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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL

USES OF ISOTOPES

(ACMUI)

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SUBCOMMITTEE ON MOBILE MEDICAL SERVICE

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MORNING SESSION

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WEDNESDAY

SEPTEMBER 27, 1995

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ROCKVILLE, MARYLAND

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The Subcommittee met at the Nuclear Regulatory Commission, Two White Flint North, 11565 Rockville Pike, Room T2B1, at 8:00 a.m., Barry A. Siegel, Chairman, presiding.

MEMBERS PRESENT:

BARRY A. SIEGEL

LOUIS WAGNER

ALSO PRESENT:

TORRE TAYLOR
JAMES LYNCH
LARRY CAMPER
JANET SCHLUETER
MARGO BARRON
GARY STEIN

A G E N D A

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

(8:19 a.m.)

MR. CAMPER: Good morning. I'm Larry Camper. I'm the chief of the Medical Academic and Commercial Use Safety Branch. I'm the designated federal official for this meeting. The purpose of the meeting for the next two to three days, which were publicly noticed, is to discuss a number of draft modules for inclusion into the existing Regulatory Guide 10.8, which is the Medical Licensing Guide. This effort is part of an updating to Reg Guide 10.8. The agency recognizes that ultimately Reg Guide 10.8 will undergo a substantial change as we move in the future to revise Part 35, following the receipt of the report by the National Academy of Science. However, the reason we're updating the guide at this point in time to the extent that we are is that over the last couple of years we've been working under a plan known as the Medical Management Plan. Janet Schlueter, who's in the audience, is a member of my staff, is the project manager for the MMP. And there was some guidance lacking in Reg Guide 10.8. Some of it was lacking in its entirety and some of it was lacking in part and needs to be updated.

So what we're going to accomplish over the next two or three days with the assistance of the subcommittee is to take a look at these draft modules, and then ultimately these draft modules will be published and will be included in

10.8.

Janet, what's the schedule and where do we go from this point forward?

MS. SCHLUETER: Okay. Just to kind of give you an overview of where we are in this entire project, there are seven different working jobs and I'm the chair of this project. And what we did is we developed those last summer and fall, meaning in 1994, and then beginning in 1995 we sent them out in about four different transmittals to the NRC regional offices and the agreement states for comment. They went out in groups of two and then the last one to go out was the revision of the existing policy and guidance director for remote afterloaders. And that's the last one that has just hit the streets for comment. And so there hasn't been a big comment period left on that one, but that document has been used for some time.

So where we're at now is that the working groups have all received all the comments and have reviewed those, have revised their modules accordingly to incorporate those comments. And we wanted to get ACMUI's input at this point so that where the groups will go from now is revising their modules based on your comments again, and then also developing a standard review plan, which will basically be the module itself, a checklist, and a model license. Now those standard review plans will be updated and modified and developed this

fall, and then distributed to the regions for use. Our goal is to get those out to the NRC regional offices by December 31, 1995. Those will be for use by the regions.

Now we realize we're putting something out for use that in fact will subsequently go out for public comment. But that's okay. The regions have had an opportunity to comment on them; they need to begin to using them, and then to tell us if there are voids or inaccuracies, or what have you.

So the goal is to get them to the regions by the end of the calendar year, and then since we began this project, BPR, the business process reengineering project has really taken off and there's been a change in how we'll issue our modules. We'll issue our modules for public comment as part of the overall, very broad materials licensing manual that's being developed by BPR. So these Red Guide 10.8 modules will no longer stand alone, but will be incorporated in the materials licensing manual. And they'll go out for public comment.

I would imagine now the timetable is February-March time frame of 1996. So they'll be out to the regions just a little bit before that. And I think that's about it as far as where the project is now.

MR. SIEGEL: What's the plan in terms of bringing the subcommittee suggestions in the revised documents back to the ACMUI as a whole?

MS. SCHLUETER: Well, we'll have to figure out how we would accomplish that if that's desired, because right now the time line for revising the modules, developing the checklist and module, is mid-November of this year, and you're meeting in October, so I'm not sure --

MS. TAYLOR: It is on the agenda to talk about generally.

MS. SCHLUETER: Okay, to talk about generally what we did? Because that's only three weeks from now obviously.

MR. CAMPER: That's right. At this point, Mary, there has not been a plan to take the revised guidance documents back before the entire committee. The plan at this point has been have the subcommittee provide comments that would be a report of the subcommittee activities and findings to the full committee. That's on the agenda for the October meeting. But there is a timing mismatch to have such a full review, and furthermore, there's going to be a special meeting of the ACMUI as you know in February, but that's going to be the focus point in the NAS report, which in itself is going to be comprehensive enough for a full meeting. So the earliest opportunity would be May. I don't know if that review is desired by the committee or if it's necessary, but we can certainly contemplate that.

MR. SIEGEL: Right. I wasn't really meaning to

press it. I think when we left it at the last meeting the notion was that the most efficient way to do this was to have small groups of people sitting around trying to talk through some of these issues, and I'm perfectly happy with the notion that either, whatever our minutes are or brief reports of what significant changes might have occurred as a result of these three days worth of subcommittee meetings, got back by way of an information report to the committee as a whole. I think the committee as a whole will not wish to take the time to go through any of these little details again.

MR. CAMPER: When it's published, Janet, what's the planned period for public comment?

MS. SCHLUETER: Well, that will be up to the BPR licensing manual. I mean I would imagine it would be no less than probably 90 days, and probably longer.

MR. CAMPER: So that would be -- You're saying February is the plan?

MS. SCHLUETER: At the earliest.

MR. CAMPER: So February, March -- put you into June, July and August. Now the May meeting of the ACMUI I assume will be talking about the licensing manual obviously as a significant agenda item.

