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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL

USES OF ISOTOPES (ACMUI)

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THURSDAY,

OCTOBER 19, 1995

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 9:15 a.m., Barry Siegel, Chairman, presiding.

MEMBERS PRESENT:

BARRY A. SIEGEL, M.D., Chairman

DANIEL S. BERMAN, M.D., Member

WIL B. NELP, M.D., Member

ROBERT M. QUILLIN, Member

JUDITH ANNE STITT, M.D., Member

DENNIS P. SWANSON, M.S., B.C.N.P., Member

LOUIS WAGNER, Ph.D., Member

DAVID WOODBURY, M.D., Member

JUDITH I. BROWN, Member

Also Present:

Larry Camper
Sally Merchant
Torre Taylor
Cheryl Trottier
Stewart Schneider
Trish Holahan
Dennis Serig
Andrew Kang

A G E N D A

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

(9:23 a.m.)

CHAIRMAN SIEGEL: Okay. We are back on the record this morning. We will resume with the agenda. We are going -- based on some discussion early this morning -- going to take some time in the agenda this morning to visit this regulatory guide relating to the patient release rule.

I learned a very important lesson again last night, which is we should never discuss rule language without the regulatory guide in hand, because we actually may have suggested some things yesterday that need some correction based on what is in the guide.

So we will fit that in after we do the STEP device discussion that Sally is going to lead now. Then we have got administrative issues thereafter, and that is what we have this morning.

So Sally, you are on.

MS. MERCHANT: Good morning everyone. I am going to talk to you this morning, more or less a status report of how we are handling the transmission source holding device that is used in SPECT imaging.

For those of you who are not familiar with the device, it is a source container with a shutter shield that is affixed to the rotating gantry of a triple headed scintillation camera patient imaging system.

It contains either a Technetium-99m source or Cobalt-57 or Gadolinium-153 source. It can have various activities, and the device is used during image acquisition to improve resolution.

CHAIRMAN SIEGEL: Actually, just to correct you, it is used to allow for attenuation correction, and probably does not improve resolution, probably degrades resolution in the final analysis.

MS. MERCHANT: They don't let me criticize.

CHAIRMAN SIEGEL: That is fine.

MS. MERCHANT: We did a radiation safety analysis to demonstrate that this device imposes minimal risk to public health and safety.

The issues are related to 10 CFR 35.49 and 35.57, which says that medical use licensees may use medical use only sealed sources or devices that have been manufactured and distributed in accordance with a license issued pursuant to 10 CFR part 30 and 10 CFR 32.74 or an equivalent agreement state license.

10 CFR 32.74 specifically identifies types of sources and devices manufactured and distributed under this part, i.e. calibration and reference sources, and uses listed in 35.400 and 35.500.

Where the problem comes in is that transmission devices are not considered to be calibration or reference

sources and are not listed in 35.400 or 500.

Manufacturers and distributors of such devices may not necessarily be licensed by the NRC or an agreement state to manufacture and distribute such devices for medical use.

CHAIRMAN SIEGEL: Can I ask a question? How do you treat, if you do, sources that licensee creates for their own use.

I will start with the simplest possible example. A syringe containing Technetium-99m that is used to do a uniform flood of a gamma camera in the morning.

MS. MERCHANT: That is a calibration source. Isn't it, Larry?

CHAIRMAN SIEGEL: You don't list that in a license.

MR. CAMPER: No. We don't. That is a very interesting point, number one.

CHAIRMAN SIEGEL: That is just a simple starting point.

MR. CAMPER: I know. We have, in fact, we discussed this very thing, the idea of Technetium flood fields which have been around forever, of course.

We currently construe that to be under 35.50, possession of calibration and check of dose calibrators.

MEMBER NELP: Flood field sources?

MR. CAMPER: Well Technetium, see, you may use sources --

CHAIRMAN SIEGEL: They are not going to be listed on your license.

MR. CAMPER: No. They are not. No. In the past when this issue come up that has been viewed as being a normal aspect of the use of Technetium.

CHAIRMAN SIEGEL: Because the next step up is an individual has their machine shop construct a lucite phantom of one sort or another for various imaging measurements.

One might be so upset about the cost of commercial Jaczack phantoms that they will try to build their own, in their own machine shop.

MR. CAMPER: Right. These devices are using silt sources.

CHAIRMAN SIEGEL: Not the refillable Technetium?

MS. MERCHANT: No. That is unsealed.

MR. CAMPER: But the others are, but the others are.

CHAIRMAN SIEGEL: All right. Okay.

MS. MERCHANT: Barry, it is one of those things that sometimes it is better not to ask the question.

MR. CAMPER: No. I think that is an interesting point. That is on the mark. We have construed and believe that the Technetium flood fields are part of the normal

customer use of Technetium.

We believe that it falls under 35.50, but I must say, having said that, if you really went to try to look and link a direct regulatory basis to use of that, I think you would get into an interesting area.

CHAIRMAN SIEGEL: The answer I was hoping you were going to give, and even though we might not be able to find a direct regulatory basis, could we accept that it is based on common sense?

MR. CAMPER: Of course. That is why we don't -- that is why we have left it alone.

MS. MERCHANT: We try.

CHAIRMAN SIEGEL: Thank you. Okay.

MS. MERCHANT: Okay. The issues for licensing with these devices is that to be authorized for the medical use of these devices, specific licenses of limited scope must seek and be granted an exemption from the requirements of 10 CFR 35.49 in order to possess and use one of these.

Specific licenses of broad scope however, if approved for any by-product material with atomic number 3 through 83 in any form, and that is the key: in any form, then no exemption is required.

MR. CAMPER: It does raise an interesting question, by the way, not one that we are pursuing. The idea that the -- we believe that the "any form" authorization for

the broad scope license covers the capacity, the ability, to possess this. Okay? But it does raise sort of an interesting academic question, and that is, in those cases where -- and this is very simple because it is a device fixed onto a camera, but let's take, for example, a sealed source that might be used in human use by a broad scope licensee, and that source has not undergone a safety review analysis such that we would do in the course of approving that source and issuing a cert sheet.

It does raise an interesting question though, and that is what process of review, and in what fashion is that review documented by a broad scope licensee in using that source.

MEMBER NELP: Common sense.

MR. CAMPER: Well, that is all fine and good, but let me give you the worst case scenario. What happens if a source that has been manufactured and used by a broad scope licensee ends up in a patient and it breaks off, and then you have a situation where there may or may not be documentation that an in-depth safety analysis was conducted of that source.

Common sense will not suffice to answer the fall out that will occur from that.

MEMBER NELP: No. You ask how broad license users will verify that their sources are safe.

MR. CAMPER: But where is the documented safety

analysis is my question, and the answer is that I am not sure that there is one.

MEMBER NELP: I don't know.

MR. CAMPER: Or that it varies. I think that they vary substantially. I am just saying it raised an interesting question.

CHAIRMAN SIEGEL: It sounds like you are addressing brachytherapy sources.

MR. CAMPER: Oh, I am.

CHAIRMAN SIEGEL: Not sources used for imaging calibration.

MR. CAMPER: Of course. Of course.

CHAIRMAN SIEGEL: Okay.

MS. MERCHANT: For those specific licenses of limited scope, the license condition that will be added to their license to use this source will read, "Notwithstanding the provisions of 10 CFR 35.49(a), suppliers for sealed sources or devices for medical use, the licensee is authorized to receive and use the [whatever the device is], and sources distributed by [whoever the individual is], in accordance with your letter dated [whatever that date is]."

Licensees were notified of the need for an exemption to possess and use the source in a June '95/July '95 issue of the NMSS Licensee Newsletter, and an information notice expanding on that is expected to be out in January,

1996, and rule making is ultimately needed to resolve this issue and will be addressed along with many other things, during the major revision of 10 CFR part 35.

Does anyone have any questions about any use?

MR. CAMPER: A comment, not a question, for the benefit of the committee. What we are trying to share with you here is really just to make you aware that this STEP device has emerged, and we have found a way to allow limited specific licensees to use these devices.

It has required a condition being added to their license that allows them to use it because currently, as a result of the requirements in 35.49 and the fact that those types of sources are not specifically listed in part 35, but obviously the licensees need to be able to use this.

It is a safe device, and we want you to be aware of the fact that we have found a mechanism to allow them to possess the devices.

CHAIRMAN SIEGEL: Dan.

MEMBER BERMAN: Just a couple of comments. We have had the opportunity to use both of these devices, and in the early evaluation they both appear to be working quite well, with modifications coming.

So on the basis of what I have seen, I think it is going to be something that will be common. So that there will probably be, in the country, thousands of these over the

next couple of years.

Just a simple correction is that the ADAC device is on a double detector. The Picker device is on a triple detector.

MS. MERCHANT: All right. Additionally, I spoke to a Picker serviceman and he mentioned the possibility of using more than one source, but I have since been told that that is not true.

So building on what you are saying, I think all of the information is not in yet as to what the configuration from different camera companies is going to be.

I know that the others who don't have it, some of them are working on it. So I think we will see a lot of applications.

MEMBER BERMAN: And then just a question is that from time to time these -- in addition to the sealed source potential use, one can load a Technetium source.

Is there any special license or requirement for that?

MR. CAMPER: No. This gets back to the --

MS. MERCHANT: For the Technetium source at 75 millicuries as a -- I am sorry. I misunderstood because I thought that the exemption would be required.

Should we clarify that?

CHAIRMAN SIEGEL: That is the part of the point

that I was driving at. It is very similar that if I have a uniform phantom of some source that I refill with Technetium, I might easily occasionally put 75 millicuries in it for a high count rate of flood with collimator on the SPECT system.

MS. MERCHANT: Yes. Well this one will, it being a transmission source, it is going to go through the patient.

So the patient is being -- there is a patient involved, and I guess my question is to clarify here for you.

MR. CAMPER: Okay. Dan, getting to your question. If we look at 35.57, Technetium conceivably could require an exemption for the following reason: 35.57, which is the part that talks about authorization for calibration and reference sources, it talks about the fact that anyone can use, may possess, use, and so forth and so on, the following by-product material for check, calibration, or reference use.

This is neither one of those things, necessarily and also there is a limitation of Technetium-99m in individual amounts not to exceed 50 millicuries.

So the loading of this device is in excess of 50 millicuries, and therefore we would be using the same exemption scenario to cover that contingency.

So if you are going to exceed the 50 millicurie limit, and you could, then it would require a condition similar to what Sally is describing.

MEMBER BERMAN: So it might be worthwhile in the

newsletter to let the user applicants know that if they are planning to load Technetium sources, then they should include that.

MR. CAMPER: Yes.

CHAIRMAN SIEGEL: Dan, in your experience have you used a refillable Technetium source?

MEMBER BERMAN: No. No.

CHAIRMAN SIEGEL: Because I guess my concern would be: one, would the source be uniform if it was refilled from day to day, and two, if the capacity for little bits of leaking, although not disastrous from a radiation safety point of view, kind of messy from the point of view of the rest of the day's imaging work, is that something that you have troubled about.

MEMBER BERMAN: We haven't used it, but it has been -- when the device was installed it was noted that it would be possible to do that.

CHAIRMAN SIEGEL: Okay.

MEMBER WAGNER: Now the exemption is only required for a specific license? Not a broad scope license?

MR. CAMPER: Broad scopes are okay.

MEMBER BERMAN: One other comment I would make is that we have had a single technologist working with the system every day for three months, and in watching her film badge reports there was zero change in her film badge readings with

this device, reflecting the comment that was made about minimal radiation exposure.

MR. CAMPER: Yes. We agree with you, and as I said a moment ago, the whole purpose of this entire exercise was to find a way to allow limited specific licensees to be able to possess it, and on one hand, one of the manufacturers --

MS. MERCHANT: Do we have to name them?

MR. CAMPER: One of the manufacturers has just recently gotten an approval by the state of California for the device, and so they have a different situation now.

There is one who has not still, and the licensees would have to be granted an amendment to do that, but the idea is we recognize that they are safe and we wanted to create a mechanism whereby the limited specifics are -- the broads are not a problem, but the limited specifics were.

MS. MERCHANT: It is important that the licensees be in compliance and that their licenses reflect what they are doing, what they are allowed to do.

CHAIRMAN SIEGEL: Have you had any experience with these, Buzz?

MEMBER NELP: No.

CHAIRMAN SIEGEL: All right.

MEMBER SWANSON: I have one concern here in reading through here. Under inspection guidance it appears

that the licensees could face a severity level IV violation if they use one of these devices that has not undergone the required safety review.

I hate to see the end user being punished, and I wonder why more pressure or the violations aren't put on the manufacturers who haven't gotten approval for this.

MS. MERCHANT: Actually, I prepared a slide for inspection. The guidance we have provided to the inspectors are that: Licensee's found to be using an NRC or agreement state approved device that is without authorization, but have not gotten the exemption, it would be a minor violation and no enforcement action would be initiated.

However, if the licensee is found to be using a transmission device that has not undergone the required radiation safety review by either the NRC or an agreement state, then there could be -- not definitely would be -- but could be a severity level IV violation, if it is not appropriately exempted.

MR. CAMPER: The idea, Dennis, is that you are using a device that has not undergone a safety review.

MEMBER SWANSON: Yes, but I think that the problem then lies with the manufacturer of that device that distributes it in violation of the regulations.

MR. CAMPER: What if the licensee is aware of that?

MEMBER SWANSON: I don't know. Is the licensee aware of that?

MR. COMBS: I am just saying, what if they are.

MEMBER SWANSON: I think many of them probably aren't. I think that is the problem. Okay.

MR. CAMPER: But it says "could be."

CHAIRMAN SIEGEL: Another sidebar.

MR. CAMPER: And each case should be looked at in the facts and circumstances for that particular scenario, but if you have a situation where the licensee is aware that the device is not, and is still using it, then the legitimate question to ask is, "Is a severity level IV violation in order?"

