

MEMBER FLYNN: So that some of the -- is it possible to put topical (surface) so that the licensees -- the authorized users who wouldn't use topical would identify it right away with what you mean, surface applicators?

MS. HOLAHAN: Right, yeah. We can do that very readily in the guidance, yeah.

CHAIRPERSON STITT: And it's in the glossary. Topical is in the glossary. If we could add the same set of parentheses, if you wouldn't mind.

MS. HOLAHAN: Right, right.

CHAIRPERSON STITT: Well, the sources we're talking about are cesium, cobalt, sealed sources in needles. And then our favorite, strontium, which I notice has a parenthesis. It says "NRC authorization for use of a Sr-90 eye applicator -- does not authorize its use on treatment sites other than the eye."

MS. HOLAHAN: And we do list strontium-90 eye applicators as a separate line item on the license.

CHAIRPERSON STITT: Separate from any other type of topical --

MS. HOLAHAN: Right, everything else -- well, everything else is listed as any byproduct material identified in 35.400.

CHAIRPERSON STITT: Okay.

MS. HOLAHAN: But we recommend that strontium-90 is listed separately. And in many cases, an ophthalmologist will have a strontium-90 eye applicator.

CHAIRPERSON STITT: It always astonishes me that so many highly educated people come together at least twice a year and we always at least have one discussion on strontium eye applicators. What is the use of that applicator in this country, does anybody know?

MS. HOLAHAN: Pterygium.

CHAIRPERSON STITT: Well, I know what it's for, but how often or how many places --

MEMBER FLYNN: There's only -- right now there's only one vendor how manufactures the sources, and the problem is, you know, there's a lot of old sources out there.

CHAIRPERSON STITT: A lot of old people using them.

MEMBER FLYNN: It's really hard to know.

MS. HOLAHAN: It has a fairly high usage in Puerto Rico where we see a lot of use. And then there -- sorry. There are also some in Region 1 -- some eye applicators.

MEMBER FLYNN: And you know, quite frankly, the patients are referred to radiation oncology by an ophthalmologist. As they operate more and refine their own operative techniques, they have more refined indications as to when they will

decide that the patient's at a high enough risk for the kinds that they refer the patient to radiation oncology.

I think we seem to be seeing fewer referrals because of maybe possibly improved operative techniques or whatever reason, at least in the northeast.

CHAIRPERSON STITT: I don't think most residents are trained in it at all. But that's -- well, let's move on to item nine, which is training.

MR. CAMPER: I have a question here if I may. The point here -- the NRC authorization statement caused me to wonder, and we've discussed this a little bit already, I think somewhere along the line the last couple of days, but the idea that in 35 currently, specific sources are listed for specific uses, and we know that is problematic. We've discussed that before.

And we think we know how to fix it in Part 35 eventually. But what we don't say anything about in here, and I wonder if we should, is that licensees have the option of seeking approval of a source for something other than what is listed in Part 35 in a fashion similar to which manufacturers can go through. And there's certain information that they have to submit.

Most of them don't ever do that, and for whatever reason the manufacturers have chosen not to submit information for some of these other uses to date. But is it worthwhile mentioning to licensees anywhere in here that they have this pathway open to them if they wanted to pursue a sealed source being approved for some use other than -- they could go through the very same kind of process, but the same information I think is set forth in 32.210, I think, or 32.110.

Is that of any value or --

CHAIRPERSON STITT: It's informational. I think it would be -- you know, we've tried to make this helpful and user friendly in a lot of other parts, so --

MR. CAMPER: Now, I don't know where we would --

MS. HOLAHAN: We could actually put it right in there following that is that if licensees wish to -- licensees may request a customer sealed source and device review for uses other than that particular --

CHAIRPERSON STITT: What about the -- in item seven, the first -- kind of the introductory paragraph, it seems like it would fit well there because it could then be applied for interstitial eye plaque, intracavitary, topical.

MR. CAMPER: Yeah.

CHAIRPERSON STITT: I mean, because it relates to any of those.

MR. CAMPER: Somewhere earlier at --

CHAIRPERSON STITT: Item seven, purposes for which licensed material will be used.

MR. CAMPER: Yeah, it may be.

MS. HOLAHAN: When we're talking about when the manufacturer end user requests that a safety review be --

MR. CAMPER: Yes.

MS. HOLAHAN: -- performed, we could add --

MEMBER FLYNN: On the top of page three, there's a sentence here that says "If you intend to use a source for purposes other than specified in Part 35.400, you must request and receive an exemption to the regulations prior to use. Medical broad scope licensees are not limited to the conditions of use specified in 10 CFR 35.400."

Can that be -- is that -- does that need a slight revision of how that's worded?

MS. HOLAHAN: No, because they would still need to -- there could be some sources that have received a sealed source and device review and yet their list is not specific in 35.400. I believe, for example, I-125 in ribbons, because again, it's not specific. So although it's approved for that use, they would still need to seek an amendment -- an exemption to 35.400 to use it for that purpose.

MEMBER FLYNN: You mean a broad scope licensee?

MS. HOLAHAN: No, not a broad scope. A non-broad -- a limited specific.

MEMBER FLYNN: I guess I want to make sure I understand. Can a broad scope licensee then use a strontium-90 applicator to treat skin cancer even if it's not appropriate?

MR. CAMPER: Well, that's an interesting question.

MEMBER FLYNN: Whether it's inappropriate I guess is a medical decision, not a --

MR. CAMPER: Right. The inappropriateness of it is a medical issue obviously, and that would not be -- but certain as currently structured, the guidance assumes and we assume that a broad scope licensee could in fact use them for purposes other than that specifically identified in Part 35.

I must tell you that I would like -- and I brought this up to Trish yesterday -- I want to go back and review the basis for that because it's not -- I can't immediately recall why that is so, and I want to go back and take a closer look at that and examine the regulatory basis for that. I know that that's an operating philosophy, and it probably is valid.

But I just can't recall the exact basis for that, so I want to go back and do that.

MS. HOLAHAN: We can explore that with the sealed source group as well.

MR. CAMPER: Yes. But again, with regards to the appropriateness or the lack thereof, that's purely a medical issue. Also for the record, I do want to point out that the information that is necessary to be submitted for registering a product information with regards to a sealed source is set forth in 32.210.

And so, what we would do is include some descriptive words probably at the point that Dr. Stitt suggested that would bring this to the attention that not only a manufacturer, but a licensee can also pursue this in getting a source approved for a particular use.

CHAIRPERSON STITT: Are there other comments on the intracavitary, interstitial, etc.? That is, all items up to -- excuse me, up to item nine.

MS. HOLAHAN: I guess if you're going up to item nine, I would ask again whether or not you think it is warranted to put item eight in here and have -- address authorized users, training and experience within this module?

CHAIRPERSON STITT: Yeah, tell us again for Dan's benefit --

MS. HOLAHAN: Okay, what it is is item eight was not included in this module because it is in the body of the Reg. Guide 10.8, which would mean that licensees would have all of it as they were preparing their license application, and that is basically very general indicating -- referring back to subpart (j) of Part 35.

And one of the questions that came up yesterday in terms of remote afterloading is that authorized users that do not -- are not board certified but are seeking it through the "or" pathway, the alternate criteria, should have experience in remote afterloading if they wish to be approved as an authorized user for remote

afterloading should that similar type of language be included in the guidance for brachytherapy.

Should we bring it up into here as well to spell out specifically what the training and experience requirements are for an authorized user?

CHAIRPERSON STITT: Yeah, and to add to that, we've been trying to keep some continuity from one module to the next so that they are set up in a similar fashion. So then my answer would be yes, right?

MEMBER FLYNN: I would think yes, and obviously you need to have it consistent with the other module.

MS. HOLAHAN: Right. Other things that are in the body, just for your information, that we expanded upon that we didn't include in these specific modules again because it's across the board is other individuals responsible for the radiation safety programs. We put in a section on senior management, radiation safety officers and individuals like that as being responsible for the radiation safety program.

CHAIRPERSON STITT: Well, are we ready to jump into the training section, which was -- we spent a lot of time on yesterday for remote, and obviously have similar areas of concern.

MR. CAMPER: A couple of general thoughts as we proceed. I think the same things that we, you know, worked through yesterday apply here.

CHAIRPERSON STITT: Why don't you bring those up again if you --

MR. CAMPER: Yeah, okay, the training for the nursing staff, whether or not we're going to segregate that as such versus the idea of the training for the medical physics staff. We need to step through that again. And Trish, perhaps you have some notes from yesterday on that.

CHAIRPERSON STITT: Yeah, we change the two topic titles. Do you want to reread those for us?

MS. HOLAHAN: Yeah, what we did is because there was some question as to exactly who do we call the nursing staff, we were going to retitle that particular section as training for personnel responsible for care of patients undergoing brachytherapy treatment, again because you may have -- you've got your registered nurses, you've got LPN's, you've got other people -- pardon me?

CHAIRPERSON STITT: Aides.

MS. HOLAHAN: Aides.

CHAIRPERSON STITT: Nursing students.

MS. HOLAHAN: That may all be involved. The other point that we raised, and I think this is getting somewhat to your concern, is that we should put in a specific statement that says all nurses must receive direct training, that there shouldn't be pyramid training. That you train the head nurse, who then trains other nurses on the floor, who may train the night staff.

But there should be direct interaction with all the nurses that would be responsible for the brachytherapy patients.

MEMBER FLYNN: My only problem with that is that, you know, when I see training for nursing staff, that means something. It's extremely clear. When you start twisting it around to training for personnel responsible for the care of the brachytherapy patient, by the time this filters down to some small community hospital in the middle of North Dakota, they're going to say well, that's not the nurses.

They must have meant by that the radiation oncology personnel, because they're the ones responsible. We provide the nursing support, but they're the ones who really provide the care. I think you have to be really clear. The nurses don't

want to -- the nurses are -- and I have to tell you that it's sort of like a balancing act.

You don't want to put on them too many hours of training because they have to be trained for many other things -- the nurses. At the same time, they need enough training if they're going to take care of brachytherapy patients. And I don't know how to make sure we focus, because look at all the misadministrations that involve nursing staff not because of -- because quite frankly, they -- an incident occurred that rarely occurs, and you know, they don't have the necessary training.

CHAIRPERSON STITT: One of the changes that was made starting earlier in the week would be -- or whatever those are called -- the ones that -- thank you, the ones that don't do too much. The phrase "commensurate with their duties" was felt to be an important phrase to try to address that, Dan. A nurse or a nurse's aide or some of those -- what do they call them? They are a variety of euphemisms --

MEMBER FLYNN: Nurse assistant?

CHAIRPERSON STITT: Yeah.

MEMBER FLYNN: Nurse's aide, nurse's assistant, LPN?

CHAIRPERSON STITT: Well, there's some substitute folks that are less expensive to buy. But commensurate with duties means you don't have to know as much radiation biology, but you ought to be able to identify a source and know how to handle it. So I think that --

MR. CAMPER: Let me make a suggestion here, I think to capture Dr. Flynn's concern. And I know that clearly Dan is on the record consistently as expressing concern on the nursing training. And as I said earlier, we do continue to seek things which defy logic. If we were to take the same approach that we have done in terms of consolidating that title -- what exactly did we call it again?

MS. HOLAHAN: Okay, what we were calling it was training for personnel responsible for the care of patients undergoing implant therapy. And then we're going to put in a parenthetical statement following that including nurses, nurse's aides, etc.

MR. CAMPER: Okay, well let me make a suggestion here on this one for nursing under this particular topic. You know you have the statement where it says individuals shall be instructed in the following topics commensurate with their duties? I would think that if we were to put a sentence in bold letters following that this training is especially pertinent to nurses because of their direct involvement with patient care and their ability to be the ones who first recognize a displacement of a source --

MEMBER FLYNN: Be a first responder.

MR. CAMPER: Something capturing that so that it's -- you know, nurses are very, very crucial in this process. I mean, would that --

MEMBER FLYNN: Yeah, because there are 24 hours in the day, and 16 hours -- maybe as many as 16 hours are considered "after hours" hours. And an incident therefore has a 2/3 chance of occurring when the nurses are by themselves.

MR. CAMPER: Right.

MEMBER FLYNN: So then you could say the nurses -- particularly for nurses who are often -- who often will be in the position of being the first responder --

MR. CAMPER: Right.

MEMBER FLYNN: -- to an unexpected event. I'm not sure how better to say that, but 2/3 of the day the nurses are basically by themselves; and 1/3 of the day there's virtually an army of radiation trained people to give them immediate support within one or two minutes.

MR. CAMPER: I think we could craft such a sentence, and I even would suggest putting it in bold lettering just to --

CHAIRPERSON STITT: Well, it does focus on what the particular problems are. And I think that same phrase then should end up in the remote section.

MR. CAMPER: That's right, that's right.

CHAIRPERSON STITT: So you want it in the unsealed sources or no, it's --

MS. HOLAHAN: And I guess the question is that may also apply in the gamma knife during the day.

MR. CAMPER: Well, the first one to notice the problem and respond is the key. And I think we could make sure that -- wherever that is -- certainly in remote.

CHAIRPERSON STITT: And you'll use your judgement as to whether it applies in the other modules.

Dan, I think that's very helpful. So in this section there's a long listing, and then this listing is also referred to as we go into the other sections. I know that yesterday we took out number 28, which is questions and answers, and we modified that into -- oh, examples of clinical situations.

MS. HOLAHAN: We called it lessons -- examples of clinical situations and lessons learned --

CHAIRPERSON STITT: Right.

MS. HOLAHAN: -- is how we revised number 27.

CHAIRPERSON STITT: Right, previous incidents. And we took out number 28.

MS. HOLAHAN: We took out number 28.

MEMBER FLYNN: You took out number 28?

MS. HOLAHAN: Questions and answers.

MEMBER FLYNN: Oh, no, 28; yes, that's right.

MS. HOLAHAN: Okay.

MEMBER FLYNN: I have two 28's here. One of them I had suggested. The first 28, communications procedures is extremely important, because what's happening is that this unexpected event may have -- it's happened that they've had the incorrect phone numbers and they haven't kept up to date with the communications aspects.

So then the nurse will make a judgement on her own, such as tape a source to a face or to a chest or -- so you know --

CHAIRPERSON STITT: Dan, could you -- I'm dying to know more about that. Why was that source -- was this the surface therapy or --

MEMBER FLYNN: This was a recent one in Philadelphia where a source was -- ribbons were sutured to the soft palate, and then when they came out the mouth, they only put tape on the skin rather than use the buttons and suture to the skin, which is -- I talked to the radiation oncologist, and the surgeon didn't want that done.

But the radiation oncologist thought it should have been done. He admitted that. That will be in my report. So the patient moving around then -- these ribbons were under some stress, so a couple of the sutures became loose on the soft palate where the tumor was. And so, the entire application -- the ribbon and the catheter in which the ribbon was fixed came out.

And then because it was kind of loose, the nurse then taped it to the skin but didn't call the authorized user to let them know that this had happened. But then it was discovered subsequently. But then the whole procedure was aborted.

They took out the entire application, and there's some uncertainty as to the dose because of when this all occurred to reconstruct the dose.

We'll be giving a little bit of external beam. But this happens. Sources become loose, and the nurses have to intervene. And sometimes they may intervene because it may -- it gets quicker to intervene than to try to locate someone. But the communications procedures are really well set up. I think it should be posted on the door the phone numbers, the beepers and everything posted on the chart like we do.

And so that communications is more accessible and obvious so that they will -- if they have to intervene, they will also immediately call someone.

CHAIRPERSON STITT: Number 28 here -- that is not in the listings that we discussed yesterday, is that right?

MS. HOLAHAN: No.

CHAIRPERSON STITT: But it will be? It's a very practical --

MS. HOLAHAN: Yes.

CHAIRPERSON STITT: Okay. Should be in the remote section as well.

MS. HOLAHAN: Okay.

MR. CAMPER: Similarly, are 24 and 25 in the other listings?

MEMBER QUILLIN: Yes, I think they are.

MS. HOLAHAN: 24 is, as is 25; yes.

MR. CAMPER: Okay, good.

MS. HOLAHAN: Okay.

MEMBER FLYNN: I had a couple of suggestions. And I don't know if -- how this will go, but one would be that -- and maybe it's covered already -- as to

documentation of the personnel who have received this annual training with appropriate dates.

MS. HOLAHAN: That is in Section 9.3 as part of the records.

MEMBER FLYNN: And the second one would be -- one of the most important ones would be ask the licensee to assess the effectiveness of the training. Let them decide how that should be, rather than be too prescriptive. It might be an examination, a written exam.

It might be in the form of a question and answer period, a little half hour lunchtime review with the RSO verbally asking questions -- what if this happened, what would you do; what if this happened, what would you do. It could be a written exam.

At one Boston teaching hospital where there's a nurse -- not my hospital, but at Brigham and Women's where there's a nurse heavily involved in radiation, she actually -- they tried to use the nurses' time efficiently, so nurses who choose to work on the brachytherapy floor, they get a manual to take home and read.

Then they get an examination to take at home. And the examination is so long and requires written responses, not just check offs, that you can't answer that examination unless you thoroughly understand that document. So, it's sort of forcing people to learn it and learn it well. And then it's done annually also.

So it's done many different ways, but I think a way to ask the licensee to come up with a method that the licensee feels would be effective as to the assessment of the effectiveness of this training, because that's not done. When I gave an exam to a group of nurses who supposedly had the training, they couldn't answer any of the basic questions.

The average score was a failure. And it wasn't -- they weren't difficult questions. They were questions that they should have known if they had just gone

through the prior week training with the RSO. But the training wasn't geared in the right direction. And so they failed the test, and they didn't understand.

Then I discussed it with them afterwards -- the kinds of issues were very key basic issues -- then they understood why it was important. But --

CHAIRPERSON STITT: There's a sentence here "Licensees may consider a periodic assessment of nurses as to the effectiveness of instruction provided."

MS. HOLAHAN: Yeah, and I added that since the May meeting to try and address that concern. Part of it is we can't require them to do an assessment. There is no regulatory basis, and that was why we had listed as they "may consider" a periodic assessment. Do you have some --

MEMBER FLYNN: I would put -- and at least make it more specific, because if you can't do that, then annual assessment as to the effectiveness of training. Because the annual assessment, if they choose to adopt it, would occur at the same time as the annual refresher training or training.

I think they will -- many of them will think it's a good idea and just do it voluntarily. This is sort of a learning user friendly document too. But what we should --

MS. HOLAHAN: We could put in after a periodic eg. annually to --

MR. CAMPER: Well, the thing of it is though, I think what I'm also hearing is the idea that once you provide this instruction, it's a good idea to assess their understanding of it and then do it periodically, ie. annually in this discussion.

MS. HOLAHAN: See, in the up front in 9.1.1, we indicate that the personnel should be instructed before assuming duties during annual refresher training, and then whenever there's a significant change.

MR. CAMPER: Oh, yeah, okay.

MS. HOLAHAN: And then if we just put in something as a reminder. Perhaps I could make that licensees may consider assessment of nurses immediately following training and periodically or annually after that.

MEMBER FLYNN: Yeah. You could put -- if you want to keep it the way you changed it before, assessment of personnel, and then in parenthesis, (including nursing staff), and then if you want to put periodic assessment as to the effectiveness of the training.

MR. CAMPER: Yeah, you see at this point, Dan, we can do something like that as a recommendation in the guidance. We have to be cautious as Trish was pointing out. If I go back to 35.410 and I say well what's my regulatory basis, what can I cause them to do? Well, it says the licensee shall provide radiation safety instruction to all personnel caring for the patient or the human research subject undergoing implant.

To satisfy this requirement, cover certain topics and they're listed. And then the other requirement is a licensee shall retain for three years a record of the individual's receiving the instruction, so forth and so on. But there's no requirement in there that they assess. It's the individual --

MEMBER FLYNN: We'll give you an example. I think you want an example, so I'm going to give you an example. We have a -- one hospital had a radiation safety officer who was -- had some difficulty with the English language. And when I see a regulation that says provide instruction, inherent in that term instruction means that the instruction is in English.

If I give a lecture to nurses in Russian and they don't understand Russian, I've given the instruction, but the instruction has not been communicated. It

hasn't been received on the receiving end. So instruction means implicitly that the instruction is effective, that the communication did occur.

And the only way you know that is to assess the effectiveness of the instruction.

MR. CAMPER: Well, interestingly enough, yesterday we discussed this very point.

MS. HOLAHAN: For ancillary personnel.

MR. CAMPER: Bob Quillin gave an example of a facility -- I guess it was somewhere in the midwest, wasn't it, where that -- a lot of the, in that case the ancillary support staff were of Polish extraction. And so, -- and we use -- we covered some words yesterday where it was --

MS. HOLAHAN: Individuals be instructed in the following topics in a manner that they will understand.

MR. CAMPER: So to bring to the attention of the licensee "in a manner which they will understand." You know, if you've got a largely Spanish speaking population, you need to think about covering it in Spanish as well as English, or whatever. So that was done to try to drive home that point.

But I wanted to leave a thought in your mind for the future. I know that -- and again, I know that historically you've had very strong feelings and been sensitive to this training issue. When we do move into a revision of Part 35, you should consider taking a look at 35.410 and ponder whether or not you want to recommend as we work our way through that in the future and discuss those regulatory issues with the ACMUI.

And there will be several opportunities to do that. You might want to ponder whether or not you want to make a stronger recommendation on what should

be contained in the language with regards to instruction. And there will be an opportunity to ponder that and do that.

MEMBER FLYNN: When you ask the licensee that they should devise a method to -- you recommend that they devise a method to assess the effectiveness of instruction, I don't think personally that's -- I'm just wondering if that -- if everyone in radiation oncology could comment on that.

I don't think they would consider that too prescriptive, because you're allowing them to decide what that means -- come up with their own method to decide what -- and you're not taking away their license or fining them. You're allowing them to come up with the method as to what they think is best in their institution and their circumstance to decide what is effective.

It's forcing them to think about it. I mean, it's encouraging them to think about it.

MS. HOLAHAN: Well, do you feel the sentence then gets at that issue the way we've restructured it?

MEMBER FLYNN: Yeah, because if you can't require it, then recommending is --

MS. HOLAHAN: Okay, all right. I just wanted to again for Dr. Flynn's benefit to point out one of the changes that we'd made yesterday for the remote afterloading is in number one, instead of saying basic radiation biology, we had said basic radiation effects.

This was a discussion that had come up in the radioactive drug module that the subcommittee felt that it was more important that the nurses understood rather than basic radiation biology, some of the effects of radiation.

MEMBER FLYNN: That's good.

MS. HOLAHAN: Another point that I'd like to make that was changed in the radioactive drug therapy module was item number 17. We had patient release criteria, and I think there was a concern that nurses wouldn't -- they are not going to be the ones authorizing the release of a patient, but they should be aware of the patient release procedures so that they know it's only going to be the authorized user that is going to release the patient when there's certain -- when the criteria are met.

So we are going to change that to say patient release procedures.

MR. CAMPER: A couple of minor edits on that page as well. Item 18, instruction procedures -- we need an "r" after "fo."

MS. HOLAHAN: Which number?

MR. CAMPER: 18. It should be for. And then on 22, once again "10" as in 10 CFR -- it cannot stand alone, to be correct regulatorily speaking.

MEMBER FLYNN: I have one other when you're --

MEMBER QUILLIN: I have one other also.

MS. HOLAHAN: Okay.

MR. CAMPER: I want to do one administrative thing real quick to which I realize I didn't do earlier. And being joined by a new member made me realize it. For the record, I'd like to point out that today we had Dr. Daniel Flynn, we have Robert Quillin, we have Dr. Judith Stitt chairing the subcommittee.

We have now been joined by Penny Nissen, who is a member of -- oh, is this new? Excuse me, what's your last name, Penny?

MS. LANZISERA: Lanzisera.

MR. CAMPER: Oh, and this is a new development. Congratulations, by the way. Penny is from our Region 1 office and was involved in preparing the

module. And of course, Patricia Holahan of the medical and academic staff. Just for the record, I didn't mention those names earlier. I apologize for that.

CHAIRPERSON STITT: Let's keep looking at the editorial or other comments on 9.1.1.1, training. Dr. Quillin?

MEMBER QUILLIN: On number five, posting requirements, we discussed this yesterday. And later in the document, rather than posting requirements, I think what you're looking for here is understanding posting requirements.

MS. HOLAHAN: You're referring to number five?

MEMBER QUILLIN: On number five, yes.

MS. HOLAHAN: Okay.

MEMBER QUILLIN: Understanding of labels and signs.

MS. HOLAHAN: Okay, that change needs to be made consistently throughout the other modules too, so I need to just keep that in mind.

CHAIRPERSON STITT: Are there other changes that we've made in other modules? I know you have certainly been bringing a variety of them up.

MS. HOLAHAN: That was it as far as this first part. As we have other changes in other items --

CHAIRPERSON STITT: Other sections.

MEMBER FLYNN: I had one more point when you get to it.

CHAIRPERSON STITT: Beyond --

MS. HOLAHAN: Are we still on --

MEMBER FLYNN: I'm still on nursing.

CHAIRPERSON STITT: Go ahead then.

MEMBER FLYNN: All right, part one was -- number one was changed to basic radiation effects. That's good. I just want to link it in to number 20,

dose to embryo/fetus limits including instruction about declaration of pregnancy. I'd like to get the instructions on declaration of pregnancy and what that -- you know, what it now has -- where we are right now with that.

And also, to give you some -- just to give you some instances, because when you do brachytherapy in a big hospital like Dr. Stitt's hospital where the nurses on the floor are doing it so constantly that the training is reinforced by the daily or the weekly procedures, then -- and so I see that also.

The nurses handle things much faster. They know -- they can see us at 200 yards. They know exactly who I am. They know my phone number without looking at the card. Then you go to a small hospital where they do it extremely infrequently, and I had situations where the nurses -- the young nurses would not go into, let's say, look at the application or check that nothing's been dislodged because they think that they won't be able to get pregnant if they go in.

And now we have number 20 says dose to embryo/fetus limits including instruction about declaration of pregnancy. I just want to make sure it's clear in whether radiation effects can somehow be linked into that. Because I had to spend a lot of time talking to nurses about what is natural background radiation, you know, including the radon 300 -- roughly 300 mr per year.

And when they go in to take a quick look at that patient standing at three -- at a meter, they will get less than one mr -- less than the dose they get daily by living probably unless they have to spend a lot of time there. They never understood that.

In this -- you know, they have the fear aspect of it, but they don't have the training aspect of it. I want to make sure they do the right thing, including looking for sources that are dislodged and making sure they can provide the care.

MS. HOLAHAN: I think there's two points that I'd make on that. First of all, number three gets at risk estimates in which we are hoping that's -- and that training will encompass the risks of the radiation, both in relation, for example, to natural background as well as other risks associated.

The other point that I was going to make is --again, this came up in one of the other discussions is referencing in number 20 Reg. Guide 8.13 which is just being revised and issued as a draft for comment which discusses the written declaration of pregnancy.

It discusses some of the risks to the embryo/fetus and why the dose limits are what they are. And so, perhaps if I reference the Reg. Guide in here and also the Reg. Guide for occupational exposure, that may give the instructor somewhere to go or something that they could provide to the nurses.

MEMBER FLYNN: Are you able to tell me so that I understand -- make sure I understand what is instruction about declaration of pregnancy? Because I'm not sure if I really understand it myself.

MS. HOLAHAN: A woman must declare in writing that she is pregnant to inform the licensee of her pregnancy status in order for the lower dose limits to be applied.

MEMBER FLYNN: Okay, because I brought this up in a meeting, and the administrator asked me what if the nurse chooses not to declare her pregnancy in writing?

MS. HOLAHAN: Then she still goes under the five rem per year occupational dose exposure.

MEMBER FLYNN: Then the administrator asked me then she -- you know, there's brachytherapy patients and she's, you know, way out to here and she's

eight months along and it's obvious that she's pregnant and she's knitting small booties at the nurses station and she's still taking care of these patients, and the administrators worry about some lawsuit later on.

So because if that unfortunately nurse has a Downs Syndrome baby or some other thing that has nothing to do with radiation, that the hospital gets a lawsuit further down the road because the licensee did not take the appropriate steps to protect someone who has very little training and understanding at the time, but may have a lot of understanding later on when she gets an attorney.

MS. HOLAHAN: Now I think one of the things -- and in the Reg. Guide 8.13, the revised -- it sort of outlines this, that it is the woman's right to choose whether or not she wishes to declare her pregnancy. If she chooses not to declare her pregnancy, the licensee's responsibility is only as far as the occupational dose limits.

They may choose to do more --

MEMBER FLYNN: Reassign her?

MS. HOLAHAN: They can choose to reassign her.

MEMBER FLYNN: Whether she wants to be or not?

MS. HOLAHAN: No, she can choose not to be reassigned.

MEMBER FLYNN: Okay.

MR. CAMPER: This was discussed at great length during some of the questions and answer sessions that occurred after Part 20 was published. And it is a dilemma. I mean, your administrator is on the mark. I mean, regulatorily speaking, in terms of NRC regulations, unless she's a DPW, declared pregnant worker, she is subject to the guidelines for an occupational worker.

Now, and this question was asked about well what happens when she's obviously pregnant? I mean, what do you do? Well, you may choose to do other

things to protect yourself or to put in place a scenario where you feel like the liability probability is reduced. But if you're doing that, the basis for doing it has to be some other reason than the NRC's regulations.

MEMBER FLYNN: If she's in her third trimester, it's not going to make any difference anyway probably. I mean, the first trimester is most important. But I just wanted to clarify it so that I understood what was going on if there are more changes being made in this area or not.

MS. HOLAHAN: No, and it must be in writing. You can't just go and tell your boss that I'm pregnant and you're not pregnant until you declare it in writing according to the --

MEMBER QUILLIN: And she can undeclare her pregnancy also.

MS. HOLAHAN: Yes, yes, that's true. She could choose to declare it in the first trimester and then by the third trimester say I'm undeclaring my pregnancy.

MEMBER FLYNN: I don't think it will happen, but it is interesting.

MS. HOLAHAN: Yes. So I was going -- that's the point I wanted to make, --

MEMBER FLYNN: Okay.

MS. HOLAHAN: -- is we were going to reference that Reg. Guide.

MEMBER QUILLIN: One last comment I have on this section. It goes back to your comments on the communication procedures. I agree with what you want to do and I disagree with what you want to do. The word procedures though to me does not capture the extent of what needs to be done here.

MEMBER FLYNN: I would put communications procedures and posting -- communications posting requirements myself. If you want to help stop some

of the misadministrations of the future, just add communications procedure and communications posting requirements. And I think you go a long way to --

MS. HOLAHAN: I think I'll be -- perhaps find another word other than requirements, because we don't require communications to be posted. But I think perhaps we could say something along the lines of communications posting recommendations.

MEMBER FLYNN: Posting recommendation?

MS. HOLAHAN: Or posting --

MEMBER FLYNN: You have posting requirements that are part of Part 35 that are very specific.

MS. HOLAHAN: Right.

MEMBER FLYNN: And so that should be changed in the future because it should be the authorized user and RSO methods of contacting them or their representatives after hours to include, you know, home phone numbers, beepers, etc.

MS. HOLAHAN: Yeah, because see -- while the posting requirements -- and that may be as in 35.415 are the specific posting requirements with what the patient's room must be posted with. But we can sort of certainly through recommendations expand what should be posted.

MEMBER FLYNN: I can't imagine how anyone would object. As a matter of fact, they would say God, we should have thought of that. You know, that's what they're going to say. We should have thought of that. That's simple to put someone's phone number down.

CHAIRPERSON STITT: Did you have any ways of making this read more direct?

MEMBER QUILLIN: No, I've been struggling with that ever since I read it.

CHAIRPERSON STITT: Things like calling tree or phone list or something -- phone directory might be phrases that could be helpful in this.

MS. HOLAHAN: Yeah, and that was one of the things that we had tried to address in number 18 is that -- and we had discussed this, I believe, at the last ACMUI meeting is that currently the way the regulations read is that in a medical emergency you notify the RSO. Well, in a medical emergency, you would probably want to notify a physician as well.

And so number 18, we have tried to address that.

MR. CAMPER: The reworked language of 19.12, we had it --

MS. HOLAHAN: We had it yesterday. No, I didn't bring it down with me.

MEMBER QUILLIN: The cases that I've been involved in in this area are instances where the nursing staff had been provided instructions where the signs were up and they just didn't follow them. That's one of the problems that -- in one case, they didn't consider it a medical emergency, so they thought the medical emergency issue didn't apply.

They thought it was routine patient care. The applicator came out. They did what was right -- they took the applicator out and put it in the shielded container, and then they put it under somebody's desk. They didn't leave it in the patient's room.

MS. HOLAHAN: And maybe --

MEMBER QUILLIN: If we could get something in here about, you know, emergencies, I think connotes something different than --

MS. HOLAHAN: Right.

MEMBER QUILLIN: -- something that may just happen.

MEMBER FLYNN: Medical emergencies and unexpected incidents?

MS. HOLAHAN: Well, I know earlier we had discussed --

MEMBER QUILLIN: Non-routine occurrences or something.

MEMBER FLYNN: Unusual occurrences.

MR. CAMPER: Well, I wanted to see the new 19.12, which was just recently changed. But there are some sentences in the version of 19.12 that are applicable. For example, this is under instruction to workers -- shall be instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of commission regulations and licenses or unnecessary exposure to radiation or to radioactive material -- shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunctions that may involve exposure to radiation or radioactive material.

So I mean, the umbrella is there. But as I said, this was recently changed, and I don't have the current language in front of me.

MS. HOLAHAN: Torre is going to go get it. The other thing to was in 35.25 individuals under the supervision of an authorized user are to follow the written radiation safety instructions as well as the instructions of the authorized user. And that may be getting at the point that was just raised.