What you might be able to do, Barry, in your subcommittee -- Let's assume for sake of discussion that this goes along fairly smoothly. The subcommittee doesn't identify

any remaining outlying issues with which you have a problem. In that case it might not be necessary for the guides to go through the full committee. But by the same token, if it turns out that there's some significant issue you could, a) address that in your report to the committee, and then we could add it as an agenda item for discussing before the full committee in the May meeting. And it might mean that we can do that under the umbrella of talking about the licensing manual at large.

MR. SIEGEL: That's fine.

MR. CAMPER: Okay.

MR. SIEGEL: Yes, I think that's reasonable.

MR. CAMPER: Does that seem like that will work?

MS. SCHLUETER: Yes.

MR. CAMPER: All right. Well with that introduction. Are there members of the audience who would like to introduce themselves for the record? There's a couple folks.

MS. BARRON: I'm Margo Barron from NUS.

MR. CAMPER: Did you get that?

Would you say that a little louder?

MS. BARRON: Margo Barron from NUS.

MR. STEIN: Gary Stein from the American Society of Health System Pharmacists.

MR. CAMPER: All right. There are members of the

Medical and Academic Section staff. We have Sally Merchant; Janet Schlueter of course, Trish Holahan. And Trish is also working with Janet now on these modules and will be here over the course the next couple days; the assistance of the subcommittee if need be.

Suzanne Woods, a member of the Medical and Academic Section staff. And of course Torre Taylor, a member of our staff, who also functions as the administrative coordinator for the ACMUI activities.

With that then, Barry, I will turn it over to you as the chair, and let's proceed.

MR. SIEGEL: Good. I must admit I don't have a plan, but we're here this morning to deal with mobile medical service module, and to try to get whatever issues there are out on the table.

Let me ask -- if unless Dr. Wagner objects -- you or someone to begin by telling us what you have encountered as the most significant problems in the last few years in licensing mobile services. What have been the most complicated issue for you all to grapple with?

MR. CAMPER: That's an excellent question, and I was looking through this last night and trying to look at some of the words we had put down and being struck by some problems -- I think the biggest problem area is that when it comes to mobile medical licensing there are two problems.

One, is that there is a regulatory problem. If I look at the language today in Part 35 there are two primary parts that deal with it, 35.29 and 35.80. I think that the regulatory criteria, while appropriate and worthwhile at the time when Part 35 was last revised, it may not necessarily be reflective of trends that are going on in industry today. We see somewhat of a increase toward mobile medical imaging. And that's really not surprising given some of the dynamics going on in health care today.

Well if you look at language in 35.29 and 35.80 I think that one can make a reasonable argument that it's fairly restrictive, particularly with regards to the capacity for one to receive radio pharmaceuticals at a scan in van scenario for example. Some of the arrangements for interfacing with hospital clients are cumbersome and may not necessarily be consistent with business practice in today's marketplace. But unfortunately that will take a regulatory fix, an adjustment in the language. And we can deal with that problem when we revise Part 35 over the next few years, and we can certainly employ the committee to help us do that. That's one problem.

And the fallout from that problem then is, is that what we do -- and in fact Torre and I worked on a case just last week on this. We're having to grant some exemptions to some of the criteria in 35.80 and 35.29, and certainly the regulations obviously allow for the capacity to grant

exemptions. You prefer not to regulate by the granting of exemptions. You probably ought to modify your regulations and over time you learn things and you ultimately do that.

So that's a major problem, existing regulations. I don't know how to fix that other than adjustments to the language which we'll do in due course. But with regards to the guidance though, what we might be able to do in guidance is to address some of these things we've already seen.

For example looking through the guidance the last day or two, a couple things I'm struck by that aren't included that we might consider including, is some discussions of some of these changes that are going on in the industry, that potential applicants should consider their need for radio pharmaceuticals' procurement, what kind of arrangements do they want to have at site for being able to receive the materials and therefore alert them to the fact that certain parts of the regulations they may need to seek an exemption to. And in particular I think at 35(a), possibly (b), 35.29(d). And then the other issue that we need to talk about is reciprocity. Reciprocity is a very large scale problem in the sense that today we have a strong program in reciprocity where agreement state licensees want to come into NRC jurisdiction. There's a mechanism and a method for filing for reciprocity, and they can get reciprocity for up to 180 days in a year.

Well, if one looks today at some of the regulations and guidelines that are subject to reciprocity, it becomes at least clear to me that they weren't developed with mobile medical imaging in mind, and the truth of the matter is that you can easily imagine the scenario where someone could be based in an NRC agreement state -- let's say Virginia for example -- and want to go right across the border to provide services in a town in North Carolina. And we say nothing literally in the guidance at this point about reciprocity and some of the things that they need to be aware of.

And my observation is, is that as mobile medical services continue to increase that will become more and more of an issue. We at this point have a strong potential to receive an application for mobile, high dose rate mode afterloading service. We have met with the company that's interested in this. They were going to submit an application by summer; they didn't do that. Currently our regulations don't allow therapy in a mobile scenario. That would require a significant exemption. It would require a significant adjustment in policy in that regard.

But again, we're faced with emerging technology and emerging changes in the way health care is provided. So, I think then those are really the two big issues as I see them of large scale.

MR. SIEGEL: Just a simple opening question which

is, the module is called mobile medical service; that the corresponding regulatory parts are called mobile nuclear medicine service in 35.29 and 35.80?

MR. CAMPER: That's right.

MR. SIEGEL: And I wasn't sure whether the module was named more broadly with the notion that it was intended to capture some types of radiation oncology practice?

MS. TAYLOR: Mainly to capture the radio therapy under 30 millicuries.