The second problem we have is that the manufacturers are not necessarily our licensees, and the only conduit of going after them if these devices are being used without a safety review, is in fact through the licensee.

CHAIRMAN SIEGEL: Is this a place where your memorandum of understanding with the FDA should come into play because these devices are being shipped in interstate commerce as devices, and therefore the FDA should have due diligence to make sure that the appropriate radiation safety review was conducted by the NRC or appropriate agreement state.

MR. CAMPER: Possibly. We can take a look at that.

CHAIRMAN SIEGEL: I normally wouldn't exercise that MOU, but this seems like a place where you might want to do that rather than beating up licensees.

MR. CAMPER: Yes, nor would I jump to the conclusion, Dennis, that a severity level IV violation is going to occur. It says that it could.

It would depend upon the circumstances and the awareness of the licensee and a host of other factors like that.

I frankly think, though, in the final analysis this is really not going to be a problem at all.

MR. KANG: Barry? Hi, I am Andrew Kang, nuclear medicine medical officer. I have the device in violation of FDA.

When originally we approved this device, the STEP device, and currently there are a few other devices approved, the manufacturer did not claim they were supplied with the radio pharmaceuticals.

The radio pharmaceuticals, the original plan was the devices are separately approved and the pharmaceutical will be supplied by the suppliers.

So they were not responsible for the supplying the radiation source. That was our understanding FDA-wise, but this issue is, I believe, a separate issue, and it is -- as far as we are concerned the licensing issue should be

between the NRC and the user of the device, and manufacturers may or may not have licenses for the user of this particular brand of pharmaceuticals.

CHAIRMAN SIEGEL: Thank you.

MS. MERCHANT: Thank you.

CHAIRMAN SIEGEL: So it sounds like we have got a little bit of a limbo situation here.

MS. MERCHANT: I think the important thing is to try to let our licensees know what our expectation is, because we are not anxious to have any kind of unpleasantness over this.

We feel like we are up front on this, and we are early, fairly early, and we can let everybody know.

There haven't been any citations, and hopefully there won't be any.

CHAIRMAN SIEGEL: Licensees just need to know when they make their budget requests to their hospitals for the device, they need to add in $500.00 for the license amendment as part of the cost.

MR. CAMPER: I would expect that information notice would be in the very near future, I would think.

CHAIRMAN SIEGEL: All right. Good. Thank you. All right.

We are going to diverge briefly from the agenda as published and -- Stewart, are you going to handle this? --

and we are going to talk about the regulatory guide that we received last night.

I hope many of you have had an opportunity to peruse it. I read it last night and -- oh, and Cheryl is there too. So which one of you wants to --

MS. TROTTIER: Stewart.

CHAIRMAN SIEGEL: Stewart is going to do it? Great. When I read this last night, Stewart, it became clear to me that we had recommended some changes in the rule language to you yesterday.

MR. SCHNIEDER: Yes.

CHAIRMAN SIEGEL: That now doesn't make sense, having read the regulatory guide.

MR. SCHNIEDER: That's true.

CHAIRMAN SIEGEL: In addition, there are some inconsistencies in the reg guide with the language in the rule that I thought we needed to point out to you.

MR. SCHNIEDER: With the current rule language?

CHAIRMAN SIEGEL: Current rule.

MR. SCHNIEDER: Okay.

CHAIRMAN SIEGEL: So let me walk you through this -- using the reg guide as our basis for discussion, let me walk you through the concerns that I had, and then anybody else can add to it in any sequence that seems reasonable.

The first problem I had was yesterday you will

recall we recommended that 35.75(c) be modified to delete phrase one, which is calculated using an activity other than the activity administered.

MR. SCHNIEDER: Okay. I looked back at this. Do you want to know why it was there?

CHAIRMAN SIEGEL: I do. I am going to tell you why it was there, but it is still the wrong language.

MR. SCHNIEDER: Okay. Probably so, but it was there because we need to know the time from the administration to the time of release as part of the record.

CHAIRMAN SIEGEL: That is part of it, although there actually could be more than one issue.

As I read on page 5 of the regulatory guide, where you talk about release criteria, in item 1.1, "activities for release of patient," you talk about, "If the activity administered exceeds the activity in column 1 of table 1, the licensee may hold the patient until the activity in the patient's body is less than" -- it should be "than that" -- "in column 1 of table 1, and then authorize release."

In this case a record is required by 35.75(c) because the release is based on an activity other than the activity administered.

Exactly correct, but what I would submit is that the language Dennis suggested yesterday is the correct language, and it should be, "if the total effective dose

equivalent is calculated using the retained activity rather than the activity administered."

That is much clearer, and then it really means what we are talking about. Does that sound reasonable to you all?

MS. TROTTIER: I agree. We will make that change.

CHAIRMAN SIEGEL: Okay. So that is problem number one.

Problem two is a more interesting conundrum, I think. Item two under 35.75(c) is, "Using an occupancy factor other than 0.25 at one meter," and although that sounds straight forward, the problem is for an isotope with a half life of less than 24 hours, table 1 authorizes a release based on an occupancy factor of 1.0.

MR. SCHNIEDER: Correct.

CHAIRMAN SIEGEL: And the problem is that means that a record would be required any time someone is released in accordance with table 1, if the isotope had a half life of less than 24 hours, and I know you didn't mean that.

MR. SCHNIEDER: That's true.

CHAIRMAN SIEGEL: So let's figure out a way to make that language be real. Dennis suggested the possibility that it could be using an occupancy factor less than 0.25 at one meter, and I think that captures it.

MS. TROTTIER: Because if it was greater it would be more conservative.

CHAIRMAN SIEGEL: Yes. It would be more conservative.

MR. SCHNIEDER: Right.

CHAIRMAN SIEGEL: That would be one way to fix it quickly. I am trying to think of any holes that that leaves open for the 24 hours, and I can think of some real practical applications.

I think copper-64 potentially was going to become quite important for monoclonal antibody therapy and peptide therapy and there is a 12.8 hour half life isotope that is potentially, people are going to be getting sent home with maybe more than 200 millicuries on board.

MR. SCHNIEDER: Okay.

CHAIRMAN SIEGEL: Comment on that, Lou?

MEMBER WAGNER: Barry, on your first comment, it seems to me that the record would be required by 35.75(c) anyway because it is based upon a biological half life.

CHAIRMAN SIEGEL: It might not be. I will give you the example. I give someone 250 millicuries of copper-64 in a monoclonal antibody form where there is no excretion whatsoever. I mean, the urinary excretion is a fraction of a percent, and I wait six hours while I have the patient in a holding room.

I am doing it on the basis of the decay down to a particular retained activity, assuming 100 percent retention, and it is other than the administered activity.

It is the retained activity.

MEMBER WAGNER: Okay.

CHAIRMAN SIEGEL: Do you buy that?

MEMBER WAGNER: Yes. I buy that.

CHAIRMAN SIEGEL: Okay. Any other comment on that? Buzz, do you have any further thoughts on that item? I don't think we are in trouble on this if you guys can make that change.

MEMBER NELP: No. I don't have anything to add.

CHAIRMAN SIEGEL: The next place I got into a problem, this is now minor. Those were the two major things, did anybody else find anything major that troubled them?

Okay. On table 1 I just had some comments. You still have non-by-product radionuclides in the table, including some that would be very tough to make in a reactor, if you chose to, and I thought in a previous life we had recommended to you that a footnote to the table saying that this information is provided for guidance and licensee's information even though it may not be subject to regulation under the atomic energy act, and I think you ought to put that footnote in.

MR. SCHNIEDER: Okay.

MS. TROTTIER: I agree.

MR. SCHNIEDER: It is mentioned in other pieces of the document, but it should be here too.

CHAIRMAN SIEGEL: In the statements of consideration.

MR. SCHNIEDER: Yes.

CHAIRMAN SIEGEL: But I think the average user will read the regulatory guide and does not read the statements of consideration.

Copper-67 is missing from the list, and I think I would probably encourage you to add it. I think there is already use of copper-67 for therapy.

I didn't, off hand, see any other isotopes that were missing from table 1, aside from copper-67. Anybody? A quick scan of that list.

MEMBER WAGNER: May I make a comment on table 1, though?

CHAIRMAN SIEGEL: I have another comment, but go ahead.

MEMBER WAGNER: I think it would just be helpful to users on column 1 and column 2 if you put a parenthetical phrase on column 1 and 2 that said something like, "See column 3 to determine if instructions are required," because usually when we are looking at tables, once we find out that we can give an exemption or we can just send the patient home, we

don't go any further in the table to peruse things, and I think an instruction would be helpful.

CHAIRMAN SIEGEL: I think that is reasonable. Why did you choose to round to one significant figure? Because in a previous version of this table you may have actually three significant figure accuracy, but at least two seemed --

MR. SCHNIEDER: It was a rough estimate the last time. The last table you saw, we went back and we recalculated a lot of the numbers.

CHAIRMAN SIEGEL: Okay, but why did you round to one significant figure, which would then make these rough estimates?

MR. SCHNIEDER: It is just the way we did it.

CHAIRMAN SIEGEL: Okay. Is there a rationale for one rather than two?

MEMBER NELP: In reference to the --

CHAIRMAN SIEGEL: The values in column 1, and actually the values in the table are all rounded to one significant figure, so that, just to give you an example, the release value in column 1 for I-131 actually is 33 millicuries.

MR. SCHNIEDER: That is what it was the last time.

CHAIRMAN SIEGEL: What it was before based on the

actual calculation, by rounding it drops down to 30. I am sure there are some examples where it was 47 and it rounded up to 50, and we have got a little more wiggle room with that one, but with I-131 we lost some wiggle room, and as it turns out, that is 98 percent of the current application, and I guess, why lose the wiggle room if we don't have to?

MS. TROTTIER: We will look at that.

CHAIRMAN SIEGEL: Okay.

MEMBER SWANSON: Can I back up a bit?

CHAIRMAN SIEGEL: Of course, absolutely.

MEMBER SWANSON: Section 1.4, I think you need to clarify. The new rule language says that you have to give guidance and ration out if it is above 1 millisievert and you have to document that you -- 5 millisieverts.

I think that needs to be specifically outlined in that section.

CHAIRMAN SIEGEL: Throughout this I am assuming that if you do make the changes we recommended yesterday in the rule language, that you will make the conforming changes in the regulatory.

MS. TROTTIER: That is correct.

CHAIRMAN SIEGEL: I assume that is a given, but thank you for reminding them, Dennis, just the same.

Okay. Anything else on that page? Lou.

MEMBER WAGNER: Well, on page 2 in the

discussion, just a point.

CHAIRMAN SIEGEL: Which page are you on?

MEMBER WAGNER: Page 2, the discussion, the first paragraph. It is worded, I think, a little awkwardly, "activities were calculated."

The activities were "determined" by using this method. You calculate the exposure I think, on the next page. Yes. You say "calculate the exposure," and then on the previous page you said, "calculate the activities."

It is just a matter of consistency in trying to understand it, and I had some trouble just trying to understand that first sentence.

So I think it is badly worded and ought to be rethought a little bit.

CHAIRMAN SIEGEL: What it really means is the activities at which patients could be released.

MEMBER WAGNER: Right.

CHAIRMAN SIEGEL: Have been calculated using the NCRP 37 methodology.

MEMBER WAGNER: Were determined using that methodology.

MR. SCHNIEDER: That is fine.

CHAIRMAN SIEGEL: Page nine, 2.2, content of instructions. "The instructions should include a contact and phone number in case the patient has any questions."

That is a should statement, and where does that stand with respect to how you propose to inspect against that statement?

If you really think it is important, you need to add it to 35.75. If you think it is optional you can suggest it in the regulatory guide, but this to me, seems like you are requesting it or requiring it.

MS. TROTTIER: Of course, a regulatory guide can only say "should" unless it references a rule.

CHAIRMAN SIEGEL: I understand, but what is your intent?

MS. TROTTIER: And often, and Larry can speak to this better than I can, is that often what is used then is licensee commitments to follow certain regulatory guides, whether this will be the approach in this matter, I don't know, but that is about the only hook.

CHAIRMAN SIEGEL: So if I, as a licensee, choose not to commit to this component, will you allow it in the license?

MR. CAMPER: From an inspection standpoint, which is where this will play itself out, the intent has been, this is what Cathy Haney pointed out yesterday, the intent has been to see that the licensee is, in fact, providing instructions, period, not the content of the instructions.

CHAIRMAN SIEGEL: I understand. So why did you

put this in here? I agree that it is perfectly correct medicine. It is common sense.

MR. CAMPER: You often find things contained in guidance documents as recommendations, shoulds, that you don't necessarily cite as a regulatory requirement or that you inspect against.

CHAIRMAN SIEGEL: Yes. I guess the word "should -- "

MR. CAMPER: From a guidance standpoint it is worthwhile.

CHAIRMAN SIEGEL: I know what you all mean when you say "should," but what I would prefer is that you substitute the phrase, "it is recommended that." Then I know that it is a recommendation, not a should.

I know that you don't think "should" carries regulatory force, but I can tell you what should really means to the rest of the world.

You are not going to change it, and I know that, but I thought I would needle you a little bit anyway.

MR. CAMPER: So your suggestion is, "it is recommended that?"

CHAIRMAN SIEGEL: Yes. I think, but frankly, if you really think it is something you want done all of the time, as part of your social responsibility to individual patients, then add it to 35.75. Then you can really inspect

the incident.

MEMBER WAGNER: May I recommend that it become a bullet item there rather than just bury it in the paragraph.

MR. CAMPER: All right. We can consider that. Sure.

MEMBER QUILLIN: While we are needling the NRC.

CHAIRMAN SIEGEL: Go for it.

MEMBER QUILLIN: I will bring up one of my favorite topics, which is the issue of waste disposal which occurs with these kinds of patients, and the fact that although it is not an NRC regulatory problem, it becomes someone else's problem.