MEMBER FLYNN: In number 23, would it be acceptable to you if it said -- number 23, each individual's obligation to report unsafe conditions to the RSO and the authorized user? Because the unsafe condition may have a lot of -- there may be some medical aspect of -- see, the radiation safety officer is not often a physician.

But the unsafe condition may be a medically unsafe condition or a

question whereby the RSO may or may not be able to provide the answer, but the authorized user may provide the answer that the RSO can't provide. I think since it's involving patient care, I think it should be the -- I have no trouble with the RSO, but also "and the authorized user."

MS. HOLAHAN: Well, what we could do is even put in a separate item saying each individual's responsibility to report unsafe conditions, because it's not an obligation pursuant to the same regulation as it is in here, but it is something perhaps they need to know. Well, let me go back up a step, because this may be addressed in some other way.

One of the comments that I had had -- in number seven, we require -- I'm sorry, we are recommending that the nurses trained in the licensee's quality management program. There has been some question that nurses don't really need to be aware of the quality management program, except our thoughts there were in terms of understanding where the source is, if it's become dislodged -- that's all really part of ensuring that the administration is in accordance with the written directive.

Within the quality management program, in the -- I believe it's Reg. Guide 8.33 -- individuals are supposed to ask questions of the authorized user when there's something they don't understand. Perhaps we could place it up in there.

MR. CAMPER: Perhaps. I know in looking at number seven, one of the things I was struck by -- we say the licensee's QMP, and we go on to say to ensure that each administration is in accordance with the written directive, attention to correct positioning, so forth and so on. Probably worthwhile inserting a few words in there about verifying the patient's ID, which is the second objective of the QM rule.

MS. HOLAHAN: That would go under the next item though in terms -- well, because the nurse would not necessarily be the one verifying the patient's ID. It

would be more in the administration aspect. This is a caring for -- the next training section is --

MEMBER FLYNN: I can tell you that --

MR. CAMPER: Well, the implant's taking place in the patient's room.

MEMBER FLYNN: I've looked at -- as all of you have -- looked at quite a few misadministrations. But I also have reviewed other people's reports, and I've also reviewed all the abnormal occurrence documents. And to my knowledge, wrong patient -- at least as far as I know -- occurred in six teletherapy cases and one strontium eye application. But wrong patient, to my knowledge, has never occurred for an intracavitary or interstitial application.

CHAIRPERSON STITT: Not for low dose, but it has for high dose.

MEMBER FLYNN: It has for high dose?

CHAIRPERSON STITT: Yeah.

MEMBER FLYNN: Then it's one I don't -- one I'm not aware of then.

CHAIRPERSON STITT: Well, that's because high dose therapy is very much like external beam therapy. You identify patients and bring them in, etc., etc.

MEMBER FLYNN: Because the patients who are admitted to the hospital, there's already in place a procedure for the name tag must be on the wrist. And if it's not there, that's a major problem. Not because of the brachytherapy, but because of the -- the patient becomes confused, you don't want some drug that's dangerous being given to Mrs. Smith when it's Mrs. Jones it was prescribed for.

MR. CAMPER: What happens if you have two Mrs. Smiths?

MEMBER FLYNN: Believe me, the nurses, because of drug applications -- I mean, medical applications to patients, they -- for an in patient, I don't -- I think that it's covered already.

CHAIRPERSON STITT: Redundant, redundant -- redundant and not duplicated -- identify patients who are hospitalized.

MEMBER FLYNN: But that's my opinion. For hospitalized patients, there is a very long standing -- it's really drilled into the nursing staff.

CHAIRPERSON STITT: If that patient goes to the operating room, more procedures for identification.

MEMBER FLYNN: Yeah, before they give the medication. If they don't know that patient, the nurse -- it's like a -- you know, they immediately look at the name tag and use the patient's name. But it's all because of the medical care for inpatients that's required, not the radiation aspects.

MR. CAMPER: Well, the only reason I raise it is we have a few words about the QMP. And as I read them, I have a question mark here -- verify patient ID. We don't make that -- I didn't know if there was any value of mentioning it or not.

MS. HOLAHAN: Do you think than it's warranted to add a separate line item that the individual should discuss with the authorized user unsafe conditions or --

MEMBER FLYNN: I think so. For example, the incident I'm looking at now from Region 1 -- if the nurses felt that the tape on the skin of the cheek of the face was getting loose because of saliva and whatever, they thought that would be an unsafe condition. And I think they should report it to the physician, who may decide to take an action to secure those sources.

Not just the radiation safety officer who may not have an answer or be in the position to intercede as the RSO to make some medical decision. He may defer it. It's better communications. So I mean, I have no objection. Obviously the RSO has to be informed about unsafe conditions, but I think the authorized user may

be able to intercede to make those unsafe conditions safe, or at least be able to explain or justify whatever the nurse may or may not understand.

MS. HOLAHAN: Okay, what I was going to put in then is communicate with the authorized user any unsafe conditions or questions regarding the patient's treatment.

MEMBER FLYNN: That's good.

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: Dan, do you have other comments on this particular section?

MEMBER FLYNN: No, I think it's an excellent section. I mean, I think -- when I look at this back, compare this to Reg. Guide 10.8 that's existing, this is like 1000% better right now. This is really good.

MR. CAMPER: Good.

CHAIRPERSON STITT: Well, let's move to the next one then. And Trish, there's a new name for this one? Why don't you read that to us.

MS. HOLAHAN: Yes, again following the discussions of the radioactive drug therapy and the remote afterloading, we retitled this to call training for staff directly involved in planning, administration and monitoring of patients undergoing implant therapy. Again, to make sure that we had encompassed -- in case there was some question as to who was the medical physics staff, if there were other individuals involved.

And then we would include the paragraph that says including medical physicists, therapists and dosimetrists. And actually, yesterday we had included the authorized user in there too.

CHAIRPERSON STITT: And then we have also put in the commensurate phrase enhanced, and then the additional topics.

MS. HOLAHAN: Right.

CHAIRPERSON STITT: Did we make any changes in those?

MS. HOLAHAN: No, we did not, no.

CHAIRPERSON STITT: Do you have a comment in that section? Then let's try training for ancillary personnel. Did we rename that one?

MS. HOLAHAN: No. But we made some changes to it.

CHAIRPERSON STITT: Right, we made some changes. Do you want to tell us those?

MS. HOLAHAN: Okay, what we did is -- oh, and first of all, in this one is we had gone ahead and revised this language that you see before you in accordance with the new Part 19.12 that individuals whose assigned activities are likely to result in a dose in excess of 100 millirem is the language out of the revised Part 19.

Then what we had said is topics -- oh, individuals will be instructed in a manner that they will understand, and that was to get at the concern to make sure that if they don't -- if English is not their first language, that they have understood what is being told to them.

Then we're going to take out the brackets around the licensees may choose to prohibit ancillary personnel and actually move that up, because that is often what is done is that housekeeping is told not to do into the room while the implant is there is my understanding. Number one was going to be revised to read meaning of posting and labeling.

Number two was going to be revised to say necessary precautions when radioactive material is present. And we were going to add a number three that says basic radiation protection to include concepts of time, distance and shielding.

CHAIRPERSON STITT: So that really enhances that section and hopefully makes it more useable.

MEMBER FLYNN: Yeah, I was one of the proponents to add that phrase, unless it's quoted by trained personnel. And so that blood can be drawn and whatever has to be delivered, if a nurse has had the training and can escort that person who may be extremely nervous, or at least to make sure that nothing happens in that room for the brief encounter of that untrained person with the patient.

But do you think that the small licensee will understand that unless escorted by trained personnel would include trained nursing personnel? Or are they going to think what does that mean? That must mean that the -- we had better call the radiation oncology department because someone down there had better come up here to do the escorting.

They should have confidence in themselves that if they've had the training, the are trained personnel -- the nursing staff.

MS. HOLAHAN: Unless escorted by personnel who have received radiation safety training outlined above.

MEMBER FLYNN: Because see, a lot of this is happening as I say two shifts -- I mean, after hours, the nurses are the trained personnel. But I'm not sure if they will understand that. They should understand that their profession -- that of course they're professional health care providers and they have gone through the training, so now they are the trained personnel. I think it should be --

CHAIRPERSON STITT: You know, I don't think we can legislate that. If somebody does not feel like they are trained, even though they've been through it, then we go back to the individual obligation to report unsafe conditions and maybe they feel that you should be the one to escort the --

MEMBER FLYNN: Okay, but can you say unless escorted by trained personnel such as trained nursing staff?

CHAIRPERSON STITT: I think Trish, the phrase you used would have done the job.

MS. HOLAHAN: Okay. Personnel trained in radiation safety procedures described above?

MEMBER FLYNN: Okay.

MS. HOLAHAN: The other point that I wanted to make -- when this question came up about looking at unless escorted by trained personnel, that could not have been done prior to the revised Part 19 because part of that was if you entered a restricted area, you must receive training.

Well now, the way that it's worded is that unless you're likely to receive in excess of 100 millirem. So we could put that statement in.

MEMBER FLYNN: Yeah, this is much better. Sometimes the nurse needs help in turning a patient. She has to get whatever help she can get. And she's the trained personnel and she's supervising the patient being rolled to one side.

CHAIRPERSON STITT: Good, I think that section is enhanced in practical -- and Dr. Quillin has made it straightforward in the way it reads. We had some discussion about training for contractors yesterday. And did we make an addition? I thought we --

MS. HOLAHAN: We said licensee should ensure that any individual, and then in parenthesis (example, nurses, physicists, therapists, etc.) who work under a contractual arrangement will be instructed.

CHAIRPERSON STITT: Right. So we added an example of what a contractor might be.

MS. HOLAHAN: Yeah.

CHAIRPERSON STITT: Records. Dr. Quillin, do you have anything about records? Are you happy with the way these record keeping phrase read?

MEMBER QUILLIN: Fine with me.

CHAIRPERSON STITT: Okay. Let's stop and just last chance --

MEMBER FLYNN: Should these records be maintained only for three years? I only say that because we've had -- and I'm not a big proponent to keep a lot of records, but we've had some incidents whereby it's gone back and it's -- the incident occurred back -- it's 1995, but the incident occurred in 1992 or 1991. Some of the incidents are old.

And they're discovered quite frankly, I'm assuming, by NRC inspectors who then look at radiation safety committee minutes or whatever they look at, and they say gee, several years ago this is in the minutes of the radiation safety committee and what happened there? And then you go back and it's now three or four years after the fact or -- maybe three years is enough.

I just bring it out to -- it should be five years.

MEMBER QUILLIN: We discussed yesterday the fact that actually if you ended your licensing next year, you could throw all of these records away basically. Not all of them, but almost all of them. And I mentioned the fact that some of these records, as licensee, I would want to maintain beyond the specified time.

CHAIRPERSON STITT: Right. And the institution can keep them as long as they want. Three years is what is in this.

MR. CAMPER: That's right. The three years is a regulatory requirement.

MS. HOLAHAN: Penny says actually the regulatory requirement is longer. I think -- what was it? Three years was --

MS. LANZISERA: I think three years was initially based on the inspection frequency for these types of licensees.

MEMBER FLYNN: But there may be some discussion in the future that licensees who have a stellar record could be surveyed less frequently, like five years? And those who have a problem licensee, it could be every year as you have fewer staff to do the inspections, you might keep it -- maybe it should be five years.

Because in case you -- something happens. Now for exposure records, isn't that now the life time of the license that's permanent? And then what happens if someone withdraws their license? Can they just then dump all of their records and then apply for a new license again?

MS. LANZISERA: They have to transfer them to us.

MEMBER FLYNN: Oh, okay.

MEMBER QUILLIN: Not all the records they don't have to transfer to you.

MS. LANZISERA: Well, those types of things.

MEMBER QUILLIN: Just the personnel exposure records. They want to add a comment someplace in the document about records licensee may wish to retain records beyond a specified regulatory requirement.

MR. CAMPER: Well, be careful how you peddle that. I mean, make sure that's clearly a recommendation, because --

MEMBER QUILLIN: It's not a requirement.

MEMBER FLYNN: Could you say maintain for three years or at least -- well, at least until the next full inspection?

MR. CAMPER: Well, I think what I would do is something along the lines of, you know, while there are specific regulatory requirements for record keeping, the applicant or the licensee may consider maintaining their records -- might want to consider maintaining the records for a longer period of time. Something to that effect.

CHAIRPERSON STITT: I think that summarizes it.

MR. CAMPER: We have to be very careful, because I don't want someone to criticize us for imposing a record keeping requirement in guidance space for which there's no regulatory --

CHAIRPERSON STITT: Right. And it's highly likely that hospitals have their own more stringent but lengthier requirements. Let's let it sit as it is.

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: I mean not as it is, but with Larry's commentary. Do you feel ready to move to item ten, folks? We're discussing the facility diagram and what has to be in that. This is much like yesterday's version.

MEMBER QUILLIN: How did we reword yesterday's version about where the patient room should be?

MS. HOLAHAN: Oh, that's the reason I brought this one down.

CHAIRPERSON STITT: Well, it was the patient room -- it's the sentence that deals with as far away from the nursing station. Let's take that out and use the phrase from yesterday. Do you want to read that to Dr. Flynn?

MS. HOLAHAN: Okay, the patient room should be located in the situation to account for ALARA considerations and is consistent with good medical care. That may not be correct grammatically yet, but --

MR. CAMPER: It's also pertinent regulatory requirements, ALARA considerations and good patient care. In other words, you can't have -- the regulatory aspect of it is you can't have dose exceeding more than two mr per hour at the boundary of the unrestricted area. ALARA dictates obviously that you keep it as low as possible.

On the other hand, good medical care -- the problem that we have, Dan, is you look at this, one gets the impression in reading this that it should be as far -- well, you clearly get the impression it should be as far away from -- and that's really not a good idea.

MEMBER FLYNN: No. I don't think it should be as far away.

MR. CAMPER: No.

MEMBER FLYNN: I was going to comment on that.

MR. CAMPER: And arguably, it should be close to the nursing station. Now what you do is you have to design the room with that in mind.

MEMBER FLYNN: It's a difficult problem, because if you look back on the nursing training procedures on page six again, 13, 14, 15 -- patient control procedures, visitor control procedures, access control procedures. Now number 15, access control procedures, I can give you examples whereby the patient's room was not in the line of sight with the nurses station.

It was so far away, and it was around a -- kind of like around the corner, the nurses from the nursing station could not see that room it was so far away. And then you have the, you know, the Polish housekeeper with the Spanish cleaning

lady who go in and start doing things. Or, you know, I hope you never have an instance where a source is dislodged and stolen or, you know, taken away out of the room.

But I think access and control of the room and people who go into that room is important. I think it -- it would be nice if it was far enough away, but in a direct line of sight of the nurses station so that they can have control -- access control, patients control, visitors control -- access. But you know, it's -- every hospital has a different floor plan, and you -- you know, I agree that --

CHAIRPERSON STITT: Well that's why we made those changes that it puts in some flexibility and makes medical care as well regulatory issue that the -- rather than as far away from the nursing station as possible.

MEMBER FLYNN: Is it just medical care or also control procedures? Because good control procedures -- let's see, what was that --

CHAIRPERSON STITT: Well, there was a phrase about regulatory --

MR. CAMPER: Well, the regulatory -- the thought that I put forth yesterday is the idea that the placement of the room should bear in mind pertinent regulatory requirements as in Part 20, good medical care for the obvious reasons, and ALARA considerations. And what you're saying is control.

MEMBER FLYNN: Well, let me just read 13, 14, 15 on page six. Patient control procedures, visitor control procedures, access control procedures. So you've used that term three times under the training section for nursing staff, but the nursing staff don't -- they're not the ones who decide where the room is going to be.

It's done by the -- often done, quite frankly, by the radiation safety officer together with the administration.

CHAIRPERSON STITT: Well Dan, would you like to see a phrase then added that reflects that nurses need to -- if it's possible, this room should be

located with the three components that we just described, plus something that indicates that there is -- nurses have control of access to that room by visitors and other staff.

MR. CAMPER: It's interesting. You know, I'm looking at the current regulatory language. What you have under 35.415 is you have not quarter the patient in the same room with an individual who is not receiving therapy unless you can demonstrate that the levels to that individual would be below those in 20 13.01 at a meter.

Post patients door with a CRM sign. Authorize visits by individuals under 18 only on a case by case basis with the approval. Promptly after implanting conduct a survey. Provide instructions to keep dose to members of the family, etc. as low as reasonably achievable. And then notifying the RSO when there is a problem immediately.

I guess what I'm trying to say is that the regulatory language with regards to controlling access is not as explicit as one might like to then embody some guidance. So we have to be careful again how we -- what we say.

CHAIRPERSON STITT: Is it all right the way it is? Do you want to try to add something to it? They're suggestions, and they're not --

MS. HOLAHAN: We could say the location of the patient room should be such -- should consider regulatory requirements in ALARA and is consistent with good medical care and ease of control or something.

CHAIRPERSON STITT: You might want to say what that control refers to. Access control, -- yeah.

MS. HOLAHAN: -- with good medical care.

MEMBER FLYNN: The control comes from the existing -- is in the existing 10.8, as you know.

MS. HOLAHAN: Correct.

MEMBER FLYNN: Controlling the patient, controlling the visitor, controlling the access -- that's in the existing 10.8. I'm not sure if it's exact. I think it's fairly much the same. So I don't think you're changing anything. But I think in terms of the facility diagram, if you can help the RSO and the administrator who is deciding where to put this room, they may not be aware of the nursing considerations that -- in terms of --

MR. CAMPER: So it comes down to then the choice of the patient room should consider pertinent regulatory requirements, good medical care -- I'd list that as far as actually good medical care -- pertinent regulatory requirements, ALARA considerations and control of access to the room.

Then it goes on to say in accordance with blah, blah, blah. That would actually work out pretty well.

CHAIRPERSON STITT: And that needs to be -- that phrase needs to be added to the remote section that we did yesterday.

MS. HOLAHAN: Right.

CHAIRPERSON STITT: Good comments. All right, facility diagram. Let's add to that thinking our comments on survey instruments. Anything over there, Dr. Quillin?

MEMBER QUILLIN: No.

CHAIRPERSON STITT: Pretty happy with your survey instruments today?

MEMBER QUILLIN: Well, I'll make the same comment I made yesterday, which is my objection to the NRC regulations requiring one instrument which has this capability. But that's in the regulation, and I can't change the regulation. Just for the record, I --

CHAIRPERSON STITT: So noted.

MEMBER QUILLIN: It's better to have two instruments that work than one that doesn't work.

CHAIRPERSON STITT: Let's -- are we ready to try radiation safety program, item 11?

MEMBER QUILLIN: I have a suggestion in the first paragraph there. To delete the words "during any brachytherapy procedure," because -- and ending the sentence that followed period and "these should include." And the reason I say that is because the first paragraph under -- is leak test. And we get to do leak test during the procedure.

CHAIRPERSON STITT: So we will change that to --

MS. HOLAHAN: Thank you.

CHAIRPERSON STITT: -- for any brachytherapy procedure. That's our editor again.

MS. HOLAHAN: Just say that will be followed. Are you saying put a period after followed?

MEMBER QUILLIN: Yes.

CHAIRPERSON STITT: Good.

MEMBER FLYNN: There's a -- I think there's really a mistake in the last sentence there, but the sentence says you should specify which survey instrument will be used to locate low energy seeds, and then iodine-125 and palladium-103, if they

become dislodged in the operating room or the patient's room. It's not really just low energy, it's in terms of low activity.

So that, you know, if you have a specific one iodine-125 seed that's .3 millicuries, you have to have an instrument that's going to detect a low enough exposure rate. So it's not just the energy, it's the activity.

CHAIRPERSON STITT: Should it be low energy --

MR. CAMPER: Low activity or energy.

CHAIRPERSON STITT: Right.

MR. CAMPER: Or I should say low activity or low energy seed, since you give the specific example.

CHAIRPERSON STITT: Okay.

MEMBER FLYNN: And then I know of an instance of that also where the source could not be located because the wrong instrument was brought into the room. It was a --

MR. CAMPER: That's a good point.

CHAIRPERSON STITT: Anybody have comments on leak tests -- on the leak test section?

MR. CAMPER: Again, just an editorial there, that that ten is standing alone for 10 CFR 35.59.

CHAIRPERSON STITT: Yeah, this hasn't gone through the --

MR. CAMPER: Right, just an editorial thing.

CHAIRPERSON STITT: Everybody happy with leak test? Personnel monitoring.

MR. CAMPER: My secretary has obviously driven that into my mind, but she's done a good job.

MS. HOLAHAN: Again, I would just like to make the same comment I made yesterday. It should be Appendix D, not Appendix L.

CHAIRPERSON STITT: And we made a change in that phrase that relates to calibration of pocket dosimeters. Do we want to make that change here also?

MS. HOLAHAN: If you use electronic dosimeters as primary method to monitor personnel exposures.

CHAIRPERSON STITT: Safe use and handling of brachytherapy sources?

MEMBER FLYNN: I have a comment on that section.

CHAIRPERSON STITT: Okay.

MEMBER FLYNN: Maybe you can help me, because maybe I don't -- maybe this is a section I don't understand. But maybe you can help me on this. If you go back -- and this links into back to nursing training part six, number six. Proper use of dosimetry, then you put in parenthesis (when applicable). And now I go over here, and I have an instance where are the nurses who take care of the brachytherapy patients always considered a "radiation worker?"

In other words, do they have to wear dosimetry?

MS. HOLAHAN: No, the only time -- the way the regulations are written is if you are likely to exceed 10% of the annual dose limits then you -- the licensee is required to provide dosimetry to individuals. Now very often --

MEMBER FLYNN: I know of a medical center where the radiation safety officer is not very well trained, and he does not provide that because -- I think because inappropriately --

MR. CAMPER: Well, in a case where nurses were involved with brachytherapy and they were not badged, we could ask for an explanation from the licensee of how you derived the fact that these individuals did not need to be badged.

MEMBER FLYNN: The RSO was lazy, that's why.

MR. CAMPER: Well, no, but I'm just saying -- I mean, and we would certainly -- we certainly could and probably would do that if we were to come across such a scenario. They can go through an exercise and demonstrate that they're not likely to exceed. That involves, you know, calculations involving time, work flow, etc.

But in a case of an occupational or a nurse involved with brachytherapy, that would be something that I think we would expect to see.

MEMBER FLYNN: Well, --

MR. CAMPER: They had to have a clear demonstration as to why they can demonstrate --

MEMBER FLYNN: They can demonstrate it algebraically, but it happened to me. And I had a dispute with the RSO that these nurses should be badged. And we started to do much more complex cases in women who are -- had many medical problems to try to provide them care that wasn't being provided previously. And the nurses were getting higher exposures, but keeping in the ALARA concept because they had to be in the room more often.

And I hope in the future that it's a requirement that brachytherapy patients -- I hope in the future if it has to be a new regulation that -- in Part 35 that for brachytherapy -- manual brachytherapy patients, low dose rate brachytherapy, that the personnel caring for the patient should be badged.

And I'm sure it's probably true in the vast majority of medical centers. I don't know. Maybe you know. I don't know. But it's not true for all them because

you've given them a way out. And I don't think they should have a way out. I think they should be monitoring their personnel.

MR. CAMPER: Again, I would --

MS. LANZISERA: Yeah, it's depending upon how many brachytherapies they do. You know, for an institution that those may be five a year, the tendency is for those individuals not to be badged. It is -- the requirement is 10% of the limits and it's if they're likely to exceed those. So it's not even, you know, --

MEMBER FLYNN: If they have to deal with a medical emergency, if they have to deal with the patient that has a problem, they're going to exceed it even though they can show you on paper that they are unlikely to exceed it because they're dealing with past history, and past history is showing that the nurse may spend only 15 minutes effective time one meter from the patient.

And I can show you the simple algebra and the -- showing you that they're going to get less than two mr per year. Then they take care of a medically unstable patient. They take care of a patient who is having an emergency, and they're there with the patient less than a meter for a couple of hours.

And then -- I just -- you know, I can editorialize -- if a program is only doing five a year, they shouldn't be doing them. They should be sending them someplace that knows how to do them. If you only do a five a year, then there's -- that's a facility that's going to have problems.

MR. CAMPER: Well, your point's well made. I mean, are likely to exceed implies a judgement. And that judgement may or may not consider the potential for an unanticipated --

MEMBER FLYNN: You're allowing people who are not expert in this nature, because they're not experts if they're only doing a couple of year, to make the

judgement. That's where I think the problem comes in. You're allowing those who are really less well trained -- I only say that not in a way to put them down, but if you do something very infrequently, by that very nature, since you're not learning from the frequency of the procedure that you're doing, then you're allowing administrators and licensees who are less well trained, less experienced to make the decision.

MR. CAMPER: I understand. And what I would again suggest, when we get into the revision of Part 35, that would be the time to bring forth that point as we discuss specific regulatory language.

CHAIRPERSON STITT: Are there other issues right now that we can deal with? I think the editorial comments are helpful, although we can't be --

MR. CAMPER: I have an editorial comment on personnel monitoring.

CHAIRPERSON STITT: All right.

MR. CAMPER: The sentence on the top of page ten that reads "Appendix L of this module provides a model procedure for a personnel exposure program." Well, not really. What it really does is it provides a model procedure for a personnel dosimetry program to monitor external exposure.

As it reads, it seems to imply that the program is for external exposure. So I would suggest that you could put for personnel dosimetry program to monitor external exposure.

MS. HOLAHAN: Okay, and just for clarification, we have to look at the appendices, because that is how the appendix is titled, is model personnel external exposure monitoring program.

MR. CAMPER: Well, then the same error exists.

CHAIRPERSON STITT: All right, you guys.

MS. HOLAHAN: I guess we have to consider --

CHAIRPERSON STITT: Clean that up then.

MR. CAMPER: We need to clean that up.

CHAIRPERSON STITT: Yeah.

MEMBER QUILLIN: Let me interject an issue here which I don't think you can address through regulation exactly. And I'm not even sure you can address it through this guide directly or indirectly. But it's one that we ran into in Colorado, and that is that this issue of contract employees dosimetry. The case we were involved in concerned a woman who worked in -- I think she said nine or ten different hospitals over time as a contract employee.

And the contractor provided the personnel dosimetry. And the hospitals thereby thought that they did not have to provide personnel dosimetry. And in fact, none of them provided personnel dosimetry. And they -- and she said only one provided any instruction also over time. And when she then asked for her personnel dosimetry record, the contractor refused to provide her the personnel dosimetry record.

And under our statute, we regulate people who possess sources of ionizing radiation. And the contractor possessed no sources of ionizing radiation, so we had no way of forcing the contractor to provide the personnel dosimetry record to the individual or to any of the hospitals where she worked.

My only recourse was to send out a letter to all hospitals saying that when you have a contractor employee, you're responsible for that contractor employee and whatever happens at your facility. But it was an interesting case because she was refused her personnel dosimetry record.

MS. LANZISERA: Just as a comment, we found that in a number of cases in Region 1 anyway, and it happens quite a bit with medical physicists that they go around and contract out to different hospitals. What we have done with those

individuals is if they have a written agreement between the contractor and the hospital to provide a copy of the dosimetry report and you know, NVLAP accredited dosimetry service, then we will accept that as, you know, their record.

Obviously you then get into problems of, you know, if each hospital were to badge them individually, how do you add up their exposure. So most have chosen to stick with their contract company monitoring them, and just send those badge reports to all the hospitals that they contract out to.

CHAIRPERSON STITT: Other comments on the section on personnel monitoring?

MR. CAMPER: That's interesting too, you know, because now with Part 20 the way it is, you know, you have this question of all exposure. You know, the licensee has this monitoring requirement and it's specified here in 20.1502 as to what they must do. But again, bear in mind that now it captures all of the exposure.

So if you're a hospital, let's say for example, and you have a contract physicist and this individual's working in several hospitals, you're in a much better position I would suggest just from a health physics management standpoint to have some kind of clarification arrangement as Penny is pointing out.

Because remember again, that this individual's getting exposure in three or four different institutions, and they're also working in your institution. You have this problem discerning from where the exposure came. So the licensee would be much better served by making sure that the contractor is badged through the contractor as an entity.

MS. HOLAHAN: That applies to more than just contractors, because many authorized users will go --

MR. CAMPER: Well, that's true, that's true.

MS. HOLAHAN: -- to multiple hospitals and they're not necessarily a contractor.

CHAIRPERSON STITT: They could be.

MR. CAMPER: Well, they could be. Yeah, right.

CHAIRPERSON STITT: In some circumstances, they would be; and others, they're not.

MEMBER FLYNN: Can I ask you how you feel about pocket dosimeters versus film badges? Because I have a strong view on that, but maybe it's -- you don't want to hear it here. But my experience has been that the pocket dosimeters aren't in generally oftentimes may not be used well. They may not be zeroed well. They bang against a door, they bang against something else and it throws them way off.

And then suddenly, Nurse Jones, who has -- thinks that she got 300 mr or something when in fact she got a 1/2 of an mr. But to me, it's -- in a circumstance where the radiation sources are well defined in terms of their activity and that the dose rate at a meter is well defined, it would seem to me it makes much more sense to have film badges.

But you're not dealing in a situation where some unknown source and some unknown activity that could be ten rem per hour at a meter versus ten millirem per hour at a meter -- you're not dealing with that situation -- the unknown, like you might want to know in the emergency room or at a nuclear power plant responders where you can get an instant reading because of this unknown quantity that you're responding to.

Here you're dealing with a very well defined sources that are used over and over and over again. And the dose rate of the meter, quite frankly, always is

between 20 and 100 mr per hour for the cesium sources we use. And it's never outside that range. But by using the pocket dosimeters, you have a less reliable measure of what the exposure record really is.

MR. CAMPER: Now there's no regulatory requirement for a pocket dosimeter, is there?

MS. LANZISERA: No, it's one of those things that for emergency cases was, you know, initially used. Again, you go back to the Part 20 requirement that if they're likely to exceed the 10%, then they would have to have a NVLAP accredited dosimetry program and you would get into that space.

MS. HOLAHAN: That wouldn't include the pocket dosimeter, so you'd have to be into the film badge space.

MR. CAMPER: So there's no regulatory requirement is the point. Okay, now you're right. I mean, they are provided for the immediate feedback type of thing, and they're much more useful in an environment where one doesn't know the exposure level to which you're about to enter.

And you can get some immediate feedback as compared to a --

MEMBER FLYNN: So the nuclear power plant scenario or the response in the emergency room to a transportation accident, I think they're appropriate because you can have the appropriate personnel there. But for nurses trying to zero these in, it -- or whatever they might do, and bang them against doors and desks and stuff, I'm not sure --

MR. CAMPER: What did we actually say? Where are we? Okay.

MEMBER FLYNN: It's page ten.

MR. CAMPER: If you use pocket dosimeters --

MS. HOLAHAN: It might be worth putting in the comment that Penny just made that if you are like -- if you are badging because the individual's likely to receive in excess of 10%, then it must be a NVLAP accredited dosimeter.

MEMBER FLYNN: I know of licensees who don't use film badges. They use pocket dosimeters. And I think it's --

MS. HOLAHAN: And they may have concluded --

MEMBER FLYNN: I think they're misguided. They haven't really thought it through. It's not because they want to avoid, they just haven't thought it through. And --

CHAIRPERSON STITT: You know, I think it's a practice stance. And we can make suggestions. I don't know how far we want to go in this type of document to --

MEMBER FLYNN: Have you not found that to be true?

MS. LANZISERA: For the nursing staff especially, many hospitals use the pocket dosimeters.

MEMBER FLYNN: But have you not found it to be true that it's difficult to -- I mean, you have to zero those things. They're not quite -- they're not always easy to zero.

MS. LANZISERA: If it's difficult to calibrate, then we do require -- if they do have pocket dosimeters in the licensing process, we require that they have a calibration program. As far as zeroing them, most institutions that I've been at they bring them to, you know, centralized location and then someone in radiation safety zeros them out every day.

MEMBER FLYNN: And what about the static and the banging against something and then you have an unstable -- you've never found this to be true?

MS. LANZISERA: Obviously not as reliable as --

MEMBER FLYNN: Right, okay.

MR. CAMPER: It can be a problem. There's no question. You're right. I mean, pocket dosimeters have their own set of problems while in use. Now, we do point out here that under 20.1501(b), which reads that the licensee shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitorings, are calibrated periodically.

But now calibration doesn't cover this couple of things that you're getting at. I mean, we probably could insert a sentence in there, Dan, that would point out that, you know, note that the use of pocket dosimeters may carry other -- may carry with them other problems, which the licensee should look for or something.

For example, dosimeters which are dropped, that type of thing. I mean, I don't mind putting in some kind of advisory sentence like that.

CHAIRPERSON STITT: Would you rather emphasize the film badge rather than making a positive statement about --

MEMBER FLYNN: I mean, I'm just throwing it out. Whatever you believe.

CHAIRPERSON STITT: I'm not sure that it belongs here. I think they're institutional methods of practice. And I'm not --

MEMBER FLYNN: A film badge is a permanent record also. I mean, if someone has a question as to what that report actually said, you have a permanent record there that you can go back and come up with the dose. With the pocket dosimeter, it's gone like the wind. I mean, you can't --

CHAIRPERSON STITT: Well, do you want to make a positive statement about what film badges do for personnel monitoring? Quillin, wake up and tell me something.

MEMBER FLYNN: Can you give a recommendation as opposed to requirement?

MEMBER QUILLIN: Well, I've used pocket dosimeters in the past, that's why I'm staying quiet on this.

MEMBER FLYNN: That's a plant. The plants are different. But manual brachytherapy, can you make a recommendation as opposed to requirement in -- no?

MS. HOLAHAN: You could say something along note that the use of film badges --

MEMBER FLYNN: Would be the recommended -- would be the preferred or recommended. But --

MS. HOLAHAN: I don't know if we could go that far.

MEMBER FLYNN: Okay.