MR. SIEGEL: But that's still nuclear medicine.

MR. CAMPER: At least in theory, most of the time.

MS. TAYLOR: I think we just changed it to give it a more general name because it wasn't going to be strictly just nuclear medicine.

MR. SIEGEL: But this module as it stands right now, isn't that designed to address mobile HDR or mobile LDR if such were to exist?

MR. CAMPER: It is not.

MS. TAYLOR: That's intended to be addressed in another module, right?

MR. CAMPER: Now let me just see if I can understand, and Lou interrupt me anytime. Some general issues related to how you think a license is currently written under a few scenarios.

Let's start with the common current scenario whereby a large hospital corporation, which is getting to be an increasingly common situation that perhaps owns 15 or 20 hospitals over a one state, two state, three state area, decides that for its ten world facilities it needs to have a mobile service because none of them is large enough to sustain a freestanding nuclear medicine department.

Each of those component hospitals is itself a medical institution. The parent corporation may or may not be considered a medical institution given this definition, which we'll talk about in a bit.

Who would the NRC most like to have the license for the mobile service? A parent corporation, or does the NRC want there to be ten licenses for each of the component medical institutions that receive the mobile service?

MR. CAMPER: Well, I'm not sure that we have a preference as such. What we're concerned about of course, Barry, is it to be a clear delineation of control and authority; be a clear delineation of who is managing the radiation safety program, and who in the management structure is responsible.

Now, in your scenario, if you have ten hospitals and let's say they all have a license; they all have limited specific licenses for sake of discussion.

MR. SIEGEL: See that's the part I'm not sure

about, is whether they -- As I read this it seemed like they have to have a license. There couldn't just be one license to the parent corporation.

MR. CAMPER: In your example as you were explaining it I was envisioning a situation where you had these ten institutions. Each were medical institutions as defined and they each had a license.

Now, they could still -- That corporation could still under that scenario come in and get a mobile medical license under Corporation A, let's say. They could then decide to go to some of those existing limited specific licensees that are their hospitals and decide to provide services to them.

And there are some administrative considerations that are talked about in 35. You have to have, of course, letters of permission if you're doing some of the same things that the institution is licensed for then you have to recognize that those things come under the control and responsibility of a licensed institution. That's the way it's currently set up. I think by the way that's an awkward arrangement, but be that as it may, it's the way that it is today and until such time that we change that. I don't think it's 1995; it's not today's reality.

But, they certainly could do that then. They'd have to operate under existing administrative restrictions.

But we would issue a licensee to one. But again, if you had ten licenses in this corporate chain and you also had one license for this corporate chain that was mobile, we would be looking in each case for a clear delineation of who's in charge, who's administratively responsible, who is a radiation safety officer, who's conducting the program and so forth. But we don't look at it as a preference for one or the other.

MR. SIEGEL: But do you currently require that if one of the clients is a medical institution that there has to be a license at the medical institution?

MR. CAMPER: No, we do not.

MR. SIEGEL: So there could be a single corporate license to cover the activities of the whole operation?

MR. CAMPER: Yes, there can be.

MR. SIEGEL: And the Navy would be --

MR. CAMPER: Well, no.

MR. SIEGEL: I mean I know that's not mobile, but that's --

MR. CAMPER: I wouldn't even think of the Navy in that same context. The Navy and the Air Force have a unique situation, that they have master materials licenses. And what's terribly unique about them of course is that they do their own licensing. They issue permits. They do their own inspections. They undergo audits by us and we participate in their radiation safety program management and so forth. But

that's a distinctly different program.

If we had a Corporation A that had a mobile license and it had ten -- Let's take a scenario. Let's say for example they had ten hospitals. They were doing diagnostic only and limited therapeutic nuclear medicine, let's say up to 30 millicuries. They decided they wanted to cancel all ten licenses and have one mobile corporate license, they could certainly do that and then go to each facility and provide the diagnostic nuclear medicine capability. And frankly I suspect in the future you'll see some of that type of activity.

MR. SIEGEL: And then would the mobile service have a radiation safety committee? Would the mobile service itself become functionally a medical institution?

MR. CAMPER: That's an interesting question. I want to talk about that in some of the language we have in this guidance today. But not as currently structured, no; not in existing regulatory parts, NRC would not be required.

MR. SIEGEL: Okay.

MR. CAMPER: I mean we have mobile licensees today that are corporate entities, that go provide services, and they do not have a radiation safety program.

MR. SIEGEL: Are there mobile services -- Is there any substantial number of mobile services that go to hospitals that are already licensed to have nuclear medicine

services?

MR. CAMPER: I don't know what the numbers are exactly.

MR. LYNCH: There are examples.

MR. CAMPER: But there are certainly mobile --

MR. SIEGEL: And so what happens at the interface between those two licenses? I mean obviously that's one of the problems.

MR. CAMPER: I think there are two aspects to the interface. I think on one hand, if you look at our regulations it says that, if you're going to go into an institution for them to be a client there has to be a letter saying, we want your services; you can come to our institution and provide services. Then it also says though that, if you're going to provide the same services that my institution, the hospital, provides, that when providing those services at my institution my hospital is responsible for what goes on.

Now I suspect as a reality that gets very fuzzy and I don't know, Jim, what we've seen in terms of inspection findings to what degree that is a problem, but I can certainly see where that could be a real area for problems. Because again, it's okay to say that as the institution that I'm responsible for this. I guess the question becomes, to what degree is the institution radiation safety officer and the institution radiation safety program truly overseeing and

monitoring what's going on by that mobile service entity while they're in their institution. And I guess like, the truth to be known, Barry, it's probably like every other radiation safety program; it's highly variable.