MR. CAMPER: You are right, Bob, it's not.

MEMBER QUILLIN: Did you get my point?

MR. CAMPER: Go ahead, sir.

MEMBER QUILLIN: If there could be some suggestion in here. I am trying to put it gently, some suggestion that the instructions include advice on disposal, I think that would be helpful.

CHAIRMAN SIEGEL: What should that advice be?

MEMBER QUILLIN: I am leaving it up to the experts at the NRC to --

CHAIRMAN SIEGEL: But now, if that is in the regulatory guide, I have to figure out what I am going to put in my instructions to the patient.

Tell me what to tell them?

MEMBER QUILLIN: If you contaminate a plate, be sure to flush it down the toilet.

MR. CAMPER: That's the only way you can get rid of it.

CHAIRMAN SIEGEL: Because that is the only way you can get rid of it.

MEMBER QUILLIN: It is a problem primarily with the disposal of diapers and bandages and that sort of thing.

MR. CAMPER: I know the problem.

CHAIRMAN SIEGEL: The real advice is that you guys should turn down the sensitivity on your detectors.

MEMBER QUILLIN: It is not our detectors. It is the landfill detectors. We have no control over those. This is private enterprise in action.

MR. CAMPER: Well, you know, Bob. I mean, on the one hand what you are saying is conceivably you could have a paragraph somewhere that alerted licensees to the fact that although patients are released, consistent with the regulatory requirements and so forth, that this may pose problems in view of landfills and so forth and so on.

MEMBER QUILLIN: Then why don't you put that in?

MR. CAMPER: I understand that, but if we were to consider putting something like that in, we would really have to be very, very soft with the message because we don't want

to in any way imply that that would then be some additional imposition on the licensee.

I don't know. We can ponder that.

MEMBER QUILLIN: I am just talking about instructions. That's all.

MR. CAMPER: I understand. I understand.

CHAIRMAN SIEGEL: Okay.

MEMBER QUILLIN: The word, "consequence" appears again on page 10.

CHAIRMAN SIEGEL: I am sorry. Where are you?

MEMBER QUILLIN: Page 10, the word "consequences" again appears there.

CHAIRMAN SIEGEL: Again, I am assuming that 2.3 will be changed to conform to what we suggested yesterday, but I have another question about 2.3.

MEMBER BROWN: Excuse me. I have a question on the previous statement.

CHAIRMAN SIEGEL: Please.

MEMBER BROWN: In the instructions that one is given, is it standard course to advise about diapers and bandages and stuff and tell the patients that they should be careful with these?

CHAIRMAN SIEGEL: If I had a patient who was incontinent that I was going to send home, an elderly person or if it was a child, then I would encourage the person caring

for that patient to wear gloves, which frankly is prudent from the biological hazards point of view far more than it is from the radiation safety point of view, and to perhaps double-bag that garbage, but I wouldn't give them specific instructions about holding it for decay because I think that would be a terrible instruction.

MEMBER BROWN: Right, but it is standard operating procedure just for the people's safety at home and exposing others.

CHAIRMAN SIEGEL: I am not sure safety at home is really the -- is really a concern.

MEMBER BROWN: Okay.

CHAIRMAN SIEGEL: I think, in general, people don't leave dirty diapers sort of just lying around the house for aesthetic reasons.

MR. CAMPER: See, the problem you have, Judith, even if one were --

MEMBER BROWN: But if you throw a band-aid or something --

CHAIRMAN SIEGEL: A band aid is not a problem.

MEMBER BROWN: But dirty diapers often go in the dirty diaper container that may not get picked up in the bathroom until the end of the week.

I am just saying, does someone let them know that their diapers are no longer just regular diapers?

CHAIRMAN SIEGEL: I would recommend the use of disposable diapers rather than reusable diapers in this setting.

MEMBER BROWN: I am sure you would. What I am getting at is: Is it standard operating procedure, as part of these instructions that people are being given when they go home, to be advised of these things that may not be thought of?

Like throwing bandages away in their trash in the bathroom which may not get picked up but once a week.

Just, "By the way, this bandage is no longer as innocuous as your other bandages were."

CHAIRMAN SIEGEL: I can say, quite honestly, that it is probably not standard operating procedure because instruction of the patient has never been required as a matter of regulatory force until this rule comes into place.

MEMBER BROWN: Do you think it is important that people be advised of this because otherwise, I mean, I never thought of that factor, but I can envision many occasions where people could, just as a matter of course, be leaving substances around that you wouldn't want around the house.

MEMBER NELP: Well, if you are talking about things like bandages, the amount of activity that ordinarily would be there would be very, very small.

MEMBER BROWN: And diapers?

MEMBER NELP: And would be below any concern or hazard. Diapers would be largely in incontinent adults, very few children will have any therapy, and those people can put their diapers in a diaper container and get rid of them.

If they are really incontinent, we would probably keep them around.

MEMBER BROWN: Okay. So you think the problem takes care of itself?

MEMBER NELP: You would for the earliest period of time when the urinary excretion is heaviest.

MEMBER BROWN: So it is a non-issue in terms of instructions, you think. You don't think it deserves mention in this? Okay.

CHAIRMAN SIEGEL: Actually, let me withdraw something I said a moment ago because 35.315 and 35.415 already require instructions for people who were initially confined and then released.

So I misspoke, and that is in part one of the reasons why the pamphlets that were generated between the NRC and the SNM in the first place was to address the need to meet the requirements of 35.315.

That was 15 years ago, but the -- where was I? The point that Buzz was making was a correct one. In the case of a patient treated with I-131 who is currently released for thyroid carcinoma, currently released after being confined for

24 hours, the fraction with the biologic half life of eight hours is essentially all down the toilet in the hospital before the patient goes home.

Now in the new scenario, where it may in fact be possible to release people during the period of significant urinary excretion, then the potential for diapers containing tens of millicuries is possible.

MEMBER NELP: That is an interesting question. I am not so concerned about the health hazard to anyone. I am more concerned about someone raising -- like these diapers going into a dump site or something like that, because it will be a more common occurrence.

MR. CAMPER: Yes.

MEMBER NELP: But not a very common occurrence. It is very unusual to have an incontinent adult. So that would be an unusual occurrence.

MEMBER QUILLIN: One of the problems that you have right now, which is outside of the NRC's jurisdiction is that both sanitary districts or sewage districts are setting criteria on what may be disposed through the sewer, and in some districts they do have regulations which say that no radioactive materials may be disposed of through the sewer.

In the landfill business there are detectors at the gates of landfills -- many landfills now are large corporations -- which look for gamma emitting radionuclides,

and our experience is, in the Denver area, about once a month one of these goes off, and they have to unload a dumpster, a big truck, and piece by piece until they find the offending part, and then they separate it out and try to determine where it came from, and then they send it back if they can determine that, and the ones that are the biggest problems right now, because they can't send them back, are the ones that come from residential areas.

MEMBER BROWN: So I am familiar with that just because of the Indiana, Pennsylvania incident. However, you are saying a diaper would trigger that?

MEMBER QUILLIN: Yes.

MR. CAMPER: Oh yes, and to pick up on your earlier concern, and Barry and I were just having a sidebar. If you look on page 9, under content of instructions to patients, you will find there is a bullet that says precautions to reduce the spread of radioactive contamination and so forth.

Let's take that to the nth degree. Even if you took that instruction, you said, "Look, you should wear gloves. You should put the diaper, for example, into a plastic bag." The problem is, even if you do those things to reduce contamination to the patient, once that diaper makes its way into the trash cycle and shows up in a landfill, it is going to set off that sodium iodide detector at a landfill,

and that is what Bob is getting at.

See, the problem is people can release and do these things consistent with our regulations or for that matter, the state's regulations, but the landfill permits, the way they are set up, says zero radioactivity.

MEMBER BROWN: I know this isn't NRC's problem because you have made that clear, but for my information, what should people do with these things?

CHAIRMAN SIEGEL: Exactly what they are currently doing.

MR. CAMPER: Normally.

CHAIRMAN SIEGEL: And hope that it goes to a landfill where it won't set off the detectors, because frankly, storing it in the house for radioactive decay and elimination when it is no longer likely to set off the detectors at the landfill will create a bigger safety problem for the members of the household.

MEMBER BROWN: Right.

CHAIRMAN SIEGEL: It might require a license. Okay. This is a question I think I have probably asked every time we have talked about this regulatory guide and this rule.

On page 10, under 2.3 in the first paragraph, it says, it talks about the activities that you can release and/or require instructions relating to breast feeding.

It says, "In order to use this table it will be

necessary to determine the breast feeding status of women patients receiving some administrations."

An appropriately vague statement, and I agree with everything you have said. How do you plan to inspect against that statement?

MR. SCHNIEDER: There is one sentence in the Federal Register notice that says it can be made part of the procedures of that facility to determine the status and nothing more.

That is the only other location.

CHAIRMAN SIEGEL: What procedures? The ones that will trip it or all nuclear medicine procedures?

See, I am wondering for example, in the case of I-131 administration, I have already built into my procedure -- and I think other people will begin to do so prudently -- part of the written directive is a check off that I, as the authorized user, have ascertained that the patient is neither pregnant nor breast feeding.

I don't do that for lung scans. My guess is that what I would do for lung scans, the advice might require interrupting breast feeding for six hours.

I have a sign posted in my waiting room. Currently it says, "If you are pregnant or think you might be pregnant, please notify us before your examination."

I am probably going to change that sign to say,

"If you are pregnant or think you might be pregnant or if you are breast feeding an infant or recently have been breast feeding an infant, please notify us."

So if an inspector comes through and sees that sign, does that mean we will have done the job with respect to the Technetium administrations that could conceivably have tripped the need to refer to table 2? Because if you need a record --

MEMBER BROWN: Is the signage followed up by a verbal question?

CHAIRMAN SIEGEL: Sometimes, but not all of the time.

MEMBER NELP: It is pretty unusual that this isn't considered in advance by the patient and the patient's referring doctor.

Breast feeding is always -- it always gets focused on, I think.

CHAIRMAN SIEGEL: I can tell you that in the last year I have encountered circumstances at our own facility and at other facilities in town of three women in their forties who have been breast feeding and who have been referred for thallium imaging, and who the issue of breast feeding was not addressed until the thallium had been administered.

Now, that is not an NRC problem, but it is a radiation safety problem of concern, and so the problem is not

always being addressed.

Now, having an NRC rule on the street will clearly raise the attention to this problem, but I guess I am still concerned about what the inspectable level of compliance is going to be because when we are talking about these Technetium -- I-131, there is no argument, this heavy hammer is required.

It has the potential to wipe out an infant's thyroid gland. It is there. It is real. It can occur. The difference between 100 millirems and 120 millirems to the infant for a woman who gets a Technetium procedure is one that is a little bit more at the gray zone of what is really important to the world at large.

MR. CAMPER: Well, the sentence, as constructed is obviously purely instructional in nature, in that if you want to use the table you need to know whether or not the female is breast feeding.

You probably don't even need that sentence. Intuitively one knows if you are going to look at that table, you have got to understand whether she is breast feeding or not.

Having said that, we have no intention in our inspection scenario of inspecting as to whether or not the female's breast feeding status was determined.

Rather, we are concerned that, is the

instructional scenario in place.

CHAIRMAN SIEGEL: Judy, any comment?

MEMBER BROWN: Not directly to what you said, but the thing that lingers for me is that if it is important --

CHAIRMAN SIEGEL: That is the key phrase, right there.

MEMBER BROWN: If it is important, and I have no judgment about that. I am not claiming to, but if someone, you all, say it is important, I would like more than signage.

I would like to know that people are asking, because I know as a patient, a consumer, I don't read the signs.

MEMBER NELP: You don't?

MEMBER BROWN: No. I don't.

MEMBER NELP: If you came into our waiting room there is a bold, big, sign. You would sit right in front of it.

MEMBER BROWN: You would be amazed at the things I don't read, things I don't see.

CHAIRMAN SIEGEL: Well, in the case of I-131 therapy, if you came to my facility you would actually be asked to sign as part of a consent form for treatment, a statement that has a box right at the bottom, "I am not pregnant and I am not currently breast feeding."

MEMBER BROWN: Right. I know, and we went

through all of that, and that sounded like it covered the territory. However, if it is important for other substances to find out if someone is breast feeding, I would like the question to be asked, not just a sign that someone can point to and say, "See I covered it."

If it is important enough to put a sign up, I would like it to be standard operating procedure that someone also asked the question of potential non-nuns or something, that, are they breast feeding.

CHAIRMAN SIEGEL: I don't disagree with you because I am not sure what the right strategy is and where the risk threshold should be drawn.

That really is a subject though, of the other rule that is still in limbo. It is the pregnancy and breast feeding rule that we discussed three and a half years ago in Reston or three years ago in Reston.

It is not directly related to this rule. This rule will go a long way to accomplishing what you are concerned about because I think people's awareness of this problem will be greatly increased by the mere fact that this rule is now in place.

I actually have a moderate comfort level that this rule will help greatly our situation right now, where there is really no obligation to check at all.

MEMBER BROWN: I guess I am not even talking

about obligation. I am talking about just standard operating procedure. Do people ask?

MEMBER SWANSON: We actually have as part of our policy and procedures that patients are routinely asked by the technologist.

Okay now, does that happen in every case? That is the problem, and how do you document that, but it is part of the standard policies and procedures.

MEMBER BROWN: And you feel it should happen in every case?

MEMBER SWANSON: I think it is going to have to, with the new rule out there. Okay.

MEMBER BROWN: Do you get my concern that if it is important enough to have a sign that --

CHAIRMAN SIEGEL: Yes. I do. I completely do.

MEMBER BROWN: Okay, and actually to elaborate on that I will just share something from the consumer point of view.