MS. HOLAHAN: But film badges may provide --

CHAIRPERSON STITT: You could just describe why they might be a better --

MS. HOLAHAN: -- less variability or less --

CHAIRPERSON STITT: Less variability, a permanent record. That would be a comment that hospitals are --

MR. CAMPER: Well, what you might be able to do under personnel monitoring and all these sections, you might be able to have a few words that would

point out that the program must be a NVLAP approved program. You know, typically this involves the use of film badges or thermoluminescent dosimeters.

Then go on -- and have that somewhere early on.

CHAIRPERSON STITT: And then why don't you use the phrase that says advantages of film badges are, and then list some things. And that's not a requirement nor a recommendation, but it does make a statement that --

MEMBER FLYNN: Yeah, that's good.

CHAIRPERSON STITT: -- that there are some advantages to film badges.

MR. CAMPER: But whatever we put in here, we've got to do it --

MS. HOLAHAN: Yes. Either here or possibly right into the Appendix D, which is the model program.

MR. CAMPER: It may be, yeah. That may be the best place for it.

MS. HOLAHAN: Except maybe if I'm understanding Dr. Flynn, he feels it's important to put it in here because the concern about --

MEMBER FLYNN: I'd leave it up to you. I just want to raise the point. Because I'm involved heavily in training and emergency rooms for handling radiation accidents, and pocket dosimeters are the preferred method, especially when nurses can see periodically during the patient care what level they have gotten.

And it certainly would be the preferred method, I'm assuming, on a nuclear power plant to get instant feedback. But in this case, it's actually the film badges is better. There's nothing you're going to do during the care of a patient if that line has moved. Because if that line is moved from zero to 300 mr, it doesn't mean anything.

It means that you must have dropped it or bumped it, because the dose rate at a meter you already know is only 25 mr.

MEMBER QUILLIN: Actually nuclear power plants are moving towards electronic dosimeters for this purpose.

MEMBER FLYNN: So the purpose for the pocket dosimeter is totally meaningless in the brachytherapy patient up on the floor, because there's nothing you are going to do to respond to the reading that you receive. If it's too much too great, if it's illogical, then it's because you bumped it.

If it goes up one mr, it's not going to affect anything you do from a nursing point of view. The key thing is that the posting requirements -- don't the posting requirements require that you give the exposure rate at -- I presume at one meter? I think also at two feet and also at the door. You're giving -- on the posting requirements on the room of the patient's room, you have all the exposure levels, don't you, at two feet, one meter and --

MS. HOLAHAN: Well the posting is basically where and how long visitors may stay in the patient's room. So you would be posting the stay lines based on the dose rate.

MEMBER FLYNN: I thought also that maybe we're doing more than we need to, but at least all the institutions I'm aware of, we're posting the exposure rates at various distances on the door so that anyone entering there will know that if you're at one meter, you could expect to get 30 mr per hour.

MS. LANZISERA: Yeah, that's something that's covered in the, you know, current 10.8 procedure.

MEMBER FLYNN: Isn't that also posted though? We post it on the patient's chart and we post it on the patient's door to the room.

MS. LANZISERA: The posting requirements note on the door and the patients for human research subject's chart where and how long visitors may stay in the patient's room.

MEMBER FLYNN: So the exposure rates aren't being posted there?

MS. LANZISERA: That's not a Part 35 requirement anyway.

MS. HOLAHAN: That's not a requirement, but it's addressed in the Regulatory Guide.

MEMBER FLYNN: Is it in the Reg. Guide 10.8?

MS. LANZISERA: The current one.

MS. HOLAHAN: Yeah, in the current -- in Exhibit 20 of the current Reg. Guide 10.8, it has what the dose rate is at the bedside, three feet from the door, and other locations.

MS. HOLAHAN: Doorway.

MS. LANZISERA: Doorway. Oh, three feet from the bed, yeah. It's Exhibit 20, right at the back.

MEMBER FLYNN: I was thinking more of Appendix Q.

MS. HOLAHAN: Yeah, that details it, and then the exhibit just basically is what's often put up for the nurses or whoever.

MEMBER FLYNN: It says following the implant, measure the exposure rate mr per hour at the bedside, which many people take as two feet; at one meter; at the visitor's safe line; and in the surrounding hallways and rooms. Record this and other necessary information on the nursing instruction form or the nurses dosimeter sign out form.

Post the room with the radioactive material sign. Okay, a lot of us have been posting the exposure rates actually --

MS. HOLAHAN: On the door?

MEMBER FLYNN: -- on the sign, on the room, and also on the patient's chart. But I guess that's unnecessary, but that's -- it can be helpful at the time when something unexpected happens is to know exactly what you're dealing with.

MS. HOLAHAN: Right.

MEMBER FLYNN: Although we always know what it -- it's always in the same range if the same source is being used over and over again. It's nothing -- there are always -- you know, the cesium sources are basically anywhere from five milligrams to 25 milligrams, and that's always the certain activity is usually, you know, 50 to 100 milligrams and rem equivalent cesium-137, and so the exposure rates are always within a range -- all the time in the same range.

MS. HOLAHAN: Right.

MEMBER FLYNN: That's what we find practically speaking.

MS. HOLAHAN: Okay.

MEMBER FLYNN: Okay.

MS. HOLAHAN: Well, it could be something as we look through the appendices and sort of see how we deal with the appendices as we're looking at this. I'm not sure what we're going to do with those yet.

CHAIRPERSON STITT: All right, so we've made some changes to personnel monitoring including that film badge phrase that we're going to put in there. My plan is to work until 11:30, and then I'm going to have Dr. Quillin finish --

MR. CAMPER: 10:30.

CHAIRPERSON STITT: Oh, 10:30. Am or pm?

MR. CAMPER: It's up to you.

CHAIRPERSON STITT: Sure.

MR. CAMPER: Name your own poison.

CHAIRPERSON STITT: We'll work until 10:30, take a break, and Dr. Quillin will finish this session.

MS. HOLAHAN: Aren't you having fun? I said aren't you having fun? You don't want to leave.

MR. CAMPER: How could you possibly leave this?

CHAIRPERSON STITT: I could. I want to get back home this weekend. I have to. All right, safe use and handling of brachytherapy sources, as well as implant source record and inventory.

MEMBER QUILLIN: On 11.7 where you have the phrase specify thickness, I think you need to say, for example, material and thickness.

MS. HOLAHAN: What was that?

CHAIRPERSON STITT: Shielding material and thickness. Specify shielding material and thickness.

MEMBER QUILLIN: Yes.

MS. HOLAHAN: Okay.

MEMBER QUILLIN: Because I was involved in discovering one time the government bought some x-ray shields which they didn't specify the material, but they did specify the thickness. And so, the vendor sold them aluminum shields.

CHAIRPERSON STITT: Oh, my.

MS. HOLAHAN: But it was the right thickness.

MEMBER QUILLIN: It was the right thickness.

MR. CAMPER: Right thickness, wrong --

MEMBER QUILLIN: 1/16 inch aluminum.

MEMBER FLYNN: Can I just ask you a question about the sentence -- it's a very short paragraph in the second sentence. In addition, you should describe the equipment and shielding available for transporting the brachytherapy sources from storage sites to place of use."

I'd ask if you would consider adding a sentence, one sentence saying to the effect that if an unexpected event or emergency sources become displaced or dislodged, that there's appropriate shielding in the patient's room to -- we use the same sort of phrase when we were working on the HDR source that broke off in Pennsylvania at Indiana, Pennsylvania and then again in Pittsburgh that there is appropriate shielding available there to -- in case a source becomes dislodged or broken as much as for transportation.

And I'm saying this because sometimes it's not the source that comes out. Sometimes it's the entire applicator that comes out. But unless you have the lead pig device that can accommodate whatever it is that's dislodged, the source plus the applicator, then that's going to be left somewhere in the corner of the room unshielded until the responders can arrive on site.

Sometimes tandem and ovoids or vaginal cylinders come out with low dose rate sources in them, and the source could fit inside the lead pig, but the entire device holding the source can't fit inside the lead pig. And so, that's happened, and those are real instances that have happened.

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: All right, we'll add that into -- before the last sentence. Implant source record and inventory. What do you have on that, Bob Quillin?

MEMBER QUILLIN: Is the quarterly inventory requirement in 35.59?

MS. HOLAHAN: Did you say is it?

MEMBER QUILLIN: Yes.

MR. CAMPER: It's somewhere else. That's what you're thinking, right? Yeah.

MS. HOLAHAN: No, that's every six months.

MR. CAMPER: Okay, leak testing is there for six months. No, I think the quarterly inventory is -- where? It's in a different area. Where is that?

MS. HOLAHAN: Yes, it is in 35.59(g).

MR. CAMPER: Where?

MS. HOLAHAN: 35.59(g), a licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession.

MS. LANZISERA: It's a six month leak test.

MR. CAMPER: A quarterly inventory, six month leak test, right.

MS. HOLAHAN: Would that help if I specified 35.59(g) in the --

MEMBER QUILLIN: Yes.

MS. HOLAHAN: Okay.

MEMBER QUILLIN: Because I looked at it and I didn't see it first. I saw the leak test requirement.

MS. HOLAHAN: Okay.

CHAIRPERSON STITT: Other comments? Do you have some other items in that section?

MEMBER FLYNN: It doesn't -- this section doesn't include the fact that some of the sources being used are very old, and the color coding problems -- and

to be able to distinguish one source from another. That's not really part of this section, is that right?

MS. HOLAHAN: No, and at this point, I don't believe we've addressed that in here.

MEMBER FLYNN: I'm not being too prescriptive, but asking can you ask that the method of distinguishing sources must be clear and unambiguous. There have been problems, you know. There's been one misadministration whereby it was discovered during a quarterly interview, and then they had to go back and look at all the patients that were implanted with a source that was supposed to be five milligrams but was ten milligrams.

But -- and part of the problem is being able to distinguish sources in a clear and unambiguous manner. If a licensee can't do that, they should not be allowed to use those sources. I mean, that should be -- there should be no debate on that, I don't think.

MS. HOLAHAN: We could perhaps put that in the safe use and handling of brachytherapy sources.

MEMBER FLYNN: I don't think the licensees would object to that. I mean, that's just common sense.

MR. CAMPER: That's a good point also. I think again here's an area where when we revise 35.406, it probably needs some enhancement along that line. Because if you take a look at it, the closest you get to it -- what you're getting at, Dan, is 406(b)(2), where it's the number and activity of the sources removed from storage, the patient or the human research subject's name and room number, the time and date they were removed, the number and activity of the sources in storage after removal and the initials of the individual who removed them.

And then it's the number and activity of sources returned to storage.

MS. HOLAHAN: Well, that's the other possibility is in item (g) of the one you were just -- Section 11.14. We talked about each time the source is removed from storage a record is made.

MEMBER FLYNN: What if the -- is this being too regulatory? If a source activity cannot be distinguished in a clear and unambiguous manner, that source must be removed from use.

MR. CAMPER: Well, must. Can you --

MEMBER FLYNN: The source should be removed from use.

MS. HOLAHAN: Or the licensee should consider removing it from use or something like that.

MR. CAMPER: See, --

MEMBER FLYNN: If a source activity cannot be distinguished in a clear and unambiguous manner, the source should be removed from use. They can put it in a separate safe so it's not even in the -- and it has the possibly of being mixed up with the source that they intend to retrieve or -- for use.

MR. CAMPER: See, under 35.59(g), we say that okay, you've got to do the quarterly inventory, the licensee shall retain an inventory record for five years. The inventory record must include the model number of each source and serial number, if one has been assigned; the identity of each source radionuclide and it's nominal activity; the location of each source; and the signature of the radiation safety officer.

MS. HOLAHAN: Did you indicate it should go under item (a)? Did you say something about you thought that statement should go under item (a)?

CHAIRPERSON STITT: Well, you could put it there. You've talked about --

MS. HOLAHAN: Locked cabinets.

CHAIRPERSON STITT: You talked about where you're going to store all implant sources. Then you could say that those sources should be up far if you wanted to, not make a separate statement about --

MS. HOLAHAN: Yeah, and then item (e) also addresses sources that are taken out of service.

CHAIRPERSON STITT: Yeah, in fact, you could call those -- you should say they could be -- you could say that they should be taken out of service. What's the phrase that he suggested? Read that back to me.

MS. HOLAHAN: If source activity cannot be distinguished in a clear and unambiguous manner, the source should be removed from use.

CHAIRPERSON STITT: Let's say the source should be taken out of service.

MEMBER FLYNN: That could be under paragraph (e), couldn't it?

CHAIRPERSON STITT: And that relates to --

MS. HOLAHAN: It should be.

MEMBER FLYNN: You can add it in paragraph (e). That will help some licensees, I think.

MS. HOLAHAN: Should we include until the source has been reidentified or just leave it as --

MEMBER FLYNN: I think I'd just leave it alone.

MS. HOLAHAN: Okay.

MEMBER FLYNN: Because they may remove it. It may be that the color codings wore off and that it's a cesium source that's been used for 20 some odd, 30 years or more and that they plan to -- they are planning to obtain new sources anyway. I mean, leave it up to them.

CHAIRPERSON STITT: Other items under implant source record and inventory? Did you have something?

MEMBER QUILLIN: Yes, under (a). The two facilities I worked at had both used a locked room where that's -- it was a brachytherapy source room, and the sources were not kept in a locked cabinet or safe.

MS. HOLAHAN: So you think we should add room in there? Room, cabinet or safe?

MEMBER QUILLIN: Yes.

CHAIRPERSON STITT: Actually several places I've worked had it that way too. They were locked because the room was locked.

MR. CAMPER: So were they just on a -- were they on a shelf or on a counter?

MEMBER QUILLIN: They were in lead safe basically, except there was -- safe with a door. It was a --

MS. HOLAHAN: It was a locked room though?

MEMBER FLYNN: Yeah, we had mostly -- we had it mostly both ways. We had a locked isotope room and a locked safe because some of the people who had access to the locked isotope room shouldn't have access to the sources. So there was -- it was -- every place I've been it's been both. The room's been locked with people who don't -- very few people have keys; but also there was a safe in there locked because it was used for other types of things like calibrations and other things.

The access to the safe was extremely limited. Even the physicians didn't have keys to that. One physicist, the chief physicist, had a key to that, but that was it. He was just mostly for the inventory.

CHAIRPERSON STITT: Other comments on how to keep your sources safe?

MS. HOLAHAN: I don't see any blue.

CHAIRPERSON STITT: We can do one more section or we can break now and then resume.

MS. HOLAHAN: While you're here, would you --

CHAIRPERSON STITT: Right. Area survey procedures.

MEMBER QUILLIN: Could we hear major items before you left?

CHAIRPERSON STITT: My major comment is every time I read through the manual brachytherapy, I'm glad I do remote afterloading.

(Laughter.)

MS. HOLAHAN: Would you direct that as a comment up front?

CHAIRPERSON STITT: I was looking last night on American College of Radiology. I'm writing the standards for both low dose rate and high dose rate, and part of the draft I have, you know, lists some potential advantages, the high dose rate. And certainly a lot of this -- these issues are just placed into the radiation oncology department or don't exist because of the difference of the two technologies.

So no, I don't have any other issues. Let's break here, and I'm going to ask Dr. Quillin to resume when we come back with area survey procedures. And I know he has some issues on permanent implants. So we'll have this done -- this document done before noon. And then teletherapy and gamma knife after lunch break.

MS. HOLAHAN: Okay, the one point that I wanted to make for your information before you leave is that this will be modified somewhat as the patient release rule is finalized in terms of the release and permanent implants. And there will be Reg. Guide for the patient release rule which will include dislodged sources.

So I just wanted to make you aware of that.

MEMBER QUILLIN: What's the status of those?

MR. CAMPER: Why don't we go off record at this point?

(Whereupon, the proceedings went off the record at 10:20 a.m. until 10:43 a.m.)

MEMBER QUILLIN: We're back on the record. Any comments on 11.15, area survey procedures?

MR. CAMPER: No, I do have one comment though. During the break, our reporter pointed out to me that I had used the term CRM sign. I should probably clarify for the record what that meant. I meant caution radioactive materials sign. Thank you.

Okay, so we're 11.15, right? I had just a minor editorial in the last paragraph there. The sentence that reads sources may become dislodged, so forth and so on -- I think after "and" should be become, shouldn't it? After surgery and --

MS. HOLAHAN: Well, there's a become up front, but we can --

MR. CAMPER: Wait a second, become dislodged during a -- well, maybe it's okay. All right. I think I overlooked the first become. It wasn't becoming anyway.

MS. HOLAHAN: That's right, very unbecoming.

MEMBER QUILLIN: If there are no comments on --

MEMBER FLYNN: I had a couple of comments, and you may want to -- you may not want to consider them, but two comments. On section (c), "Promptly after implanting sources," etc, and then the next sentence, "Record should include time and date of survey," etc. Now this record is kept for the purpose of later review, I assume.

MS. HOLAHAN: Correct.

MEMBER FLYNN: I think sometimes when you have a record, it's good that it be of value to those who are taking care of the patient. Therefore, I'd like to go on record to endorse that the record should be posted. The record -- it does not require it be posted, but I believe the record should be posted either on the -- where the current posting requirements say that it should be posted so that individuals taking care of emergencies will be aware.

I think it's their right to be aware at the time they're taking care of the emergency, not a month later, as to what exactly is -- the exposure rate is. Not that they're going to do anything differently. As a matter of fact, they feel more comfortable that someone has taken the time to -- made a record that is obvious to what the exposure rates are rather than this fear.

I mean, people go into the room and they're fearful. Then they don't handle their duties as well. That's been my experience. But that's the point of -- and I also, down below, the last paragraph said sources may become dislodged during implantation, etc. You should submit your procedures to ensure that dislodged sources are located and recovered.

For example, any information of a survey -- brachytherapy patient linens before -- for example, you should provide any information of a survey of the brachytherapy patient bed linens before removing them from the patient's room or a

survey -- okay, it might be helpful if you should provide a survey of anything that leaves that patient's room, including the bed linens and bed pads.

For example, in Region 1, the one instance in Boston was -- not my hospital, but that the source was found in the bed pad, which is the -- when a patient has secretions or bleeding, sometimes the linen is not changed. Sometimes the patient is rolled to one side and the pad, this thick pad which absorbs secretions or whatever, is changed.

MR. CAMPER: Yeah, it could be fairly easily fixed too, Dan, just by saying the patient linens or other items before removing them from the patient's room.

MEMBER FLYNN: Well, when we train the emergency rooms near nuclear power plants in terms of handling radiation emergencies and injured workers from nuclear power plants, we tell them that when they bring the patient into the trauma room and address the medical needs first and then the radiation needs in surveying the patient, and then they decontaminate the patient.

We go through those procedures how to decontaminate the patient. Then nothing leaves that emergency room control area until it's surveyed. And I think it certainly should apply to -- and in that instance, you're dealing with counts per minute type like contamination. You're dealing with very low levels of contamination has been the experience so far.

But in -- when a source leaves the room and goes down to the laundry, or the source leaves the room and gets lost, you're talking about a much more higher activity source. So I don't see why that anything leaving that room should be surveyed, because the other option is -- and some licensees do this, and it's perfectly fine -- that nothing leaves the room during the implant procedure.

The bathroom is not being used in many cases for a patient who's bedridden. Let's say for a -- most of the implants for cesium are gynecological implants. The patient cannot stand up because they -- number one, it would be too uncomfortable to stand up. They have a Foley catheter in, so their urine is being collected.

They're put on medication to keep them mildly constipated so they use the bed pan less frequently. But they do not use the bathroom. They do not get out of bed. Therefore, the bathroom is not being use. So a lot of times, the licensee -- and I think it's a good idea -- will take those items which have been discarded like bed pads or linen or whatever, put it in their laundry container and put it in the bathroom because the bathroom's not being used for a bathroom.

And then anything leaving there either on a daily basis or after the implant is done, is first surveyed before it leaves that room. You remember the hospital in Region 1 in Connecticut where there's been a couple of instances, they're even considering themselves voluntarily about putting -- and I don't think you should do this; it shouldn't be a requirement -- putting a monitoring device outside the patient's room so that any source that leaves that room in the unshielded condition sets off the monitor.

Well, they've had -- and I think it would have been better for that large medical center, large academic medical center in Connecticut, to just have people who -- to survey the patient and survey the material before they leave the room. Then they would have not had to go to that extent to take those steps.

MR. CAMPER: Well, as you know, the sources end up in strange places. I mean, --

MEMBER FLYNN: Right. It's happened -- it doesn't happen frequently, but when it happens, it can be a significant problem if they lose control of the source for an extended period.

MS. HOLAHAN: I think the other point there that your change will capture is, for example, dressings and things like that.

MEMBER FLYNN: Right, dressings are extremely important. If they -- they say gee, we only have to survey the linen, but there goes the dressing with the iridium ribbon in it.

MS. HOLAHAN: No, I think that's a very good point. Thank you.

MEMBER FLYNN: It doesn't have to leave the room. It can stay in the room. There's plenty of room in the room to keep material until the implant is over.

MS. HOLAHAN: But even once the implant is over, when you take it, I mean --

MEMBER FLYNN: Everything should be surveyed.

MS. HOLAHAN: Yeah.

MEMBER FLYNN: Yeah.

MR. CAMPER: Okay, good point. All right, where are we, Bob?

MEMBER QUILLIN: 11.19 is the next paragraph, implant therapy and release of patients.

MS. HOLAHAN: Okay, before -- I just wanted to again mention as I'd mentioned before is that there is currently the patient release rule will impact on -- at least for release of permanent implant patients.

MEMBER QUILLIN: 11.19.1? 11.19.2, permanent implants?

MR. CAMPER: I had a little bit of a problem with our paragraph at the bottom of the page where we say the licensee is not responsible for the radioactive

patient after the patient has left the hospital. In our next sentence, we say the patient's home is an unrestricted area since the licensee has no control over access by other individuals.

I don't -- there's a lot more to it than that. I mean, it's not that the licensee doesn't have any control over it only because it's an unrestricted area. They don't have any control over it because it's a private residence, and that could go on and on. It seems to me that the first sentence is sufficient. It makes the point. We no longer have control.

And then you can move on into the following -- the next sentence then. It is important therefore that you include instructions, blah, blah, blah. In other words, the second sentence, I don't think really helps the argument much, and it's a lot more to it than that.

MEMBER FLYNN: And I agree with you.

MEMBER QUILLIN: Well, I have a problem with the first sentence. My problem is that when you say you're not responsible, it infers that once the patient walks out the door, you have no responsibility. And I don't think that -- I think there's a problem with that because I think hospitals are taking that literally.

MS. HOLAHAN: Would it help if we put in has no regulatory -- is not regulatorily responsible because under the regulations they are not responsible, but perhaps they have --

MEMBER QUILLIN: Because being in the role I am, we're continually responding to materials that are being put in the trash basically now because of the issue of alarms at the police disposal receiving facilities. And hospitals say it's not responsibility because that's -- I mean, whatever the patient does, the patient does.

And the waste companies take an entirely different view of this when they receive a set of bandages or typically diapers from a patient who has been released from a hospital after diagnosis or treatment. And so this idea of responsibility says you know -- it goes too far as far as I'm concerned.

I recognize there's no control there.

MEMBER FLYNN: I can give a suggestion. Keep the sentence as it is. The licensee is not responsible for radioactive material after the patient has left the hospital provided the licensee has complied with the -- provided the licensee is in full compliance with the patient release criteria. Because this implies that even if you make a mistake you're not responsible for it once it leaves the hospital.

This implies -- that sentence is so stark by itself, it applies that even if you've made a mistake, well, okay, we made a mistake but we're not responsible anymore because the patient's left the hospital. And I think you should have the phrase left the hospital provided the licensee has complied fully with the patient release criteria.

MR. CAMPER: I would even say set forth in 10 CFR 35.75.

MEMBER FLYNN: Because then they have to think well, we better make sure that even after they've gone that there are no problems for which we could be held in a non-compliance with the patient release criteria that they shouldn't have left in the first place because something wasn't quite done thoroughly enough.

MS. HOLAHAN: Is that getting at your point though, or is that still --

MEMBER QUILLIN: Well, there's also -- I saw the comment from Region 1 and the response there was that this will be addressed in the patient release regulatory guide. And maybe --

MS. HOLAHAN: Okay, but that is dislodged source and handling of bodies while they're in the hospital.

MEMBER QUILLIN: Okay.

MS. HOLAHAN: The other point that I wanted to raise is one of the questions has come up and we have put out in an information notice is that once a patient is releasable, they are considered released. So if they have met the patient release criteria, they can be -- but they're still being kept in the hospital for other medical purposes -- I think we've seen some cases where it's permanent brain implants or something, and they may be in the hospital for reasons other than the implant that are not subject to the requirements in Part 35.

I mean, once they're releasable, they could be considered released.

MR. CAMPER: See, the problem is that the release criteria in 35.75 has certain underlying assumptions. And that is, -- well, in the revised language you have a 500 millirem exposure, dose; and that's really based upon some of the old NCRP 37 assumptions, which if one goes back and looks at the history of that, it assumed taken to decay, quarter occupancy, meter distance and this type of thing.

And that criteria was inconsistent with the operating parameters for permitees today that operate sanitary landfills. Because often, their charter from the local municipality is zero radiation. And so this hot diaper or toothbrush or whatever shows up triggers the sodium iodide detectors, and we're off to the races.

Now, on one hand, the licensee in terms of our regulations once they're released according to 35.75, they no longer have a regulatory responsibility so they're home free in that context. But it's problematic in that their patient or something from their patient may end up triggering this alarm.

Now, the question is what can we or should we say about that?

MEMBER QUILLIN: Well, one thing you can say is something that you say I think elsewhere in your regulations that this does not waive any other

regulations that may exist for other purposes. In other words, the problem is that the licensee thinks that once they've released the patient, their job is done and that is it.

But they do have some -- in my estimation, some responsibility for this material that it's appropriately disposed of after the patient excretes it or whatever or the source is dislodged. Especially for a dislodged source. If it's in somebody's house, are you going to just throw it in the garbage, or is the licensee going to take care of it?

MEMBER FLYNN: See, that's why I would add the phrase. You know, after the patient's left the hospital provided the licensee has complied fully with the patient release criteria. And if you go back up to those little bullets above there -- for example, if the patient did not avoid a public place because it wasn't made clear to him that he should and something happened, then the licensee hasn't complied with the patient release criteria.

Or, if the patient did not take "action following discovery of the dislodged source including notification of the licensee" because it wasn't clear to him, then maybe the licensee didn't comply with the patient release criteria fully enough or clear enough. And so they still have to be worried about what happens after the patient has left the hospital if they have to be in full compliance with the patient release criteria.

MR. CAMPER: Well, you know what you might do? Up above we have brought to bear this idea of you may not release until you meet the criteria in 35.75. Maybe what we need to do is add another dot under the guidance that picks up this concept of how to handle a dislodged --

MS. HOLAHAN: Fourth dot down.

MEMBER FLYNN: Fourth dot down. That's why the licensee has to be really sure that he has given clear guidance. Because if he doesn't give clear guidance, then he's not off the hook by that sentence down there.

MR. CAMPER: No, I understand. What I'm saying is why do we even need to have this sentence that reads the licensee is not responsible for?

MS. HOLAHAN: Because again, on a regulatory basis, once that material has left the hospital, they are no longer required to do anything with the material.

MR. CAMPER: Yeah, but isn't that clear, or could it not be embodied within the paragraph above? A licensee may not release a patient with a permanent implant until so and so and so and so. If a patient is authorized for release, you should provide them with so forth and so on.

I mean, what do you gain by saying -- I mean, if you stop and you think about it, the sentence starts off by saying you're not responsible, but then it concludes by saying you should provide instruction. That's sort of a contrary thought pattern if you stop and think about it. If you're not responsible, why should you provide instruction?

MS. HOLAHAN: No, you have to provide instruction prior to -- maintain doses to individual's ALARA. That's why the instruction would be required if there was a dislodged source.

MR. CAMPER: But that's right. But you're doing that because you have a regulatory obligation to do that.

MS. HOLAHAN: Right.

MR. CAMPER: You're not doing it because they're now gone and you no longer have a responsibility. You're doing it in the first instance because you are in fact required to do it.

MEMBER FLYNN: Quite frankly, I sort of like the fact that that sentence is there that you're not responsible for material after the patient left the hospital because it makes it clear that you're not responsible that if they have a question, I have to go down and survey their house or survey the house next door.

MS. HOLAHAN: Yeah, and that was --

MEMBER FLYNN: But at the same time, I believe the phrase is added provided the licensee is in full compliance with the patient release criteria doesn't get them off the hook for having provided an effective communication to the patient prior to release.

Because if something is discovered that the patient did not follow the instructions and the patient says well, they didn't give me that paper or they didn't explain it to me or they explained it wrong, then the licensee is not off the hook. Maybe if you put that sentence up in the top paragraph, the licensee is not responsible for the radioactive material after the patient left the hospital provided the licensee is in full compliance with the patient release criteria, and then you can put, you know, if the patient's authorized for release, you should provide them with, and then put the guidance bullets -- end with the guidance bullets.

And if you don't want to -- even if you want to put that sentence up in the -- the sentence up in the first paragraph.

MR. CAMPER: Trish, the new patient release criteria, isn't there an instruction requirement specified?

MS. HOLAHAN: Yeah, in fact, what will happen is the 35.415(a)(6), which is currently what is to provide radiation safety guidance will go away, and in the revised 35.75, if an individual is likely -- may exceed in excess of 100 millirem, then the licensee is required to provide written instructions to the patient to maintain doses ALARA prior to releasing the patient.

So it would be written instructions that would be required. Whereas currently, they only have to provide radiation safety guidance, and it doesn't specify that it has to be written.

MEMBER QUILLIN: Do you have a copy of 10 CFR? Let me look at it for some language. I know you have elsewhere.

MS. HOLAHAN: Part 35?

MEMBER QUILLIN: Not 35, the larger part. I promise not to write on it.

MS. HOLAHAN: That's only Larry I have to worry about.

MEMBER QUILLIN: The other thing in this paragraph is at the end of the paragraph, it says in addition, if you become aware a radiological problem exists, good health physics practices should be followed. It just leaves me on the -- first you say you've got no responsibility, then you end up the paragraph saying good health physics practices should be followed.

MEMBER FLYNN: It should is the key thing.

MS. HOLAHAN: And the point that we're -- that's right. And the point that we're trying to make -- no, the --

MEMBER FLYNN: Not responsible is pretty clear. Not responsible is pretty clear, but should is simply -- it's like a recommendation.

MS. HOLAHAN: And this is the -- also addresses the same point where if they're releasable they can be considered released and moved to another area of the hospital and you're not required to do certain things. But again, good health physics practices should be followed. So we're trying to differentiate between what's actually required and what would -- you should take into account based on your program.

MR. CAMPER: Well, it's interesting because 30 -- the sentence up there if a patient is authorized for release, you should provide them with radiation safety guidance, etc., etc., etc. Under 35.415 -- I understand, I understand. But I'm just saying what is 35.415(a)(5) at this point tell them?

You're supposed to be providing the patient or the human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public ALARA before you release them. Now, 35 -- the patient release rule reads how now, do you recall?

MS. HOLAHAN: It says -- you mean the revised patient release?

MR. CAMPER: Yeah.

MS. HOLAHAN: Okay. What it states, and this is not verbatim, is that if an individual is likely to receive in excess of 100 millirem TEDE from the released patient, then the licensee must provide written instructions to the patient. I think to maintain doses ALARA. I'm not sure of the full language.

MR. CAMPER: All right, so then the thought becomes if you look at -- we go on to say then this guidance may include as appropriate the need for, and we list certain things. Now bullet five, no four, gets at the idea of the dislodged source, which does pick up the idea that we had in the last paragraph.

Is there any merit to doing a couple of things? One is eliminating the last paragraph because it does send a signal that Bob Quillin has trouble with because it implies that if this source becomes lost in the patient's -- in the individual's home, the hospital has no responsibility. Is there any merit to putting in a bullet that would bring to their attention that there may be other requirements imposed by local jurisdictions?

MEMBER QUILLIN: I have 20.2007.

MR. CAMPER: 20.2007. You're becoming quite the regulatory scholar, Bob. 20.2007, complies with environmental and health protection regulations. Nothing in this subpart -- relieves the licensee from complying with other applicable federal, state and local regulations governing other toxic or hazardous materials. Materials may be disposed of under this subpart.

Governing any other toxic or hazardous properties of materials that may be disposed of -- so arguably, what you're saying, that does bring to bear the fact that there's some local ordinance --

MEMBER QUILLIN: That's right.

MR. CAMPER: -- that prevents the disposal of any material -- radioactive material.

MEMBER QUILLIN: We have a county which is a nuclear free zone, for example.

MS. LANZISERA: So does Massachusetts.

MS. HOLAHAN: I guess we could just refer them back to 20.2007, you know, bearing in mind. But I think the bigger -- the point that we were trying to make is just because you can release them doesn't mean that you shouldn't forget good health physics practices.

MEMBER QUILLIN: I understand, but there's a dichotomy in the way the paragraph is written.

MR. CAMPER: It is. If you can release them and you have no responsibility, but then you turn around and remind me that I should bear in mind good health physics principles, I mean, that's a contradictory message.

MS. HOLAHAN: Except it's guidance. Again, you've got a regulation. There isn't -- in Part 35, you're not longer bound by that regulation. But again, because we're providing guidance, you know, you should keep these in mind.

MEMBER FLYNN: I agree with you, Trish. I think that we've done it before. We've made recommendations which was outside the scope of the regulation. And this is giving -- and if you add the phrase has left the hospital provided the licensee is in full compliance with patient release criteria, and then you can add your part about the state, county, whatever.

Then after -- what follows after that is recommendations. I think the licensees will follow the recommendations. I don't think that because it's not a regulation, I don't think you should put should in there. You should put -- I mean, you shouldn't put a must; you should put a should.