MR. WAGNER: That's the difficult thing as I was going through the module that I found very difficult to understand. If the mobile service provides services to a place that doesn't have a license then the mobile service is responsible for everything.

MR. CAMPER: Right.

MR. WAGNER: But if the mobile service goes to a place that does have a license then it is the place they're servicing that is responsible for everything.

MR. CAMPER: For those licensed activities of the institution that the mobile service is also providing. If we take the most simplistic example, 35.200, which obviously is the broad band of imaging, if they're in there doing bone scans, liver scans, mugas, etc., yes, if the institution has 35.200 authorization and the mobile service is doing it, the institution is responsible as the regulations are currently structured.

MR. SIEGEL: So the mobile service under those circumstances is just a contractor?

MR. CAMPER: True.

MR. SIEGEL: It's just providing contract

services to a licensed institution in a way then gets treated the same way that a contract, god forbid, radiation safety officer or health physicist is treated by you all?

The institution has the responsibility.

MR. CAMPER: That's right.

MR. SIEGEL: But even though the mobile service itself has its own license. It has to have its own license.

Now, if a mobile service just moves an imaging instrument around does it need a license?

MR. CAMPER: No.

MR. SIEGEL: If the administration and by product material occurs in the institution for use on the mobile service's imaging instruments, but the mobile service itself never possesses by product material --

MR. CAMPER: That's correct. It's about possession and use of by product material. That's what causes the license to be required. In the scenario you're describing, that would be by product material, licensed, and under the control of the medical institution.

Now, with regards to the mobile for medical and some of these administrative requirements that are currently in 35.29, I think what you have here -- and this gets back to the first problem that I was addressing. In 1987 when the regulations currently became effective and they were promulgated and developed back in '85-86 time frame, I don't

think that mobile medical imaging was the same thing then that it is today. And so much responsibility was placed upon the medical institution in the classical sense of how have we approached licensing. There's two major components; the institution and the authorized user. It's been that way for years.

But I think what you have today, is you have business arrangements today for an authorized user for example. It's an active player in a mobile medical service. Then you face a question -- again, this is something we'll have to deal with in the future as we revisit the regulations. Under that scenario or some similar scenario, shouldn't the mobile medical license be clearly identified as being responsible for all aspects of the radiation safety program, even if an institution has a license. I don't know, there's a question we have to discuss.

MR. WAGNER: Well I must admit I was extremely confused as I was going through and reading these things. It would be very very confusing to understand who is responsible for certain activities given the fact that both would have a license. The mobile medical service comes in with their services and yet once they get on their property the institution that they're servicing takes over the responsibility for the regulatory practice, and that to me is extremely cumbersome. I can't imagine how that could be

worked out in a reasonable event if something occurred. Who'd be responsible for what? It would we very very difficult. I mean if something goes on inside the van that is a problem then technically the institution they're serving is the one responsible for that, and how can they possibly be responsible for that when they are not the company providing those services? I mean it seems to me that we have created a very convoluted problem here that may be intractable.

MR. CAMPER: I would agree with that. Again, the logic that was applied -- and I don't think you'll find an awful lot about this in statement of consideration. If you go back and read them you'll find some limited discussion but probably not to the detail that we would like to have today.

But the idea is that, the institution has a license, the institution has a defined radiation safety program. They have a designated radiation safety officer. They have a radiation safety committee. And that being is in a position then to oversee what's going on in that scan van just like it would any other component of its by product material use program. And therefore you're going to apply certain management and administrative controls and reviews in that just like you would for the nuclear medicine department, or even some satellite cardiac imaging room or something of that nature. That was the mind-set that brought those requirements in 35.29 to bear.

MR. WAGNER: So I see what you're saying. What you're saying is basically times have changed and those regulations were developed on certain scenarios. Those scenarios no longer exist, but unfortunately we're set with regulations that apply to scenarios that don't exist and now we're trying to figure out ways to apply inappropriate regulations to the current situation.

MR. SIEGEL: Well appropriate is a strong word.

MR. WAGNER: Something like that.

MR. LYNCH: There is one other issue and that's the ownership of the material. If there's some technetium 99-M spilled on the floor of a nuclear medicine lab, I can't tell if that's from my hospital program or if it's from your mobile service. So theoretically both licensees could be using material, the same material in the same area, and you can't physically tell them apart.

MR. SIEGEL: How big a problem is this? I mean, what kinds of problems have you encountered, not at the licensing end, but at the compliance end? When you inspect the operations of mobile services and the clients they serve have you found problems?

MR. CAMPER: Do you want to follow that?

MR. LYNCH: I can't think of any significant problems that were identified.

MR. CAMPER: Similarly here. I can't recall any

kind of compelling case.

Is anyone else on the medical staff? That's an interesting question for the following reason. As I see mobile applications today -- we've had two or three recently. One out in the west that wanted to transport generators on the van, which requires an exemption to do so. The scenario we had recently when they were talking about wanting to receive materials at the van, and so forth.

What I'm saying, Barry, is that, I think that historically mobile medical services have performed in a satisfactory manner. We have not seen unusually high violations in that type of licensing entity as compared to normal, the medical institutions.

But having said that, at least my sense is -- and seeing some of the things that have been going on today -- mobile medical imaging, mobile medical services involving radiation are changing, are evolving.

Now, is that a precursor to increased problems in the future? I don't know. I couldn't predict that. But I certainly see scenarios today where people want to do things differently than the regulations currently allow them to do. And you would think then if they assume more responsibility for receiving materials. They want to transport materials in the van; the generators and so forth and so on. You certainly can see a heightened possibility for problems. Will that

materialize? I don't know, but it's changing.

MR. WAGNER: But this module that we were going to review only applies to diagnostic, it doesn't apply to giving you any advice regarding how you would grant exemptions for other issues.