I had a biopsy done, and I probably went to the surgeon's office four times between the time of diagnosis to end of the procedure, and on the fourth time I was there I noticed they had this neat little brochure in the office saying, "Breast Biopsies."

I said, "Well, look at that. I could have learned a lot from that," and someone who has got kind of a

heightened awareness of these things totally missed it, and I am sure that that physician and others think that they have covered the field by putting this nice brochure out that I never saw.

No one pointed it out to me, and I would just like to say that signage is not --

CHAIRMAN SIEGEL: You have suggested a relatively simple fix to me, which is to have our receptionist hand out a piece of paper with the question on it that says the same thing on the sign, directly to every woman of childbearing or breast feeding potential who comes in the waiting room.

I am not likely to do it for 10 year olds and I am not likely to do it for --

MEMBER BROWN: Nuns.

CHAIRMAN SIEGEL: Most Medicare patients.

MEMBER BROWN: Right.

MEMBER NELP: I think you must realize that patients don't come in off the street. They are referred to us by their own physicians, their obstetricians in this case, or their pediatricians might be involved, and the medical community is very careful about --

MEMBER BROWN: Right, but I didn't come off the street either, to the surgeon. I am saying that the medical community inside the beltway that I went to was not careful about my particular procedure.

I did not come off the street. I was diagnosed by my private physician, and I went to this guy four times as I said, before I realized way after the procedure, which I had no clue about what was going to happen, that it was all clearly drawn and illustrated in this nice little brochure.

I just would like to make the medical community aware through their transcripts, through whatever, that even people who have a heightened sensitivity, such as myself, to the need for patients to be involved, often miss huge things that you may think are unmissable.

MEMBER NELP: I realize that. I am just trying to reassure you that in this particular arena we are very heavily regulated, specially licensed, and we are -- in general the physicians and the referring physicians are quite sensitive to all of these issues.

So as a consumer I am trying to reassure you that things are pretty good shape.

MEMBER BROWN: I would like to take that reassurance and feel good about it, but I don't know how you, personally, can reassure me of anything since you have a exemplary practice, as does everyone around the table, and I don't know about the rest of the bell shaped curve.

MEMBER NELP: I am commenting on the curve.

MEMBER BROWN: How can you comment on the curve?

MEMBER NELP: Because I know hundreds of people

who are in practice and I see -- like Dr. Siegel and I know many, many, many people. We have trained people. We know all of the practitioners in our states.

MEMBER BROWN: I would assume that anybody you have trained would be on one end of the curve. I am talking about the other end of the curve.

MEMBER NELP: Well, I am trying to just reassure you.

MEMBER BROWN: I guess I am just saying that I am not reassured.

MEMBER NELP: I can understand that.

CHAIRMAN SIEGEL: This debate could go on for days.

MEMBER BROWN: It could.

CHAIRMAN SIEGEL: The point is well taken and I think that getting it into this record helps, and you have actually suggested things that people will find useful. No problem.

Table 2, again you need a footnote that some of this is non-by-product material to remind people for guidance, and then a couple of questions.

I am not sure that I-123 OIH is still available in the United States. So I am not sure what that helps, but you might, and I am not sure I-125 OIH is available, but you might want to add I-125 iothalamate, which is available.

I-123 MIBG is not commercially available, although it is used, but you have left off I-131 MIBG, which is commercially available, and which is far more likely to be a problem.

I have gone back and forth and stewed and I have corresponded about this a little bit --

MEMBER NELP: What table?

CHAIRMAN SIEGEL: I am on table 2 on page 11, Buzz.

The thallium-201 recommendation of complete cessation for three millicuries, I am very confused now by the literature, and I was wondering where the source of this is.

Is this based on Oak Ridge calculations?

MR. SCHNIEDER: Yes.

CHAIRMAN SIEGEL: So that came from Mike Stabin?

MR. SCHNIEDER: Yes.

CHAIRMAN SIEGEL: Okay.

MEMBER SWANSON: I think that it gets back to one of my questions. This table has absolutely no references as to where these numbers came from, how they were calculated, based upon what rationale, et cetera; and probably, I realize the work involved in that, but I think it would be a benefit from having some references to where this --

CHAIRMAN SIEGEL: To the extent that this table could be referenced a little bit more than it has been, this

would become a surprisingly helpful search document for people in the field, and you have got them all, Stewart. I have sent you almost all of the references, and there has been two or three review articles since the last time I sent you things.

There was a good thing in the European Journal of Nuclear Medicine and there have been several other articles since then.

MR. SCHNIEDER: A couple of things. You sent me an E-mail during the summer where you suggested some other columns which are not here.

Such as, I believe, millirem per millicurie. Is this adequate, what you see here?

CHAIRMAN SIEGEL: Well, certainly you want to change millicuries to megacuries, I mean megacuries to millicuries.

MR. SCHNIEDER: That is from Word Perfect. When you do a spell check in Word Perfect it does this sometimes.

CHAIRMAN SIEGEL: I think that this table is workable. I know I had suggested making it much more complicated, but I think this provides the information people need to make the decision.

MR. SCHNIEDER: Also, what is your opinion on the fourth column where we have added more than one time period for different amounts of material?

CHAIRMAN SIEGEL: I think that is reasonable. I

think you are reasonably on target for those two.

MR. SCHNIEDER: And you can interpolate between them?

CHAIRMAN SIEGEL: I can do even better than interpolate if I had the references to the tables. I could go back to the source documents and make an actual calculation from the assumptions used in the source documents.

MR. SCHNIEDER: A couple of changes you provided, are there any in addition to those, as far as the actual radiopharmaceuticals?

CHAIRMAN SIEGEL: No. That is it, just the hippuren, the MIBG, and the iothalamate. Those are the only ones I particularly noticed.

Technetium ham, is no longer available in the United States either. Correct, Dennis?

MEMBER SWANSON: Correct.

CHAIRMAN SIEGEL: It has been off the market for six or seven years, I think. You can leave it in, but it won't do much good.

I didn't have much then on the calculations. I am delighted to see that the calculations now use more realistic biological assumptions for the examples.

The only thing I would suggest, and this is not meant to offend Dr. Pollycove, the esteemed Dr. Pollycove, who is not in the audience, but I am wondering, rather than citing

this information as a personal communication from him, whether you would prefer to cite the source documents.

Since I don't have a computer with me I couldn't logon to MedLine last night to get you the source documents, but there are real references that you could use to support these data, and I think -- this is simply in defense of your own scientific credibility -- if you can cite the stuff from the open, published, literature, even though we all know Myron is a great guy, it would serve you better.

MR. SCHNIEDER: I just want to make one comment. On appendix A we actually went and individually calculated the exposure rate constants.

So there may be some variation from what is in the published literature, very slight, if any, but in our regulatory analysis we explained how we did that, and as we have attached, I am not sure if you have it, but I do, the spreadsheet tables from where we actually calculated those values.

CHAIRMAN SIEGEL: You have -- oh, I see. Never mind. It is two columns. I didn't understand that. Got it.

So everything that is in table 1 is in appendix A?

MR. SCHNIEDER: Yes, but as far as the exposure rate constants go, we calculated those numbers, we did not -- for a couple of them we didn't, but for the majority we

actually went and calculated them.

CHAIRMAN SIEGEL: You mean you didn't trust the radiological health handbook?

MR. SCHNIEDER: There was too much variation between different sources.

CHAIRMAN SIEGEL: Okay. The only other thing I have got is on page B-11, under 3.2, internal dose. I think we have made this comment before.

Internal dose may be a consideration with certain radiopharmaceuticals now being developed such as radiolabeled antibodies, for those that are developed in the future.

I don't think that is a particularly good example. In fact, internal dose is much less likely to be a problem with radiolabeled antibodies than it is with just straight old I-131 sodium iodide because the excretion rate of the radioiodine is going to be much, much slower.

In the case of most metallic radiolabeled antibodies there is almost no excretion of the metal, almost none, not none, but almost none.

So it just -- I know you keep wanting to focus on watch out for those nasty radiolabeled antibodies, and watch out for those alpha and beta emitters in the future, but they are not necessarily going to be all that different.

Considerations are going to be the same as always. Intelligent practitioners are going to think about

the pharmacokinetics of the drug and the radiation safety profiles of the individual radionuclides and act accordingly.

Right, Dennis? I know you will agree with that concept.

MEMBER SWANSON: Yes.

MEMBER NELP: Mr. Chairman.

CHAIRMAN SIEGEL: Sir.

MEMBER NELP: I would like to call your attention to page 5. As a reader the scenario for releases seems a little obscure to me.

You have paragraph number 1 says, "activities used as a basis for the release of patients," number two says, "dose rates used as the basis for the release of patients," and then three really is a paragraph saying, "dose rates being used for the release of patients."

This thing of case specific factors, if you read through that whole paragraph, not in that paragraph do you say what the dose rates are.

You don't refer them to any tables, and I read through this and I said, well, I heard that you guys were preparing this for 500 MR as the maximum exposure to any patient, but it is not even intimated here, and really the case specific factors are really dose rate exposures.

CHAIRMAN SIEGEL: They are integral dose exposures based on using assumptions other than those already

specified in the NCRP equation.

MEMBER NELP: It is cumulative exposure to --

CHAIRMAN SIEGEL: It says, "Licensee's may calculate the maximum likely dose to an individual exposed to the patient."

So there is dose. Right there. Remember in NRC parlage, dose means rems or rem.

MEMBER NELP: I understand that.

CHAIRMAN SIEGEL: Dosage means millicuries.

MEMBER NELP: Yes, but why don't you change release based on case specific factors to something that says release based on dose to patients or dose to the people in the environment.

CHAIRMAN SIEGEL: It is based on case specific factors.

MEMBER NELP: Those are dose factors.

CHAIRMAN SIEGEL: You have lost me.

MEMBER NELP: It is exposure to other people, that is the case specific factor, as you are going to take me, if I am your patient, and you are going to release me on the basis of how much dose I am giving to people in my community.

CHAIRMAN SIEGEL: But that is what everything is based on, Buzz. The whole, the entire rule is based on the calculation of a dose to other human beings.

MEMBER NELP: All I am saying is does it say that

in the title of that paragraph? If I read that I say, "Umm, I wonder what those case specific factors are."

It is more dose related factors or special dose related factors. It is just a heading, you know, it is pretty obscure if you read it.

You are very familiar with this thing. I know you have written it. You are very familiar with it, but if you just read it over, it comes out --

CHAIRMAN SIEGEL: What would you change it to?

MEMBER NELP: I think you should right up front say you may release a patient if he won't expose another individual to more than 500 millirem.

CHAIRMAN SIEGEL: That is the rule.

MEMBER NELP: But you may do that.

CHAIRMAN SIEGEL: The rule already says that. This is trying to provide an example of one other way that you can reach that conclusion.

MEMBER NELP: Right, but it is based on a dose rate, a cumulative dose to someone in the environment.

CHAIRMAN SIEGEL: That is the whole -- everything in this document is based on a cumulative dose to someone in the environment.

Even if you just default to the numbers in table 1, that is what they are based on. They were calculated so that --

MEMBER NELP: I am just talking about the wording. I know how they were calculated.

CHAIRMAN SIEGEL: Okay.

MEMBER NELP: I think you have gotten wed to this dose or this case specific factor, which is just a piece of jargon.

CHAIRMAN SIEGEL: I am not wed at all.

MEMBER NELP: And you don't refer them to that table, either, in the appendix, you see. Whereas --

CHAIRMAN SIEGEL: What table in the appendix?

MEMBER NELP: Well, your dose table that is in B-7, "such as seen in B-7," or something. I don't want to belabor this, but I do think it is --

CHAIRMAN SIEGEL: That is only one specific example of I-131 where --

MEMBER NELP: Yes, but "such as seen in table 7." That was my comment.

CHAIRMAN SIEGEL: But then in the next paragraph, appendix B contains procedures for performing case specific dose calculations and it describes how.

MEMBER NELP: So why don't we change "factor" to "case specific dose calculations?" That is what it really is.

CHAIRMAN SIEGEL: Yes. I could live with that.

MR. CAMPER: That would be an easy change.

MEMBER NELP: That would help me.

CHAIRMAN SIEGEL: That is fine. Lou, do you have anything?

MEMBER WAGNER: Yes. Just a couple. Page B-1.

CHAIRMAN SIEGEL: Yes, sir.

MEMBER WAGNER: Last paragraph, the last part of the second paragraph there. It is garbled. I don't know if something went wrong with that. The language is not there.

CHAIRMAN SIEGEL: Tell me where you are.

MEMBER WAGNER: Page B-1, second paragraph, last part of it. It is about the fourth or fifth line up. "Radiation in tissue. Biological elimination." I mean, something has gotten messed up there. I am not sure what it is.

CHAIRMAN SIEGEL: Yes. There needs to be a comma there.

MEMBER WAGNER: Well, there needs to be more than that. I think part of a sentence got lost.

Page B-9, third paragraph, under "solution," I believe you mean, in the last sentence before the equation, an occupancy factor rather than an exposure factor.

CHAIRMAN SIEGEL: Which line are you on? You have lost me.

MEMBER WAGNER: It's under the paragraph, "solution." Before the equation. It says "exposure factor." I think it is an occupancy factor.

CHAIRMAN SIEGEL: Got it. Yes.

MEMBER SWANSON: I continue to have -- I am sitting here thinking to myself on this table for breast feeding women, what if we, using a radiopharmaceutical that is not included on the table, we assume our worst case assumption and document that we gave instructions to the patient.

MEMBER NELP: Such as? Do you have one in mind?

MEMBER SWANSON: I have several in mind. We have Technetium-99m DISIDA, but that is not nebrofenin. Okay. Nebrofenin is not on the table.

There are probably several radiopharmaceuticals that are just not specifically addressed on the table, and certainly ones coming down the pike that aren't going to be addressed on the table. Okay?

CHAIRMAN SIEGEL: It would be nice if this table could include all of the radiopharmaceuticals that are currently commercially available in the United States.