MR. CAMPER: Well, you know what you could -- if you do it like it is there, your last paragraph -- I mean, here's an idea to think about too. While patients may be released consistent with the criteria in 10 CFR 35.75, licensees are reminded of the requirements set forth in 20.2007 and that today that results in landfills in most instances refusing to accept any radioactive material.

And that a dislodged or a lost source may become problematic in that regard.

MS. HOLAHAN: But if it goes into the --

MR. CAMPER: All you're doing there is bringing that to their attention. I mean, I'm envisioning a softly worded paragraph that would bring it to their attention. I mean, Bob Quillin's concern that to simply state that you're not responsible -- I mean, Bob might even argue now to say how can you not be responsible when you have this stipulation in Part 20.

That's an interesting question. I'd have to explore that a little more with OGC.

MS. HOLAHAN: What we can do is look into it a little bit more and look into what the actual -- look at the statements consideration on the 20.2007 as to what that actually is applicable to and how it's interpreted.

MR. CAMPER: Yeah, we need a little more background on that.

MEMBER QUILLIN: The trouble is, I've had hospitals say when it goes out the door it's not our responsibility anymore. And then -- I mean, that's a --

MS. HOLAHAN: When hospitals come back, because we have had hospitals that have chosen to go out and retrieve the material, but have not been required to go out by us.

MS. LANZISERA: Once it went out the door and it wasn't supposed to go out the door.

MS. HOLAHAN: Right.

MEMBER QUILLIN: I understand that, but I'm just saying that states are -- and local entities are wrestling with this problem now. And we get a call a month on the average about this situation.

MEMBER FLYNN: If a high dose rate source broke off again like in Indiana, Pennsylvania, once it's left the hospital they can just leave it out there?

MS. HOLAHAN: No. That is not authorized release. That's unauthorized release.

MEMBER FLYNN: Right. Sure, I understand.

MS. HOLAHAN: They are still -- yeah. It is only when it's been authorized release.

MR. CAMPER: See, in a case -- the survey measurements weren't done.

MEMBER FLYNN: Right.

MR. CAMPER: I mean, that person literally did not meet the requirements of 35.75(a)(1).

MEMBER FLYNN: If they did, they didn't put the batteries in the survey meter.

MR. CAMPER: That's right, they didn't turn it on, right?

MS. HOLAHAN: Let me --

MR. CAMPER: Well, we need to explore this 20.2007 issue. Trish's point about looking at the SOC is a point well made. And let us see what we can do to work this. I understand your concern about the not responsible. I understand the comment about how can you say I want you not responsible, but yet on the other hand suggest you do good HP practices.

MS. HOLAHAN: Except we inform licensees of that on a regular basis.

MR. CAMPER: Yeah, we do.

MEMBER FLYNN: Well, let's put it this way. If they did meet the patient release criteria and they did meet the Part 20 requirements, there still could be many instances where they meet both those, and yet they're in compliance with all of

that; but and yet, there is a situation whereby they're not required to respond. They're not responsible because they have met those conditions, but they still -- it would be good health physics practices to -- let's say retrieve that source or to do whatever's necessary.

In other words, I can see circumstances where they meet the release criteria, they meet Part 20, but it still would be prudent that they should follow good health physics practices.

MS. LANZISERA: Well, and we've had numerous examples of that, not with brachytherapy sources, but you know, with -- medicine.

MEMBER FLYNN: So you think you're making it better, but you may be making it worse by not recommending to them to follow good health physics practices, even though they're not responsible to.

MR. CAMPER: Yeah, I understand. I'm a little concerned at this point though. I'd like to know a bit more about the history -- the regulatory history as set forth in statements of consideration about the requirement in 20.2007. I mean, I can envision, depending what that really means, a situation where you really ought to be advising clients -- advising licensees as to that requirement and what it might mean.

Particularly in view of the operating posture that you are seeing in local municipalities today with regards to zero radioactivity. And I -- it just needs to be explored more is what I'm saying.

MEMBER FLYNN: See, one thing you don't want to do is to drive up medical costs by keeping patients in the hospital for a long time. I'll give you an example. They do iodine implants for let's say brain cancer patients. And these patients have a very serious malignancy. They often die from them despite the attempt to control it.

So what happens when they come into the emergency room in a seizure and they die? It might be a year later. It might be another hospital. Is the hospital and the authorized users that implanted those sources which helped that patient -- and the dose rate by that time is, you know, inconsequential.

But are they required to pursue that person? Are they required -- at what level --

MS. HOLAHAN: You see, and in the patient release rule, we are saying no.

MEMBER FLYNN: Yes.

MS. HOLAHAN: Once they are released -- and this goes back to the question of being releasable, can you move them to another area of the hospital because you could release them and therefore they could go out the door and go to another hospital where they wouldn't have to --

MEMBER FLYNN: Should they wear a wristband -- a permanent medical alert thing that says, you know, if anything happens to me, call the RSO and call the authorized user?

MR. CAMPER: Also too, as I look at this more, Bob, the language in 20.2007, it says nothing in this subpart relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of under this part.

I think what that gets at is something like --

MEMBER FLYNN: Unradioactive --

MR. CAMPER: Well, I think it gets like --

MEMBER FLYNN: Uranium.

MR. CAMPER: It gets like at LSC and tolulene, for example.

MEMBER QUILLIN: That was what it originally written for.

MR. CAMPER: Right.

MS. HOLAHAN: Right.

MEMBER QUILLIN: But I'm just saying that, you know, our -- I think we call them in Colorado certificates of designation for solid waste facilities basically all say that they do not accept radioactive waste. That's a local ordinance.

MEMBER FLYNN: Another example would be uranium. If the radiation isn't a problem, you can still destroy the kidneys that kill a person with the toxic effects of the uranium on the kidney.

MR. CAMPER: Well, why don't we take a look at -- for purposes of economy of time, why don't we take a look at the background on the 20.2007 and make sure there's no problem there. Let us see if we can craft a paragraph that would point out that if the patient has been released according to the patient release criteria in 35.75, the licensee may not have a direct regulatory responsibility; however, it may be prudent to exercise good health physics practices and become involved in the recovery of a source lost in a residence or something to that effect.

See if we can't come up with some paragraph that makes some sense. And then what we'll do is we'll sent it to the two of you and see what your thoughts are about it.

MS. HOLAHAN: We also may want to look at how the guidance is being revised in the patient release rule.

MR. CAMPER: Right.

MEMBER FLYNN: When would we have access to that patient release rule if it's signed? In other words, would we be able to -- so we can make an

intelligent comment, we'd be able to -- once you can release it. There's a certain process you have to go through. But then you can send it to us once it's finalized?

MS. HOLAHAN: Yeah, and I think the ACMUI meeting is -- there's going to be an update on the status of that.

MEMBER FLYNN: Oh, I see.

MS. HOLAHAN: And this won't be finalized before then. So --

MEMBER FLYNN: Okay.

MS. HOLAHAN: -- hopefully we'll have some better feel by the time of the next ACMUI meeting.

MEMBER FLYNN: Maybe you could put that on the agenda of the next ACMUI.

MS. HOLAHAN: Well, I think the patient release rule making status is already on the agenda.

MEMBER FLYNN: In terms of these documents though? The effect on the --

MS. HOLAHAN: Okay, we could perhaps --

MEMBER FLYNN: Are we discussing these again?

MS. HOLAHAN: The subcommittee meetings are.

MR. CAMPER: No, no.

MEMBER FLYNN: I thought --

MR. CAMPER: The chairperson will be providing a -- we discussed this earlier in the first day. For your benefit, let me go through it. The chairperson of the subcommittee meeting is on the agenda to provide back a report of these proceedings for the benefit of the committee as a whole.

There is not a plan at this time for the committee to see these guidance documents again before they are published for public comment. Now, the schedule for public comment for these documents was originally on the order of November or December. But that has subsequently changed because these document are now being considered in process within an overall larger process to develop a licensing manual under our ongoing business process reengineering program.

Now Barry Siegel did ask me the same question would the committee see these guidance documents as a whole. And I indicated to him no, that they would not. That was why the subcommittee was formed to function as the eyes and ears of the committee in reviewing these with the status report then back to the committee.

I told him on day one if there were any significant issues that could not be resolved during this series of meetings, that that issue could then be a subject of discussion by the entire ACMUI. Now, from a timing standpoint though, I can see a problem because we currently have an agenda prepared and we've noticed a Federal Register notice.

Which would mean then that the committee wouldn't have a chance to explore this issue until the next regularly scheduled ACMUI meeting in May, by which time these documents would have been published for public comment. I'm sorry?

MS. HOLAHAN: I'm just saying if we could provide based on when the two coincided, we could just provide them a copy of --

MR. CAMPER: When the two -- which two?

MS. HOLAHAN: Patient release rule has been finalized.

MR. CAMPER: Right.

MS. HOLAHAN: Then we could finalize this before it goes out.

MR. CAMPER: For public comment?

MS. HOLAHAN: Right.

MR. CAMPER: Yeah.

MS. TAYLOR: Let me make another -- we have an hour on the schedule to report on the subcommittee activities. That doesn't preclude us from bringing up specific issues.

MR. CAMPER: No, that's a good point.

MS. HOLAHAN: Oh, we have an hour?

MS. TAYLOR: Yes.

MS. HOLAHAN: Okay, well maybe we could --

MR. CAMPER: Well, perhaps that's what we should do then. Because that would be -- that approach would be consistent with what I told Barry Siegel the other day -- Dr. Siegel. That if there were any remaining issues, we could bring them before the committee.

MS. HOLAHAN: Torre, is that hour on the subcommittee meetings before or after the status report on the patient release rule? Do you know offhand?

MS. TAYLOR: I believe it's before.

MR. CAMPER: I can tell you on that. The subcommittee report is on day one in the afternoon, and then the -- it is followed subsequently later in the day by the status reports.

MS. TAYLOR: Larry, actually the report has been moved up into the morning to adjust for the medical consultant issue. But either way, it's still before the rule making.

MR. CAMPER: So at this point, Torre, you're saying the plan is to move --

MS. TAYLOR: We can change that. We haven't finalized those times. So if we need to change that, we can explore that.

MR. CAMPER: But in either case, it would be before the report on the patient release rule making?

MS. HOLAHAN: Yeah, but what she's saying is it could be changed.

MS. TAYLOR: You can swap them. Because I haven't committed to times with anybody.

MR. CAMPER: Well, maybe we ought to -- maybe that would be of utility to get the status report on the patient release rule or the rule status reports that morning. You can hear what the patient release rule looks like.

MEMBER FLYNN: Right.

MR. CAMPER: Then later, at some time to be determined, we could do the report of the subcommittee meetings --

MS. HOLAHAN: And address this issue.

MR. CAMPER: -- and address this issue, yeah.

MS. HOLAHAN: I guess the other question too though is we need to see what the status of the guide is, because we're talking about the patient release guide as being an important aspect in this.

MR. CAMPER: All right, well we can do that. Why don't we make a point to do that? We'll find out the status of the guide on the patient release rule in the meantime, and we'll adjust the schedule -- need to talk with research about that, because they're the ones who are covering the updates on rule makings and guidance. But I don't think it would be a problem.

That may be the most orderly way to proceed. Torre Taylor can make that happen for us. Torre can make that happen. She has the capacity to do that.

MEMBER QUILLIN: Well, are we finished with this paragraph yet?

MS. HOLAHAN: Well, can we finish with it in the sense that we'll address it later?

MEMBER QUILLIN: Yes.

MS. HOLAHAN: If that's acceptable to you two.

MEMBER QUILLIN: Acceptable to me.

MS. HOLAHAN: Okay.

MEMBER QUILLIN: You know my concerns.

MS. HOLAHAN: All right.

MEMBER QUILLIN: 11.19.3?

MS. HOLAHAN: Okay, this was discussed somewhat at the last ACMUI meeting when we were discussing the brachytherapy issues paper and the whole issue of release of patients with temporary implants. And I think at that time the ACMUI's recommendation was to just address it on a case by case basis and deal with it in guidance space, which is what we have attempted to do here.

MEMBER QUILLIN: I don't have any comments on this section. No comments? Then on to --

MS. HOLAHAN: Well, yeah, let me make one -- raise one question. A question was posed the other day as to why we would feel strongly about having a non-hardening bonding agent. Now, one of the things is whenever we have had some of these requests come in, the licensees have committed that that is part of what they use is these non-hardening bonding agents.

And I think that's because in order to keep them in place, they feel that's important. But at the same point, they don't want to glue them. And I was wondering if there were any comments on that? Dr. Flynn, have you had experience with these or --

MEMBER FLYNN: No, I don't -- I'm sorry, I can't comment on that.

MS. HOLAHAN: Okay.

MEMBER QUILLIN: If that's what your licensees have been asking for, I think that's --

MS. HOLAHAN: Yeah, they have committed to them when they've been asking for this release, is they say these are one of the things they're going to use. And so, that's why we have put it in the guidance.

MEMBER QUILLIN: 11.20, other safety procedures?

MS. HOLAHAN: This is just an administrative, but I think to be consistent with the other modules, I looked and I think we should actually call this 11.23; and therefore, move it and call it non-human use. Because that's really the only thing it's dealing with.

MEMBER QUILLIN: That's right.

MS. HOLAHAN: Now one of the comments that we did receive was that we should expand that section. But since this is a Part 35 license and non-human use is not dealt with under Part 35, we didn't feel it necessarily appropriate to deal with it in this module unless --

MEMBER QUILLIN: 11.21, access control?

MEMBER FLYNN: I had a couple of points. But again, part (c), authorized visits by minors only on a patient by patient basis with the approval of the authorized user and consultation with the RSO. I personally think with approval of the

authorized user is sufficient. And to try to reach the RSO in a situation, it's probably not being done.

The authorized user, if he makes a -- I can't imagine there being an improper judgement. But that authorized user would be responsible to the RSO and to the whole -- to the radiation safety committee. But I can't -- I don't know of any instance where an authorized user has not been very careful in terms of discouraging visits by minors and limiting them significantly and explaining to the patient why.

MS. HOLAHAN: I believe the reason that is in there, and it's not an I believe, I know -- is the requirements in 35.415 specify it's after consultation with the RSO. So I mean, again, this is one of those questions that perhaps we could look at as we revise Part 35. But currently, in order not to do that, require an exception to the license.

MEMBER FLYNN: If a 17 year old is going to see grandpa for the last time, you don't want that visit to be limited because the RSO couldn't be contacted to get approval. That's all. I think this is a case where -- we tell them quite frankly -- we put phones in the rooms to call by phone. We have had instances where -- this is a true story -- where the grandmother was going through a two day implant.

Ten or 15 grandchildren haven't seen her for two years, and the day they visit happens to be the day they want to visit with her is the day that she has the implant in. And then they won't see her again for another two years. So we discouraged them to even visit very strongly. Unless there's a good reason. But the physician -- they will then have to give a good reason.

And then they seldom are able to. But when they are, then I have said then go ahead -- you know, go ahead in the room. And five minutes and stay back here, you know. But then for me to try to have to reach the RSO somewhere and get a

consultation and get approval is -- turned out at least in the cases that I've been involved with to be very impractical.

But that's just a comment. I mean, you may want to keep it. But I guess if they don't follow it, they'll be responsible. They may just decide not to do it and just be responsible if something goes wrong.

MS. HOLAHAN: Yeah, I just think at this point that's something that we'd again have to deal through the regulations. But the regulation is very specific.

MEMBER FLYNN: Yeah.

MR. CAMPER: I have a concern about item (b), mark a visitor safe line on the floor with red tape as far from the patient as possible. I essentially have the same concern with that statement as I had with putting the patient in a room as far from the nursing station as possible.

Now I know if I look in the existing Appendix Q, Reg. Guide 10.8 under model procedure, there is the same statement. Mark a visitor's safe line on the floor with tape as far from the patient as possible. Well, that doesn't make a lot of sense. I mean, literally that would be a line right at the entrance to the door to the room. That's as far away from the patient as possible.

And that's not really what we mean.

MEMBER FLYNN: You say as practical -- as far as practical?

MS. LANZISERA: Do you want a dose rate?

MR. CAMPER: Well, that's what I'm getting at. If you go on then, the next line in the current Appendix Q says following the implant, measure the exposure rate in mr per hour at bedside, at one meter from the bedside, at the visitor's safe line, and in the surrounding hallways and rooms.

The last rates, plural, must conform to the requirements in paragraph 20.105(b). That's the old Part 20.

MEMBER FLYNN: Where are you reading from?

MR. CAMPER: I'm reading from Appendix Q of Regulatory Guide 10.8.

MS. HOLAHAN: The old Reg. Guide.

MEMBER FLYNN: Right.

MR. CAMPER: The existing revision to Reg. Guide 10.8. Now see, the old 20.105(b) is what now -- anyone know? Penny, do you know off the top of your head?

MS. LANZISERA: It is public dose limits, isn't it?

MS. HOLAHAN: Now we defined safe line in the glossary as a specific location beyond which personnel and visitors will not exceed a given exposure within a specified time.

MR. CAMPER: That's my point. The safe line is driven by an exposure rate.

MEMBER FLYNN: That's right.

MS. HOLAHAN: Right.

MEMBER FLYNN: That's why it should be posted.

MS. HOLAHAN: Right, which is why we're marking it or posting it. Now, we could just make it -- is mark a visitor's safe line on the floor with tape and that particular item, and then we've defined what safe line is.

MEMBER FLYNN: I would strongly recommend, even though you can't require it, that the note on the door also includes -- I recommend that it includes the exposure rates at the bedside, at the safe line, right on the door.

MR. CAMPER: Well, it used to read, you know, you can't exceed a certain dose in a period of time not to exceed a cumulative dose in X number of days.

MEMBER FLYNN: What I'm saying is like we do at our hospitals, I think the dose rate -- exposure rate, excuse me, at the bedside, at one meter and at the safe line should be recorded -- should be posted. Those numbers should be posted on the patient's door. I think that should be recommendation.

Because that again helps the emergency responders -- that question that the nurse -- if I take this EKG, you know, what kind of a dose do I get? And then the judgement can be made that you defer the EKG until the radiation safety -- until the radiation oncologist removes the sources or the chest pain is such a nature and the exposure rate is so low that the EKG can be taken for that patient with chest pain and the brachytherapy implant without removing the sources because of the medical urgency of that.

But at least if you have that information on the patient's door, I think it's important. Why do you record it if no one knows what it is?

MS. HOLAHAN: Yeah, we can just add into item (d) is note on the door the dose rates -- the exposure rates.

MR. CAMPER: You know what I would do for purposes of guidance? I would -- I'm reading through this now very quickly here, I admit, and I'm reading from -- there are two things that come to bear on what is -- the safe line we all acknowledge should be -- is driven by exposure rate.

Now then the question becomes okay, what exposure rate? Now, if you go to 20.1301, you have (a)(1), which is the 100 millirem limitation to a member of the public; and then you have the second one, which is (2), which is a dose in any

unrestricted area. Well, that doesn't apply here. Because that room in fact is a restricted area.

So the two mr per hour is not it. So what are you stuck with? Well, you're left with 100 millirem to a member of the public, and one would have to ensure that whatever dose line you set up under some defined period of time would not allow an individual to receive 100 millirem. And then I'm also looking quickly at 20.1302, which says a licensee shall make a cause to be made as appropriate surveys, radiation levels and unrestricted and controlled areas and radioactive materials and effluents release, so forth and so on.

And the licensee shall demonstrate compliance of 20.1301 by demonstrating by measurement calculations, so forth and so on; and it goes through some criteria. I think what I would do is this: I would point out that mark a visitor's safe line on the floor with tape --

MS. HOLAHAN: To demonstrate compliance --

MR. CAMPER: -- to demonstrate compliance with 20.1301 and 20.1302.

MEMBER QUILLIN: I would -- based upon my experience in risk communication, risk assessments, recommend that you delete the word safe in some future time, because safe --

MR. CAMPER: Yeah, I see what you're saying.

MEMBER QUILLIN: -- has connotations which are individually defined and not defined by the licensee.

MS. HOLAHAN: Well, we could delete the word safe. I mean, it's only within guidance space currently that we have the word safe line. It's not in the regulation.

MEMBER QUILLIN: I would have just a visitor's line.

MR. CAMPER: That's right, visitors.

MS. HOLAHAN: Visitor's line and then -- yeah, you're right. We can --

MEMBER FLYNN: I agree with that.

MS. HOLAHAN: That's an easy fix.

MEMBER FLYNN: I think if you post -- if you recommend that the exposure rates at these areas be posted, then individual judgements could be made on site at the time. So that if a visitor asks a question can I stay in another ten minutes, you can answer the question immediately because the exposure rates are posted on the door.

Also, I think the other thing is you need to keep -- you know, keeping the ALARA concept in mind. That allows nursing personnel to have access to that number. At the safe line, the exposure rate is two mr per hour -- to either -- to discourage visitor's from staying longer than they should.

MR. CAMPER: Well, I think what it comes down to if you step through it is basically you end up with -- you have a given exposure rate. And the point is, you can't let that member of the public get more than 100 millirem.

MS. HOLAHAN: Actually, let me go back a step.

MR. CAMPER: So then it becomes a question of --

MEMBER FLYNN: There's more than that though. There's the ALARA action steps.

MR. CAMPER: No, I understand, I understand. I'm just talking pure regulatory limit.

MS. HOLAHAN: 35.415(a)(1) will be changed in the patient release rule. And that will impact on these numbers because currently the way 415(a)(1) reads is it says you must demonstrate compliance with 20.1301(a), which is what Larry is currently reading.

However, as the patient release rule was being developed, they went back and prior to the new Part 20, that reference in there was 20.105(b). And that had a dose rate limit. And so, what is being done as part of the patient release rule that is currently -- is not yet final. But they are putting a dose rate back into 35.415.

And so, again, that number may impact what we're doing here in the access control.

MEMBER FLYNN: Is that number something like two mr or five mr?

MS. HOLAHAN: Two mr per hour.

MR. CAMPER: What is it?

MS. HOLAHAN: Two mr per hour at a meter.

MR. CAMPER: But that doesn't make -- that doesn't work because it's restricted area.

MS. HOLAHAN: But it -- no, because we're not going back to 1301. They're going back based on what the former 20.105(a) was. They are not tying it back to 1301(a) now. They are putting in a specified number. I believe it's two mr per hour at a meter.

MR. CAMPER: And that is what? That becomes what, the patient safe line?

MEMBER FLYNN: No, not a meter, but two mr per hour, wherever that distance should be. Usually for cesium implants, two mr per hour is quite frankly at

a distant part of the room without being at the door. My experience has been two mr per hour sort of like halfway to the door.

MS. HOLAHAN: Yeah, and I'd have to go back --

MEMBER FLYNN: A typical implant. I'm talking about -- I've done a couple of hundred. I do it myself -- the surveys myself, not the RSO. So I've done a couple of hundred, and it's basically about halfway to the door. When you get to the door, it's about one mr per hour or half or --

MR. CAMPER: Right.

MS. HOLAHAN: Yeah. And I can't remember the exact number and the exact language that is being proposed.

MEMBER FLYNN: That's a good number, I think.

MS. HOLAHAN: But I think there would be some changes.

MEMBER FLYNN: Now for radiation workers, you have a quarterly -- like nursing personnel or people who -- let's say who are badged and monitored and trained. What is the quarterly limit now? Is it 1.25?

MS. HOLAHAN: There's no longer a quarterly limit.

MEMBER FLYNN: Okay.

MS. HOLAHAN: There's only an annual limit.

MEMBER FLYNN: The annual limit is five?

MS. HOLAHAN: Five rem.

MEMBER FLYNN: And then a lot of times I see such things as if the -- at 10%, there's a 10% action limit?

MR. CAMPER: Well, that's badging.

MEMBER FLYNN: Excuse me?

MR. CAMPER: Badging.

MEMBER FLYNN: Badging. No, but in terms of if a person receives 10% of their allowable annual dose, you -- at least the RSO might look in to see if there are measures that can be taken to further minimize that exposure. Action levels --

MR. CAMPER: No, that's associated with the ALARA. That's the ALARA.

MEMBER FLYNN: Okay, action levels. So what is the action level -- would be 500 mr?

MS. LANZISERA: Well, the guidance, I think it's 10% and 30%.

MEMBER FLYNN: What's the week -- there's no weekly?

MR. CAMPER: That's correct. The action level for ALARA --

MEMBER FLYNN: Yeah, that's what I'm talking about.

MR. CAMPER: -- are 10% and 30%.

MEMBER FLYNN: Okay, 10% --

MR. CAMPER: For occupational workers. In other words --

MEMBER FLYNN: 10% of what, five?

MR. CAMPER: For the occupational dose limit.

MEMBER FLYNN: And that's the only one is the yearly?

MS. HOLAHAN: Right.

MR. CAMPER: That's right.

MS. HOLAHAN: Yeah, there is no quarterly anymore.

MEMBER FLYNN: There's no weekly?

MS. HOLAHAN: No.

MR. CAMPER: And even the old ALARA action levels were based upon the annual limit.

MEMBER FLYNN: Somehow I'm thinking of -- I'm probably thinking of something that's no longer applicable.

MR. CAMPER: But it's all about occupational workers.

MEMBER FLYNN: The declared pregnant worker or something like that. Or someone -- I thought there was some footnote in there somewhere where there's a weekly or a monthly limit.

MS. HOLAHAN: It was -- there used to be in the old Part 20 is that it was 100 millirem in a week.

MR. CAMPER: Even now for the declared pregnant worker, you're supposed to -- the exposure is 500 millirem, and it's supposed to occur at a monthly stable rate. You're not supposed to have some dramatic --

MEMBER FLYNN: And is there an action level at 10%, which is 50 mr?

MS. HOLAHAN: No.

MR. CAMPER: No.

MEMBER FLYNN: I'm just trying to -- what I'm trying to do is bring in some logic as to -- I don't think visitors should be getting 100 mr. There's no -- for one thing, for brachytherapy, they shouldn't even be in there. I don't think there should be any visitors except for a specific -- I discourage it. And of course, you have a lot of the patients are elderly, and the spouse is elderly.

And so, the same sort of concerns aren't the same as with a pregnant woman or for a young child. If they're both 80 years old, we're not usually looking for the long term effects. But the -- and because the woman is terrified or the husband is terrified, then the fact that they can visit is much more important medically than a small dose they might receive.

But at least we discourage visitors that don't have to be there and encourage those that should.

MR. CAMPER: The way that reads, by the way, just so you'll be aware for the -- under 20.1208 for the DPW, this is a dose to the embryo/fetus, the licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limits in paragraph (a) of this section which is the 500 millirem.

For purposes of the exercise at hand on item (b), have we changed that to mark a visitor's line on the floor with a tape to ensure compliance with the requirements in 20.1301 and 1302, and possibly 35.401(5)? That would probably do it, wouldn't it?

MS. HOLAHAN: Yeah, except the only thing I'm wondering about is the actual ALARA program where the licensee shall -- basically ensure doses to members of the public are ALARA.

MEMBER FLYNN: Yes.

MS. HOLAHAN: That may be the point that you were --

MEMBER FLYNN: I was trying to make that. And also, I feel strongly about recommending that the exposure rates be posted on the door. There's no reason why they shouldn't be. The people who are working with that patient should know what that information is.

MR. CAMPER: See, I mean, technically the safe line could be a variable.

MEMBER FLYNN: That's right.

MR. CAMPER: A function of time.

MEMBER FLYNN: So that's why you should have the exposure rates posted on the door. If the RSO's gone on vacation or if he's -- you know, when you take these measurements, where do you put them? You're putting them in some black hole that won't help anybody. I think they should be posted. It could be recommendation they be posted so that you can then --

MR. CAMPER: What -- I mean, you have to come up with some workable safe line. I mean, --

MEMBER FLYNN: Yeah, because the safe line could be changed. It could be changed during the procedure.

MR. CAMPER: Well, sure. I could stand at point A for X amount of time; I can stand at point B for X plus time.

MEMBER FLYNN: Yeah.

MR. CAMPER: Then -- yeah, so you have to come up with some reasonable working safe line.

MEMBER FLYNN: Yeah.

MS. HOLAHAN: Let me see what we can do with that.

MR. CAMPER: And then bringing ALARA to bear as well, right?

MS. HOLAHAN: Right.

MR. CAMPER: Okay.

MS. HOLAHAN: Okay.

MR. CAMPER: That was an interesting discussion.

MS. HOLAHAN: Okay.

MEMBER QUILLIN: On to item 12, radioactive waste management. And we had some discussion about wording on this yesterday.

MS. HOLAHAN: By returning sources as waste management?

MEMBER QUILLIN: Yes.

MS. HOLAHAN: I missed that yesterday.

MR. CAMPER: So the same thing applies, right?

MS. HOLAHAN: Again, this will fit in with the former 313 as it stands is --

MEMBER QUILLIN: Right.

MS. HOLAHAN: -- in a way for the licensee returning sources is dealing with things that otherwise they would be considered waste if they didn't return it.

MEMBER QUILLIN: Right. And also --

MS. HOLAHAN: Change on the first sentence?

MEMBER QUILLIN: Well, I just wanted to give Dr. Flynn an idea of what we discussed about yesterday, which was that we were wording the lead in paragraph and also in reference to the five items there that they have to comply with 49 CFR and 10 CFR transportation criteria, which is what really are the controlling factors.

MEMBER FLYNN: And there are also regulations in the Department of Transportation in terms of the kinds of --

MEMBER QUILLIN: 49 CFR is --

MEMBER FLYNN: Is all covered in the --

MEMBER QUILLIN: Yeah.

MEMBER FLYNN: Okay. In terms of the source -- the kinds of transportation methods that are required.

MEMBER QUILLIN: Require -- it's got packaging, labeling, the whole works is --

MS. LANZISERA: So you want to refer to all the parts of 49 for each one of those?

MEMBER QUILLIN: Well, no. That reference was generally to the applicability of packaging surveys, labeling, etc. to meet the requirements of 10 CFR -- was it 70 or 71, something; and 49 CFR.

MS. HOLAHAN: Okay, any other comments on that?

MEMBER QUILLIN: Definitions, or glossary, I should say?

MR. CAMPER: I had a couple. Well, the first one is the general comment that I made this morning. I'm really very interested in knowing from Dr. Stitt's comments from Dr. Flynn if all of those definitions are medically acceptable. And one that I was struck by as I looked down through there was intraluminal -- within the lumen of the tube?

MS. HOLAHAN: Again, these definitions -- just for purposes -- because Dr. Flynn wasn't here yesterday, I think came out of Steadman's.

MR. CAMPER: Out of what?

MS. HOLAHAN: Steadman's Medical Dictionary is where I got these definitions.

MR. CAMPER: Oh, okay, I see.

MEMBER FLYNN: And then intraluminal is an example of intracavitary. And intraluminal, often what physicians mean is that we're putting the radioactive source in the bronchus of the lung or the esophagus. That's by far --

MS. HOLAHAN: Does that help to give examples in these definitions?

MEMBER FLYNN: That's good. And intracavitary is classically just a different word for the same thing that we're putting the source most often in the vagina for post-endometrial localized radiation. If you take intraluminal to mean esophagus and bronchus, and you take intracavitary to mean vagina, then you've covered 99% of what those terms really mean.

And they all really mean intracavitary.

MS. HOLAHAN: Okay.

MEMBER FLYNN: It's just that intraluminal has -- intracavitary is a very, very old term. And intraluminal is newer because of the use in the bronchus and in the esophagus. But it's still -- it's so that they really mean the same thing as distinguished from interstitial, which of course is quite different.

MS. HOLAHAN: Let me --

MEMBER FLYNN: Topical could be -- can be also a surface -- the radiation oncologists use the word as Dr. Stitt pointed out, surface.

MS. HOLAHAN: Yeah, we'll put that in --

MEMBER FLYNN: But it's in there.

MS. HOLAHAN: Okay, I have -- oh, I'm sorry.

MEMBER QUILLIN: I'd suggest again that safe line be changed to visitor's line.

MS. HOLAHAN: Right. Okay.

MR. CAMPER: It's actually a good definition really.

MS. HOLAHAN: Actually we should also have that visitor's line in the remote afterloading for patients receiving low dose rate brachytherapy.

MEMBER QUILLIN: Right.

MS. HOLAHAN: Another question that I had is one of the comments that we had was to define applicator, medical physicist, therapist and dosimetrist. Now yesterday we discussed medical physicist, but indicated that we could only really refer back to how we define it within the space of the remote afterloading module for HDR.

And I had some concerns about trying to define medical physicist in this module since we don't have a requirement for a medical physicist or whether or not

-- and that was why at this point we had stayed silent on it. Now, I guess I'm asking for input as to is there an advantage to attempting to define a medical physicist in this glossary?

And then what about therapists and dosimetrists, because I think at different places those names are used differently perhaps.

MEMBER QUILLIN: Well, I know that the -- there's been a long history of trying to come up with an agreed to definition of medical physicist, because I was on a committee that was meeting in the early 80's for the American College of Radiology on this issue. And I don't think they still have adopted a definition yet.

MS. HOLAHAN: Is there a definition for therapist or dosimetrist, or does that fall into the same type of category that --

MEMBER FLYNN: It probably doesn't add anything because you're going to have a lot of debate if you try to add a definition, I think.

MS. HOLAHAN: Yeah, I was afraid that I was going to --

MEMBER FLYNN: I'm not sure if it will help.

MS. HOLAHAN: Right.

MEMBER QUILLIN: I'd leave it out myself.

MS. HOLAHAN: Okay. That was where we currently were.

MEMBER FLYNN: This document, I would leave it out.

MS. HOLAHAN: Okay, now what about applicator? Again, is there any advantage to defining it, or is that a pretty well understood term that if --

MEMBER FLYNN: Yeah, I think it's a well understood term. I don't think that you have any advantage of defining it -- trying to define it.