MR. CAMPER: It's diagnostic and limited therapeutic up to 30 millicuries. But a couple of things I think we ought to ponder is, to what degree should we put any language into this guidance where we bring to the attention of potential applicants some of the changes that we're seeing. And again, the two that come to mind are the 35.29(d) and the 35.80(a) and (b) which we can talk a bit more in detail. And what should we be, if anything, informing potential applicants about the possibility to seek exemptions if that's not consistent with the business that they want to provide. And then the second thing is this issue of reciprocity, and to what degree should we alert them to the need for pursuing reciprocity. If they're going to an NRC jurisdiction, to an agreement state, have a reciprocity scenario they need to address that. And it may be as simple as awarding them to the reciprocity process and informing them that if they want to pursue imaging in an agreement state they're going to need to contact that agreement state and do whatever is necessary for reciprocity in that specific agreement state.

And by the way -- and this is further compounded

by the fact that, remember that agreement states handle reciprocity differently, and in varied fashions than we do. They don't all have the same reciprocity scenarios.

MR. SIEGEL: How do we want to do this? Do we want to start just walking through this thing? These comments that came from the regions and others we obviously just got, and so have not had much chance to digest them.

MS. TAYLOR: And to be honest, most of them are pretty editorial; clarify this or change this word to that. There are a few things that the regions had asked that we put in that we felt would be too prescriptive in the sense of limiting programs.

MR. SIEGEL: Let's just start walking through this thing. Let me start off by asking a question.

It says on page 2, Location of Use; that locations of use may include, medical institutions, medical non-institutions -- I'll come back to that in a moment -- and commercial -- I'll have a term for you that will solve the practice -- and commercial facilities.

And then on the very next page, it says, if the application is for medical use located in a medical institution, only the institution's management may apply. And I didn't get it. Is that true? I just asked you a moment ago whether there could be one license provided by the corporation and the medical institution didn't have to have a license.

And this suggests that the medical institution has to have a license.

MS. TAYLOR: This is where the mobile service is located within a medical institution.

MR. SIEGEL: I'm very confused about that.

MR. CAMPER: Well, I look at this a little differently. I was looking at this last evening, and I can give you my notes in the margins, say, it doesn't work; it's a problem.

What we've attempted to do here, is we've lifted the definitions on Part 35 currently for medical institutions, medical non-institution and commercial facility. And we have moved them verbatim almost. Now, if poses some problems because again, as you just were pointing out, a pure commercial entity, they want to do services in the medical institution, some of the things we have written here as definitions I think are problematic in that regard.

MS. SCHLUETER: Well I think the reason that that statement's in there is because of 35.12, in the sense that, if the applicant to perform mobile services is a medical institution then the medical institution's management must apply. But that does not apply to the client who may be medical institutions that may be having services at their facility by the mobile service.

MR. LYNCH: Right. So what you're saying is that

if the licensee, the proposed provider of mobile services, is a corporate entity that is a medical institution then management has to apply as opposed to a person?

MS. SCHLUETER: Correct.

MR. CAMPER: That's correct.

MR. SIEGEL: But then we need to say that more clearly. Because a mobile service that is a free standing corporation could provide service inside its van parked next to an medical institution, and at that point the licensed activity is not considered cited at a medical institution, or is it? See, that's where you're running into a language problem here.

MR. CAMPER: Well, if you look at the first one for example --

MR. SIEGEL: I'm looking at 35.12.

MR. CAMPER: Well, if you go back up to page 3, if you look at (a), if you're reading this -- You're out there, you're a potential applicant. If the application is for medical use located in a medical institution -- Well, if I've got a mobile service I'm going to be providing it for medical use. I'm going to be providing in a medical institution. Only the institution's management may apply. But what we're really saying here is, if a hospital, which is a medical institution, wants to provide mobile, medical imaging services then the management of that medical

institution must apply. But we're not as clear about that.

MS. TAYLOR: That's what it needs to say.

MR. SIEGEL: It clearly does need to say that, because that, I thought, was very confusing.

The definitions of a medical institution in a other --

MS. SCHLUETER: I have to go back to my desk --

MR. SIEGEL: No, but I can fix it for you in two minutes.

Where are those definitions? They're not in Part 35.

MS. SCHLUETER: Those definitions come from an office of the general counsel interpretation in June of '94, which helped the staff try to figure out when the management needed to apply, when they did not, and if you needed a radiation safety committee and other management program aspects. What precipitated that was the fact that there are more and more private physicians, more as you know, which are combining, incorporating themselves and so forth and so on, and are licensed for activities in the same types, quantities and program aspects that medical institutions are authorized for now.

So in other words, you have these groups which are combining and growing and are in fact offering the same type of services and are licensed for the same kind of things

as the hospital next-door, but because they're private physicians they've been coming under a different program code, they've been licensed in a different manner, they haven't had to have a radiation safety committee, and so forth and so on. So there are groups of private physicians that are beginning to walk and talk like a medical institution. So there was some attempt at trying to set some criteria for deciding, how big could they be, how much could they grow, what could they offer, what could they be authorized to do and not hit that threshold for medical institution, radiation safety committee and other kind of program management requirements.

Now, we made an attempt at trying to define that line, that threshold. There are some problems with the definition when we began to apply it. There are minor ones, but it gets back to how does the physician group function versus how the medical institution. The term is cumbersome and we tried for a long time to figure out something else.

MR. SIEGEL: Would you like --

MS. SCHLUETER: Sure.

MR. SIEGEL: Non-institutional medical practice. Medical non-institution is not a language that I'm familiar with.