It would be ideal if it could include those that are soon to be on the street, at least we hope, in the United States based on activity down the street.

So Dennis points out that we only have got one hepatobiliary agent, but it is only one of the two that is commercially available in the United States.

MR. SCHNIEDER: We did say at our last meeting that we would give you a copy and discuss this with you.

MEMBER SWANSON: Okay.

MR. SCHNIEDER: So you will get one and we will discuss it with you.

MEMBER NELP: Yes. I think in practice, most people say, "Well, wait six or twelve hours," it is not a big deal with Technetium.

CHAIRMAN SIEGEL: But there are a fair bunch of drugs you don't have to do anything.

MEMBER NELP: Yes. I understand that.

MR. SCHNIEDER: I have one question. Oh, sorry.

MEMBER SWANSON: I think, yes, we either need to include them all or give some kind of guidance on how it is going to be addressed if it is not included in the table, both from an end user perspective and in an inspectional perspective, I think.

CHAIRMAN SIEGEL: And I think these are probably drugs for which Mike Stabin could probably get you pretty quick estimates fairly fast.

I am missing things just by perusal. Dennis mentioned Technetium nebrofenin, but in addition, in renal you are missing glucoheptonate, you are missing DMSA.

MEMBER SWANSON: Glucoheptonate is there.

CHAIRMAN SIEGEL: Where is gluco? I don't see it.

MEMBER SWANSON: It is about halfway down the

column.

CHAIRMAN SIEGEL: I am sorry, but you are missing DMSA, which is almost certainly not going to be a problem.

MEMBER NELP: You can't get it. Dennis, is DMSA available?

CHAIRMAN SIEGEL: It is currently off the market, but it is intended to come back on the market. It looks like you are missing HMPAO, and you are missing the new agent which is ECD, trade names for those respectively are ceretec and neurolite.

MEMBER SWANSON: Do you mean serum albumen?

CHAIRMAN SIEGEL: Correct.

MEMBER NELP: Tech albumen. I guess you are never going to have a complete table.

CHAIRMAN SIEGEL: No, but --

MEMBER NELP: I guess you can start with a complete table.

CHAIRMAN SIEGEL: It should be at least complete on the day that it goes to the street, based on the list that we know FDA has approved, to the extent data are available.

In some cases there could be no data. I would not be surprised, for example, if there were no data on neurolite.

You would just have to say it is based on available data, this is the best we can do.

Indium-111 labeled octreotide.

MEMBER SWANSON: Not there.

CHAIRMAN SIEGEL: It is not there, and indium-111 labeled oncoscint, not that anybody would use that drug. That is what I heard, but that is another story.

MR. CAMPER: Well, what I am a little bit more concerned about on Dennis' comment, though, we can go through and update the table and that is worthwhile, but I guess, let's say for example, you don't have a brand new pharmaceutical.

Is it clear enough, do you think Dennis, as to what process the --

MEMBER SWANSON: If I don't have a table, I guess that is my question, if it is not on here and I don't have the information, I am going to assume the worst case scenario and give instructions and document.

MR. CAMPER: What I am saying though, is if the licensee needs to move into the calculation mode, is there enough guidance, is it clear enough to --

MEMBER SWANSON: Well, I think that gets back to where did these calculations come from and how did you go about doing them.

MEMBER WAGNER: But with the breast feeding child there is not likely to be any data other than what we already have.

So it is not likely that the person using this is going to have any additional information.

CHAIRMAN SIEGEL: Let me tell you. The guidance that is in the U.S. Pharmacopeia dispensing index, a drug information document, has varied over the years.

The guidance is that it is likely that this drug will appear in breast milk, and you need to keep the dose to the infant as low as is reasonably achievable, and it is recommended that breast feeding be interrupted until actual measurements of breast milk activity demonstrate that it is safe to resume breast feeding.

So that in a not-on-this-list drug, the average practitioner is going to have a tough time because most people actually don't know how to do the calculations, even if you actually have measured the activity, and you have been doing it sequentially, and you have watched it decay away.

You still then have to go into the calculations that Mountford and Coakley and others who have written these articles have put forth, and make some assumptions about the excreted factor continuing in the breast milk, the absorption factor in the infant, the transit time in the infant's GI tract, and make some pretty arcane calculations that I want you to know I personally have trouble with, and my physicist and I worked with them on a couple of occasions.

The average practitioner will not be able to do

those calculations. They are too tough.

MEMBER NELP: But in reality, I don't think this is a very common problem.

CHAIRMAN SIEGEL: I don't either.

MEMBER NELP: It is a very, very infrequent problem. You just can't cover all bases, and there is intelligent life out there, you know.

People are very capable of practicing medicine in general, in a very satisfactory manner.

CHAIRMAN SIEGEL: It is reasonably safe to say that with any Technetium radiopharmaceutical --

MEMBER NELP: I am sorry, you can't give them everything.

CHAIRMAN SIEGEL: -- if you stop for 48 hours, you did do diligence, and you basically have done the job, because even if you assume, if you just do radioactive decay and assume worst case scenario that everything that is left after 48 hours is transferred to the infant, and is concentrated in the smallest organ in the infant, you will still be okay.

You can do such a worst case scenario calculation that you are home free with dumb assumptions, but getting really good numbers is exceedingly tricky.

MEMBER NELP: It is just that that infant would be subject to diagnostic study if there were some purpose to

do it.

You know, that same infant, you would not hesitate to do a diagnostic study.

CHAIRMAN SIEGEL: That is not the crux --

MEMBER NELP: That is not the criteria. I realize that.

MEMBER SWANSON: Let me give you a scenario. My concern here, what if I administer a new radiopharmaceutical, indium-whatever.

CHAIRMAN SIEGEL: Fortunately it is non-by-product material. So you can say nah-nah-nah-nah.

MEMBER SWANSON: Well, it still comes down, nonetheless, let's present --

CHAIRMAN SIEGEL: Pretend it was I-131 for the sake of argument.

MEMBER SWANSON: Okay. I-131 something or other, okay, and I have administered to the patient, and the patient is breast feeding, okay, and I come to find out later on that the exposure was greater than .5 rems, and I didn't document that by regulation. Okay.

Remember I am required to document, they gave instructions now, by regulation, if it is over .5. Right.

MEMBER NELP: This is outside of breast feeding now.

MEMBER SWANSON: I am talking breast feeding.

Remember we discussed the regs.

MS. TROTTIER: The instructions are over .1.

MEMBER SWANSON: The instructions are over .1, required documentation of that is over .5.

MS. TROTTIER: Right.

MEMBER SWANSON: Okay. Now I am in violation of the regulations. Right?

CHAIRMAN SIEGEL: Sounds like it.

MEMBER SWANSON: And so all I am saying is, you know, if it is not on the table I think the only avenue that I would have as a licensee would be I would probably give the -- if I went ahead and did this to a breast feeding woman, which is I think the initial question, okay, I think I would probably document that I had given instructions, and document that I gave instructions, otherwise I have got nothing to go back to.

If the instructor comes in and says, "Well, why didn't you give instructions?" I can't say, "Well, look this table here was below the limits because it was not on the table." I have got no basis.

MEMBER NELP: These are all pretty unlikely scenarios.

MR. CAMPER: Yes. I agree.

MEMBER NELP: I don't think we need to chase every particular scenario.

MR. CAMPER: I agree, they are unlikely scenarios, but under the scenario that Barry was describing where you have this difficulty in making certain assumptions and then carrying through the calculations, are any of those radionuclides likely to trigger the threshold of item A, this 500 millirem, and then therefore a record of the basis for the release, and if it is, what would be the basis for release in that case?

What I am hearing you saying is --

CHAIRMAN SIEGEL: Interruption of breast feeding for a period of time.

MR. CAMPER: As opposed to the calculational documentation.

CHAIRMAN SIEGEL: No. You would have to calculate.

MR. CAMPER: I understand, but you are saying it would be very difficult, if not impossible to do that in some cases.

CHAIRMAN SIEGEL: You can use extreme assumptions and come up with a number based on extreme assumptions.

MR. CAMPER: Okay.

CHAIRMAN SIEGEL: Like, only physical decay and all of the activities in the breast milk, and all of it is completely absorbed by the infant.

MR. CAMPER: All right. So you are just using

extreme assumptions.

CHAIRMAN SIEGEL: I am using extreme assumptions.

MEMBER BROWN: I have a question.

CHAIRMAN SIEGEL: Yes.

MEMBER BROWN: When you are advising someone to interrupt breast feeding, is it necessary or desirable to tell them how, whether they should express their milk in the interim and not just hold up for six hours and then give the baby.

CHAIRMAN SIEGEL: Holding up for six hours is not a problem.

MEMBER BROWN: I am not a woman, but six hours you can do. Holding up for two days is difficult at best.

MEMBER BROWN: Not if it is an intermittent kid. I have friends who are breast feeding kids who are three years old and they -- what I am wondering is are there instructions --

MEMBER NELP: They should stop.

MEMBER BROWN: Yes. They should stop. That is my opinion.

MEMBER NELP: It is time to stop.

MEMBER BROWN: It looks strange too. These people could go for a number of days. Is it necessary or desirable to tell them to express their milk in between?

Is the milk contaminated in the meantime?

CHAIRMAN SIEGEL: It depends on the radionuclide.

MEMBER BROWN: Okay. So you want to tell them, "Get rid of your milk and get some fresh milk."

MEMBER NELP: Some people will pump their breast milk and store it until it has decayed. Some people have that close association with it.

Most people will pump their breast milk and discard it for several days.

MEMBER BROWN: Right, and pump ahead of time for that time if they want to.

MEMBER NELP: And they can store it ahead of time.

MEMBER BROWN: It would be okay, you are saying, to pump that very milk and just let time --

MEMBER NELP: That is one possibility. It is not a very attractive one because it has got to sit around and you have to take care of it.

MEMBER BROWN: And you have to figure what does freezing do to the process, I don't know.

MEMBER NELP: Exactly. There are people who do that.

MEMBER BROWN: Is that something you tell people?

CHAIRMAN SIEGEL: Yes. In fact, as we have discussed here before, with I-131 treatment, I just don't tell someone they have to stop breast feeding, I tell someone they

have to stop breast feeding two weeks ago, because now we are dealing not with the infant, we are dealing with the dose to the breast of that woman, and it takes at least a couple of weeks for the lactating breast to calm down its I-131 uptake to a level where the dose is reduced.

There is now pretty good data on those doses. They are substantial.

MEMBER NELP: Yes. They are.

MEMBER WAGNER: I would like to recommend that NRC consider putting in some guidance to users for radioisotopes and radiopharmaceuticals that are not on this list.

Just have a guidance section as to what do you do. There is going to be new pharmaceuticals introduced. This problem is going to only grow in size as years go on.

MR. CAMPER: Well, that is the point I was getting at. I think there is a weakness there, and I think you are on the mark.

CHAIRMAN SIEGEL: So I think we are recommending both, that you try to complete the table with the things that are on the market to the extent that you and Mike Stabin can do it, and two, that you go to those lovely review articles and add some of the guidance that was in them about what to do when you are faced with an agent that isn't in the table.

Any comments on this? I am glad we had a chance

to do this.

MEMBER BERMAN: I would just like, on table 1 to note, at the bottom of table 1 where it says 400 millicuries of Valium would be the amount that the patient could be released with.

We are dealing with bizarre amounts that would trigger other problems.

CHAIRMAN SIEGEL: What is the point? Yes. It would trigger bankruptcy.

MEMBER BERMAN: It is a long way from --

MEMBER NELP: May I ask when you perceive this will hit the street, Larry?

Do you have any feeling for when these provisions will actually be instituted by the users?

MS. TROTTIER: Are you asking about the rule or the red guide or both?

MEMBER NELP: These release criteria specifically.

MS. TROTTIER: Probably at its very best it will in the beginning of 1996. It could be later.

All of this depends on how quickly it goes to the commission, which could be a matter of a week or months, and then how quickly the commission decides on it.

CHAIRMAN SIEGEL: Is there anything we can do to help you with the roadblock?

MEMBER NELP: There is no -- you don't sense any objections from the point of view of the commission?

MS. TROTTIER: No. We don't know. We actually don't know at this point what the commission's view is.

MR. CAMPER: No. We have no idea. We certainly haven't heard anything to that effect.

There is a problem. There is some degree of urgency associated with this rule, I would argue, in the sense that we are attempting in this rule to eliminate a conflict that exists in part 20.

Now, we have previously gone on record and tried to rectify that conflict in terms of the specificity part 35, as we discussed yesterday, but there is a need to clear this issue up, but we have absolutely no idea where the commission will be on this.

MS. TROTTIER: If there is any clue from wrong patient, they voted without comment on that, not that that was a very significant rule, but it went through very quickly.

CHAIRMAN SIEGEL: It was a very significant rule.

MS. TROTTIER: Not to them.

MR. CAMPER: Well, that rule and this rule I would argue are both significant. I would be surprised, but golly, I would not begin to speak for --

CHAIRMAN SIEGEL: This rule is important for a couple of reasons, this rule is not only important because it

resolves the conflict with part 20, but in addition, because it will allow release with people with higher levels of activity and has medical economic impact.

This rule also has important impact with respect to members of the public and breast feeding infants, which has never really been addressed, and this rule actually is going to raise awareness of this issue in a very beneficial way.

So even, Judy, even though you may be a little nervous about exactly how far this is going to go, this is a big step in the right direction, and I feel very positive about it.

MR. CAMPER: You could resolve it. That the commission review this as promptly as possible, take action upon it as presented by the staff.

You could have a resolution from the committee to that effect.

CHAIRMAN SIEGEL: Should we say to the EDO, also move it quickly without any further changes?

MR. CAMPER: Just say that the agency would move it. If you feel strongly about it you simply might want to have a resolution on the record of the transcript that you urge the agency to move promptly to complete this rule.