MS. HOLAHAN: All right, I just wanted to raise those and see if --

MR. CAMPER: The brachytherapy source definition where it says an individual sealed source or manufactured similar source -- is there any need to put any words in there that it's a sealed source which has been reviewed and approved -- you know, this is the registry initiative? Is there any value in that at all or is it necessary?

MS. HOLAHAN: The definition is --

MEMBER FLYNN: Could you repeat that again?

MR. CAMPER: I'm saying the definition of brachytherapy source, an individual sealed source or a manufacturer assembled source train that is not designed to be disassembled by the user. Well, there's really a lot more to it than that.

MEMBER FLYNN: Yeah.

MR. CAMPER: I mean, you're using brachytherapy sources for implantation in the human being which has undergone a certain review and approval process.

MS. HOLAHAN: The definition that is in there is the one that is in Part 35, so we didn't want to get into a separate definition than is currently defined in Part 35.

MR. CAMPER: Ah, so that's where the problem is.

MEMBER QUILLIN: Good reason to keep it the way it is.

MR. CAMPER: Great reason to keep it the way it is.

MS. HOLAHAN: Just thought I'd mention that.

MEMBER QUILLIN: Yes, it's in 35.

MR. CAMPER: I think the definition is a little flawed then.

MS. HOLAHAN: But we will be revising Part 35, so we can look at the definitions as we do that.

MR. CAMPER: The definition doesn't bring to bear at all the idea that it's been reviewed and approved for implantation into humans. It's kind of --

MS. HOLAHAN: Well, and I know we have had questions as to what we mean by design not to be disassembled by the user. But again, it's the way that the current definition is read.

MR. CAMPER: I see. I see the problem. Okay.

MEMBER QUILLIN: Anymore comments on the glossary? The last page I have is the table of contents. I have no comments on the table of contents.

MS. HOLAHAN: It's all right -- little bit backwards with the table of contents at the end. That's how I was operating yesterday too going backwards all the time.

MR. CAMPER: I have a comment about the agenda for the afternoon. We have -- no we're still on the record. We are currently this afternoon scheduled to discuss teletherapy and gamma stereotactic radiosurgery. And given the amount of time, what I'm very concerned about is that we would get input from the two subcommittee members on gamma stereotactic radiosurgery as opposed to teletherapy.

I feel that way for two reasons. Number one, the teletherapy guide has been around since 1985. Now it was recently revamped by Jim Smith of our staff and is an improved document. But by contrast, the one on gamma stereotactic radiosurgery has not undergone any kind of scrutiny from a public context.

And given that gamma stereotactic -- the nature of the modality, the fact that it's emerging while teletherapy at least arguably is decreasing in use, I would -- if we have to do one or the other, let's do gamma stereotactic. And if time permits, then

proceed into -- is that -- okay, very good. So we'll proceed accordingly. That's it for the morning then, right?

MEMBER QUILLIN: And I will have to leave sometime between 2:30 and 3:00.

MR. CAMPER: Okay.

MEMBER QUILLIN: And how quickly can we come back into session? How much time do you need?

MR. CAMPER: Shall we go off the record at this point?

(Whereupon, the proceedings recess for lunch at 11:55 a.m.)

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

(12:45 p.m.)

MEMBER QUILLIN: Okay. We're now working on the gamma stereotactic radiosurgery (GSR) module. Is there any major issue that you have with this document that we should try to make sure we address?

MEMBER FLYNN: I have no major issues. Are we going to go through this step by step?

MEMBER QUILLIN: Yes, I would -- that's fine with me.

MR. CAMPER: Yes, we can. One significant issue I think -- and it's the one we discussed the other day -- Bob was here at the time, but, Dan, you were not, and this is on page G-3, at the top. We had this, "Individuals not previously authorized by AEC or NRC or an agreement state as a GSR physicist or medical physicist, and not certified as defined in," blah, blah, blah, "must submit."

Now, the other day we discussed that. If you look currently in Part 35, an authorized user is defined and includes someone who has been listed as an AU on an agreement state license as well. No similar provision exists in Part 35 currently for a medical physicist. A teletherapy physicist is defined in Part 35, but that provision doesn't apply.

MEMBER QUILLIN: Okay.

MR. CAMPER: So that gets us back to a policy issue that we need to explore, and there's no way we can resolve it at this point. It's something we're going to have to take a look at, and so forth. But that's the only big issue that I had.

MEMBER QUILLIN: Let's start, then, on the first page. Purpose. Any comments on purpose? Do you want to let's go on to item 8, individuals responsible for radiation safety? Did the AEC ever authorize somebody as a GSR physicist?

MR. CAMPER: No. GSR came along long after the AEC.

MEMBER FLYNN: Are we on just 8 right now?

MEMBER QUILLIN: Yes.

MR. CAMPER: Yes.

MEMBER QUILLIN: That's the only comment I had.

MS. HOLAHAN: Let me just make the point again, which we have dealt with in the last two modules, should we bring authorized users, again, specifically into here? And should we ask or look for any experience with gamma stereotactic radiosurgery?

Jim, for your awareness, this came up both with remote afterloading and manual brachytherapy, in terms of the "or" category, if it was a board certified -- someone other than a board certified physician that wanted to do gamma -- wanted to do remote afterloading is we thought that it was important enough for individuals responsible that we should include authorized users in here. And I guess I just put that on the table again.

MR. SMITH: When I wrote this one, I didn't include that, because I figure the authorized user would be under the general module. So --

MS. HOLAHAN: It is. But in the last two subcommittees, we've decided to bring it in here as well.

MR. SMITH: Oh, okay. All right.

MEMBER QUILLIN: If there are no more issues with item 8, let's go on to item 9, training for individuals working in or frequenting restricted areas. Any comments on 9.1.1, training programs?

MEMBER FLYNN: I had a comment in this section, because we don't use any -- we don't -- in our facility, we don't use the -- we don't use cobalt; we use linear accelerator. But some of the same principles apply, of course.

And one very important area that the physicist plays a key role, not just in the detailed dose calculations, but in the details of the quality assurance procedures that happened just before the treatment, that that physicist in our facility is acting in a supervisory role. The nurse and the technologist play an ancillary role.

But he has to be physically present and go through all of the quality assurance checks, which in our institution takes about 20 minutes to a half an hour. Just before the treatment is delivered, they go through all of these quality assurance checks and doublechecking everything. Everything has to be doublechecked, and that person needs to -- I think that's typical.

So I think the medical physicist, in addition to, at a minimum, the team should include a well qualified -- who can make detailed dose calculations. Also, to physical -- physical quality assurance procedures are -- physical quality assurance procedures and checks are accomplished.

I'm not sure how to state that, but that's very key in terms of stereotactic radiosurgery, because the high dose that you're given -- you're getting a very high dose in a single moment in time. And so the quality assurance, in terms of targeting before the treatment is given, is important, not just the dose calculations. You have the right arcs, the right part of the brain is treated, and the setup -- the device setup that the -- that before the treatment begins that things are doublechecked if they're -- that they're going to proceed as intended.

That's the only comment I have.

MEMBER QUILLIN: One of the comments I had on this training program issue was that I felt there was a little bit of inconsistency between this and the remote afterloading section about qualifications. And the remote afterloading document we looked at yesterday went into some more detail about qualifications of the physicist who is responsible for these procedures, and especially for those who don't meet the minimum qualifications that are set forth in 10 CFR 35, as far as board certification.

And I wondered if there could be some consistency from section to section on how you're going to address this particular issue, because --

MR. CAMPER: Do you mean you're getting at whether there is an "or" pathway?

MEMBER QUILLIN: Yes. Because the way I read this, it implied that anybody who was a physicist, and not necessarily a medical physicist, could be trained in two weeks to do these procedures. And I think that's rather brief training myself for somebody who has not had --

MR. SMITH: Most of the requirements for a medical physicist can be found in the regulations, whereas for brachytherapy physicists you don't have that listed in the regulations.

MEMBER QUILLIN: Well, this is different than both brachytherapy and teletherapy. This is a unique field of its own, and there is just some inconsistency between the approach used as we saw yesterday and this approach here.

MS. HOLAHAN: I guess the -- possibly one of the questions is would we require them to have some form of experience with gamma knives, and would we need to include that in here? Whereas, as with teletherapy -- or would we just accept it as experience with teletherapy in it? And I don't know. Is that --

MR. SMITH: Well, we have -- if you'll look at 9.1.1, the last sentence recommends that all personnel involved in patient treatment attend the training recommended by the manufacturer. And the manufacturer has a specific set of training where they almost apprentice the medical physicist.

MS. HOLAHAN: Where are you?

MR. SMITH: 9.1.1, the first sentence on page G-4. The other thing is you --

MR. CAMPER: Well, I think what Bob is getting at, though, is is that we have on one hand, if you take a look at remote afterloading, HDR, you've got machine-specific training, operator training, and so forth. But in addition to that, before you get to that point, you've got some specific training and experience.

You have a teletherapy physicist. To be a brachytherapy physicist, we're looking for a teletherapy physicist, if you will, that has particular experience with --

MR. SMITH: Brachytherapy.

MR. CAMPER: -- with brachytherapy. And what he is saying is is if one reads 9.1.1, one gets the impression that it's only about a very limited amount of training is defined in 9.1.1. And the question I think, Bob, and don't let me put words in your mouth, but I think it is -- it isn't they are parallel with this modality for -- with HDR, in terms of having a specifically trained and experienced type of physicist. Isn't that really what it comes back to?

MEMBER QUILLIN: I think that's what it comes down to, yes, that you start off with a certain basic credentialing so to speak, and the way the NRC regulations read you have either the board certification route or the alternate route. And the alternate route approach is really discussed in the HDR document, but is really not discussed that well here. It just assumes somebody starting off as a qualified person --

MR. CAMPER: That's right. That's exactly what happens here. It assumes you're a qualified medical physicist.

MEMBER QUILLIN: Based on --

MR. CAMPER: There isn't any discussion of what is a qualified medical physicist in this context.

MR. SMITH: Okay. Well, I can elaborate on that.

MS. HOLAHAN: So that's in Section 8 that you're talking about elaborating? Item 8?

MEMBER QUILLIN: Not necessarily. This is -- we're talking about the physicist now, and the only place where it goes -- where it goes into the training of the physicist, actually in 9, for the operation.

MS. HOLAHAN: Okay.

MEMBER QUILLIN: So it's a -- I don't care where you put it. I just think it needs to be expanded upon.

MR. CAMPER: Well, there's something -- now that I look at this, you get me thinking about this, there is another problem with this section, too, and that is should -- the header "Training for Individuals Working in or Frequenting Restricted Areas" normally means something. And I think that something is different than what's being expressed in 9.1.1 text.

The training for individuals working in or frequenting restricted areas has a lot to do with making them aware of radiation safety-related kinds of things, posting, etcetera, etcetera. But what's going on in 9.1.1 is really about the -- an acceptable approach to using this modality.

MS. HOLAHAN: Yeah. But to be consistent with remote afterloading, that's where we have also put it for the remote afterloader, is it's in item 9, and since there will be additional --

MR. CAMPER: And in teletherapy also.

MS. HOLAHAN: -- emergency and operation procedures that you need to be trained in are in item 9.

MR. CAMPER: Yeah. But --

MS. HOLAHAN: They're not as part of the requirement.

MR. CAMPER: Yeah. But this is not about being trained in it. The idea that you're using these individuals in a need for a team approach, you must provide a description of the procedure for your team approach and the treatment of patients, this is not just about visiting and frequenting in --

MR. SMITH: Well, that particular section, 9.1.1, isn't. But I think the one that you would normally see is 9.1.4, training for ancillary staff.

MS. HOLAHAN: Well, actually, maybe the section that you're talking about should be 9.1.1, could actually be moved up into item 8, because --

MR. SMITH: Well --

MS. HOLAHAN: -- it's in the terms of the license application that you're looking for the --

MR. CAMPER: Actually, now that I'm really beginning to think about it, there are a couple -- let me just throw a couple more things out as food for thought.

I think Bob Quillin has got an interesting point, in that if one reads 9.1.1, it is really about this short period of time, getting together as a team, etcetera, and it doesn't address the medical physicist problem in a fashion parallel to what we've done for remote afterloading. Now, we need to explore should that happen, and, more

specifically, should we be looking for GSR experience like we're looking for HDR experience?

But here is another one, too. Item 8, we go under individuals responsible for radiation safety. Then, we go into the physicist. Now, that physicist may or may not be responsible for radiation safety.

MR. SMITH: Well, basically, it was put there because in teletherapy, that's where the teletherapy physicist came in at. I mean, it can be moved anywhere else you want to put, but I think we still need that information.

MS. HOLAHAN: I think, too, if we can go back and look at the way that the body is structured, under individuals responsible for radiation safety, the first section is senior management, then there are the authorized users, then the medical physicist or physicists, then there is radiation safety officer and the Radiation Safety Committee. And I think under item 8 in the body all of those people, or sets of people, are responsible in some way for radiation safety.

And in the HDR module or the remote afterloading module, the training and experience required for the RAL physicist is listed in item 8, and then the additional training that all medical physics staff, to include the physicist and authorized user, would need -- is addressed further in item 9.

So I think possibly that first section where you're talking about the team approach that is initially listed in item 9, we could move that up to item 8, and then expand possibly on the physicist, if we felt it was needed to, for the actual training and experience required to be approved as a physicist for gamma knife.

MEMBER QUILLIN: If you look at the other documents, the other documents are -- that we've been reviewing, item 9, the topics are rather generic. I have no qualms about that, because I think they need to be generic. It just happens that

in this one, when you start off with really specific topics about -- on page G-3, the issue about this training, which I think probably would be better in item 8, really, the first two paragraphs, because continuing on the other training -- it's all the same sort of generic training that we've discussed before.

MS. HOLAHAN: Because I think you could possibly argue that the team is responsible for radiation safety.

MEMBER QUILLIN: Okay.

MS. HOLAHAN: I mean --

MR. SMITH: I agree with you. But I think the reason why you don't see the team approach in any of the other modalities is because this is the one that we --

MS. HOLAHAN: It doesn't apply.

MR. SMITH: Yeah.

MS. HOLAHAN: No, that's right. But it's a matter of where do you actually put it to --

MR. CAMPER: Well, that's right. That's what I was getting at. You know, this is truly a unique modality, because it is an active team approach.

MEMBER QUILLIN: Well, there's a team approach in the HDR, too. I mean, it's --

MR. CAMPER: Yeah. But in the case of GSR, you have --

MS. HOLAHAN: That's true.

MR. CAMPER: -- a neurosurgeon who is not even an authorized user, who is a key player, if not the key player, in the use of this device. And he is not even an AU.

MEMBER QUILLIN: I understand.

MR. CAMPER: Is not required to have one iota of radiation training. That's kind of interesting.

So what am I saying? I guess I'm saying is the -- is there a need to talk about this team approach earlier in the document, before you actually get into a discussion of individuals responsible for the radiation safety? Because the individual who is going to be responsible for the radiation safety is either going to be the RSO, who may or may not be the authorized user involved, and the physicist may or -- and the physicist involved with a GSR procedure may or may not be responsible for radiation safety. He may be a pure medical physicist who is doing treatment planning.

MR. SMITH: That's true. I mean, just based on past practice is why it's there. I mean, you still are going to need the information regarding this physicist. Now, I think historically item 8 is where you get the information about the authorized users, medical physicist, and other persons.

MS. HOLAHAN: That's correct.

MR. SMITH: So if we don't put it there, I don't know where we'd put it.

MS. HOLAHAN: And I think we need to leave the physicist in item 8 to be consistent with the other modules.

MR. SMITH: And we could change the title of item 8.

MS. HOLAHAN: Well, except that's a line item in the Form 313. So that's why we are trying to --

MR. CAMPER: Yes. But in the RAL, the HDR, the RAL module?

MS. HOLAHAN: We have physicist listed under item 8, and then we have additional training that the physicist must -- that the institution -- the particular licensee must provide.

MEMBER QUILLIN: Actually, the team approach concept you could weave into the purpose.

MS. HOLAHAN: That was --

MR. CAMPER: But we've got them --

MS. HOLAHAN: That's an idea, yes.

MR. CAMPER: But my point is, under item 8, in the RAL module, it's under the category of authorized users, not under the category of individuals responsible for radiation safety, is my point.

MS. HOLAHAN: Oh, well, then we may need to rename that, because it has to -- we need to be consistent within all of the modules.

MR. CAMPER: I'm saying --

MS. HOLAHAN: And that item 8 is classified as individuals responsible. I didn't recognize it. That is a misnomer. It should not be classified as authorized users, because there is no such item 8 in Reg. Guide 10.8.

MR. CAMPER: Oh, I see. Okay.

MS. HOLAHAN: Yeah. See? It's individuals responsible for radiation safety programs or training and experience. And as I say, in the body, 8.1 is senior management, 8.2 is authorized users, under which 8.2 -- and then 8.3 is radiation safety officer, 8.4 is Radiation Safety Committee, and 8.5 is physicists, and 8.6 is authorized nuclear pharmacists.

MR. CAMPER: Well, if you're going to truly talk about it under the category of individuals responsible for radiation safety, I don't think that you can only talk about the physicist, because the physicist may or may not be responsible for radiation safety.

MS. HOLAHAN: They are a part of it, though.

MR. SMITH: Yes. It's assuming -- you see, 8.4, it's assuming that the authorized users and RSO are included in the main body of 10.8, so this is just sort of an add-on to it.

MS. HOLAHAN: I think we can bring in the authorized user specifically within this module and address the authorized users and the physicists within the module, and then the radiation safety officer and Radiation Safety Committee can remain in the body.

MEMBER QUILLIN: We were also advised that unless it's an existing regulatory requirement that you can't use the words "shall," "must," or --

MR. SMITH: Correct.

MEMBER QUILLIN: -- equivalent language, and you used "must" provide a discussion in this paragraph also.

MR. SMITH: Which one is -- where is that?

MEMBER QUILLIN: It's in the fourth line from the bottom of the first paragraph in 9.1.1.

MR. SMITH: You're correct.

MEMBER FLYNN: Where is it? You should provide. Okay.

MEMBER QUILLIN: So do we have some closure on this, how we're going to approach this issue?

MR. CAMPER: Well, I don't know. Well, why are we only listing the GSR physicist under individuals responsible for radiation safety?

MR. SMITH: Because it's assumed that the other individuals will be included under the main body of 10.8. This is sort of an add-on, or at least that's my understanding of the way the modules work. The general requirements for getting a medical use license will be included in the main --

MS. HOLAHAN: Body.

MR. SMITH: -- body, and then any additional requirements that are specific to that modality would be included in the modules. So I'm assuming that authorized users --

MR. CAMPER: Is that clear to the reader? I mean --

MS. HOLAHAN: Well, except it's -- it says in the body, but one of the things that we have identified throughout the subcommittee meetings is that it would be helpful for the authorized users to be included in each module, because there are sometimes specific things that you want to make sure that they have experience in that modality for -- of authorized use.

So the authorized users we will move in here, but the body does say -- and that's why we were discussing the other day that you do have a tendency to be going back and forth from the body to the module. But you would have both documents, or the licensee would have both documents.

But if it does seem to get confusing, then perhaps we should just have very basic information in the body to include, you know, where you send the license application to and the place of use. And then, for example, list everything in items 6 through 9, or 12, through -- in the module. I guess that's something we can consider.

MR. CAMPER: Well, it seems at the very least there needs to be some kind of reference in item 8 about the RSO, or the AU possibly being the radiation safety officer, because as one reads this now, I mean, you're right, you have to have them both and go back and forth. But, I mean, maybe the simplest fix is to put something in there that points out to them that the AU or an RSO, which may be one and of the same or not be, has responsibility.

MS. HOLAHAN: Yeah. And I -- we can explore this further, because I think we can do more to make it more clear.

MR. CAMPER: And the second concern that I raised was under 9.1.1, training program for individuals. It's not certain to me that that discussion there about how it should be a team approach, and so forth and so on, isn't something that should be sort of a lead-in discussion.

MS. HOLAHAN: I think that's -- Bob Quillin mentioned to put it in the purpose.

MR. CAMPER: Yeah. Maybe that will work, yeah. Yeah. I'm sorry. I guess I didn't hear that, Bob. Yeah, that's a good suggestion. And --

MEMBER QUILLIN: I think it fits there better.

MR. CAMPER: Yeah, I think it does, too. I think it does, too. And then, your training sort of picks up more consistently with what has gone on before in the other modules.

MS. HOLAHAN: Right.

MR. CAMPER: Okay.

MEMBER QUILLIN: That's what I would recommend.

MR. CAMPER: Okay.

MEMBER QUILLIN: Can we go on to page G-4, then, where we start getting into the listing of items?

MS. HOLAHAN: Okay. And perhaps for Jim's information, since he wasn't privy to the last two subcommittee discussions, we were going to revise the titles of those sections.

MR. SMITH: Okay.

MS. HOLAHAN: And training for nursing staff will become training for staff responsible for the care of patients undergoing GSR treatment, in your case, and then we would put, "including nursing," and that encompasses in case there are aides that are involved or somebody other than what would be traditionally classified a nurse.

MEMBER FLYNN: I understand. I just did one of these procedures a few days ago, and here is what really happens. And you're treating patients by external beam in the morning, in the afternoon. This -- if you're using a machine for both external beam and stereotactic, the stereotactic portion ties up that treatment room for an hour to an hour and a half, two hours.

What happens is during the day, like at lunch time or at the end of the day, the patient goes through this whole procedure. Physically present are the radiation oncologist, the neurosurgeon, the physicist, medical physicist, often a dosimetrist, and several therapists, technologists. The nurse, except to take care of the patient before and after the procedure, is not involved at all, in any way, and is not even near the radiation and is away from the room.

So here is a case where the training for the nursing staff, where it's crucially important for brachytherapy low dose rate, it is not as important for stereotactic. As a matter of fact, it may not be important at all. I say that only because they are not involved. There is a team of individuals involved. This happens during the daytime. It's not being -- it's a situation where the patient is not being taken care of by the nurse, basically.

Unless you've found some circumstances where that's not true, I mean --

MR. CAMPER: Well, I have seen a circumstance different than that.

MEMBER FLYNN: Have you?

MR. CAMPER: Yeah, I have. In the institution that I went to, I observed their GSR procedures. They had a situation where the patient was brought to the GSR suite. They had a four-point verification source of the coordinates being dialed into the helmet.

MEMBER FLYNN: Yeah.

MR. CAMPER: And what they did was the nurse was involved, and the four individuals -- you had a physicist, the neurosurgeon, you had a nurse, and the fourth person might have been a technologist or something like that, some type --

MS. HOLAHAN: Authorized user, was it not?

MR. CAMPER: It might have been.

MS. HOLAHAN: Radiation oncologist.

MR. CAMPER: But they would go to the computer screen and get the coordinates for the helmet settings.

MEMBER FLYNN: Right.

MR. CAMPER: Independently and individually. Would go from the computer treatment plan, get the coordinates themselves, and write them down. They would then go into the suite, the neurosurgeon would look at his set of coordinates as written down, set it, write down what his coordinates were. And then, the second person would go look at the person on the calipers at that point, write down what they observed, and each in turn would do that.

They would then go back into the computer treatment planning room and take their observed value, as compared to their observed written value, as compared to their observed treatment plan value on the computer screen. And the nurse was an active player in that process.

MEMBER FLYNN: Really?

MR. CAMPER: Yes.

MS. HOLAHAN: But perhaps if we just have it as professional staff responsible, and we could include nurses, etcetera, we are making it more general.

MEMBER QUILLIN: Well, you have the phrase here "for patient during treatment." And if you retain that phrase, and it covers whoever is involved in the actual treatment part of it.

MR. SMITH: Yeah, I think the main concern is that if there is some medical complication while they're undergoing this treatment, and there is not a physician available, the nurses will be able to respond and won't run away from the GSR unit. I don't know if that's a practical feeling, but I would like to know that the nurses understand how the device works, so they won't be afraid to render assistance to the patient.

MEMBER FLYNN: Well, in that -- I mean, if there are treatments being done out there where the authorized user is not physically present, then I would think that would be a major problem. It's I think --

MR. CAMPER: I would agree.

MEMBER FLYNN: The only -- I have never even assumed that that would ever be the case. Maybe I'm being naive -- that the authorized user is physically present there through the whole treatment, that there's not a nurse running this treatment, where a nurse can't get a couple of hours of training when a patient is going to get 2,000 rads that could kill the patient if it's delivered in the wrong place. If it's delivered to the optic chiasm, they would be permanently blind.

So I'm assuming that the authorized user is physically present, and the team is physically present, that this is not being turned over to a nurse to run.

MS. HOLAHAN: The only situation I've seen was the neurosurgeon and authorized user were present, but I don't know. I mean, we have no requirement for them to be physically present, but it could just be the nature of the procedure would be such that they would be present.

MEMBER FLYNN: I'd be very nervous. I mean, that would -- to me, that would be the same as if I was having brain surgery and that the neurosurgeon went to play golf and left a nurse there to finish the operation. I mean, that's the same thing, the same level of hazard.

MS. HOLAHAN: Right.

MEMBER FLYNN: It's not that the nurse is not a professional; it's that that's not in their whole training. They can't be trained in an hour to do that. So I think physical presence, you -- now, you require that for the HDR, is that correct?

MR. CAMPER: Yes, we do.

MEMBER FLYNN: That's in the NRC Bulletin 92-03 and 93-01.

MR. CAMPER: That's correct.

MEMBER FLYNN: And I don't see why physical presence shouldn't be -- I can't imagine, that would really scare me if the authorized user and the physicians aren't physically present. That's why I assume that it was less important. See, that's why I think the brachytherapy training for nurses is so important, because they're there by themselves, alone, and they have to be, because the patient is there for 72 hours, day and night, through the weekend.

MR. CAMPER: Well --

MEMBER FLYNN: Where this is a case where the treatment takes a very short time, and I'm envisioning this well qualified team who have gone through

years of safety training -- well, years of training, is physically present. That's -- so if I'm wrong, please --

MR. CAMPER: Well, I don't think you're wrong as a practical matter. I think that's what is going on. But we don't have such a regulatory requirement. We impose that upon the HDR user through license condition, but we do not do that for GSR, and that raises an interesting question. I mean, should we require that AUs be there?

MEMBER QUILLIN: I agree with Dr. Flynn. I think that they should be there.

MEMBER FLYNN: This is a single, big-time dose.

MS. HOLAHAN: Right.

MEMBER FLYNN: Once you give it, you can't take it back.

MR. CAMPER: Correct.

MEMBER FLYNN: No, there's no turning to dose. You can't turn the dose back in. And the part of the brain being treated, it could be potentially lethal if the wrong dose, the wrong place, or cause a permanent injury like permanent blindness.

MEMBER QUILLIN: Paralysis, also.

MEMBER FLYNN: Paralysis.

MR. CAMPER: No, we just have not gotten into this.

MR. SMITH: Yeah. I think you can look at teletherapy as an example. I mean, routinely, patients are treated with teletherapy, and there is no physician present. The differences that the teletherapy doses --

MS. HOLAHAN: Smaller.

MR. SMITH: -- if I talk to cobalt teletherapy therapists, I mean, their training has been drilled into them so much, and they have been through it so much,

and the physicist has calculated the dose, and the setup is -- you know, they're administering 100,000 treatments, and they're doing it all of the time, both on the cobalt machine and then they go over to the linear accelerator and do the same thing, that the doses tend to be where the single fraction for the central nervous system is so important.

If you give 200 rad to the central nervous system and it was in error, like the wrong patient, I can pretty much guarantee you that -- I can't guarantee you, but I can nearly guarantee you that no harm will come, no matter what. If you give 2,000 rad in one single dose to a part of the brain, you could have -- if something would go wrong, depending on where you gave it, then permanent harm could result from that. That would be the difference.

And the teletherapy treatments are spread out over five weeks or four weeks. This is a one-shot deal. So that you know that in your quality management program, you require that -- you know, that a misadministration is reported to you if the weekly dose exceeds a certain percentage, and this patient is being treated over four or five weeks.

If small errors occur in the dosimetry and the physics checks which occur weekly, that dose error is compensated for in the following week, and this is what happens in real life, the dose is given a little bit less so that the total dose is within guidelines. You've got five weeks of treatments, whereas this is a single-shot deal. Once it's over, it's over. You know, it's like an HDR treatment.

MEMBER QUILLIN: If you have some reason that this procedure should not continue, you have to have the authorized user there to decide whether to abort the treatment. And this is --

MR. CAMPER: Well, this one is a little complicated, because what's the role of the neurosurgeon in that scenario? I mean, you're doing this for the neurosurgeon. It's kind of interesting. The AU, in this case, becomes the hands of the neurosurgeon, if you will.

MEMBER QUILLIN: That's right.

MR. CAMPER: It's a strange situation in radiation.

MEMBER QUILLIN: If the neurosurgeon is there, then that -- the neurosurgeon's prime role is to make sure the helmet is affixed by bringing -- in the proper manner. The neurosurgeon, the radiation oncologist, and the diagnostic radiologist are looking at the CAT scan, the MR scan, the patient, they're making sure of the target -- the neurosurgeon is used to doing stereotactic biopsies, so they fix a helmet to the patient's head, and they get three-dimensional coordinates where a tumor is, maybe it's benign, maybe it's malignant, and they stick a pinpoint needle right at that location and biopsy that. If it's cancer, then they go on for treatment.

The same scenario is when -- for this stereotactic radiosurgery. The neurosurgeon is the person who is trained to fix the device for the three-dimensional coordinates for -- it's invasive, so he wants to -- he is the most appropriate person to be fixing in by doing some minor surgery, where the helmet will fix on the skull.

And the radiation oncologist's role is more to do with the radiation, to make sure that -- the authorized user and radiation oncologist are making sure that everything seems correct in terms of the physicist running off all of the dosimetry plans as to the intended treatment, that something doesn't look strange in terms of the dose, that there is no critical structures in the brain, such as the optic chiasm, that's getting more than -- more dose than intended, because the neurosurgeon doesn't necessarily understand the risk of complications, depending on what is being hit with the radiation,

where the radiation oncologist, that's what we're trained to do. So it is a team approach.

MS. HOLAHAN: That's why it's called the team approach. For purposes of this guide, could I perhaps suggest that what we might wish to do, then, is combine Section 9.1.2 with 9.1.3, and just have it as training for individuals responsible for the planning, administration, and care of patients, because if you're not going to have nurses necessarily specific -- the nurses that may be involved probably do need perhaps more specific training, and they could just be categorized together, and then that training would be including the physicist, therapist, authorized users, neurosurgeon perhaps, to have some knowledge of the radiation risks and things.

MEMBER FLYNN: And can you recommend, instead of require that? I mean, if it has to be a recommend. Can you recommend that a neurosurgeon, if appropriate -- in other words, if it's a neurosurgery procedure, if the neurosurgeon, if appropriate, and the authorized user, you recommend that they be physically present through the entire course of the procedure.

In terms of the economics of it, the economics is probably not important to you, but, you know, you have to make an impact, an economic impact. Well, the compensation for this procedure is considerable. So a licensee cannot come back and say that this will adversely affect our practice, because it imposes an unnecessary restriction, etcetera, etcetera, because the compensation for this treatment is very, very considerable to both the neurosurgeon and radiation oncologist, and so that that cannot be an argument.

And I don't think -- I'd be surprised, I mean, but this is the first time I've even thought of the fact that perhaps there could be a situation where the authorized user in other appropriate surgical specialties are not physically present.

MS. HOLAHAN: Well, I think in the one instance that we have seen in which there was -- well, it was not a misadministration, but in which due to a valve failure the -- following the end of the treatment, the bed did not retract. So it actually -- it took the physicist to try and do some emergency procedures to try and get the bed to retract, and then it ended up being -- the whole team went in and manually pulled the bed out to disconnect the patient.

MEMBER QUILLIN: I thought that, actually, they had to take the frame off of the patient's head because the valves were stuck.

MS. HOLAHAN: Yeah, they had to go into the room, disconnect the helmet from the head of the unit, and then they literally had to manually pull the bed back, because the hydraulic pressure had -- you know, the valve had failed and they couldn't retract the bed.

MR. CAMPER: Bob, what does Colorado require for -- in terms of an AU being present, or do you?

MEMBER QUILLIN: We haven't thought about this, but it's a -- we're thinking about it now. I think it should be.

MR. CAMPER: I honestly don't think we thought about it either. It does raise an interesting question. I'd like to believe, like Dan is pointing out, that, Jesus, I mean, you would not do it in the absence of an AU. But --

MEMBER FLYNN: In terms of American College of Radiology recommendations, we are -- I'm the Chairman of the ACR accreditation subcommittee. And as far as the big committee that writes the ACR standards for radiation oncology in general, not the ones that Judith Stitt was talking about, but the -- for the teletherapy, that now a major change has been that the authorized user, not using that term, the radiation oncologist be physically present in the immediate facility of the -- in the

immediate facility of the treatment area, in the vicinity of the treatment area. Could be somewhere else in the hospital, even during teletherapy treatments, which is not -- this is way out -- this is much more significant than a teletherapy treatment.

And they get quite a bit -- the ACR circulated this to everyone, all radiation oncologists in the country. They got quite a bit of criticism for it, but they also got more -- they got quite a bit of support for it, a tremendous amount of support. And they adopted to stay with it -- stay with that as a recommendation. Of course, it's not binding, but it's a standard. You can imagine that some of the radiation oncologists who don't meet that standard, because they're not required to.

Should there be some sort of an inadvertent problem? There are some medical legal implications down the road as to the fact that that person did not meet national standards. You could see where that would come into play. That wasn't the reason for that. The reason for the standards was for quality assurance. This is -- it's much more important for HDR and for stereotactic radiosurgery, much more important than teletherapy. If there's a level of concern, that's certainly up there with HDR.

MR. CAMPER: Well, we could ultimately consider such a requirement, of course, again, in the revision of Part 35. I would think in Part 35, in the future when we revise it, there will be a separate section, subpart, that deals with gamma stereotactic radiosurgery, just like there would be a separate subpart for HDR, this type of thing.