MS. SCHLUETER: Well I don't think it was a language anybody was familiar with. We were just trying to come up with --

MR. SIEGEL: Non-institutional medical practice will capture your spirit --

MS. SCHLUETER: Similar but more descriptive.

MR. SIEGEL: -- and I think is English.

Now let me tell you about your definition of a medical institution here. Three or more medical disciplines are practiced, and more

than one physician is associated with the medical practice regardless of the number of authorized users. By this definition -- I think I said this at the last meeting -- two physicians practicing together in a partnership could constitute a medical institution. You could have one guy who's a surgeon and an obstetrician, and does both, and another guy who's an endocrinologist and a nuclear medicine doctor, and is an authorized user and that makes those two guys a medical institution.

Who would be on the radiation safety committee?

MS. SCHLUETER: If there are three or more medical disciplines.

MR. SIEGEL: I just said there were. But there are only two guys. They have no staff. They don't even have a secretary. Two guys in an office put up a shield somewhere. This definition is cumbersome; it don't work. No offense to the lawyers, but I don't think they got this one right. I mean that's as clearly a group medical practice as I can think

of, and it could be set up as a partnership so it would not be licensed in any state as a medical institution the way hospitals are licensed, the way free standing clinics are licensed. It'd just be a couple of guys who hung out a shingle and went into business.

MR. CAMPER: Well let me take that a little differently. What makes an institution and institution?

MR. SIEGEL: I haven't got a clue. I don't know. I mean that's part of the problem. And if you think about it -- and we've dealt with some of this before -- you've got this corporate entity called the hospital that has a bunch of doctors working in it who are sole proprietors, who come in and use the hospital's facilities, and agree to follow the rules while they're working in the hospital, but really have essentially no other fiduciary relationship to the hospital. And that includes authorized users in many hospitals who are, not employees of the hospitals. The only authority the hospitals has over those physicians is the ability to take away their staff privileges and not allow them to practice in the hospital.

MS. SCHLUETER: I guess --

MR. SIEGEL: But can't otherwise directly supervise the activity of those physicians. That's actually a fairly traditional medical institution.

MR. CAMPER: Is there something -- Over the last

25, 30 years, we've grown to think of the hospital as a medical institution. Is there something in the charter they're given or when they're licensed by the state? Is there some criteria that gets at what an institution is?

MR. SIEGEL: My guess is yes, but I don't know.

MS. SCHLUETER: The one case that we had that sort of put the definition to the test, and we soon realized that we had some problems with it was, a scenario in which a private physician office building located next to a hospital had several physicians in it, one of which was an endocrinologist, one of which was a nuclear medicine specialist, and there were other physicians, non-by product material users in the group.

Now previously they had separate distinct licenses, but the physician group had incorporated themselves, so there was one organization at the top that these physicians all reported to, if you will. And so then we had this scenario where we had this corporation, this entity, this building with several authorized users in it, that in theory had a corporate relationship, but were holding separate licenses. And so the question was, shall we re-issue the license to the corporation instead of the single users?

And so in the long run I'll tell you that we did not. We did not actually apply our own definition, because it seemed illogical to force the corporation to have the license

instead of the endocrinologist for example, mainly because the inspection history was very good, was very limited, and why impose the burden on both the NRC and the licensee to go through a licensing process again.

So we've only had a couple of cases really where we've had to try to apply this working definition, and there is some difficulty in applying it, and we do have to make case by case reviews of these situations. And it may be that over time we can revise it to reflect how we evaluate these scenarios. It was a shot at distinguishing a threshold and it's just not quite there yet.

MR. SIEGEL: I missed this definition in 35.

MS. SCHLUETER: Well it's not there in the sense that you'll find 35.2 has a very limited definition of medical institution.

CHAIRMAN SIEGEL: No. But I like the way it's in 35.2. It makes more sense. An organization for which several medical disciplines are practiced is actually easier for me to understand and apply common sense logic to than this definition, which I find to be very, very awkward.

MR. CAMPER: I did, too, Barry, but, you know, I mean, I can quickly identify a scenario of organization. I mean, what if you have a corporate entity, five or six physicians get together and form a corporate entity and they're practicing several disciplines? I mean, arguably,

that's an organization. I mean, a corporation is an organization.

CHAIRMAN SIEGEL: Well, according to this definition, you would license that as an institution.

MR. CAMPER: Yes. But bear in mind another reason why this has become a problem in recent years is fees.

MS. SCHLUETER: Fees.

MR. CAMPER: That same private practice group that I just described would argue that it's a private practice physician scenario, not a medical institution. It's, therefore, subject to a lesser fee.

MS. SCHLUETER: Fees do come into play. And that's why we also worked with the Office of the Controller to develop that definition.

MR. CAMPER: In fact, I think it's fair to say that fees were a significant --

CHAIRMAN SIEGEL: Were the driving force.

MR. CAMPER: -- driving force, certainly one of them. Janet's described a couple of others, but that was also one of them.

CHAIRMAN SIEGEL: Well, this is a killer. I just --

MR. CAMPER: Well, you know, and what's really problematic about that is, you know, the regulations and the definitions in regulations were designed and built about

radiation safety, control of materials. Well, that hasn't got anything at all to do with fees.

CHAIRMAN SIEGEL: Right.

MR. CAMPER: And, I mean, the regulations are really blind to fees, as they should be, but let's face it. The reality of the matter is you move along and fees continue to increase. And you have this private practice scenario and so forth. People begin to try to find ways to lessen the burden of fees.

CHAIRMAN SIEGEL: Well, then let's forget fees for a moment.

MR. CAMPER: Right.

CHAIRMAN SIEGEL: What is it you think needs to be achieved from a radiation safety point of view that compels you to distinguish between --

MR. CAMPER: Right.