CHAIRMAN SIEGEL: The chair would entertain a motion that the ACMUI recommends that the rule with the recommended changes we have suggested, along with the

recommendations we have suggested to change the regulatory guide, be acted on by the commission as quickly as possible.

MEMBER SWANSON: So moved.

CHAIRMAN SIEGEL: Second.

MEMBER BROWN: Second.

CHAIRMAN SIEGEL: Any further discussion. All in favor.

(Ayes.)

CHAIRMAN SIEGEL: Opposed. Let the record show that we voted unanimously in favor of that motion.

MR. SCHNIEDER: I have one additional question.

CHAIRMAN SIEGEL: Stewart.

MR. SCHNIEDER: On B-7, do you have any comments on table B-1, the biological retention and elimination table.

This is a first cut at it, and you discussed it at the last meeting as a table of concern.

CHAIRMAN SIEGEL: I didn't. I thought it was reasonable. I understood it. It has got the same Myron comment. Specifically it relates to the biological half life numbers assumed at the different retained fractions.

MR. SCHNIEDER: Additional footnotes will be provided, but this was a draft.

CHAIRMAN SIEGEL: The only other thing is that you have lumped hyperthyroidism and thyroidoblation together at a 60 millicurie dose, and 60 millicuries is on the very

high end for hyperthyroidism.

The average hyperthyroidism treatment is going to be less than 20 millicuries, and in the average case, closer to 10.

So whether you want --

MEMBER NELP: Well, they do say thyroidoblation. Is that the old 30 millicurie. Was that the intent to get rid of remnants as well?

CHAIRMAN SIEGEL: I think it is a little of both, but our radio oncologists wouldn't use 60 millicuries for that. They use 100.

MEMBER NELP: Yes. Well. That is true.

CHAIRMAN SIEGEL: So the problem is the 60 millicurie number, it is kind of nether. It is not entirely right for hyperthyroidism except in the extreme case of a multi-nodular goiter that is very large, and it is not the right number for getting rid of remnants.

MEMBER NELP: but it is useful.

CHAIRMAN SIEGEL: Certainly this table provides you -- you can extrapolate that if you can release a patient in six hours if you gave them 60 millicuries, and the thyroid fraction is 90 percent, well then if you only gave them 10 millicuries you can release them sooner than six hours.

You can figure that out. I think this table works.

MEMBER WAGNER: The only recommendation would be to just take out hyperthyroidism and thyroidoblation and just put 60 millicurie dosage.

MEMBER NELP: Well, I don't object to that.

CHAIRMAN SIEGEL: But then you need to explain why you have chosen four different retention fractions.

MEMBER WAGNER: Right. Right.

CHAIRMAN SIEGEL: As opposed to just the one example of 5 percent for thyroid cancer.

MEMBER WAGNER: Right.

CHAIRMAN SIEGEL: I would leave it in.

MEMBER BERMAN: Is this a relief time of zero hours after 150 millicuries for thyroid cancer?

MEMBER NELP: The -- you know the terminology here is not quite the common terminology of the road. For instance, people talk about thyroid component.

They rarely talk about thyroid uptake, and I presume this is a 24 hour thyroid uptake.

CHAIRMAN SIEGEL: Correct.

MEMBER NELP: And I wondered if you might just call it what it is. We don't talk about uptake in fractions. We talk about uptake in percent of the administered dose.

CHAIRMAN SIEGEL: The equations that one has to use are based on a multicompartmental analysis.

MEMBER NELP: But they are never going to go

through that though.

CHAIRMAN SIEGEL: I think so. If you wanted to do this on a calculation basis as opposed to defaulting to the table, and you personally as a physician, didn't feel comfortable, you would ask your health physicist to do it for you, and your health physicist would be entirely comfortable with those first order differential equations. Straight forward.

MEMBER NELP: Yes, but I think that is a highly unlikely scenario. All I am saying is thyroidal uptake is a little more of the language of the street than thyroidal component.

That is just a comment because I am looking at the guy in Wanachie who is going to be reading this and says, "Oh, fraction two on TB2."

CHAIRMAN SIEGEL: A footnote somewhere in the earlier example that refers to this usually is taken as the 24 hour thyroid uptake.

MEMBER NELP: Then why don't you say it on the table.

CHAIRMAN SIEGEL: Because it is not mathematically correct to say it on the table.

MEMBER NELP: Then you convert it.

CHAIRMAN SIEGEL: Dr. Wagner, is it mathematically correct to say it on the table?

MEMBER WAGNER: No. No.

CHAIRMAN SIEGEL: It would be wrong to say so.

MEMBER NELP: Really? Why?

CHAIRMAN SIEGEL: Because it is not scientifically correct. You couldn't publish this in a reputable journal and call it, "the thyroid uptake."

MEMBER NELP: That is what it is, though. Isn't it?

CHAIRMAN SIEGEL: No. It is the thyroidal fraction based on a multi-compartmental analysis of the retained fraction in the body.

MEMBER NELP: So it is the retention in the thyroid?

CHAIRMAN SIEGEL: It is the retention in the thyroid, and it really is not just the 24 hour uptake, because it is how you fit that retained fraction.

MEMBER NELP: Okay, but it is retention. For my edification, is it retention at what time?

MEMBER WAGNER: I don't know what time they took. I don't know what they are using or how they are arriving at that number.

CHAIRMAN SIEGEL: This is an incorrect assumption assuming instantaneous distribution.

MEMBER NELP: Right. At T equals zero.

CHAIRMAN SIEGEL: At T equals zero, which of

course is wrong.

MEMBER NELP: Yes.

CHAIRMAN SIEGEL: But in fact, the way we clinically back into it is we take the thyroid uptake to be the 24 hour value, and we assume that that is what it is, is T zero for purposes of this calculation.

In actual fact, the thyroidal fraction is initially lower because of the fact that there is a build up factor that goes with that fraction, but if you think this is confusing, you certainly don't want to do that, I would argue.

MEMBER WAGNER: No, but I believe the extra thyroidal component is based partly on that in terms of the biological half life of .33 days.

It is based upon the fact that you have circulating thyroid that is being eliminated.

CHAIRMAN SIEGEL: Absolutely.

MEMBER NELP: Now, why do you have F1 and F2 in there? That is to refer to the mathematical formulation?

CHAIRMAN SIEGEL: Right.

MEMBER WAGNER: Right.

MEMBER BERMAN: Could you explain. I am missing something. How the thyroid cancer patient with 150 millicuries has a release time of zero?

MEMBER WAGNER: Because the extra thyroidal component is used so quickly.

CHAIRMAN SIEGEL: It is because by when you do the calculation, and now assume that the extra thyroidal fraction is only 5 percent, you literally can let that patient go immediately.

That is the whole point of this rule. That was the whole point of the petition submitted by Dr. Marcus and submitted by the American College of Nuclear Medicine was that in fact people who are currently being hospitalized do not need to be hospitalized.

MEMBER WAGNER: The point is that that large component is down the toilet in a very short time and it does not stick around long enough to expose anybody to any high dose.

MEMBER BERMAN: Zero means zero.

MEMBER WAGNER: Yes. He can walk out. That's right.

CHAIRMAN SIEGEL: He is going to get 150 millicuries and go home. Now, medical prudence says if you are getting 150 millicuries and you are planning on flying to Hong Kong from Cedars Sinai, that that is a bad idea because you are going to be on an airplane for 14 hours sitting next to another person at a meter, which means that the .25 occupancy factor in the first 24 hours has been violated.

So consideration of the individual clinical circumstances is medically prudent even though it may not be

NRC inspectable.

MR. SCHNIEDER: This table is not immediate release like you are saying.

CHAIRMAN SIEGEL: It could be.

MR. SCHNIEDER: It could be, but it is also one of the special cases.

CHAIRMAN SIEGEL: This is a case specific factor. In case specific factor says, "Given that I have convinced myself that there is, in fact, going to be an occupancy factor of .25 or less, then I could actually release someone with 150 millicuries."

MEMBER NELP: Alternatively you can do your own measurements on these patients and document what the exposures would be.

MEMBER BERMAN: It is not going to be that low at times zero.

MEMBER NELP: Oh yes. It will be about 20 mr per hour at a meter, at T zero, at 150.

CHAIRMAN SIEGEL: Okay. Good. We set?

MEMBER NELP: Would you define for me, as what occupancy factor is, so I can explain it to someone else?

CHAIRMAN SIEGEL: Sure. Occupancy factor as defined in NCRP 37 means the length of time in a 24 hour period that you are one meter away from another human being who is assumed to be a point source of radioactivity with no

attenuation.

This, of course, is not a realistic number, but the average value of .25 is taken based on the assumption that the maximally exposed person will spend six hours a day away from you at one meter.

MEMBER NELP: And the rest of the time they will be more distant.

CHAIRMAN SIEGEL: The rest of the time they will be further away or they won't be anywhere near you at all.

MEMBER NELP: Thank you, Dr. Siegel.

MEMBER BERMAN: Do you think it would be reasonable to extend this since table B1 took 200 millicuries instead of 150, since 200 millicurie doses are frequently given.

CHAIRMAN SIEGEL: I think this is just an example.

MEMBER BERMAN: Is it?

MEMBER NELP: You can get your own meter out, which we do all of the time and measure. I guess the other question is, Dennis, was it Louis who did these calculations?

CHAIRMAN SIEGEL: No.

MEMBER NELP: Who did these calculations?

CHAIRMAN SIEGEL: The NRC did these calculations.

MEMBER NELP: How much of a factor in this thyroidal is 100 -- just for my information, at 150

millicuries, how much of a factor is the 5 percent uptake as opposed to the extra thyroidal component in terms of the dose exposure to the environment.

In other words, if that F2 went down to zero --

CHAIRMAN SIEGEL: You could release them even sooner than zero.

MEMBER NELP: I know you could, but I am wondering how --

CHAIRMAN SIEGEL: You can release them even before you give them the dose.

MEMBER NELP: I am wondering how that 5 plays what role in the overall exposure.

CHAIRMAN SIEGEL: It is very significant. Look at the data up above. The bigger the thyroidal fraction, the longer you have to hold on to the patient.

MEMBER NELP: I know that, but I was wondering, I guess you can estimate it from looking up the list, couldn't you.

CHAIRMAN SIEGEL: Yes. If you are one of the people who treat thyroid cancer based on first getting a tracer dose whole body retention measurement like Harry Maxon, for example, then you could individualize this as much as possible.

In a case where you are treating thyroglobulin positive disease where you can't see anything on an image,

whether retained fraction might be as little as 1 percent or even less, you could potentially release him with 500 millicuries and send him home.

Then the non-thyroidal fraction becomes the dominant part of the equation.

MEMBER NELP: I was just wondering when that would happen.

MR. SCHNIEDER: What is the dose from that 5 percent?

MEMBER NELP: Say you had your thyroidal fraction was zero.

MR. SCHNIEDER: With the 5 percent, I think the number I calculated was about 100 to 200 millirem.

CHAIRMAN SIEGEL: All right. Can we answer any other questions? We need to take a break. We will get to the human factors on teletherapy and brachytherapy.

So let's break for 10 minutes. Thanks for letting us revisit this regulatory guide. I really appreciate you coming back to us this morning.

(Whereupon, the proceedings were recessed at 11:02 a.m. and resumed at 11:18 a.m.)

CHAIRMAN SIEGEL: We are back on the record and we are going to talk about human factors evaluations of remote afterloading brachytherapy and teletherapy.

Dennis?

MR. SERIG: I have overheads prepared and I also have handouts for everybody that has all the overheads. I prefer not to use the overheads to keep from moving back and forth. Is that okay?

CHAIRMAN SIEGEL: I think that's acceptable to me.

MEMBER NELP: That's acceptable.

MR. SERIG: Okay, for the audience there are some on that chair near the door.

The first one is, the first slide is self-evident. I'll add that my boss would usually introduce me as one of the few people at the NRC responsible for human error.

The second slide indicates that the folks who actually did the reports about which I'm going to give you a little overview of how we got to the reports and a little overview of what's in the reports.

There may be some expectation that I'm going to tell you at least a synopsis of what's in the thousand pages. I'm not.

CHAIRMAN SIEGEL: Thank you.

MR. SERIG: The third slide, what is human factors? I think this is a fairly important notion for you. Human factors is a discipline that thinks they go back about 50 to 55 years. We think we got our start in World War II and it's when terms like man-machine interface and knobs and dials

and things like that came into vogue and we were talking about airplanes crashing because a pilot grabbed lever A when they should have grabbed lever B or moved the lever in the wrong direction or something like that. Military and aviation roots, still very strongly rooted in those areas. Actually, the roots go back further for some of our practitioners, back into the late 1800s, the academic specialty of psychology development in World War I with applied psychology, intelligence testing and those kinds of things for the Army.

The roots undoubtedly go much further than that. Some of my colleagues quote Plato. I can't quote Pogo so and I won't.

The definition here that you see on the slide, the third line down it says about human performance and I think we might substitute the word "behavior" for that because I don't want any of you to infer that we're only talking how well people do things. We're also talking about whether or not they do things and patterns that develop in behavior over time, practices in medical settings, for instance, may lead to excluding some things that need to be done or including some things that don't need to be done. So I am working toward a definition of human factors that includes the notion of behavior as opposed to simply human performance.

Next slide talks about the interest of people involved in human factors and basically it's a question of

mismatches. We're talking about a system, some system that people work in and it can be a very prescribed system or it can be a very broad system, but there are some expectations about what people have to do within that system in order for the system to function.

When there are mismatches between those expectations and what people can reasonably be expected to do, that's when human factors folks get interested because that's when things like, we'll use the term for now, human error, occur; or are highly likely or are more likely than we can accept. There, of course, are other potential results of mismatches which we won't talk very much about today, but an example is that people who are interested in occupational health and safety issues where a mismatch between what you're expected to do and what you can be required to do and reasonably be expected to do might lead to carpal tunnel syndrome or other things like that.