MEMBER FLYNN: Can you put a -- I mean, is it improper to put a sentence that the authorized user, and other medical staff, as appropriate, should be physically present during the procedure?

MR. CAMPER: No, we could do that. We could --

MEMBER QUILLIN: I'd recommend you do that.

MEMBER FLYNN: They're going to interpret that as being a must, but it's really not a bust.

MR. CAMPER: But that comes -- again, that would then come up under this discussion under the team approach.

MS. HOLAHAN: Or would it -- actually, if you're trying to be consistent with the remote afterloading module, in terms of location, it comes under operating procedures.

MR. CAMPER: Oh, okay.

MEMBER FLYNN: Unlike teletherapy, you know, where treatment over five weeks, that should something occur during treatment, the people there who are most qualified to intervene, on the spot, immediately, should be there, just like with HDR. The people who are most trained to intervene of this treatment that should only last a few minutes, should be there to intervene.

MS. HOLAHAN: Okay.

MEMBER FLYNN: So --

MEMBER QUILLIN: Moving on to the training list, we made some changes this morning and yesterday, which I don't think we need to go over again. Do we?

MS. HOLAHAN: No, I'll just --

MEMBER QUILLIN: 9.1.2.

MS. HOLAHAN: 9.1.2, okay. Do you think those two, 9.1.2 and 9.1.3, should be combined?

MEMBER QUILLIN: I think there are significant differences between 9.1.2 and 9.1.3.

MS. HOLAHAN: Keep them separate.

MEMBER QUILLIN: Yeah. Because --

MS. HOLAHAN: Okay.

MEMBER QUILLIN: -- if there is a nurse, the nurse may not need to know about the computerized treatment planning system.

MS. HOLAHAN: Okay.

MEMBER FLYNN: I think also under 9.1.3 should be the quality assurance -- the detailed quality assurance checks. Also, number 6, dosimetry protocol, protocol is misspelled. But I think detailed quality assurance checks, detailed pretreatment quality assurance checks, should be part of the physicist. That's what they do.

MEMBER QUILLIN: Well, 9.1.3, you changed the title on that also, didn't you?

MS. HOLAHAN: Yes, and I can share these with Jim afterwards, how we're revising the names of the titles. I think they are now training for staff responsible for planning, administration, and care of patients undergoing GSR treatment.

MR. SMITH: Okay. I'll get that from you later.

MS. HOLAHAN: Yeah. And then there are some minor changes in some of the other words, and then the changes in 9.1.4, we will just make that consistent with the other modules for the training for ancillary personnel.

MEMBER QUILLIN: In this particular case, do we need to have dietary services entering restricted areas?

MS. HOLAHAN: Oh, I --

(Laughter.)

MEMBER FLYNN: I agree with you. We can take that out.

MS. HOLAHAN: The patient may be hungry while they're waiting for their treatment, if they had their helmet on in the morning.

MEMBER FLYNN: There is usually a minimum amount of time between the placement of the helmet and the treatment, because it is -- gets uncomfortable.

MS. HOLAHAN: Yeah. I just know that some of the -- one of the facilities that I visited, they said the helmet could go on at 7:00 and the patient may receive treatment at 3:00 in the afternoon.

MEMBER FLYNN: Really?

MS. HOLAHAN: In which case --

MEMBER FLYNN: Keep the patient medicated, you know, to keep them comfortable and medicated.

MS. HOLAHAN: Yeah, those --

MR. SMITH: Actually, it's just the frame, right? The helmet doesn't go on --

MS. HOLAHAN: Oh, yes, I'm sorry. The frame.

MEMBER FLYNN: Yeah. Under that -- are we on 10 now, or where are we?

MEMBER QUILLIN: Anything more on 9.1.5 or 9.3?

MS. HOLAHAN: And 9.1.5, again, we will make consistent with the other modules.

MR. SMITH: 9.1.5 was -- basically, this goes beyond what I think you would normally see as contractors. This would include the people who put together the treatment suite and also load the unit. I received some comments that we should include more information about the design and construction of the temporary hot cell,

but I figure that these people are going to be licensed by the NRC to perform these activities, and we don't really need to address that in the medical module.

MS. HOLAHAN: Okay. Some of the -- one of the things that we did in the other modules is we gave examples of who might be contracted, like therapists, physicists, nurses, maybe contract employees, to just sort of -- and that, I think, addresses -- emphasizes what you're saying.

MR. SMITH: But in this case, these people would actually have an NRC license to come in there and load these sources into the helmet, or into the unit itself.

MS. HOLAHAN: Yes.

MEMBER QUILLIN: We had a discussion yesterday about -- and I can't remember whether it was in this paragraph, the 9.1.5, or where it was, about the reciprocity issues. And there was a proposed reciprocity sentence which I think needs to be added wherever it's appropriate.

MS. HOLAHAN: Yes. It wasn't in this section, but I know we added it. You're correct. It was under maintenance, maintenance and servicing.

MEMBER QUILLIN: Wherever it was, I just thought about it now, so --

MS. HOLAHAN: You're right. That's a good point.

MR. CAMPER: There's a discussion over under 10.5.

MEMBER QUILLIN: Okay.

MS. HOLAHAN: Okay.

MR. CAMPER: That may lend itself to that insertion. You're right, that definitely comes to bear. See where it says, "Must be performed by service companies specifically licensed to perform such activities. Must provide a copy of the

license," blah, blah, blah, blah, blah. Probably a good place there to make them aware that there's reciprocity.

MEMBER QUILLIN: Let's start on 10. Comments? I'd like to comment that your description of the information on the plans is probably the best one I've seen of all of the documents here.

MR. SMITH: It's a cut and paste right out of the teletherapy module.

MEMBER QUILLIN: Well, some of the others were not as well written.

MR. CAMPER: Are you looking at 10.1., do you mean, facility diagram?

MEMBER QUILLIN: Yeah.

MR. CAMPER: The only thing I had on that was I did have some -- a point here where it says -- I made a note in the margin, "Adjacent areas and occupancy factors." You've got, let's see, the type of use of all -- under item 3, "The type of use of all areas adjoined to the treatment room, including the areas above and below. Note that areas should be described as restricted or unrestricted areas, as defined in" -- you've got the type thickness and density of the shielding materials used in all sides of the treatment room, including the floor and ceiling.

Is it adequate for them to simply tell us the thickness, without -- or are you also looking for some in consideration as to how they got to those values?

MR. SMITH: I think, basically, when you do shielding calculations, you need to know what kind of materials you're dealing with, what kind of concrete you're pouring in, in order to make the calculations. Now, I guess they could go ahead and design it and hope for the best.

MR. CAMPER: Well, you also need to know beam position, occupancy on the other side, and so forth.

MR. SMITH: But that's under, what, item 3?

MR. CAMPER: GSR is a little different, in the sense that you don't have the same, you know, beam movement characteristics as you do with a --

MR. SMITH: That's correct. And actually, the facility I've seen, there is very little shielding in the walls of the room, because I guess most of the beam is directed down to the unit. It's usually in a basement area, so most of the primary beam is heading to the couched portion of the treatment.

MS. HOLAHAN: Would there be a hot lab?

MR. SMITH: They'd make a hot lab during -- a temporary hot cell during the loading of these, but I believe that they disassemble that when they're complete.

MR. CAMPER: That's right.

MS. HOLAHAN: So would they provide that to -- oh, okay.

MEMBER QUILLIN: Any more comments on 10.1? If not, we'll go to 10.2. My comment on 10.2 is actually on the next page, G-8. In the middle of the page, it says, "Your response to item 11.17 should be one of the following." And I assume that item refers to the application forms, as I went back here to try and find 11.17, and I couldn't find one.

MR. SMITH: Well, actually, I think this was one of the renumbering. This would probably be 11.17, but they were all renumbered. But I think that's supposed to be item 10.2.

MEMBER QUILLIN: 10.2, okay.

MR. CAMPER: Under item 10.2, number 4. Why are we looking for that?

MR. SMITH: Well, I think we have the requirement if you have a sealed source, that you have to perform leak tests on it at certain intervals. I believe it's six months.

MR. CAMPER: Yeah. But you can have a service do that for you.

MR. SMITH: You can, but I believe you can also do it yourself in-house.

MR. CAMPER: Yeah, but here you're saying, "You must agree to have the following" -- well, "must" is too strong, for one thing. "To have the following radiation protection instruments in your possession or available for use." And amongst those things, we're looking for a sodium iodide well crystal hooked to a multi-channel analyzer.

MR. SMITH: Well, I know what you're saying. It all goes back to the definition "or have access to it." If you're using a contract service to perform the leak test, then I guess that's access to one. Basically, it's the individual has to agree to have some capability to do the leak test and detect it.

MR. CAMPER: Or they can agree to have someone do it for them.

MR. SMITH: Okay. So we could have --

MEMBER FLYNN: Access to it implies that they must do it themselves.

MR. CAMPER: We don't have a similar requirement for people who are using brachytherapy sources in our guidance document.

MR. SMITH: Okay. If we had a preamble, "If you are going to be performing your own leak test, then you must have"?

MR. CAMPER: Well, no. Actually, I think in the other modules dealing with brachytherapy sources, we have required survey instruments, radiation monitors, but we have not required them.

MR. SMITH: Well, generally, aren't brachytherapy, especially HDR sources, returned before they have to do a leak test on them?

MR. CAMPER: Pardon me?

MR. SMITH: Brachytherapy sources are only kept for, what, three months at a time? HDR --

MS. HOLAHAN: But not -- yeah, not manual -- and you have to -- so you'd have to do leak tests on the manual sources, or the low dose rate sources I should say.

MR. CAMPER: Yeah, I don't know what the basis is for us having four in there. I mean, correct me if I'm wrong, but we didn't say anything of a similar nature on --

MS. HOLAHAN: Did not --

MR. CAMPER: -- brachytherapy.

MS. HOLAHAN: -- in the manual. I'm going to check on the HDR.

MR. CAMPER: Now, we talked about leak tests. Yeah, we did.

MS. HOLAHAN: We talked about it under the radiation safety program.

MR. CAMPER: I'm trying to see what did we say this morning about -- well, let's see, under brachytherapy, in 11.4, leak tests, what did we say? We said, "You must submit procedures for leak testing all sealed sources, as required pursuant to 11.35.59. Requirements for possession of sealed sources and brachytherapy sources."

MEMBER FLYNN: Can you use the same type of language parallel in that section here?

MR. CAMPER: Yeah, I would think so. See, what you're going to do is you're going to -- let's see, you're going to leak test that head at an accessible position. You're obviously not going to stick your hand up in there and leak test the actual --

MR. SMITH: That's correct.

MR. CAMPER: -- source ports themselves. You would be trying to do some kind of --

MR. SMITH: Near successful spaces.

MR. CAMPER: Yes, near successful space. And that leak test -- that wipe, that smear, would be counted at a level sensitive to detect .005.

MS. HOLAHAN: Yeah, what it says in here is, "Leak test may be performed in-house or by a contractor, as long as the method is sensitive to detect .005 microcuries."

MR. CAMPER: And you're reading from -- is that from this guide?

MS. HOLAHAN: No, this is remote afterloading.

MR. CAMPER: Right. So I think parallel language applies, as opposed to requiring --

MS. HOLAHAN: Do you have leak testing in the --

MEMBER FLYNN: Teletherapy.

MS. HOLAHAN: No, in the --

MR. CAMPER: Which one?

MS. HOLAHAN: In this module.

MR. SMITH: I believe so.

MR. CAMPER: GSR?

MS. HOLAHAN: Yes. Or is that moved into the body?

MR. CAMPER: Well, you have surveys. You have on page G-12, under 11.22, you have GSR survey reports. Let's see, no, that's not it. This is just radiation surveys.

MS. HOLAHAN: It may have been because it is addressed in the body.

MR. CAMPER: That's right. It is --

MS. HOLAHAN: Again, part of that problem is we're now getting inconsistencies between the modules.

MR. SMITH: I believe it was taken out.

MS. HOLAHAN: Yes.

MR. CAMPER: Well, it seems that what you really need is a discussion of leak tests in this module, in a fashion parallel to what we've done in the other modules, in pointing out to them how it needs to be leak tested at the nearest point of access, and similar language that they can do it themselves, or they can use a service.

MR. SMITH: Okay. Is that in the remote afterloader module that --

MS. HOLAHAN: It's in the remote after -- and the manual.

MR. CAMPER: And the manual, right. And in the manual, Jim, it's 7.4.

MR. SMITH: Okay. Now, the section that we were in, though, 10.2, is for survey instruments and radiation monitors that a licensee must agree to have.

MR. CAMPER: Yeah. But what I'm trying to say, that's what my point is. I don't think that a GSR licensee has to have a sodium iodide crystal with an MCA.

MS. HOLAHAN: Or have access --

MR. SMITH: I'm sure they have to, so this is an example of one that would meet the requirements.

MR. CAMPER: But again --

MS. HOLAHAN: Could we say "have access to it through a contractual" --

MR. CAMPER: Why do you have to have access to it? If I -- what if I want to use a commercial entity to do my leak test? I have a physicist who comes in quarterly.

MS. HOLAHAN: That's through the contractual arrangement.

MR. CAMPER: Right. Does my leak testing. I don't have to have an MCA and a sodium iodide crystal under that circumstance.

MEMBER QUILLIN: I agree with Larry on this. I don't think it's a necessary requirement. I mean, it would be nice to have, obviously, but the requirement is the ability to do the leak test, either yourself or through a contractor.

MR. CAMPER: Right.

MEMBER QUILLIN: And that needs to be put in 11, I think. That's consistent with the other one.

MR. CAMPER: I have a broader question, and maybe it's -- as I read number 2, maybe it's an opportunity to raise the question. And I think I know the answer before I raise the question, but I will -- to stimulate discussion.

As I read through here, and look at number 3 under 10.2, we -- well, it actually starts off in number 1. We reference a portable survey meter meeting the requirements of 35.620. We, in item 3, we talk about a dosimetry system for making full calibration and spotcheck measurements, described in 630.

Elsewhere in here we use very -- a much stronger reference to the language in the 35.600 series. Do we have an interpretation from the --

MR. SMITH: We do. We have actually had a technical assistance request from Region 1 that requests that we interpret whether or not GSR is actually a form of teletherapy.

MR. CAMPER: And so we have that --

MR. SMITH: We have no legal objection to it by the Office of General Counsel, in which we said that GSR is a special form of teletherapy. Therefore, the --

MR. CAMPER: Okay. Well, I did not remember that. That's good. Good. Because we make strong regulatory reference throughout here to that, and I want to make sure we had covered that base. That's good. Okay.

You know, we have done that with HDR and brachytherapy, of course, specific interpretation.

MR. SMITH: We actually addressed that specifically about two years ago.

MR. CAMPER: Good.

MR. SMITH: All right. So, where are we here, Bob?

MEMBER QUILLIN: We're at the bottom of page G-8.

MR. SMITH: Okay.

MEMBER QUILLIN: The last comment I had on this section was discussion on the paragraph, "A service company may not have a license," etcetera, etcetera. The way this bottom half of the page is paragraphed, your response to item now 10.2 should be one of the following, colon, and then you have a large paragraph, and then you have a second large paragraph. And the first time I read it, I thought the second large paragraph had something to do with -- should be one of the following.

MR. SMITH: I see.

MEMBER QUILLIN: And if you could --

MR. SMITH: Sort of clean that up, so that 1, 2, and 3 of that first paragraph --

MEMBER QUILLIN: Yes.

MR. SMITH: Okay.

MR. CAMPER: Well, the other thing, too, on that particular paragraph is the first sentence kind of threw me a little bit. I had to read it several times before I could pick up what your theme was. And I think what you were saying in this paragraph is if you're going to use a service company to do this, recognize they may or may not be licensed.

MR. SMITH: They may have radium source that they use to calibrate their sources, and they may be an agreement state.

MR. CAMPER: Well, but a service company could be licensed by an agreement state and be perfectly acceptable as well.

MR. SMITH: That's correct.

MS. HOLAHAN: So you're saying in that first sentence, the service company that may not have a license can't do your calibration, right?

MR. CAMPER: Right. That's what he's saying.

MS. BHALLA: No. The last three lines, it says, "then send their procedures."

MS. HOLAHAN: Oh, okay. I'm sorry.

MS. BHALLA: If they don't have a license, then send their procedures, so that we can review. And just because it doesn't have a license, doesn't mean that --

MS. HOLAHAN: You can't use it.

MS. BHALLA: Right. You can't use or they are not --

MR. SMITH: We've done that in a few situations, even where they had a license but it wasn't specifically to perform instrument calibrations. The one I think of is where a nuclear power plant was offering to calibrate the survey instruments for the small university down the street, and what we said was even though they're not specifically licensed to do calibrations, if they will provide you with a copy of their procedures for the instruments, and we'll review them and look at them as though the licensee were actually performing procedures, and base our judgment on that.

MR. CAMPER: Well, yeah, but -- I'm with you. I understand. But couldn't you do something to that first sentence? Rather than saying, "A service company may not have a license because, perhaps, for example, it is located in a non-agreement state, uses radium, a radioactive material not regulated by the NRC." I mean, what are you trying to say there? You can calibrate a survey meter with materials other than what we regulate.

MR. SMITH: Yeah. But you can also --

MR. CAMPER: I mean, radium is an example.

MR. SMITH: That's correct.

MR. CAMPER: So what are we trying to say there?

MEMBER FLYNN: I agree with you. I think that sentence has to be totally rewritten.

MR. SMITH: Okay.

MEMBER FLYNN: The radium is really immaterial.

MR. CAMPER: Yeah, it really is.

MEMBER FLYNN: The radium just confuses it. I would just take that out.

MS. HOLAHAN: I think he is just trying to describe why it doesn't have -- why it wouldn't have a license, and yet it does instrument calibrations, right?

MR. SMITH: If you were in a non-agreement state and had a radium source, you wouldn't necessarily have a non -- an agreement state license, right, not necessarily even have a license by any regulated body.

MEMBER QUILLIN: I think all you need to say is if a service company does not have a license, you need to submit the description of the radioactive sources and procedures --

MR. CAMPER: That's right.

MEMBER QUILLIN: -- used by that company.

MR. CAMPER: That's right. That's the point.

MS. HOLAHAN: If the service company doesn't have a license or is not specifically authorized on the license to provide --

MEMBER QUILLIN: Yes, just submit the procedures and --

MR. CAMPER: Have we gone into this in the other modules?

MEMBER QUILLIN: Not in this detail.

MR. SMITH: I would imagine in teletherapy.

MS. HOLAHAN: Pardon me?

MR. SMITH: Teletherapy is in there.

MS. HOLAHAN: It's not in yet, no, but --

MR. CAMPER: What have we said about -- this is about survey instrumentation, right, calibration of survey instrumentation?

MR. SMITH: That's correct.

MS. HOLAHAN: I guess the question is is should this actually be in? This type of detail should perhaps be in the body, because this does apply to all of them.

MR. CAMPER: Well, if you're going to -- that's right. If you're going to -- in the general part of 10.8, if you're going to use a company that calibrates your survey meters, your survey detection instrumentation, you've got to indicate who it is, or submit the procedures they will follow.

MR. SMITH: Okay.

MR. CAMPER: Now, many times these companies have gone through and had their procedures submitted and reviewed and they're on a list. It used to be called the STIS list, or something like that.

MS. HOLAHAN: Yeah.

MR. CAMPER: I think that still exists. I'm not sure how formal it is this day and time, but it still does exist. But in that case, those procedures had been reviewed and approved, if you will, and found to be acceptable, I should say.

And, therefore, in recognizing -- when reviewers see that name of that company, XYZ Consulting Company, they know that, okay, XYZ can do survey meter calibrations. If not, that company or that physicist needs to submit their procedures, and we look to see if they are at least equivalent to those in Reg. Guide 10.8, Appendix C, I think it is, right?

So that really is --

MR. SMITH: Well, we can do that. We can --

MR. CAMPER: -- in the primary body of the submission. It may not be best served, at this point, in the guidance document, because we didn't get into this at all, I don't think, did we, in the other modules?

MS. HOLAHAN: No.

MR. CAMPER: And that's probably the rationale why we did not.

MS. HOLAHAN: Well --

MR. CAMPER: Right?

MS. HOLAHAN: I don't know the rationale why it wasn't addressed in the others. Having authored one of them, it probably didn't cross my mind. But --

MEMBER QUILLIN: When you have multiple authors, that's what you expect.

MS. HOLAHAN: That's right.

MR. CAMPER: And I don't mean to beat you up. But it just -- it's -- I don't know, it's not -- it doesn't seem like --

MR. SMITH: No, I think you're right. It's generic enough in the wording that it can be moved up or some other wording can be devised in the main body of 10.8.

MS. HOLAHAN: Right.

MR. SMITH: Because just about everything --

MS. HOLAHAN: I think we really need to sit down and look at what we need to have in the main body and what needs to be in the individual. Right now, we're getting confused because some modules have some things and other modules don't.

MEMBER QUILLIN: Moving on --

MS. HOLAHAN: Yes.

MEMBER QUILLIN: -- to 10.5. Any comments?

MR. CAMPER: Well, just the one we've already discussed quickly, and that was the reciprocity. This may be a good point to make it.

MEMBER QUILLIN: Yes. As a matter of fact, I did highlight it in here.

MR. CAMPER: Right.

MEMBER QUILLIN: 10.6, viewing systems. 10.7, warning systems and access control. 10.8, adequacy of shielding. I have one comment, and that's on 2.e, where it says, "All patients treated in one hour using the critical orientation" --

MR. SMITH: There's no orientation.

MEMBER QUILLIN: Pardon?

MR. SMITH: I guess there's no orientation with GSR, other than they flip the patient face down sometimes and face up.

MEMBER QUILLIN: Well, that was one issue. And my question is, Dr. Flynn, how many patients can you treat in one hour with this machine?

MEMBER FLYNN: Well, I've never used the gamma knife or the cobalt. With the stereotactic radiosurgery with the accelerator, it's just that the quality assurance checks and the setup, verification of the setup, and the treatment takes long enough where it's tying up the accelerator for at least one hour for one treatment. The treatment itself is actually fairly short. It's a matter of minutes, five minutes, 10 minutes.

MS. HOLAHAN: Depending on how --

MEMBER FLYNN: Depending on how many --

MEMBER QUILLIN: One case I observed --

MEMBER FLYNN: Shorter time, the actual beam on time is not tremendous. But everything that goes up to that point gets considerable --

MEMBER QUILLIN: One case I saw, once they put the patient in the room, it was, you know, on the order of an hour.

MS. BHALLA: Yeah. Even with gamma knife, the -- I have seen was at the most one patient, which took the entire day, too much, between the localization and, you know, patient, etcetera, and --

MEMBER FLYNN: But the time in the actual treatment room is what we're talking about.

MS. BHALLA: The actual treatment also was not -- there was -- they couldn't -- the way it set up was the whole team is concentrated on this one patient, and even to think of another patient the same day, let alone same hour, just seems not possible.

MR. SMITH: Well, the facility I saw had two different systems set up, so that they could actually be lining up two patients to be treated at one time. So it's conceivable that they could actually treat two patients in an hour.

MS. HOLAHAN: Yeah. I've been to two facilities that say they do -- on a busy day, they'll do three to four patients in a day. But that's a full day's work.

MR. CAMPER: That's pretty busy.

MS. HOLAHAN: Yes. They can do that much, but I don't -- so, again, yeah, I guess if you had them all --

MEMBER QUILLIN: How long were they actually in the room?

MR. CAMPER: Two hours.

MS. HOLAHAN: Well, I guess the question is is they're not actually in the room during the treatment planning. I mean, they're down there and everything, but I think --

MR. CAMPER: The room is tied up.

MS. HOLAHAN: Right.

MR. CAMPER: You're going from the placement and the treatment planning and all of that, but the room isn't ready. The room is waiting until the patient is --

MS. HOLAHAN: And I guess it depends --

MR. CAMPER: -- prepped, ready, and then -- and the actual procedure itself, of course, doesn't take a long time.

MS. HOLAHAN: But it also depends on how many shots you're doing for an individual patient. I think in the cases that I've seen they're doing more than one position, so then they have to redo the planning again, or realign the --

MR. CAMPER: Spatial fractionation as it were.

MS. HOLAHAN: Correct.

MR. CAMPER: Right.

MR. SMITH: Would you recommend that I take the examples out?

MEMBER QUILLIN: I think what they should use is a realistic situation.

MR. SMITH: Okay.

MS. BHALLA: But after beam size, maximum beam on time --

MR. SMITH: Okay.

MS. BHALLA: -- rather than patient --

MR. SMITH: Okay.

MS. HOLAHAN: But it may -- maximum beam size, does that address the number of --

MR. CAMPER: Plugs?

MS. HOLAHAN: -- plugs? Is that what that is referring to?

MR. SMITH: Actually, I was thinking the collimator size, because they have several different sizes.

MR. CAMPER: That's right. You can change the size, you can -- and you can plug them.

MR. SMITH: Yeah.

MR. CAMPER: Well, I don't think it's all patients treated in one hour. That's not it. Worst case scenarios are maximum opening septums, no portals plugged, time that the door is open, because, remember, this is a heavily shielded --

MR. SMITH: Unit, yeah.

MR. CAMPER: -- unit.

MR. SMITH: Actually, it's --

MR. CAMPER: So if I'm looking at shielding, I'm not worried about, so many times, about one patient in one hour. I'm worried about what's the maximum beam exposure probability, and that would be door opened, the big one.

MR. SMITH: Well, actually, this is for when you're trying to do the calculations, is to make sure that the dose limits outside meet the Part 20 requirements.

MR. CAMPER: Oh, I understand that. I understand that.

MR. SMITH: I think on a normal work day, you wouldn't expect them to have the sources exposed with the door open. But I guess it's not uncommon.

MR. CAMPER: But that very thing is what you're bringing in to bear. That's exactly -- when you're doing those calculations for those walls, that's the primary consideration, because your ambient radiation as a result of the design of the head has got to be pretty low. If you add a bit of distance to it, you get into a --

MR. SMITH: Well, maybe we're talking about the wrong door. You're not talking about the door into the treatment room, right?

MR. CAMPER: No, I'm talking about the door on the unit.

MS. HOLAHAN: Oh, okay.

MR. CAMPER: Oh, I'm sorry.

MR. SMITH: Okay.

MR. CAMPER: No, I'm talking about when -- the worst case exposure scenarios are when that door is opened, the largest opening septums are in place and there are no plugs.

MR. SMITH: I think probably, yeah, and also when the doors are opened before the helmet actually moves up.

MR. CAMPER: Right.

MS. HOLAHAN: Right.

MR. CAMPER: The door open. Yeah, there's a point there, as you know, where the doors open and the couch is going in. Those are your worst case exposure scenarios, and that's what you're designing to.

MR. SMITH: That's correct.

MR. CAMPER: And it would be different at different walls and at different distances, of course.

MR. SMITH: Okay. That's a good example.

MR. CAMPER: So those kinds of things are your worst case situations.

I have a question on (f). It's not clear -- I have two problems with (f). Number one is it's not clear why you're saying "a consideration of continuous occupancy, i.e., occupancy factor of one." You're saying they must consider that.

MS. HOLAHAN: We --

MR. CAMPER: But they could demonstrate other occupancy factors, and then, so, therefore, they wouldn't necessarily have to consider one.

MR. SMITH: That's right.

MR. CAMPER: And the other one is I think the reference to 20.1301(c) doesn't work, because I don't have to consider an occupancy factor of one. It's not that I don't have to consider an occupancy factor of one, if I'm going to move to a 20.1301 position. That is not -- one does not have anything to do with the other one.

MR. SMITH: Okay.

MR. CAMPER: And secondly, the 20.1301 is only a temporary provision to allow you to go to 500 millirem for some period of time. So I think it doesn't line up.

MS. HOLAHAN: The other -- yesterday, when we discussed the remote afterloading on this issue, we modified it to say, "The calculations that determine the dose received by individual present in unrestricted areas should consider an occupancy factor appropriate for the possible use of the adjacent area." So that it left it to the licensee to tell us what the occupancy factor was for the adjacent rooms.

MEMBER QUILLIN: I like that.

MR. CAMPER: Yes, that's really -- that's exactly what will happen when they're designing the shielding.

MR. SMITH: Okay. So this is remote afterloaders, coming from 2?

MS. HOLAHAN: Yes, it's my -- it's the handwritten copy that you just -- or marked copy.

MR. SMITH: Okay.

MS. HOLAHAN: Page 20.

MEMBER QUILLIN: Any more on this, Larry?

MR. CAMPER: No, I think that's it.

MEMBER QUILLIN: Let's go on to 11.

MR. CAMPER: Did we speed, Jim, up enough on this one?

(Laughter.)

I don't mean to. You've done a good job, but there's just a couple of things that --

MR. SMITH: It's Friday. I can take it.

MEMBER QUILLIN: 11.21?

MS. HOLAHAN: Before we get to 11.21, just we were going to insert 11.4 and insert the leak tests in there.

MR. SMITH: Okay.

MS. HOLAHAN: Based on earlier discussions.

MR. CAMPER: Actually, I take that back. I do have one thing. In (g), where we list millirems and millisieverts, etcetera, etcetera, I guess we have to move toward the metrification, don't we?

MR. SMITH: Yeah.

MR. CAMPER: We have to be listing both English and SI units?

MS. HOLAHAN: He has.

MR. SMITH: Not there.

MR. CAMPER: No, he hasn't either.

MR. SMITH: Oh, yeah, I do. Millirems and millisieverts.

MR. CAMPER: Millirem -- no, no, I mean, classically how you list them. You list the English value. You list the value, and you immediately behind it put what that is in the unit.

I think we've done -- expressed in millirems in one hour. Wouldn't you then have to put the SI unit that corresponds right there behind it, parenthetically? I believe you do.

MR. SMITH: I think, actually, what --

MR. CAMPER: I think there's a format for doing that.

MR. SMITH: The way we've been doing it recently is the SI units and then the English units in brackets --

MS. HOLAHAN: Right.

MR. SMITH: -- after it.

MR. CAMPER: Yeah. And we had a discussion a couple of days ago or so which one went first.

MS. HOLAHAN: Yes.

MEMBER FLYNN: I think now it's the international units.

MR. CAMPER: I think you're right. I think you're right.

MR. SMITH: SI units for --

MEMBER FLYNN: It used to be the other way around, but now --

MS. HOLAHAN: Yeah, it's --

MR. CAMPER: So take a -- just take a look see at that, make sure we're --

MR. SMITH: Okay.

MEMBER QUILLIN: On to 11 again.

(Laughter.)

I'll let you go this time.

(Laughter.)

MEMBER FLYNN: We're on 11.21, are we?

MEMBER QUILLIN: 11.21.

MEMBER FLYNN: I had one point here, and this brings me back to the old days of HDR, Indiana, Pennsylvania. And that is that maybe it's -- maybe I missed it. That we also have -- all equipment necessary to handle an emergency is available and immediately in the room, or however you want to put it, just like we do for HDR.

I mean, in the HDR, we require the things such as wire cutters, whether or not the wire will be cut or not, but in case it had to be that it's there, that suture removal equipment is there, and anything necessary to -- all equipment necessary for emergency procedures is available and immediately accessible in the room.

It won't take up much space. It will take up a small part of one drawer, the things I'm thinking of.

This instance that you've cited, where a patient had to be taken out of a -- a valve failed, and they had everything there to remove the helmet there, rather than take the patient someplace else in the hospital and remove the helmet, right? They had the -- like in our facility, we have the wrenches to remove the helmet and remove the frame right there in the room.

MS. HOLAHAN: Yeah. Actually --

MEMBER FLYNN: But in some places, they may be going back to some place in the surgical suite, or something.

MS. HOLAHAN: Actually, there are two long-handled tools you can use to separate the helmet from the head. And in the particular case, they had one of the two tools, but at that time they didn't have the other one. They were only provided to

-- they did not have the second tool. I think the manufacturer has, since that time, provided all licensees with the tool that will rapidly disconnect the helmet from the head.

MEMBER FLYNN: I don't think you should depend on the good will of a manufacturer and the thoughtfulness of the licensee. I think you should require that they have those tools there. I mean, I think it should be in there. It should be that --

MS. HOLAHAN: What are they, remote -- there's a special name for those tools.

MR. SMITH: I can't remember. It's a special kind of --

MEMBER FLYNN: It doesn't even have to be specific. You can say that "all equipment necessary for -- all equipment necessary for emergency procedures should be immediately accessible in the treatment room." And then you could put, "For example, these may include," and then you can list the other things.

MS. HOLAHAN: Right.

MEMBER QUILLIN: Any more comments on 11.21?

I have two comments on 11.22. 10 CFR 35.641 requires you to perform a survey, but 10 CFR 35.645 requires you to mail a copy of the survey.

MR. SMITH: Okay.

MEMBER QUILLIN: And it's not -- 10 CFR 36.606 is 10 CFR 35.606.

MR. SMITH: Thank you.

MR. CAMPER: Also, the paragraph on page G-13, where it says, "In order to fulfill the requirement in 30.6 for reporting the results of the radiation survey to the appropriate Commission," that should be NRC as opposed to Commission, "Regional Office, in 30 days following completion of the action." Why --

MR. SMITH: Where is this? I'm sorry.

MR. CAMPER: G-13.

MR. SMITH: G-13.

MR. CAMPER: Under item 11.22.

MEMBER QUILLIN: Second paragraph.

MR. CAMPER: Second paragraph. "Commission" should be "NRC."

MR. SMITH: Okay.

MR. CAMPER: And secondly, why are we expecting this survey to be reported to us within 30 days?

MR. SMITH: That's in the regulations.

MR. CAMPER: But we don't get all surveys of these things in 30 days.

MEMBER QUILLIN: I didn't have the regulation, so I couldn't cross reference it.