CHAIRMAN SIEGEL: -- a medical institution and a non-institutional medical practice?

MEMBER WAGNER: That's the point.

MR. CAMPER: Well, I think sort of a quick layman's response is that the radiation safety committee concept grew out of a need to have an organization within this institution that was overseeing the fact that materials were being used for many different purposes and in many different settings in the classical medical institution, the hospital,

if you will.

I mean, you know yourself you've got them going on on several different floors. You generally have a cardiac scenario. You have a primary group of medicine scenario. You might have an endocrinology clinic. I mean, the idea is that the committee assumes responsibility for the institutional oversight.

By contrast, a private practice scenario, they're typically smaller. And the use scenario is more confined. You ultimately have one or two docs, as you pointed out before. You can't make a committee. You don't have all the players necessarily.

So I don't -- I think that's the primary difference, this idea of multiple use sites, multiple program uses, and then an entity that oversees that for the institution.

MEMBER WAGNER: But that makes sense. The difficulty I think is that these definitions don't address that. These definitions seem to be more arbitrary than that. And it's not clear how these definitions address that radiation safety issue.

If you were to use that scenario, then medical institution and medical non-institution would be defined according to the types of procedures and quantity of procedures that they do.

CHAIRMAN SIEGEL: Yes, yes.

MS. SCHLUETER: Yes. I mean, we recognize that, having tried to apply them in several cases, it's not working and that we probably want to reconsider writing that section, basically in the tone that you two gentlemen have just described, and eliminating the definitions that are there now because I think it really will take a case by case review. And there's not such a fine line of a threshold.

MR. CAMPER: You know, your point if you look through the definitions, you're not struck with radiation safety.

MEMBER WAGNER: Right. That's exactly the point.

MR. CAMPER: It's a driving consideration.

MEMBER WAGNER: That's what I had so much trouble with. I go, "Why are they doing this?" And now we're enlightened. We know why you're doing this.

MS. SCHLUETER: Right.

MEMBER WAGNER: And I think we want to focus you back onto doing it for the reasons you should be doing it.

CHAIRMAN SIEGEL: And, really, from a radiation safety point of view, the key element is who is ultimately responsible: a single authorized user or a small group of authorized users working together versus management with the requirement that management have an intervening radiation safety committee. Isn't that really a fundamental --

MS. SCHLUETER: Well, and I think operationally we were moving in that direction, but this definition doesn't reflect that.

CHAIRMAN SIEGEL: Now, the problem with simply suggesting that you go backwards to a simplistic approach is that, I mean, one way to do it is to say more than one category of use in a practice constitutes a medical institution.

But then the problem is, well, I mean, you have -- but many people have asked this question: Do you really need a radiation safety committee in a hospital that only has a nuclear medicine department and only does imaging and has one authorized user who does the work? What does that organization need a radiation safety committee for?

MR. CAMPER: Well, it's a fair question. The theory is that you have this committee and it has to consist of three, at least three, entities: nursing. The reason for that is because materials are being administered out on the floor and so forth.

CHAIRMAN SIEGEL: Right.

MR. CAMPER: And, therefore, the potential for contamination, the potential for exposure, --

CHAIRMAN SIEGEL: Right.

MR. CAMPER: -- having nurses who are in and about and around this, having a representative and being

involved, institutional management obviously for management awareness and control purposes, obligations and responsibilities of the institution procure and has the license, the authorized user for the active hands-on understanding of radiation safety, et cetera, cetera. I mean, that is the logic applied even in a strictly nuclear medicine scenario. That's where we are today and why, roughly.

Now, as you expand the program, you're supposed to bring into bear --

CHAIRMAN SIEGEL: Other categories.

MR. CAMPER: -- these other categories of users, again for the same purpose: oversight, awareness and oversight.

CHAIRMAN SIEGEL: Okay. I'm stuck on this one. So where do you think you're going to go with this?

MS. SCHLUETER: You know, I think we should remove the definitions that are there now because it places us in a box that we don't want to be in.

MS. TAYLOR: From our discussion, it sounds like we could just take it all out, just rewrite it, ask them to describe in detail their management, corporation structure, describe the oversight, who has responsibility for what, and --

MS. SCHLUETER: Well, the type users, yes, the quantities, --

MS. TAYLOR: The type users, types, --

MS. SCHLUETER: -- all that kind of thing.

MS. TAYLOR: -- disciplines being done and do it from a very general -- let them bring it in in a license --

CHAIRMAN SIEGEL: Inpatient versus outpatient.

MS. TAYLOR: Right.

CHAIRMAN SIEGEL: Because, I mean, you don't need nursing involved if you never do an inpatient; correct?

MS. TAYLOR: Outpatient; right.

CHAIRMAN SIEGEL: If you only do outpatients?

MS. TAYLOR: Right.

MS. SCHLUETER: I think we just need to let the applicant be aware that we are going to look at all of those aspects of the program to determine whether or not --

CHAIRMAN SIEGEL: I sure think that's better than this.

MS. SCHLUETER: -- you know, what radiation safety requirements apply.

MR. CAMPER: Yes. I think Janet's got a good point there. If we were to take Page 3, Page 4, Page 5 and turn that into text that said, you know, "Describe what this thing is that you're applying for. Is it a medical institution that wants to provide mobile medical services? Is it a private practice scenario that wants to expand their capability to include mobile medical? Is it purely a

commercial entity? You know, describe what's going on," get the key points that we're looking for because I -- you know, you're right. These definitions just --

CHAIRMAN SIEGEL: Could you include as part of that text, just as you did, several of the most common examples, not to be exclusive, but to say, --

MS. SCHLUETER: Right.

CHAIRMAN SIEGEL: -- "Common organizational structures of mobile medical services include" --

MS. SCHLUETER: Right. That would help.