Next slide, again, in this slide it's very appropriate to substitute the word "behavior" for performance in line 2. That sort of allows us to go beyond some mechanistic views of how humans work in systems and extends us to some other approaches not that a mechanistic view is all wrong, but it's incomplete.

MEMBER STITT: Dennis, can I ask you a question?

MR. SERIG: Certainly.

MEMBER STITT: Because my neighbor didn't know so I guess that makes it okay to ask. That's EPRI NP?

MR. SERIG: Electric Power Research Institute and the NP is probably Nuclear Power. It's an outfit that is funded by the nuclear utilities or the electric utilities, excuse me.

MEMBER STITT: So if I steal this to use it in a talk I can cite that?

MR. SERIG: You can use the citation.

MEMBER STITT: Okay.

MR. SERIG: Or call me and I'll give you the rest.

MEMBER STITT: Okay.

MR. SERIG: Basically, when we're talking about human error, human factors, professionals ask two kinds of questions. What does the system require people to do? And what can you reasonably expect them to do?

There's a key phrase in the third line, the only two words in the third line, "specified standard." And what we're saying here is it's the standard that, in fact, defines error, not the performance of the human per se, but only when compared against a standard. And there are some difficulties in working through that and I'll, in a subsequent slide, suggest another term that we use to get away from talking about a human error a little bit, because frequently events

with adverse outcomes are attributed to human error only after the fact. It was only a human error after the fact. And only because somebody said why any fool would have known. Well, obviously, at least one fool did not know.

(Laughter.)

And in many cases, that fool may have been led down the path, rather than just simply failed to recognize something.

Next slide, this is an error-likely situation. It's one that may sound familiar to a few of you at least. There are devices that -- medical devices across international borders and some of them are importer in this country from Europe and may hypothetically and in reality require input of a date and the format may well be give me the day, give me the month, give me the year and we can expect Europeans to perform that task correctly, almost all the time or at least follow that format all the time. When you ask Americans to do that and they know that that's what they should do, you can also expect fairly reasonable performance, but you can't expect as good a performance as you would from Europeans for other reasons: distractions, whatever. We have a much stronger stereotype to right month, day here.

The question is so what? It may not matter at all. We may have some people inputting a date incorrectly, in an incorrect format and it may have absolutely no consequence

on system performance. On the other hand, it might be very important. Some of you may be familiar with a remote afterloading brachytherapy device that requires input of a date in the European format and may also know that we've had one, I don't know where we fell down on it, whether it was a misadministration or not, but an overdose to a patient because of an entry error of this type. And that was a one time occurrence. It was one of several fractions to the patient. Actually, it was the only fraction to the patient because of the overdose that they received.

So it's episodic. It only happened once and it was deemed to be not medically important. We could have systematic consequences of the same kind of error. We have seen errors in teletherapy, for instance, where every fraction that a patient receives is wrong in that for instance both ports received the intended dose for the whole fraction throughout the course of therapy.

You can also have programmatic consequences and I think you're all aware of the Riverside Hospital and Sacred Heart situations where every patient on every fraction received an incorrect dose. And the point is that the same error may lead to any one of these kinds of things.

How did we at the NRC get into the business of doing a human factors evaluation of remote afterloading brachytherapy and/or teletherapy? Well, we had some

experience in these areas. Following Three Mile Island, human factors was cited as an important discipline that needed to be addressed and we had a seven or eight year experience doing that and we are, in fact, continuing to do that. Then the opportunity for our human factors analysts to come to NMSS occurred and one did and the question was well what are some of the things that we might look at and see whether the experience we have with human factors evaluation could apply to materials areas and remote afterloading brachytherapy was one because we had an introduction of devices that was being -- we had a fairly rapid market penetration at the time. We had some reports of hardware problems. We had a few reports of misadministrations, not many, but there appeared to be a very small margin for error and particularly since many of the processes were involving only a single fraction at that time and so people were getting a whole dose or a whole prescribed dose in a single fraction and with very little opportunity to detect or correct an error before the whole fraction was delivered.

Most remote overloading brachytherapy systems involve relatively few fractions compared to teletherapy.

Teletherapy is a little different. We had a much longer experience with teletherapy. We did know that the misadminsitrations that occurred were attributed to human error and this was usually after the fact, implicit this fools

should have known and didn't. Occasionally, we had events with serious potential and actual outcomes where the consequences were either systematic or programmatic and we had and this is a perspective of a human factors analyst, we really had little indication that human error was being addressed in an effective way. There were some, the extremes were firings and reprimands. Some were in the middle, there were admonitions to pay attention, reinstruction, that kind of thing. On the other extreme were things like "it was only a random human error. It won't happen again. It was random."

Anyway, a lot of it was admonitions to pay attention and you and I are living proof that while one of the functions of attention is to be paid so that we can do our jobs well, another very important function of attention is to be switched and many times people are in situations where attention switches for very valuable reasons and so there is some misunderstanding of attention if that's thought of as a corrective measure for many of the kinds of situations we see.

If we look at the next slide, it will be No. 10. There's some analogy between what human factors evaluation is about and medical practices. If you look at the first two bullets there, essentially that's a diagnosis. We're looking at a system and trying to find out what kinds of things are we interested in that might have bad effects on the performance of this system and when we talk about system performance we

could talk about its primary performance measures, its reason for being which might be therapy or diagnosis in a medical system or we can talk about some of its other goals like safety or having a nice black number at the bottom line or things like that as well. And you can talk about all those things, if you would like.

When you look at bullet 3, that is what I see as a frequent next step in the medical process and in our human factors evaluation. We're simply defining a useful set of treatment options. We're not saying this is the treatment we're going to use, but here's the set that might apply and here's some kind of evaluation of which ones of those sets do which things for us. And so we're looking usually not a situation where emergency surgery is needed. We're probably looking at lifestyle changes and long-term health kinds of changes, but here's the set that might lead to those things.

CHAIRMAN SIEGEL: Are the current tools used for identifying human factors problems similar to or identical to those used in TQI, used Preto analysis as the principal tool or are there more sophisticated tools currently available?

MR. SERIG: I won't swear to more sophisticated. As I say, we're a young discipline and not more sophisticated, but becoming more sophisticated. The typical tools are look at events that have happened in the past and try to learn from them, aggregate the information or do an investigation such as

the one outlined here on page 11 which is -- begins with the function task analysis and in essence describe in as much detail as possible what it is people within the system have to do and then look at the system and see how much support they have for doing those things and whether or not given your knowledge of human performance you can expect them to satisfy the standards that are inherent in the process.

So we could again look at the chart on page 11 and the first thing is simply doing that, it's asking what are people required to do within the system to excruciating detail and that's because when you do incident investigations which is another human factors technique, you find that quite often the devil is in the details. Some architect said God is in the details, but human factors folks usually recognize that the devil is there also. It's when you get down to the nitty-gritty understanding of what people have to do that you find situations where they might not reasonably expect it to do that.

The bullets 2 through 5 on that chart are really looking at that next question, what can people reasonably be expected to do? It's situational and within two systems as similar as remote afterloading brachytherapy and teletherapy is similar in many respects, you might find that some of these areas had greater influence than others.

And then the sixth thing is simply looking for the important

mismatches and seeing what we can do to resolve those.

This outline we just talked about is the outline for the two studies that were conducted. There are some weaknesses in this and they're recognized. They're probably more than I listed. We were looking at systems that really hadn't been looked at this way before so we didn't know what we were looking at. That means that the ramp up was a little more difficult in some areas. We tried to advance the art of human factors evaluation by integrating more things. We look at not just the human machine interfaces, the interfaces with the knobs and dials and hardware, but we also tried to look at training procedures and other things all at the same time because they all influence past performance.

We had a dependence on a human factors industry that's young and it's mainly composed of small organizations. That means that they didn't necessarily have the breadth necessarily to attack issues as we would have liked. Another weakness, we ask for a generic approach. You're seeing in each of the two sets of volumes a look at about 25 facilities. That means that hiding in there are some that don't have -- you're hearing an average, but nobody is average.

Another potential weakness was our sponsorship. Certainly, we can be perceived as an outsider in that area and there is a long-standing interaction between the medical community and the NRC that might have affected performance of

the studies.

On the other hand, --

CHAIRMAN SIEGEL: Enough said.

(Laughter.)

MR. SERIG: NRC sponsorship might have been a strength as well. We are an outsider and we can come in with an outside view and we can come in with a broader view.

CHAIRMAN SIEGEL: Is the glass half full or half empty?

MR. SERIG: Correct. Depends on -- well. We also have a great deal of experience in human factors evaluation and probably at the time these studies started were at the forefront in our ability to define that kind of work and get it done.

Another strength is we didn't rely on relatively sparse event data. As I said, we could look at an aggregation of event data, but there was not very much event data. There's a very strong chance it would bias us or mislead us. There's also the problem of unreported events and here I'm not indicating that they were unreported, recognized but unreported, but there is a lot potential for events to be unidentified and therefore unreported and so we wanted to make sure we handled those types of events as well.

Our emphasis on the systems approach, multi and interdisciplinary aspects of the systems being evaluated -- I

often talk about the medical community as a feudal society because when I look in from the outside, I see a lot of fiefdoms, a lot of princes and protection of turf and I see professionalism as work being within a very prescribed area, but maybe not as much communication across those lines as might be beneficial. We forced a look at the broader picture and tried to break as many of those barriers as we could and that simply is working on our perception. I know you believe differently.

CHAIRMAN SIEGEL: No. Why do you think so? I'm really serious. I don't think we think that way. I think systems analysis errors in medicine generically point out that that may be the fundamental problem.

MR. SERIG: I would agree with you.

CHAIRMAN SIEGEL: Doctors have been taught from the beginning of time that they can do no wrong and therefore if any wrong occurs, it obviously was their responsibility and there's no desire to even look at the rest of the system. That's fairly flawed thinking.

MR. SERIG: We also use more than one contractor. And this turned out to be, I think, a major strength. We didn't know how our contractors were going to perform. They hadn't been asked to do this kind of work before. They were both small companies. They both, however, brought on medical consultants that assisted them throughout, but we simply

didn't knox what we were going to get back. We had a lot of hopes that we would get a good product, but we didn't know what we were going to get back. So we tried to assure that at least something got back valuable and we had a redundant and diverse approach.

I think that when we get to the results you'll see the two studies turn out to be complementary.

Another thing that I think is a strength is we stopped. We stopped at a point where we defined what looks like a reasonable set of things to do given the human factors problems that were identified, but none of those things to do were defined down to a gnat's tooth because this was not the right forum. This was not the right group to do that. Their job was diagnostic and to at least indicate given the diagnosis what types of things might be done, but not then to go on and say this has to be done, this has to be done, this has to be done. That's a job for a much broader forum.

What you're going to hear now is the briefest part of the presentation. There's very detailed coverage in the reports. I encourage you to read at least the Executive Summary, maybe the conclusions in Volumes 1 of each of the reports if you're interested, because Volumes 1 are where all the information is pulled forward into what was listed as task 6 here. It is the -- here's what we saw went wrong, here's the kinds of things we think might be developed to resolve

those problems and here's some evaluation of how good those alternative approaches are.

As far as results, both studies did what we asked them to do. They identified human factors' problems and a human factors problem which I didn't -- it's defined on a previous slide and it's defined here, I didn't define it earlier, but I will for you because this is my favorite substitution for human error. It's a task which humans are not likely to perform to the level required by the system. It doesn't point at the human even connotatively and say the human screwed up, it just looks at what people are being required to do in detail and then it brings the knowledge that we have from a fairly broad range of psychology to those tasks and say well, can you reasonably expect those things to be done to some standard? If it has to be done all the time, if date always has to be done in the European format, can you expect that?

Again, both studies identified which factors which could contribute to the various human factors problems, that is, they very specifically indicate interfaces between the humans and the hardware which might lead to problems, interfaces between humans and the geography that might lead to problems, how far an operating room is from a simulation room is from a treatment room, that kind of thing. They also indicate some -- and I'll phrase these as differences from

what has become an accepted practice in other fields. They indicate that training is different than it would be if it was up to snuff in other fields, some of the organizational factors, as well as some of the procedures.

Those studies then prioritize those human factors problems and identified a number of critical tasks or critical task areas that were not only likely to -- there was likely to be a human error, but there was likely to be some kind of adverse outcome.

The next two slides list the coincidentally ten critical tasks or ten critical task areas. There's a little bit different terminology from one study to the other, identified for remote afterloading brachytherapy and for teletherapy.

I'd like to point out that given about four years' experience with these reports or their generation in the studies, I know that these lists are more similar than they appear. What you're seeing to some extent is different people trying to tell you the same thing and they use different phrases, but when you read the information as I hope some of you do, you'll find that there's a considerable overlap, but not entirely. There are also some things that one contractor points out, the other contractor does not. To that extent I think they're complementary though. They really, it's not that one guy is wrong and one guy is right.

It's that one guy made an observation that another guy didn't and I think they're both important.

Finally, for results, both studies identified alternatives for improving system performance of the critical tasks or the critical task areas and both studies found some alternatives to offer greater potential values than others in evaluating these things.

Page 19 is a general approach for addressing human factors problems. It's straight out of one of the documents. In essence, you could use this as guidance for choice among or integration of alternative approaches when you have a problem and certainly you'd like to decrease the likelihood of human error before thinking about damage control at the bottom, so they really are listed in order of preference.

I'd like to read a passage though that has a little bit to do with what you just saw on page 19. In the other contractor's report there's a passage that says "the multiplicity of contributing factors limits the usefulness of alternative approaches that focus on singular fixes to the neglect of factors that interact and permeate the system. The pervasiveness of the contributing factors also suggest that approaches that address the problem in one task area also are likely to be beneficial for performance in another task area."