MR. CAMPER: Okay. 35.641, what does that do? Let's see, okay, so we have to do a survey, blah, blah, blah, a survey, get a bunch of values, do some surveys.

MS. BHALLA: It's in the 314 requirements.

MEMBER QUILLIN: 35.645 is the mailing the reports in within 30 days.

MR. CAMPER: Okay. That's it, yeah. It's 30.645, not 30.6.

MS. HOLAHAN: 35.645?

MR. CAMPER: Yes.

MEMBER QUILLIN: And they use the term "Commission Regional Office" in that regulation, by the way.

MR. CAMPER: 35.645?

MEMBER QUILLIN: Yes.

MR. CAMPER: Well, I don't think that's consistent with the format. We can doublecheck that, Jim. I think when you're referring to the NRC staff or the NRC regional office, it's referred to -- the Nuclear Regulatory Commission office or staff is referred to as the NRC. When you're referring to the Commission, you're referring to the Commission itself.

MR. SMITH: Okay. I can take that out.

MS. HOLAHAN: That's a change in policy since this was -- Part 35 was written.

MR. CAMPER: That's right. And what Trish is saying is she thinks that is a change in policy, since Part 35 was written and revised in '87, and that's probably correct.

MR. SMITH: Okay.

MR. CAMPER: But doublecheck that point. I think that's the way it is. I could be wrong, but let's just make sure.

MEMBER FLYNN: Where are we now?

MR. CAMPER: I think we're still on 11.22, on page G-13, I think, right, Bob?

MEMBER QUILLIN: Yes.

MEMBER FLYNN: Again, when you go through this, like in number 9, activity source in curies, you've got to just look at all of the -- every time you have a -- when you go through all of these documents, every time you have units, and you make sure it's all consistent, that you put the SI units and then the English units in parentheses. Just -- you know, go through all of the modules at the same time and just for that purpose.

MS. HOLAHAN: Yes. That will be sort of one of the -- as we go through the final editorial checks to check that. I think we have traditionally used curies in many of these, because licensees are sometimes confused with becquerels.

MR. SMITH: Some people don't deal with curies either.

MS. HOLAHAN: Milligram radium equivalents.

MEMBER QUILLIN: Any more comments on 11.22? Just a question I had for my own information. Item 16, if the GSR unit or its sources were removed, provide the date of removal and the name, so forth, who took it. Is this survey required to be done on removal? Is that part of the regulation? I didn't read the regulation.

MR. CAMPER: Jim, where did all of these surveys come from?

MR. SMITH: They actually came out of the --

MR. CAMPER: Manufacturers? Where did they come from, the manufacturers?

MR. SMITH: No, these came out of a teletherapy guide.

MR. CAMPER: Well, let me ask you a question, then. Maybe that prompts me. I look at 11, "Provide the maximum and average radiation levels measured at one meter" -- that's about what, three feet, right?

MR. SMITH: Yes.

MR. CAMPER: -- "from the sources in the off position." When is a GSR unit off?

MR. SMITH: When the doors are closed.

MR. CAMPER: When the doors are closed. All right.

So how am I going to measure? I guess I could, what, put some platform or something inside and --

MR. SMITH: No. Actually, this is a measurement for the safety of the unit itself. It is not unlike when you do a measurement on a teletherapy unit or a radiography unit. You have to have a certain dose rate at a distance.

MR. CAMPER: Well, then, how does that follow the following sentence, then? "The average radiation level may be obtained by averaging measurements taken at 14 to 26 points on the surface of the sphere, one meter in radius centered on the isocenter of the sources."

MEMBER FLYNN: You may get different exposure rates at different positions.

MR. CAMPER: But my isocenter --

MEMBER FLYNN: The orientation from the --

MR. CAMPER: Yeah, I know.

MS. BHALLA: This is when the sources are still -- I mean --

MR. CAMPER: In the shielded position.

MS. BHALLA: Machine is not turned on. Machine is off, and yet there will be some radiation coming through the head, around the unit.

MR. CAMPER: But how are you measuring that when you're doing it on the isocenter of the sources? What do you mean by "isocenter" in this case?

MR. SMITH: Well --

MR. CAMPER: Do you mean the point where all of the beams converge?

MR. SMITH: Yes, that's what I'm assuming. Well --

MR. CAMPER: That's inside the head.

MR. SMITH: I guess mathematically you could figure that the isocenter is somewhere outside --

MS. BHALLA: Right. You can -- where one meter would be.

MR. CAMPER: Well, what am I getting when I do averaging measurements at 14 to 26 points on the surface of the sphere, one meter in radius, when I have an isocenter that is on the order of a millimeter or two?

MS. HOLAHAN: If the isocenter is in the middle and you're doing your measurements one meter from that, so around the outside of the head basically, right?

MR. SMITH: Like when you do a measurement on a teletherapy unit. You have little points on the head, and you place a meter stick on it and go perpendicular to --

MR. CAMPER: So what is it? This is --

MS. BHALLA: This is really referred to as the head leakage measurements.

MR. CAMPER: Right.

MS. BHALLA: And you can, by knowing the -- how much is that sphere from the focal point for all of these beams --

MR. CAMPER: I understand what you're saying. But in this case, your sphere, your one meter radius sphere, is inside the head, correct?

MR. SMITH: Correct.

MS. BHALLA: Yes.

MR. SMITH: Well, I --

MS. BHALLA: No. It's not exactly one meter. It could be --

MEMBER QUILLIN: You have an imaginary sphere here, which is one meter around the isocenter of the sources.

MR. CAMPER: What is the isocenter of the sources in this example?

MR. SMITH: It's where the beams intersect.

MR. CAMPER: Where the 201 beams merge.

MR. SMITH: Right.

MEMBER FLYNN: But for teletherapy, this new teletherapy, it reads as follows, and the other module we won't get to probably. The average radiation level maybe obtained by averaging measurements taken at 14 points on the surface of a sphere, on meter in radius, centered on the source. This is for teletherapy.

MR. SMITH: And since we don't have a single source for that, I took a reference point as being --

MR. CAMPER: Okay. So what you've got is you've got -- okay. So you're coming out a meter, and you're taking these -- you're taking 14 to 26 measurements at a meter from the head, right?

MR. SMITH: Yeah.

MEMBER FLYNN: It certainly would be easier to take the measurements a meter from the head, actually, than try to figure out where the center is. But --

MEMBER QUILLIN: Actually, you don't know where the isocenter in the sources is. You know where the isocenter of the beam is.

MR. SMITH: That's right. Mathematically, I guess you could figure it out. You could add up all of their coordinates.

MEMBER FLYNN: It would be a lot easier if you could take it a meter -- just a meter from the surface of the head, surface of the machine.

MEMBER QUILLIN: So, actually, what you really want to do is you want to imagine your isocenter of this unit, wherever it is, and then take the measurements. And then that's just your guess as --

MR. SMITH: Yeah. That's my guess as to where the average --

MEMBER FLYNN: It says the sources went out a meter from the center of the machine.

MEMBER QUILLIN: No, I just said a meter from the center of the head.

MR. SMITH: Yeah, that would be the isocenter, and I think if, mathematically, you worked it out, that would be the average location of the activity. It would be somewhere close to there. It would probably be --

MR. CAMPER: I understand what you're doing now. It's --

MEMBER QUILLIN: It seems to me that it would be just easier to -- well, you can say you can go through that whole exercise of trying to figure it out, or, as an alternate, you can --

MR. SMITH: I think basically since it's a hemisphere, or you're -- the manufacturer probably can tell you how far it is from the surface of that unit to the isocenter.

MR. CAMPER: Well, here's another --

MR. SMITH: And then it might be a simple matter of placing a stick on the outside of --

MR. CAMPER: But here is -- okay. I follow you. I'm with you now. Dan's point is interesting, because if you stop and think about it, if you're taking measurements over 14 to 26 points of an imaginary sphere, one meter from the head, that is a more representative explanation of the actual exposure rate than saying that you're taking it one meter from the isocenter, because the sources are in the head of the unit.

And if I do a measurement at one meter from the actual placement of the sources, I am getting a truer indication of the ambient exposure rate than if I'm

taking it one meter from the isocenter. In other words, you've got a beam coming down in the center. I'm measuring one meter from that. What exposure rate do I get at one meter from that, as compared to one meter from the actual head of the device itself?

MS. HOLAHAN: Probably much higher.

MEMBER FLYNN: Probably much higher.

MR. CAMPER: Probably much higher. Now, what are we trying to get at here? We're looking at what is the average exposure at 100 centimeters?

MEMBER QUILLIN: You're doing a leakage measurement on the head.

MR. CAMPER: That's right. That's all you're doing. So --

MR. SMITH: Generally, at one meter, you're --

MR. CAMPER: So why don't you take your measurements --

MR. SMITH: -- of the sources so that you can assume that's a whole body dose. Whereas, if you get up real close to the unit, then you might be getting --

MR. CAMPER: The point is, you can't get more than 10 mr per hour and meter, right?

MR. SMITH: Yeah.

MS. BHALLA: Right. That's the max.

MR. CAMPER: So why you just measure it, 14 to 26 points at one meter?

MR. SMITH: Yeah. But from where, Larry? I mean, there is 201 sources in there. What are you going to use as your reference point for one meter?

MEMBER QUILLIN: Well, if the manufacturer can't tell you, then you're just going to have to guess. I don't think I would go through the exercise of --

MR. CAMPER: Well, what I'm saying there, Jim, is if you do your measurement at one meter from the isocenter, you get a value. Let's say that value, for sake of discussion, is -- just pick a number. Say it's 20. If I do my measurement at one meter from the sources, okay, that value is going to be, let's say, I don't know, lower. It's going to be lower. Let's say 10, all right?

The bottom line is I can't exceed 10 millirems -- an element of 10 milliroentgens per hour at a meter. Right?

MR. SMITH: Right.

MR. CAMPER: So what is the relationship of the value I get, then, between a measurement taken at one meter from the isocenter, as compared to one meter from the sources themselves?

MR. SMITH: I would say that you probably have a virtual source near the isocenter. It just --

MS. BHALLA: Yes. At the isocenter, you really have a combination of -- or the -- a summation of radiation coming from these 201 --

MR. SMITH: Sure, of course.

MS. BHALLA: -- sources. And, therefore, if anything, that is the point where you can assume that your source now, as Jim said, like a virtual source is now at this point. And, therefore, based on the geometry, just like with teletherapy, you don't really know exactly where the source is, but you have an idea.

It's, you know, maybe 30 centimeters in from the head, and, therefore, you go 70 centimeters out from the outer shield to get to that one meter. You don't go one meter from the head from that outer shield, whatever they have.

So keeping that in mind --

MR. CAMPER: You go one -- you're right. You're going one meter from the assumed center.

MS. BHALLA: Right.

MR. CAMPER: Right.

MS. BHALLA: So taking a parallel from that, you could -- and you have a good idea, because your dosimetry system you are going to send to the point of this focal -- focal point, focal -- where the beams are all merging in. And now you go conversely, you go just outside and took your readings, and --

MEMBER FLYNN: So that there's a regulatory interpretation that is consistent and as simple as possible and get what you want to get out of it. It's always nice if you can have different modules using the exact same language. I mean, I don't see why you can't have it from the -- using the same language for the teletherapy, and that is one meter in radius centered at -- on the -- you can change it a little bit. The center of the head, and not use the word "source" or "source isocenter." Isn't that what you really do?

I mean, you're walking around the machine and you're -- like you said, you assume that it might be 30 centimeters in there. That's 70 centimeters, you take measurements. I think it might be worthwhile, because I've never seen one of these machines, because we use a stereotactic with a linear accelerator. The same principles, though.

But to actually take measurements using these different interpretations and make sure that all of the existing machines out there don't go -- aren't in violation of some proposed regulation right now, because you're measuring so close to the source it might be 12 mr per hour. I don't know. Have you taken any measurements on these heads?

MS. BHALLA: Yes.

MEMBER FLYNN: For the stereotactic?

MS. BHALLA: Stereotactic, and pretty much your dose is higher where the shield door opens, the door through which the patient's head goes in. So --

MR. CAMPER: It's really high, too, isn't it? What's that?

MS. BHALLA: Yes, it's -- I forget the numbers, but it's fairly high. But then, when you go and do your average of 2 mr, my only experience is limited to the University of Pittsburgh. There is a gamma cell unit there. And it did meet the 2 mr average.

MR. SMITH: I think following the Lawrence Livermore's teams, there is a -- didn't the manufacturer fix that problem? There was some leakage around those interfaces, and I believe that was one of their fixes, because they found that there were pencil beams coming out.

MR. CAMPER: Well, one of them had -- the boring of the septum was wrong, wasn't it?

MR. SMITH: I don't remember that.

MR. CAMPER: You opened the door. I think one of the --

MR. SMITH: It was a generic problem, I think.

MR. CAMPER: -- was too high, and one of the sources was throwing out a beam further out than was the design specification.

MR. SMITH: I don't recall that. I think it was something different.

MEMBER QUILLIN: Larry, could --

MR. CAMPER: Well, anyway, we --

MEMBER QUILLIN: -- could you work on this and language, so --

MR. CAMPER: Yes. Okay. Well, we'll take a look at what the teletherapy says and see if that makes more sense than this, although I --

MEMBER FLYNN: I think teletherapy would have to be changed to the center of the head.

MR. CAMPER: right.

MEMBER FLYNN: Because teletherapy uses the word "source," and, of course, the gamma knife has many sources. So --

MR. CAMPER: Yes, 201 I believe.

MR. SMITH: So I think if you're doing a one over R squared dropoff, you'd have a virtual source in the center. That would give you a better idea of the doses away from the unit.

MR. CAMPER: All right. Well, we'll take a look at it.

MEMBER QUILLIN: Okay. Let's move on to 11.23, operating procedures.

MS. HOLAHAN: The operating procedures was what I was suggesting we could -- to be consistent with remote afterloading module, insert something about the physical presence, recommending the physical presence of the authorized user and physicist.

MR. CAMPER: Now, is this where you would talk about the team approach, or would you have already talked about that earlier on?

MS. HOLAHAN: I think we're moving that up to the purpose.

MEMBER QUILLIN: I think it should be in the purpose.

MR. CAMPER: Okay.

MEMBER QUILLIN: That's okay with me, to put the --

MEMBER FLYNN: I mean, the safety device checks is not the same as quality assurance checks. So I would -- and it's not -- so I would include in the first -- in the second sentence, quality assurance checks also.

MS. HOLAHAN: Where?

MEMBER FLYNN: Well, the second sentence says, "These duties may include, but are not limited to, safety device checks, instrument calibration, monthly spotchecks and leak tests." The quality assurance checks should be in there.

MR. SMITH: I think in our regulations, though, this monthly spotchecks include the first portion of it under (a), include QA checks. That's checking a set of dosimetry calculations and measurements. And in the (b) set, it's where they look at the safety parts, like --

MEMBER FLYNN: Well, we do -- because we spend the first -- when the patient goes in the room, we spend the first -- when the patient is about to go in the room, and then the patient is in the room, we spend about a half an hour doing the pre-treatment, patient-specific quality assurance checks. And I don't know -- and I assume that it's -- all of the same principles apply. But --

MR. SMITH: But you're using a linear accelerator, though, right?

MEMBER FLYNN: Yes.

MR. SMITH: And there's a lot more QA that you have to do with a linear accelerator than a --

MEMBER FLYNN: Yes.

MR. SMITH: -- cobalt-60.

MEMBER QUILLIN: I have a comment on the paragraph at the top of page G-17. And since I serve on the ANSI nuclear standards boards, I have some

familiarity with their terminology and their issues. Both of these ANSI standards are no longer current standards.

MR. SMITH: Okay.

MEMBER QUILLIN: ANSI standards are published for five years and can be renewed for five years after that. They are no longer supported by ANSI. That's the first thing is that they're not valid anymore, so to speak. But the second item is that they are standards; they are not recommendations.

MR. SMITH: Okay. Oh, I see.

MEMBER QUILLIN: So if you're going -- and an NCRP report is a recommendation. It does include recommendations, but it's not considered a standard.

MR. SMITH: Okay. Would you change the last sentence to "standards or recommendations"? It says, "If the recommendations."

MEMBER QUILLIN: Yes.

MR. CAMPER: Bob, has ANSI done anything at all specific to gamma knife, or has ACR done anything specific to gamma knife?

MEMBER QUILLIN: ANSI has not done anything. As a matter of fact, just for your information, at the AAPM meeting in Boston, there was a suggestion brought forward to the AAPM Radiation Safety Committee that the AAPM encourage the development of standards. And this was not done from a totally scientific point of view, but as more of a job security point of view. But nobody other than the suggester wanted to work on this project, so there was no interest in developing standards. So the recommendation died, I would say, at that point.

MR. CAMPER: Interesting.

MEMBER FLYNN: ACR has standards in radiation oncology and for radiation -- radiation oncology physics and published in 1991/1992. And Judith is

working on standards for HDR and LDR. The standards for radiation oncology are being extensively reworked, in much more stringent standards right now as we speak, and being finalized. And I'll ask if there are standards being developed for stereotactic radiosurgery. It won't necessarily be just with a cobalt source; it will be for linear accelerator also. But it will be all encompassing --

MR. CAMPER: Yeah, I understand.

MEMBER FLYNN: -- for recommended procedures.

MEMBER QUILLIN: 11.23.3, periodic spotcheck measurements. 11.23.4, inspection and servicing of the GSR unit. 11.23.5, limitations on work done on GSR unit. Hearing no objections, we'll continue. 11.23.6, survey reports. 11.23.7, relocation of GSR unit. 11.23.8, recordkeeping.

MS. HOLAHAN: This gets at the point that I think you raised yesterday, is that either we need to have, as a separate index or within the body, something that lists specifically all of the required records, and they raised it yesterday and felt that either all of the modules should list specifically the required records, which you've done here, and perhaps reference the --

MR. SMITH: Regulation.

MS. HOLAHAN: -- regulation, but what we should probably do is compare it. There is a NUREG published that includes all of the recordkeeping requirements, and just make sure that we have an encompassing list, so that we don't have any gaps.

MEMBER QUILLIN: This is a recommendation that was made yesterday that we have a listing similar to this and just so it's done consistently.

MS. HOLAHAN: Right.

MEMBER QUILLIN: Okay.

MEMBER FLYNN: And there are no records for -- I see that there is records of training of new personnel and annual refresher training of personnel. That probably is meant -- is that meant to include records of emergency training and emergency training procedures? Emergency training for personnel, etcetera?

MS. HOLAHAN: Yes, that would be included in the training, in the records of that training. What does it -- the records of the training need to include what was covered in the training.

MEMBER FLYNN: But they could submit training that doesn't include emergency procedures, because they're not specifically asked to do so? This is training of personnel in how to perform their tasks for delivering the treatment.

MS. HOLAHAN: Right.

MEMBER FLYNN: Not necessarily safety training or emergency training.

MR. SMITH: I believe that the training requirements for individuals requires that they also be trained in the emergency requirements, although -- that money.

MS. HOLAHAN: I'm just trying to think. I know, again, going back to one of the other modules, there was a separate section on training and the emergency response.

MR. SMITH: 9.1.3, training for medical physics staff says, "The emergency procedures, to include drills for emergency extraction of patients from the unit," and we're going to change that to, "Personnel involved in the treatment of patients."

MS. HOLAHAN: Right.

MEMBER FLYNN: I know. But my point is with HDR, at least when I was working with Bob Ayres, and I didn't even know I was working with him because I was dealing with John Glenn and Cunningham, but saying that they should have -- they should provide records that this emergency training was done.

MS. HOLAHAN: Yeah. Well, the records of the worker training include the date and duration of training topics covered, name of the individuals providing training, and attendees, and that --

MEMBER FLYNN: Okay.

MS. HOLAHAN: -- that record has to be kept, and I think that's how, currently, even the remote afterloading module reads is the requirement for records needs to include what topics you address. So if we indicate that you need to provide the training, then that has to be included in the record.

MR. SMITH: Okay.

MS. HOLAHAN: But it's -- I mean, I think the 9.3 encompasses that.

MEMBER QUILLIN: Anything else on recordkeeping? If not, we'll go to 11.23.9, safety instructions.

MS. HOLAHAN: The only point I might make that we might want to consider is that this includes emergency instructions and procedures, and I think we may want to consider focusing on emergency procedures as a separate section to emphasize --

MEMBER QUILLIN: Right.

MS. HOLAHAN: -- what needs to be done for emergency procedures.

MR. CAMPER: That would be parallel to --

MS. HOLAHAN: Right.

MR. CAMPER: -- all of the others.

Okay. Let's see, I didn't have anything there.

MEMBER QUILLIN: On the bottom paragraph on page G-20, there is a reference to technologists. I wasn't sure --

MS. HOLAHAN: Therapists?

MEMBER FLYNN: Therapists.

MR. SMITH: Therapists, okay.

MEMBER QUILLIN: That was a current term. So we agree that we'll split this into emergency instructions and --

MS. HOLAHAN: Yes.

MEMBER QUILLIN: Okay. Waste disposal --

MS. BHALLA: Excuse me, before that. So leak tests would go as a separate --

MS. HOLAHAN: Yes, leak tests would come up as 11 -- was that in here? No. It would come in as 11.4, to be consistent with the other numbering.

MEMBER FLYNN: Can I just bring up one thing? It just occurred to me that -- and because I've never seen one of these specific units, I only can tell you about our linear accelerator. But you require that you may use an electronic monitor to observe the patient, or you may have a window and you have to specify the thickness of the material on the window. Do you also have the audio requirement?

Because what happens is the patient says, "I can't breathe," and you -- you know, they are lying very motionless there, and you don't see anything on the TV camera. But if they say, "I can't breathe," or, you know, "I have chest pain," or whatever, we have audio monitors in all of our teletherapy rooms, as do I think probably every one in the United States.

But are you saying that you don't require it for the GSR, though?

MS. HOLAHAN: Oh, no. The only --

MEMBER FLYNN: The patient can speak and make a noise. You know, we can hear them, and we can talk back to them. We can tell them it's only a couple more minutes. Hold -- you know, whatever.

MR. SMITH: Well, the viewing system is not really there, to my understanding, to protect the patient. They are there so that anyone entering the room will know the status of the sources. I mean, it came out of the teletherapy because they mostly had a mechanical indicator that would stick out when the source was still exposed.

If you could see the source out, you knew not to go into the room. Because one of the ways to get around this requirement is to have a radiation meter with you, so that when you go into the room following the completion of the treatment, you can assure that the sources are --

MEMBER FLYNN: If something is going wrong and the patient is the only one who is noticing it, it would be nice that they could vocalize that.

MS. HOLAHAN: Particularly since you don't see their head.

MEMBER FLYNN: Yeah.

MS. HOLAHAN: And their --

MEMBER FLYNN: Like, for example, something is going here. The temperature is up to 200 degrees, you know, or whatever, or something -- you know, I'm getting an electric shock or -- if something goes wrong with the device, it's nice that the person who is in there who is at risk can verbalize, "I'm having a problem. Something is going wrong here."

MS. HOLAHAN: The two units I've seen, there is a two-way communication, so not only can the patient be heard, but the patient can hear.

MEMBER FLYNN: That's what we do. But you're not required to.

MS. HOLAHAN: But I don't know. Now, in your viewing system, Jim, you did say that, "Describe the system you will use to view the patient continuously." So it makes it sound as if it is a patient monitoring, I mean, which --

MR. SMITH: The way that you can get around it is to have a radiation --

MR. CAMPER: It's picked up from 35.615.

MS. HOLAHAN: Okay.

MR. CAMPER: (6)(e), "A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient, or the human research subject, from the teletherapy unit console during a radiation." But it doesn't have a communication requirement.

MEMBER FLYNN: Yeah. I did tell you that in intraoperative radiation, have you heard about intraoperative radiation, where the patient is basically in -- on an anesthesia machine under general anesthesia, with life support systems. And we focus the TV monitor on the patient, the TV monitor on the rhythm strip that shows the heart is beating in the fashion that it should be, and a TV monitor on the bevels of the anesthesia machine to make sure that there is air going in the lungs and out of the lungs. And we are monitoring the patient because the patient can't verbalize, is not awake.

They are under life support, and so we are watching -- the anesthesiologist is physically present there. Very nervous because they're not at the patient's bedside watching the -- you know, the EKG rhythm of the heart, the

anesthesia machine, the oxygen saturation in the blood. All of these things can be monitored remotely, but this patient who is awake doesn't have all of that monitoring device but does have the ability to speak or to alert that there is some problem.

MS. HOLAHAN: Now, for remote afterloading, we do have viewing and intercom systems. So there is an intercom system that is required for --

MEMBER FLYNN: There should be two-way communication.

MS. HOLAHAN: -- remote afterloaders.

MEMBER FLYNN: There should be two-way communication.

MS. HOLAHAN: For HDRs at least.

MR. CAMPER: So why don't we change that? What is our basis for doing that on the RAL?

MS. HOLAHAN: We don't describe it.

MR. SMITH: Probably because they've had one or two sources pop out in the middle of a room and the patient is curious about whether that's -- there was at least one situation where the source fell out in the room --

MS. HOLAHAN: That's true.

MR. SMITH: -- and the patient wondered what this little wire was hanging off the end of the --

MS. HOLAHAN: But I think the basis could be that you cannot see the patient's head, and so it's the patient's only way of communicating with the authorized user.

MEMBER QUILLIN: It's just good medical practice.

MS. HOLAHAN: Pardon me?

MEMBER QUILLIN: It's just good medical practice that you be able to communicate with the patient.

MEMBER FLYNN: Do you need a regulatory reason? That -- just say that -- so the patient may alert in case there is a problem develops -- a problem develops with the treatment device.

MS. HOLAHAN: Medical problem or something like that.

MEMBER FLYNN: Not a medical problem.

MS. HOLAHAN: Oh, okay.

MEMBER FLYNN: You can always get around it by saying a problem --

MS. HOLAHAN: Right.

MEMBER FLYNN: -- has developed with the treatment device.

MR. CAMPER: So we would call it viewing and intercom.

MS. HOLAHAN: That's on page G-9. Does that sound reasonable, Jim?

MR. SMITH: It sounds good to me.

MR. CAMPER: Pick up some words similar to what we did in the RAL.

MS. HOLAHAN: Two-way communication.

MEMBER QUILLIN: I'd like to just comment on your comment about the reason you have the viewing system is to see whether the rod is out. I can assure you that wasn't the reason that we had a viewing system. We had a viewing system because every once in a while, in our teletherapy unit, the table would start floating away.

MR. SMITH: Oh, really?

MEMBER QUILLIN: Or the patient would decide to get up and leave the room is another reason, and you wanted to be able to turn the unit off as soon as the patient decided to get up and leave the room.

MR. SMITH: Oh, okay.

MEMBER FLYNN: But teletherapy really is because if the patient sneezes or coughs, or the patient is not completely oriented, they have a brain tumor, and they start to -- even though you tell them, "Don't move," after about a minute or two they've forgotten that you told them that and they start to move, and you can shut the beam off, go in, position them, and then go back out and turn the beam on again.

And that happens, believe me, every day in the United States. It happens 100 times a day, maybe 1,000 times a day, right now, and that is for teletherapy, both at linear accelerator or cobalt. And basically, if the patient moves, you shut the beam off, you go in and say, "Remember, don't move now," and then you check the tattoo alignments for the lasers, and you say, "Okay. You're almost over. You're halfway done," go back out and turn the beam back on again.

MR. SMITH: That's right.

MEMBER FLYNN: Happens every day, many times.

MEMBER QUILLIN: Waste disposal?

MR. CAMPER: Waste disposal.

MS. HOLAHAN: Jim, for your information, there was a concern raised in the last two discussions that returning sources is not really waste disposal, but we're still going to continue to address it here because of the way that the Form 313 is written. But actually, I think that first paragraph may well be suited in the other two modules, as well, because I think that really provides some basis. So --

MR. CAMPER: I would agree, yeah.

MS. HOLAHAN: -- I think that can be inserted into the manual and remote afterloading, and possibly the others.

MR. CAMPER: Possibly. Good point.

MEMBER QUILLIN: The only thing I'd comment on is adding the reference to 49 CFR.

MS. HOLAHAN: Oh, okay.

MR. SMITH: I think that comes under, what is it, Part 71 or 72?

MEMBER QUILLIN: Yeah, Part 71 refers to it, but I think you ought to refer to it very directly.

MS. HOLAHAN: We also have the specific listings on the other modules that we may want to just, again, bring those in here to make all of them consistent.

MEMBER QUILLIN: Okay. We're down to glossary. Any additional words you wanted to put in the glossary or want to discuss on the glossary?

MEMBER FLYNN: When this will go out for public comment later on, and, therefore, the people who use these specific machines on a day-to-day basis, since none of us do on the ACMUI, then if there's anything that they would note because they use it every day, they will bring it to your attention, I'm sure.

MR. CAMPER: We hope so.

MEMBER QUILLIN: Are you going to send these to the licensees and agreement states, or are you going to expect the agreement states to do it?

MS. HOLAHAN: Well, when we provide the documents for public comment, we generally provide it to the Office of State Programs to forward to the agreement states.

MEMBER QUILLIN: Most of these are in agreement states, so there is --

MS. HOLAHAN: Yeah, I believe there's only five of them in --

MEMBER QUILLIN: We'll comment on it, but the agreement states have to be stimulated to make sure this document gets out.

MR. SMITH: And we'll also have to make sure that it gets to the manufacturer, or that it's actually distributed, because they're also located in an agreement state.

MEMBER QUILLIN: Right.

MS. BHALLA: On this -- on the glossary, for the GSR physicist, perhaps it should include "on our Commission or an agreement state license."

MR. CAMPER: Well, we have to be careful. There is a policy question there.

MS. HOLAHAN: Because we don't know if they're listed on an agreement state license, and there's a policy question which came up the other day as to whether or not we recognize the physicist on an agreement state license.

MR. CAMPER: Let me explain for your benefit, since you weren't here. We -- certainly, it would be preferable that it would be what you just said, NRC or agreement state license.

MS. HOLAHAN: Right.

MR. CAMPER: The problem that we have is -- there are two problems. One, in Part 35, today we don't have anything identified as a medical physicist or a GSR physicist. Okay? But we do have teletherapy, but it doesn't say that either.

MS. HOLAHAN: Oh, doesn't it?

MR. CAMPER: No, it doesn't.

MS. HOLAHAN: Because I was just looking at page G-3. We talk about an agreement state as we talk about --

MR. CAMPER: But the problem is if I go to the closest thing I have, which is the teletherapy physicist, it says, "Means the individual identified as the teletherapy physicist on a commission license." That's all it says.

Now, if by contrast I go to an authorized user, and really what should happen is the language should ultimately be fixed to embody all of these, an authorized user means a physician who is board certified, or, number 2, identified as an AU on a commission or agreement state license that authorizes the medical use of by-product material." You really need similar wording to that for the teletherapy physicist, and we need to identify specifically a category -- a medical physicist or brachytherapy physicist, or whatever -- and have similar words, so that you don't have a policy call. But we need to explore that a bit.

But our preference would be to do what you're suggesting. We just have to get that resolved.

MEMBER FLYNN: Do you keep track of how many devices there are in the United States? I mean, there is only -- how many manufacturers or vendors are there? A couple? Two?

MEMBER QUILLIN: One.

MEMBER FLYNN: One? Do they give you the -- do we know what their users' list looks like? I'm sure they share it with anyone who asks for it.

MR. CAMPER: Well, Jim, what we know -- we -- how many are there? We went through this a little while back.

MR. SMITH: I don't remember the specific number. I believe there were about nine in the country, but I don't know the specific number.

MEMBER FLYNN: Is there any way that the nine who have this machine, either as members of the general public or however, because they're in agreement states, can at least comment on these documents?

MS. HOLAHAN: There's 21 units.

MEMBER FLYNN: 21 units?

MR. CAMPER: Yeah, I think there was --

MS. HOLAHAN: 21.

MR. CAMPER: Yeah, the last I heard was 21, and I think it was -- it's going to 25, projected, by the end of calendar year '95, I think. Wasn't it?

MS. HOLAHAN: Yeah, I think so.

MR. CAMPER: So your population is on the order of 20 to 25.

MEMBER FLYNN: It would be nice if the manufacturer and the 21 users could comment on the document, at least on an informal basis. It might be very helpful. Is there a way that can be done? Can they be considered members of the general public but get a special --

MR. CAMPER: Well, what we could do is when we -- one thing we could do is when it's published for public comment, we can make it a point to see to it that it specifically is provided to those entities.

MEMBER FLYNN: Right.

MEMBER QUILLIN: I'd recommend that to make sure that it gets wide circulation.

MR. CAMPER: Yeah, given the small population.

MEMBER FLYNN: And feedback.

MS. HOLAHAN: Right.

MR. SMITH: I believe we have a list of them, though, because when they did --

MS. HOLAHAN: Yes.

MR. SMITH: -- the survey, Lawrence Livermore survey, they actually went out to a number of these sites. Now, that might not include people who have received the device since 1993, because I think that's when they collected data for that.

MS. HOLAHAN: Yeah. But we got the list of users after that valve failure incident.

MR. SMITH: Oh, you did?

MS. HOLAHAN: And that's why I have the --

MR. SMITH: Oh, okay.

MS. HOLAHAN: -- relatively current --

MEMBER FLYNN: I can get a complete, up-to-date list of users as of today by simply picking up the phone and saying, "I'm interesting in buying a gamma knife, but can you tell me who is using it so I can check to see how it" --

(Laughter.)

And they will supply on a fax machine the list of users and their phone numbers.

MS. HOLAHAN: Yes.

MEMBER FLYNN: And if it's open information, they're not trying to keep it a secret anyway.

MR. CAMPER: We can make a point and see to it that copies are provided to them.

MS. HOLAHAN: Yeah, because I think when we did the information notice, we wanted to make sure that all of the users got the information notice.