So if you change human machine interfaces and if

you're careful in doing that, if you evaluate -- you don't just make a change, you evaluate the impact of that change, you might find that it improves performance not only in the particular task you were interested in, but in others as well. But of course, you have to be concerned that it could make performance in other areas worse, and so you have to continue your evaluation as you make changes.

CHAIRMAN SIEGEL: Because potentially that's counter-intuitive and we've argued often that attention to certain small areas of performance would divert attention from the really important tasks.

MR. SERIG: I would argue the same thing, but I did not bring with me, as an example, the association for advancement of medical instrumentation has a document whose name is much too long to remember. Human factors engineering guidelines and practices for -- Section 5 in there is a conversion from a military document, but it outlines a process of human factors engineering and it's really human factors engineering for devices, but it could be translated to full systems where people are components as well as devices, that stresses the iterative look at the consequences of a change, not just at the local point, but throughout the system. And I think that's one of the things that's very strongly brought forward in both of these reports is that you really have to look at the whole system and the influence of changes at any

one point on other points.

CHAIRMAN SIEGEL: You make a very strong argument for experimental validation of regulations where they become regulations.

(Laughter.)

MR. WAGNER: Are we kicking the dog again?

CHAIRMAN SIEGEL: No, not at all, not at all. In fact, the NRC has actually tried to do that. I mean if we recall back to the pre-QM rule days, there was an attempt to take an early version of the QM rule and put it in a place in the facilities before it became a rule to see whether it had much impact on the way they worked and I think you make a very compelling argument for doing that as much as possible.

MR. SERIG: Change whatever, for whatever reason should be analyzed prior to --

CHAIRMAN SIEGEL: If you've got a complex system, much of which is a black box and despite the attempts to analyze this, a lot of this really is a black box. If you change some input in the system or some cog in the system, you've got to look at the whole system to find out what's really happened.

MEMBER STITT: I just want to make some self-serving comments here.

CHAIRMAN SIEGEL: Please do.

MEMBER STITT: I love to see it when it's in

writing. This area of interest has gotten me turned on over the past year and a half, have gotten together with some people from the University of Wisconsin called CHPCS, Center for Human Performance in Complex Systems and the NRC is aware of that. It's not uncommon that people from the NRC show up to give talks and put on some shows at our annual meetings, one of which will be coming up next week and we've invited a variety of people in the bracytherapy instrumentation area to come and try to learn, but some of the things that I've gotten out of this are that through some readings that you've recommended and other people have recommended that the whole business of human error in medicine which used to be just simply ignored can be very easily described and identified and documented and in fact, one European investigator has a computer software program that you can take a whole variety of different events, whether they're medicine or transportation or nuclear power plant and look at human performance, look at mechanical, look at organizational issues and you can literally compile this into a research format.

I guess the point is that more money is being expended and grants are competitive to try to look at human performance. There's a large grant that's out in blood banking that uses a variety of new systems and you can be very objective about how these things occur and then try to look at what you can do about them. So I guess, part of it I want to

say is the NRC and my work here has gotten me involved in this and I want to say thanks for that exciting twist of events. People ought to be looking at the literature for these issues. I think a lot of what we do in nuclear medicine as well as brachytherapy really fits into this whole human factors business.

MR. SERIG: I've got a couple of windup slides and again my discussion is going to be perfunctory. The high level bullets I'm going to provide are covered in excruciating detail in the stack of documents in front of me, but really we're looking at what are these sets of alternatives that might lead to a healthier system for remote afterloading brachytherapy or for teletherapy and in this case we have a short list for remote afterloading brachytherapy and a little bit longer list for teletherapy, but I think that again the differences in style and the content, once you boil it down, would be very much the same.

Human system interface and equipment modifications, it's very clear that there could be some changes to the equipment and facilities, particularly for remote afterloading brachytherapy and to some extent for teletherapy that would reduce the likelihood of error, that would make it more detectable and that might make it easier to correct, prior to misadministration or at least prior to 20 fractions of misadministration.

Job performance aids, that may be jargon that you're not familiar with. I tried to stay away from that, but it's unavoidable. A job performance aid might for you guys be a post-it that you put on your computer to remind you to hit the F7 key to do something. It's just in some fashion a reminder. It might be a sequence of steps that you list some place. There are lots of other examples that aren't so cognitive, but it's easy to see them once you have a feel for them. For instance, if you watched the Olympics in '92, Summer Olympics in '92, whenever, you might have seen Carl Lewis at the 4 x 100 relay putting some tape on the track. And that was the point where he intended to start his run to accept the baton, so that he would still be within the legal pass zone. So it was simply a job performance aid. You can't go out on the track during the race until it's your turn. Where are you going to stand? Well, here's where you stand, a piece of tape with "Lewis" marked on it. That's where you stand. A job performance aid.

Procedure modifications, one of the studies, what I think did a very good job on the question of linkages between one activity and the next, what needs to flow between one activity and the next. Very strong analysis of definition of the kinds of things that might need to flow from one thing to the next and then a look to see whether they actually did flow, and they don't. In many cases, they do not. In

particular, what does not flow quite often is information that would allow me to check to see whether what I'm doing is correct. The verification information. This is Patient So and So. This is Patient So and So. Do I have to continue to ask that or is there some way to verify this? This is the dose that is supposed to be administered. Is there some independent way to verify other than just looking at the chart. A number of kinds of things like that in particular in one of the reports.

Training and organizational modifications, I think both of the contractors would describe -- I know one of them does all the time and the other one does some time, the training they saw as see one, do one, teach one. As being the medical model for training. A vendor comes out, you bought the piece of equipment. Vendor rep allows you to see them perform. Then you do one, maybe under their observation, but then you're the teacher. They go away. Now you're the teacher. That is certainly not consistent with the training models that have been built by human factors professionals and others in other industries. That's a rather heavily discussed and --

CHAIRMAN SIEGEL: Actually a moderate amount of medical activity is do one, do one, do one. You start off never having done it before and say I'll figure this out.

MR. SERIG: Well, I don't think anybody uses this

term, but it occurs to me that coping behavior in a medical setting might not be what you want, but that's what you get quite often and enough said.

Organizational modifications, again, there was an attempt, at least on the part of one contractor to identify some very specific organizational functions that supported operational functions and to identify places where that support might not have been adequate to lead to reasonable expectations that the operator did what they were supposed to do.

I'm not going to go through the teletherapy list in any detail. I'll just point out that this is in order from top to bottom where they thought that workload contributed to more things than did implementation skill. In other words, the ability to do the task was very often there, but workload may have meant that you got distracted in the middle of the task, came back to the wrong point in the task or something else. So -- and again, if you parse these and look at them against the set that the remote afterloading brachytherapy folks came up with, you'll find that there's a lot of overlap, the two lists look different, but are not as different as they look.

I think that what that leaves us with is some opportunities and challenges. There's no doubt in my mind and I don't think there's any doubt in either of the contractor's

minds that we have available the technical skills to resolve a lot of the human factors problems in teletherapy and remote afterloading brachytherapy. And I think the key challenge for us now as I thought five years ago when I talked to the ACRS about this, is well how do you get it done and we're still wrestling with that, but again, as I pointed out, a different forum is required to answer that question. You need to think about what players need to be involved, how to get them involved and what activities need to be done and how do you break down or manage to assure that there are not barriers between the groups that need to play together.

Current follow up in the NRC, there are two items. NRC just developed an agency-wide human performance program. There are two items in that that relate to specifically to follow up. One is to review the findings in a lot more detail than I did today. And to try to come up with an integrated plan for dealing with them and again, the questions might well be how to involve the larger community. We're interested in leverage and using very real resources and very knowledgeable resources. Let me say that the folks that were visited by these contractors were very receptive, even though occasionally they were put upon. This was not noninvasive diagnostics. This was invasive. But they understood to a large extent what was going on and probably would see being a player in the follow up activities as being

important.

A second item is to investigate the feasibility of using something called task network modeling to estimate human contribution to a risk associated with activities of materials licensees. That's the way it's in the human performance program plan. Task network modeling is a computer simulation. You can event based simulation, you can put in mechanical events, human events, all kinds of events. You link them together as they would in the natural environment to the best of your ability and you can manipulate them and what we hope to be true is that you can make changes to a model that might be representative of situation A and see whether you successfully reduce the number of overdoses or wrong patients or whatever, yet to be done though.

There are also presentations being made. Last spring, I talked to the Great Lakes Chapter of the Health Physicists Society and in November, I'll talk to the Northwest Chapter of AAPM.

The last thing on the list is one of my favorites and it's been spurned once. I'm hoping it will be more successful next time, but it would be a colloquium to try to bring together a interdisciplinary, multi-disciplinary group to sit down and try to cut up the pie, what things need to be done and who can be involved.

That's where we are today and I think I'll

entertain any questions now.

CHAIRMAN SIEGEL: Thanks, Dennis. Questions?

MR. QUILLIN: Have you gotten any feedback from the manufacturers of these devices?

MR. SERIG: No, I have not.

CHAIRMAN SIEGEL: Based on the recent literature that has dealt generically with errors in medicine, do you think these areas of medical practice are about average, better than average or worse than average?

MR. SERIG: I can only work with the hearsay I have and everybody around this table will tell me you're better than average and I think that's true. I think that's true because I hear one in a 100 therapy-drug misadministrations. I hear numbers which are much worse or appear to be much worse than what we experience here. On the other hand, some of the things that we see in other medical settings are consistent with what we see. Wrong patient is wrong patient, regardless of what the medical procedure is and frequently, you know, the medical procedure is irrelevant to the fact that a wrong patient showed up, got treated or whatever.

CHAIRMAN SIEGEL: Thank you. All right, that brings us to final administrative issues. First is status of positions on the ACMUI. Are you going to bring us up to date on that, Trish?

MS. HOLAHAN: Okay. There are two currently open positions, one being the radiation therapy technologist and we had forwarded one nomination to the Commission and that individual withdrew her nomination so we have another paper, another alternate candidate and that nomination is currently in the process of Commission approval. Also, we had a position for a therapy medical physicist and we had a screening panel and they ranked the top three candidates from that screening panel and the staff is in the process of forwarding the nominations to the Commission again for Commission approval of the candidates selected by the Panel.

The third item that's not on your list is that with Dr. Siegel departing next year, I believe, is we are also in the process of replacing the nuclear medicine physician and selecting a new chairman and the Commission paper is prepared and is in the process and all the Committee members, I believe, were contacted on that.

MEMBER NELP: I didn't receive any information about replacement. Are you circulating for suggestions?

MS. HOLAHAN: No, we're just basically saying, the Commission paper that is going up is indicating the need to replace.

MEMBER NELP: I see. Thank you.

MS. HOLAHAN: Yes.

CHAIRMAN SIEGEL: Is there any question that will

occur? My question was when is the Federal Register notice for nominations to replace this nuclear medicine physician on the Committee going to appear?

MS. TAYLOR: I would have been comfortable if it had already been done.

CHAIRMAN SIEGEL: Me too.

MS. TAYLOR: But due to the process of the managers and concurrence process and issues, it wasn't able to happen.

CHAIRMAN SIEGEL: Let me suggest that given some of the very important issues that the Committee is likely to deal with in the near term, that although we have tolerated not having a radiation oncology physicist on the Committee for a relatively longer period of time than we wish to, not having a replacement for this particular nuclear medicine seat on the Committee, it's a suboptimal approach.

Does anybody disagree?

MEMBER STITT: Strongly agree. So please pass the word upstairs we'd like to move this one along.

MS. HOLAHAN: Okay, I'll take that back. Okay?

CHAIRMAN SIEGEL: Okay. Next is release of list of ACMUI members.

MS. TAYLOR: Yes, we often get a lot of requests to release this list. I just want to make everyone aware that it is released. It is considered a public document. Not

released, residential addresses and phone numbers and I have this directed to my attention. Currently, there's only one member that has a residential address listed.

CHAIRMAN SIEGEL: Okay, I'm also, on the same note, I'm pleased to announce that there are not only two people let on the Committee who don't currently have E-mail. Dr. Berman has joined the electronic ranks in cyberspace.

MS. TAYLOR: I have one question on that. Does your secretary have access to that?

CHAIRMAN SIEGEL: So ideally everybody can be electronically connected before I finally rotate off the Committee.

Travel?

MS. TAYLOR: The secretary requests that everyone be sure and include their airline itinerary they get with their ticket. It makes it easier for her to process the reimbursements.

CHAIRMAN SIEGEL: Finally, just note for your calendars that at least in theory we're scheduled to meet February 21 and 22 and we will discuss over the next weeks whether we're going to extend that meeting an additional day to include a first foray into training and experience. In part, that will depend a little bit on what the NAS says.

We also need to get the calendar circulated soon so we can schedule the May meeting or the April meeting or

whatever because I'm going to be in Korea and China for a good fraction of May so we'll need to pick these dates soon so that there's time left on the calendar.

Are there any other administration issues which any of you wish to bring up?

MS. HOLAHAN: The only other thing I'd like to raise is if anybody has any suggested topics for the May meeting at the time they're being contacted for scheduling.

CHAIRMAN SIEGEL: A continuation of the training and experience discussion is going to be high on the list of things that we hope we'll be dealing with.

Failing that, I once again would like to thank the staff who are still remaining in the room for all the hard work you guys do in putting this meeting together and preparing to speak to us and walk us through these complicated issues. I hope we've provided you with some useful input. Torre, particularly, thanks for all your logistical help. We're not going to execute you for getting the agendas mixed up yesterday because you came through with that wonderful suggestion of allowing us to deal with the closed session during that period we opened up, so everything worked out great.

As far as I'm concerned, we may adjourn, but Trish needs to do it officially.

MS. HOLAHAN: Okay, I'd like to just thank all

the members for their participation in this meeting and as the DFO, I formally close this meeting.

(Whereupon, at 12:13 p.m., the meeting was concluded.)