MR. CAMPER: All right. May I suggest that we take a break? Bob Quillin has to depart, and then we probably, during our break, should decide how we want to proceed. It's 10 minutes until 3:00. We have, conceivably, a couple of hours. I don't know what your schedule is like, Dr. Flynn.

MEMBER FLYNN: I'm open. You mean I will have a chance to be chairman of the subcommittee of one?

MR. CAMPER: Yes, you will.

Okay. We're going off record for a break.

(Whereupon, the proceedings were off the record from 2:51 p.m. until 3:18 p.m.)

MR. CAMPER: All right. We're back on record.

At this point, Dr. Flynn is the only remaining member of the subcommittee present, so he will chair the remaining time. And what we're going to try to talk about, hopefully for maybe the next 45 minutes, to an hour at most, would be the teletherapy module. So with that in mind, Dr. Flynn, how would you like to proceed?

MEMBER FLYNN: Maybe I can give a little bit of background and then ask for comments.

I recently went through all of the abnormal occurrence reports and every incident report that I could find regarding teletherapy with cobalt, and tried to find common patterns. And I'm sure that in the NRC the same sort of exercise was done.

But I did so because I was giving a talk at a national meeting for all of the therapists who -- The Therapist Society. And I was able to, at least in my mind, feel comfortable in categorizing misadministrations and incidents in six different categories.

Number one was the wrong patient, and the wrong patient I had with teletherapy six occasions, actually several at one institution over a period of some time.

The second was the wrong site, which was much more common -- you know, right hip instead of the left hip. You know, right side of the neck instead of the left side of the neck. Mixing up right and left, basically. So that was the most common wrong site, in terms of teletherapy, in terms of delivering treatment.

Dosimetry error was also fairly common -- a dosimetry error that wasn't picked up.

The fourth, and the most concerning to me, was a prescription change that wasn't communicated, because in the standard radiation oncology charts, there is typically a prescription page where the authorized user writes the written directive, which we call a prescription. And the authorized user may change the prescription.

However, the therapist, if they are very busy, when they're setting up the patient on a day-by-day basis, they may be giving the patient Mrs. Smith her 22nd out of 30 treatments. They know Mrs. Smith very well by this time. They know her setup very well by this time. So in a very busy department, they immediately will call in Mrs. Smith, identify her visually, set her up, and immediately go to the treatment page, not bothering to check the prescription page, because the prescription, they assume, has never changed.

Occasionally, the physician has changed the prescription, such as "Stop treatment after the 20th treatment," or "increase the dose to 300 centigray or rads, instead of 200," or "decrease the dose from 300 to 200" -- some prescription change -- but the therapists who already have the timer calculations precalculated for them by the physicist go on and deliver the treatment as have they been doing day after

day, week after week, without realizing a prescription change. So that was the fourth common cause for a misadministration.

A fifth cause just had to do with setup, whether a wedge, a beam wedge was in when it shouldn't be, or the beam wedge was out when it shouldn't be. Some device was left out of the setup for the patient.

The sixth type of error was very concerning to me, because it actually led to the most serious problems. The other five are serious enough as they are, but the sixth one is the type of error which could potentially cause, with a reasonable frequency, some level of harm to the patient. And I call this a double-up error, and the double-up error was of two kinds.

First of all, for example, in whole brain treatments, when one is setting up the patient to deliver the treatment, one will take a separation. So actually put calipers on the patient's skull and take a separation, so many centimeters, 12 centimeters. So when you are giving treatment to the whole brain, you give treatment from the right lateral brain and the left lateral brain, so the prescription is such that a patient might receive, for example, 300 rads to mid-plane brain.

Well, the separation errors occur when there's a miscommunication by the therapist, who is usually the one doing the separation, and the dosimetrist or physicist, who is usually the one doing the calculation, where the physicist has prescribed, or the dosimetrist, the dose to 12 centimeters deep rather than 12 centimeters deep divided by two, or six centimeters.

And this occurred on a number of misadministrations in recent years in the State of Indiana, the State of Ohio. One case where the patient was, therefore, being given much higher doses per day than intended, because the dose was being

prescribed -- was being calculated at 12 centimeters' depth rather than six centimeters' depth.

One of the other prescription double-up errors is a totally different kind. It's in the prescription style, and I'll give you an example. And this doesn't occur too often. But if it does occur, it creates a real problem.

A prescription is written such that a patient with, let's say, brain metastases again gets 300 rads per day for 10 treatments, right and left lateral brain. Well, there have been cases where, using that as an example, the technologist has interpreted that to mean 300 rads from the right and 300 rads from the left, and got a double dose to the brain.

Now, this occurred in one of the misadministrations that I also investigated, and that patient -- that wasn't picked up until late in the treatment, and the patient got severe skin burns, which -- and hair loss and irritation and weeping of the skin between the ears that caused them to think that the patient was just having an exaggerated reaction to a normal dose of radiation. So then they decreased the dose. I believe the dose was decreased to 200 rads per day.

But instead of giving 100 from the right and 100 from the left, they gave 200 from the right and 200 from the left, and then it was finally picked up by a physicist who had been away, and the checks -- the chart checks weren't being done quite as frequently because of the physician being on vacation and others doing the checks on behalf of the physicist. So that's the kind of double-up error that I have seen.

I had asked the technologist, and I asked them why when they saw that the timer setting on the cobalt machine was so high -- I mean, after all, they are treating many patients on the cobalt machine. A typical timer setting for their given

machine might have been one minute, a minute and a half, two minutes, a minute and a half, a minute and a quarter, a minute and three-quarters, two minutes.

If you're doing that all day long, day after day, week after week, month after month, when you suddenly get a timer setting that is written down as four minutes, like I said, there should be some trip wire, some level of action that should cause you to at least question the prescription. Was the calculation done right? Was the prescription interpreted appropriately?

And so when I lecture to the therapists, I encourage them, as being professionals, that they have to be the quarterback. They're on the teletherapy machine. They have to bring up questions and concerns to the authorized user, to the physicist, to the dosimetrist, if anything seems that there could be any possibility that there could be a problem with overdosing, because overdosing is the problem. Underdosing is not the problem. Underdosing you can make up. Overdosing you can't take back, if the dose fraction is too high and you've been giving it for too many days in a row.

So I encourage them to, depending on what the output is of their cobalt machine, if their cobalt machine -- or they just had a source change and the output is quite substantial, then the treatment timer settings will be quite short for that given machine. It will take several years for that source to decay and for the timer settings to be longer in terms of how many minutes and seconds.

If they have a very weak source, then the timer settings tend to be longer, but they're longer for all of the patients, every day for months and months and for years. So I encourage them to set some kind of a trip wire that will cause them to take an action, so that if the timer setting that they're getting on their prescription page

seems longer than some level which is out of the range of their typical timer settings for that facility, that they should question immediately both the physician and the physicist.

So this teletherapy module doesn't really -- because what I'm talking about is more the quality management program, but this teletherapy model really doesn't address that. Those sorts of issues -- I think that personally that somehow the trip wire -- I call it the trip wire concept.

I'm the only one who uses that term. But that somehow that the therapists should question any timer settings which seem to be unusually long in terms of the timer settings that they typically use day by day, or if the dose prescription seems to be unusually large, just to doublecheck to make sure that that is what is really intended, that it's not a matter of misreading some handwriting.

Going through this document, though, that being a background, on page 2, teletherapy physicist, does everyone know today what AEC stands for? Because as years and years go by, it is not explained in the glossary, is it, Atomic Energy Commission? But that would be one I would say that -- to at least let some people know, in case there are therapists or new physicians. New physicians coming out of training don't know what it means.

The other point is on -- since you want to ask me to focus on my concerns first, 10.6, the viewing system on page 4 and page 5. I would also add two-way communications.

Now, intercom may be -- intercom is a type of two-way communications. It may be that they have open microphones instead of intercom per se. The patient, to talk, doesn't have to press a button. There's an open microphone on them, basically, so any noise the patient makes gets picked up. The patient doesn't have to press a button to speak. It has a two-way microphone.

MR. CAMPER: I think that's an excellent point. You know, this is the same point we just went through as we discussed the previous session, but I think that that's an excellent suggestion.

MEMBER FLYNN: The only other point I had was on page 9, part G, is again the units, where millirems and millisieverts. Just going through it, just a few concerns I have, and then I'll turn it back.

MR. CAMPER: Okay.

MEMBER FLYNN: On page 16, paragraph 11, the last sentence, I did see the reference here to, "Note that the NRC agrees with Section 5.3.5 of NCRP Report 102," and then -- and that "maximum exposure rate providing that the average over 100 square centers at one meter from the source does not exceed 10 milliroentgens per hour." So the 10 milliroentgens per hour is there.

And then, on page 18, paragraph 17, it says, "for each measured radiation level reported in paragraphs 15 or 16 of the survey report that exceeds two milliroentgens per hour," so there's where the two milliroentgens per hour, I guess comes in. But I don't know if it was meant to be paragraph 11, paragraph 17, whether, you know, they should be tied in closer. I mean, I --

MR. SMITH: I agree with you.

MEMBER FLYNN: Right.

MR. CAMPER: Okay. So you're saying a link back to the two previous.

MEMBER FLYNN: Yes.

MR. CAMPER: Okay.

MEMBER FLYNN: And then, on page 21, at the top of the page, the second paragraph, I guess you'd have to check to whether those ANSI documents still apply.

MR. SMITH: I would imagine that since they did when we were looking at them with gamma knife --

MEMBER FLYNN: It's just that -- you know, look at that. And those are all of my comments. I mean, I think there should be some way in here where the -- on the teletherapy unit, the therapist is running the machine, not the physicist and not the physician. It's not like brachytherapy. It's the teletherapy therapist -- the therapist, who is running the machine and setting the timer settings.

So I know of no center in the United States -- I don't know of a single center in the United States where either the authorized user or the physicist is putting -- is actually delivering the treatment, although they can, but I don't know of any place where that is being done. So I think that the therapist is the key person, and I don't know if -- it's really part of the quality management program.

But in terms of teletherapy module, I don't know if it is appropriate if a section under teletherapy -- if that section under therapist, whereby the therapist -- and bring in some of the language of the quality management program, whether the therapist should check with the authorized user and physicist for any questions regarding the written directive.

And, in addition, the therapist set action levels appropriate for that cobalt machine, such that either written directives in terms of doses are physicist calculations, in terms of timer settings, exceeds what normally is being delivered on a day-by-day basis for that specific unit. And if you do that, then you eliminate some of

the misadministrations that will occur in the future. I just don't know whether this is the place to do it, or the quality management program.

But if it's part of this, it's part of the training of the -- training expected of the therapist when you site visit licensees, it will certainly help cut down the misadministrations. That's all I had.

MR. CAMPER: Okay. I had a couple of questions for you. One was looking through the glossary, did you have any problems with the glossary? Although as I look at those terms at this moment in time, I don't see a lot of them that are truly medically oriented, but I wanted to make sure that those terms, you found them to be acceptable.

MEMBER FLYNN: We always use the term "beam stop." I never used the word "beam catcher." But that might be something that comes from some -- I never saw that term before, beam catcher. But beam stop is used both for, you know, cobalt and for -- I mean, we've used the term beam stop kind of loosely, I guess, in linear accelerators also, if there's a beam stop.

MR. SMITH: Well, in the way that it's used here, it's not really like a beam catcher. These are electrical/mechanical --

MEMBER FLYNN: Oh, I see.

MR. SMITH: -- mechanisms that keep the head from rotating in a certain orientation.

MEMBER FLYNN: Oh, okay. All right. Okay. We use it loosely, but these are fine. I mean, I don't see any problem with this.

MR. CAMPER: Okay.

MEMBER FLYNN: I don't know how many licensees use cesium-137 in their teletherapy units, but it's probably a very, very small number of licensees.

MR. CAMPER: Yeah, that's cobalt-60.

MEMBER FLYNN: For medical use?

MR. CAMPER: No, no. I'm saying it's cobalt-60.

MEMBER FLYNN: Cobalt-60, yeah.

MR. SMITH: I think that the regulations still allow for it, though.

MR. CAMPER: They do. You're right, they do.

MEMBER FLYNN: The cesium irradiators are used for animal work for sure.

Okay. Barrier, up at the top, the definition of barrier, let me ask you. Shielding of the interior of the teletherapy treatment unit used to attenuate the primary beam, and it's not just a primary beam, is it? We can call it the secondary beam or the scatter, too.

MR. CAMPER: Yeah, that's correct, because in many cases, the beam stop is the actual attenuator of the primary beam. There were some systems -- I don't know if they're still around anymore -- that used to not have a beam stop. Remember that?

MEMBER FLYNN: Right. There are systems without a beam stop.

MR. CAMPER: But the beam stop is the primary attenuator of the primary beam, and the walls are, in the case of beam stop presence, are designed for the secondary and scatter. Yeah.

MEMBER FLYNN: Okay.

MR. CAMPER: The other question I had for you, and it was to try to get some sense of -- now, this guidance document was published in 1985 for comment. And when we decided to update this one, the feeling was that, look, it has been around a long time, we ought to rework it, clean it up, modernize it, and so forth.

And in doing that, I would like to get some impression from you, Dr. Flynn, as to whether or not -- what is the help of teletherapy?

I mean, people say teletherapy is on its way out. Sometimes I read articles that say teletherapy might still be hanging on and sort of catching a last breath. I mean, what is your opinion on --

MEMBER FLYNN: No, it's on the way out and it's on the way out very quickly. I surveyed -- I was on the planning board for the State of Massachusetts, so I surveyed all of the megavoltage machines in Massachusetts, and there was 50-some-odd machines, and there were eight cobalt machines. And of the eight cobalt machines, several had been taken out of use in that year, and several more were being planned to be taken out of use. And a couple of machines that I thought existed even no longer existed.

The room was locked. It wasn't being used at that point in time, because it was being changed -- the facility was changing to use a linear accelerator. In some cases, the facility might say to the State of Massachusetts that we realize there's a certificate of need requirement. We have to get approval by the State of Massachusetts before we can purchase a linear accelerator, megavoltage machine of any kind, cobalt also. That in case the megavoltage machine breaks down, some facilities have liked the fact that they could have a cobalt machine over here that they could use to treat the patients while the linear accelerator is being repaired.

MR. CAMPER: Right.

MEMBER FLYNN: Especially in a facility with one machine that is not located near any other facility, like in Western Massachusetts.

Now, sometimes they have not made that request, they have just taken the cobalt machine out. This one hospital in Eastern Massachusetts, which has

the cobalt machine, but, again, they're not using it unless the other machine -- the accelerator is not functional. And I think they apply to the State of Massachusetts on a case-by-case basis to get approval.

But basically, the cobalt sources are expensive and getting more expensive. The linear accelerators, especially the used ones, are getting cheaper, especially the low energy ones that are refitted. And it is to the point whereby with -- additionally, with the NRC license fees, that it, quite frankly, becomes economically better in some cases to just get a used linear accelerator, which is refitted and use that, because then you don't have to worry about the regulatory concerns, but primarily about the economic concerns, changing the source and getting license fees.

So I think there has been a movement towards the linear accelerator, which these low energy accelerators are very reliable now. I mean, they are very reliable. There is very little down time, whereby the machine is not in operation. The high energy machines are more complex, and they usually have more down time where the machine is not in operation for a day while engineers replace some major part. But the low energy accelerators have very little down time now, so their reliability has been proven. They deliver a much sharper beam. There is less penumbra than the cobalt machine.

So I think the American College of Radiology has been doing what they call patterns of care studies where they actually -- it's excellent data, by the way. They survey all of the facilities in the United States every four years. They actually count how many megavoltage machines there are, how many of those are accelerators, how many of those are cobalt machines, how many physicians there are delivering the therapy, how many new patients per year are irradiated, and these are not estimates. They contact all 1,500 facilities.

When they don't get a response, they send out another questionnaire. When they don't get a response, then they start the phone calls. They actually get 100 percent of the data.

They are just finishing right now -- I just talked to -- for another reason, I just talked to the statistician for the ACR in Philadelphia, Dr. Jean Owen, and she tells me she has 99 percent of the responses now, plus 99 percent, for the survey that occurred in -- for treatments that occurred in 1993. This is a 1994 patterns of care study, which is -- they don't start the study until January of '94, so they can count all of the patients treated in the calendar year of 1993. So it has taken them a year and a half, a year and three-quarters, to gather all of the data.

But the cobalt machines are going down very significantly where the linear accelerators are going up very significantly, and I'm guessing right now today, in terms of the United States, there is probably -- as far as taking the agreement states and the non-agreement states, there is probably -- being realistic, there are probably 400 machines in operation, and half of those machines are only being -- are only partially utilized.

So probably, I'm guessing, 200 machines or fewer in full-time operation, and 200 machines in part-time operation, as opposed to 10 years ago when you may have had 1,000 machines in full-time operation. Something like close to 1,000.

MR. CAMPER: So that would argue, then, that in -- certainly, in 10 years, if not five years --

MEMBER FLYNN: Well, in Massachusetts, all --

MR. CAMPER: -- they will be gone.

MEMBER FLYNN: -- all -- in Massachusetts, of the eight machines, only two facilities said, "The machine is in full-time operation, and we have no plans at the present time to replace it." Both of those machines are over 20 years old, and I predict by the year 2000 both of those machines will be gone. As they get older, the more problems -- some -- not many problems, but as they get older and they get older, different things can happen.

I guess there was one situation with some machines, not all of them, but some machines had a problem with the cracking in the head. And as they get older and as linear accelerators get cheaper, and as cobalt sources get more expensive, I think you'll see them replaced.

MR. CAMPER: Well, I'm thinking in terms of the utility of the guide. In other words, we probably have another three, four, or five years of utility for this guidance document. I don't anticipate we would see any new applications, although we might see a veterinary application, or something.

MR. SMITH: Well, those would be coming in under Part 36.

MR. CAMPER: Right.

MR. SMITH: They wouldn't be considered medical use.

MR. CAMPER: Well, that's true.

MEMBER FLYNN: If you asked me how many machines --

MR. CAMPER: No, I understand that. But many of the same kinds of criteria would apply.

MEMBER FLYNN: If you asked me how many machines will be in operation in the year 2000, I would say my best estimate is 200 machines, as opposed to linear accelerators, 2,500 to 3,000 machines. Compared to 20 years ago, where there were more cobalt machines than linear accelerators.

Imagine, less than 20 years ago, there were more cobalt machines that linear accelerators. Now we're going to have 2,500 linear accelerators and 200 cobalt machines, more than a 10 to 1 ratio. So that's a pretty significant change.

MR. CAMPER: All right. I appreciate it. That kind of sums it up nicely.

Jim, the changes that were made in the guidance document. Can you summarize those? And, again, the idea being that this guidance document has been around for --

MR. SMITH: It's been around since 1985 --

MR. CAMPER: -- 10 years.

MR. SMITH: -- in a draft state. It was never issued in final. When I did the revision to it, it was mainly to update the references to Part 20, the new Part 20, and to take out some of the requirements that had been written in as far as a Reg. Guide that didn't exist at the time this was written in the regulations. We have had -- Part 35 was also revised since this was put out, and at that time, there were a lot of conditions that we put on licensees, because there was no regulatory requirement at that time. We did it through the Reg. Guide.

There are some things in here that were taken out because they are now currently required in the regulations. I mean, there is a reference to it, but we don't have to get as specific as we did in the previous version.

MR. CAMPER: Okay. Is there anything in particular that you wanted to bring up, Jim, or Neelan, for that matter, that when you were doing the work on this?

MS. BHALLA: Yeah. Well, I agree with Dr. Flynn here that I think in all of our Regulatory Guide 10.8, the original one, there was no mention of quality management programs, because at that time, in 1980 -- QMP really came about in

January of 1992, we asked the licensees to submit QM plans. And, therefore, the original guide, the 10.8, even Rev. 1, has absolutely no place, there is no reference to QM plans, because it wasn't required at that time.

Now that we do have -- it's part of regulation 35.32, and I think it should be addressed in the front somewhere. And also, as we go along for each of the modules, and especially things like even for the gamma knife we don't address it, it's just so crucial that we address the quality assurance, the quality management, that the proper dose delivery is done in accordance to what the intended dose is.

And for the same token, teletherapy -- I agree, we should make -- place some very definitely quality management, and in that incorporate the QA and the dose delivery as such, and so that these errors can be minimized, the ones that Dr. --

MEMBER FLYNN: I looked at all of the errors and saw them. These weren't solitary incidents. These were five and 10 and 20 incidents that were the same thing.

MS. BHALLA: Yeah, they're trends.

MEMBER FLYNN: I think, you know -- and it makes common sense that, you know, that if you're a therapist at a machine, and you're using timer settings over a period of a month, and the timer has never been less than one minute, and it has never been more than two minutes, that at some point in time if you get a timer setting that is excessive, you're going to question it.

But instead of leaving it up to someone to think, gee, this timer setting says 30 minutes, I've never treated someone more than two minutes in my lifetime on this machine, and they say, "Well, there's a decimal -- we are giving a big dose, but it's only a three-minute treatment. There's a decimal point that you didn't see, 3.0." That's just common sense. I'm just giving you a radical example.

So I think that the trip wire concept is -- would prevent a number of misadministrations that are going to occur in the future.

MR. CAMPER: Let me make sure I understand the point here, and, Jim, perhaps you can help me out a little bit here.

Clearly, the existing version of 10.8, which was Rev. 2, 1987, does not include anything about quality management because, you're right, it became effective in January of '92. Now, these modules are being -- have been created specific to a particular modality, and the idea being that those things that are general to the program, any number of types of programs, are contained within the primary body of Reg. Guide 10.8.

MR. SMITH: That's correct.

MR. CAMPER: Now, what have we done, if anything, in the primary body of Reg. Guide 10.8, as part of this effort, to bring to bear the QM rule?

Now, I don't think we've done anything --

MR. SMITH: We haven't.

MR. CAMPER: -- and I observe that we're not saying anything in these modules specific to the quality management program requirements in any of these modules. And then the other thing is is that we do have a Reg. Guide 8.33 that deals with quality management at large across the board for all modalities affected, and that was published at the same time the rule was published.

So I suspect, then, that in the final analysis the quality management area has not been addressed under this initiative at all. Is that pretty much --

MR. SMITH: That's correct.

MS. TAYLOR: Well, my understanding is it was going to be included in the body of 10.8. We made reference to it in the mobile guide and refer them to the

Reg. Guides. But I thought it was going to be included in the body, because there were so many that it applied to. But, I mean, that may have changed and I wasn't aware of the change.

MR. CAMPER: Well, I think what that -- I'll tell you what I think that comes down to, then. I think it comes down to another issue similar to what Trish was raising shortly before -- after the other session broke, and that is she was bringing to my attention that we really ought to stop and look at the existing appendices and Reg. Guide 10.8, which are not undergoing adjustment as part of this initiative.

And, again, bear in mind and remember that this initiative was sort of a stop-gap measure, recognizing that ultimately Reg. Guide 10.8 would be revised in toto, to coincide with the major revision to Part 35, which will occur over the next three or four years.

So we didn't adjust the appendices primarily for that reason. But I think we need to go back and take a good look, as part of this initiative, at those appendices. Are we comfortable -- because in some cases we're referencing those appendices in these modules. And are those appendices up to date? I mean, are they capturing the new Part 20, for example? Are they up to date? Are there any glaring problems?

And, secondly, take a look at the QM, whether or not the QM should be embodied in any adjustments to the primary part of 10.8 at this time.

MEMBER FLYNN: I wrote the response to -- I was the one from my institution, Mass. General Hospital, and also at the time I was at BU Medical Center, where I was the Acting Director since we were professionally running the Boston University Medical Center, and two satellite hospitals which both had cobalt machines,

Mount Auburn Hospital in Cambridge and Waltham Hospital in Waltham, Massachusetts.

And so I was the one, with my department physicist and the QA physician, with the chairman, I was the one who wrote the response in terms of the QM program, which was polished and revised upward. But this concept of trip wire effect wasn't part of the QM program. It was something -- it wasn't specifically a part of the QM requirements. It was something that, because I felt it was important, we added in. It's in there, that the therapist question -- specifically are required to question if a dose exceeds a certain level, just to make sure that that was what the intention is, rather than blindly administer something which is out of the ordinary.

So if you're thinking in terms of this being part of the QM program, it wasn't specifically. It's just something that I have noted by seeing misadministrations, some misadministrations.

MR. CAMPER: Well, again, at some point, I don't know what the history -- excuse me, I don't know what the future is of the quality management rule. When we get into revising Part 35, will it survive? Will it survive in its present form? Will it be modified? Will it be enhanced? It's impossible to predict at this moment in time. But as we go through a revision of Part 35, in the public process, public meetings, etcetera, etcetera, meetings of the professional organizations, we will clearly be revisiting the QM rule.

It has been a rule of some controversy. It seems like those who hate it, truly hate it, and those who think it's a good idea, feel pretty strongly. So it will be interesting to see that debate play itself out over the next three or four years. As part of that process, we'll figure out what is right with it and what's wrong with it and what needs to be changed, and so forth.

But I think for purposes of the immediate drill, and Trish Holahan just walked back in, I think for purposes of the immediate drills, we -- similar to what you were talking about on the appendices, we would need to take a look at what we are or are not saying about the quality management program in these modules and/or in the adjustment to the primary body of 10.8, so that someone today, because it is a requirement today, can pick up this module and either be steered to it or have it discussed in the module.

MS. HOLAHAN: Okay, and I can just sort of say there was some discussion that we were going to address some of the QM issues that had arisen, perhaps in the body. But I think the question, and we can explore this further, is that Reg. Guide 8.33 is out there, and whether or not we would want to update Reg. Guide 8.33 at this point, or what we do with the modules. So you're right. It is a question that we need to explore.

MEMBER FLYNN: Even without referral to the quality management program in 8.33, actually what happens out there in the field is that the physicist and one of the physicians in charge of quality assurance put together the response to the requirement for the QM program, and sometimes the therapists -- those are the people who are flying the plane, so to speak -- aren't as heavily involved as they should be.

So even whether you -- my point before you walked in was that regardless of whether you referred it -- the quality management program or not, since you've cited, you know, teletherapy physicist on page 2, paragraph 8.7, whether it's reasonable in a module such as this to cite the therapist, and that one main way to cut down on misadministrations is that the therapist -- I guess the verb would be "should" notify the medical physicist and authorized user if either the dose setting -- the dose or the timer setting seems excessive or unusual, seems unusual for the particular

machine in normal daily operation, and that all questions -- any questions must be addressed prior to treatment -- prior to administering the treatment.

MS. HOLAHAN: I think that's a good point, and I think we should look at it not just in this module but perhaps in all of the modules, as to when questions with regards to a treatment that are specific maybe should be raised with the authorized user.

MEMBER FLYNN: Specifically in teletherapy, that, as I say, the therapist is the person who is flying the plane.

MS. HOLAHAN: Right.

MEMBER FLYNN: Not in brachytherapy, and not in stereotactic radiosurgery. It's generally the -- in general, in brachytherapy, it's the physician and physicist that are interacting. And in stereotactic radiosurgery, it's the physician -- the physicians, the physicist, and the therapist. But in teletherapy, the therapist is flying the plane alone.

There is nobody in the cockpit with the therapist. I mean, that's -- they are really on the machine, and they are seeing things and making judgments based on the physician and the physicist are close by, but they're not there specifically at the console as they would be for HDR treatment.

MS. HOLAHAN: Yeah, that's correct. And I think, too, as we have seen in -- even with manual brachytherapy, that some of the incidents that we have seen have occurred when the authorized user hasn't been around to address -- you know, and questions haven't been raised that perhaps could have been.

MEMBER FLYNN: Right. That's all I have.

MR. CAMPER: Okay. Jim, did you have any other observations or comments on this?

MR. SMITH: No, I think I've -- well, the only thing that has really been changed about this is that formerly this included a section on non-human use. But currently, non-human use is covered under Part 36, and there's a separate Reg. Guide to be addressed by the licensee, so non-human use has been --

MR. CAMPER: That's a good point.

MR. SMITH: -- taken out.

MEMBER FLYNN: I should say the term I was trying to think of for the therapist inquiring, the therapist should set action levels based on their own machine output and their own typical daily use, as to which doses or which timer settings should be questioned, should be doublechecked with the medical physicist or authorized user. I think action levels was the term I was trying to think of, and I couldn't think of it, but --

MS. HOLAHAN: That's a good point.

MEMBER FLYNN: And for different machines and different licensees, there would be different action levels, because I was giving the example before you walked in that sometimes you have a source change, a cobalt source change, so that the output is pretty -- is substantial, and that the typical timer settings may be only a minute. Whereas, if you have a very weak source that is going to be changed in the coming months, the output would be very low. And the timer settings were typically -- for the typical -- same prescription would be much longer.

But for that particular unit, typically timer settings are within a very narrow -- a relatively narrow range. Therapists can be treating 30 patients in a day, and the timer -- the lowest timer setting could be one minute, and the highest timer setting could be two and a half minutes for that given machine.

As soon as they see something very unusual that could result in an overdose, like a five-minute timer setting, it should be an action level which they decide

where it should be, helps them think, so that they should question the timer setting or question the prescription, to make sure that that was what's really intended.

Let me -- and that doesn't create a lot of work because they may only do that once a year or once every six months. It's not something that interferes with the operation, because it's very infrequent that you get a -- such an outlier, such a high timer setting or a high dose prescription.

MS. HOLAHAN: Well, I think the other aspect, and perhaps I don't quite know the way to address it, but we have seen, again with teletherapy, where you've got the therapist operating the unit, is in cases where the physician has even, say, prescribed a lower dose than normally is given, but they're looking at the normal timing and just go and key it in, but not necessarily making that physical linkage between what's on the written directive and what the timer settings are.

And I think -- and then just the standard dose is, for example, four minutes, even though what would have been calculated would have been two minutes, and actually given twice the dose that was prescribed. But I think, again, you need to emphasize the role of the therapist in verifying what is prescribed. And this may be along the same lines as you are discussing.

MR. SMITH: Well, I think also you see that -- the case the other day where they ordered seeds that were an order of magnitude higher than what's normally used. I think that the technologist or whoever it was who actually ordered those sources, if they had had some action levels to realize --

MEMBER FLYNN: And that was in -- do you mean the Connecticut example?

MS. HOLAHAN: Right.

MEMBER FLYNN: The person who ordered them isn't the -- see, typically, for prostate implants, it's the physicist, the radiation oncology physicist who does this every day. And a radiation oncology physicist would have never made that error, because the trip wire, the light would have gone off, would have never ordered sources 10 times the strength. But because it was being done through nuclear medicine, it was someone who was unfamiliar with the typical source strength, and then --

MS. HOLAHAN: But again, that's an advantage of these action levels or --

MEMBER FLYNN: Action levels, yeah.

MS. HOLAHAN: Yeah.

MR. CAMPER: All right. Neelan, anything to add to any of this?

MS. BHALLA: Nothing at the moment.

MR. CAMPER: Okay. Trish, any other thoughts? Torre, any further thoughts?

All right. Well, let me just take a couple of minutes, then, to try to summarize, if I may, where I think we -- what I think we've done over the last couple of days. We've gone through several modules, and we've taken those modules -- really gone through them item by item. And out of those efforts came some fairly substantial adjustments.

The staff now has to go back and bring to bear a number of these changes which have been suggested by the subcommittee members, as well as derived even by the staff in some cases. And I think that once we do that, the documents are going to be even stronger than they already are.

The next step in this process would be during the upcoming Advisory Committee, the full Advisory Committee of the Medical Uses of Isotopes, which is currently scheduled for October 18th and 19th, we have a line item as an agenda item on day 1 of that meeting in which there will be a report of these subcommittee meetings.

Now, the thought at the outset was is that Dr. Siegel and Dr. Stitt, Dr. Flynn, having chaired this part of the session this afternoon, would give some impression and feedback to the committee as a whole, which is, you know, characteristic of subcommittee meetings.

Now, what we may need to do that day is to let each of them do that briefly, and then perhaps I would provide some general comments along the lines of what I'm pointing out here in terms of observations about how things changed, and so forth and so on, for purposes of the benefit of the committee.

We do have one or two issues that we need to go back and pick out that have to be discussed before the committee. We had one earlier today --

MS. HOLAHAN: Patient release.

MR. CAMPER: -- regarding patient release, and I think there was one from the other day, although I can't remember now. They're all beginning to run together at this point. But I think there is probably at least two issues that we want to talk about with the committee sitting as a whole during that session, and so we'll do that. And then, these documents will be published for comment -- for public comment, from what I can gather at this point, some time along the lines of March, most probably. I think that -- is that the current schedule?

MS. HOLAHAN: Based on the BPR schedule, yes.

MR. CAMPER: Right. As part of the overall BPR process. Which would then mean, if need be, the committee could talk about them during the May meeting, but I doubt that that would be necessary. I think at that point the committee is going to be heavily involved in issues associated with the National Academy of Sciences report, and staff efforts, and the Commission directives, and so forth and so on, with the medical program at large at that point.

So I think that covers it. I would like to thank Dr. Flynn and Dr. Stitt and Dr. Siegel, and Bob Quillin of Colorado, Dr. Wagner -- that's all, isn't it? Oh, and Dennis Swanson, the subcommittee members who participated over the last three days. I certainly would like to thank each and every one of the members of the staff, those who wrote these guidance documents or updated them and participated in discussions. Your thoughts and ideas were very valuable.

And I would only conclude by saying that I think, once again, this is an example of how the Advisory Committee on the medical uses of isotopes is working very well and provides the staff and the Commission with a lot of valuable input. And that would be all I have to say. Dr. Flynn, did you have any concluding comments?

MEMBER FLYNN: No, I don't.

MR. CAMPER: Okay. Very good. Well, then, as the designated federal official, I call this meeting to a closure.

(Whereupon, at 4:05 p.m., the subcommittee meeting was adjourned.)