CHAIRMAN SIEGEL: -- and list four or five? I guess it's unlikely that people who haven't got a clue how to do this are going to be applying for it, but I suppose it's --

MS. SCHLUETER: It's happened.

MR. CAMPER: Business is business.

MS. SCHLUETER: That's right.

CHAIRMAN SIEGEL: Let's go into mobile nuclear medicine and see what we can --

MR. CAMPER: Car sales are down. Let's go into mobile medicine.

CHAIRMAN SIEGEL: It sounds good to me.

MS. SCHLUETER: Got a good deal on a van.

CHAIRMAN SIEGEL: Well, good because I think that if you can make these arbitrary definitions disappear about the number of --

MS. TAYLOR: We can do that.

MS. SCHLUETER: Yes. We're not wedded to those at all. And there's nothing final, formal, regulatory about them. There's a guidance tool, but --

MR. CAMPER: Yes. In the future at some point, you know, when we head down the pathway of revising Part 35 in the future, over the next three or four years, these kinds of things will be obviously, you know, significant, subject to discussion with the ACMUI. Getting some definitions will make some sense that are modern and that will work.

MEMBER WAGNER: Should we go over the comments by John Glenn in this memo?

MR. CAMPER: Okay.

MEMBER WAGNER: I don't see the date on here. I mean, he addresses many of these issues. And much of the issues that he addresses in here are apparently based upon finances. I mean, he's got all kinds of things in here.

MS. SCHLUETER: This is the June 1994 interpretation of the definitions for medical institution and non-institution. Well, this wasn't a commentary to the --

CHAIRMAN SIEGEL: This was a TAR.

MS. SCHLUETER: Yes. It was a response to a TAR, which was created. The definitions that we recognize now in applying them aren't working.

MEMBER WAGNER: So this is what created those

definitions?

MS. SCHLUETER: That's right.

MEMBER WAGNER: And clearly it's based, at least in my gleaning over this, it appears to be based, upon finances.

MS. SCHLUETER: Well, it's not based upon finances. We had to consider the impact --

CHAIRMAN SIEGEL: No. It really shouldn't be.

MS. SCHLUETER: -- of the decision to categorize one group one way versus another. And so we had to consider that from the Office of the Controller. But it was us, the Program Office, working with general counsel with input from the controller. But that certainly was not the driving force behind why we did it and how it came out.

MEMBER WAGNER: No, but, I mean, it comes into the consideration here, obviously. He's talking about license annual gross receipts of a million dollars or less to qualify as a small entity and pay the reduced annual fee. I mean --

MR. CAMPER: I recall that, at least to some degree, there were several things that converged at one time that prompted us to do this. But, amongst those things, I believe the situation -- Janet, help me out here. I think that in a couple of cases our inspectors had found themselves in situations where they had questioned their management as to whether or not this large, sprawling physician entity which

was growing and expanding was, in fact, a private practice scenario versus an institution. And some of those questions, some of those concerns from inspectors were motivated not by finance, --

MS. SCHLUETER: No.

MR. CAMPER: -- but by the question of whether or not a radiation safety committee should be --

MEMBER WAGNER: Yes. Okay.

MS. SCHLUETER: Right, right.

MR. CAMPER: And then in a couple of cases there were some questions where some of these small entities were questioning or medical institutions were questioning, "What's going on over here? Why am I subject to this?"

MS. SCHLUETER: Right. "Hey, these guys look like us, and they're paying a lower fee."

MR. CAMPER: Yes. "These guys look like us." So there were several things going on.

CHAIRMAN SIEGEL: You know what? Stuart Treby got it right, man.

MR. CAMPER: Where is he?

CHAIRMAN SIEGEL: Well, in his note at the end, the very end of this thing, --

MR. CAMPER: I don't have a document.

MEMBER WAGNER: Is it the whole thing, very end of the whole thing.

CHAIRMAN SIEGEL: Well, the very end of this whole thing, it says, --

MR. CAMPER: Yes. Stuart Treby. There he is.

CHAIRMAN SIEGEL: -- "The size and composition of the radiation safety committee as specified in 35.22 suggests that a medical institution would be sufficiently large so as to have a management structure and nursing service and also might have varied authorized users for different types of byproduct material use."

He goes on in the next paragraph, further down, and says, "Based on the definition of medical institution in Part 35 and the special requirements in Part 35 applicable to a medical institution, it is apparent that it must be an organization in which several medical disciplines are practiced of sufficient size so as to have at least three individuals on the radiation safety committee, including an authorized user of each type of use: nursing and management."

So it seems to me that in a way the key element is if there ain't a nursing service, it's not a medical institution. If there isn't an independent management structure outside of the authorized users, it isn't a medical institution. And that also really gets to the heart of the radiation safety issues, too.

MR. CAMPER: Yes, it does. Yes.

MEMBER WAGNER: I really like a lot of this,

although I still can come up with a little bit of difficulties on scenarios. And that is if you have the mobile service there. The mobile service then injects the patient, does a scan, sends the patient back into the hospital, where the patient is going to be taken care of in the hospital by the hospital staff. The mobile service itself doesn't supply any nursing, but, of course, the patients when they go back go back into the hospital.

So now the issue is you've got the mixture here. And do you need a radiation safety committee in that regard? You're going to have other people involved, but you're not going to have it involved with the mobile service.

MR. CAMPER: Well, yes. I think that there are two things that are going on here simultaneously. I think that when we ultimately revise Part 35, we need to go back and look at the definitions in Part 35.2, be more explicit and clear about the role of the radiation safety committee.

I agree. I think Stu has done a very good job of articulating.

MEMBER WAGNER: Yes.

MR. CAMPER: In this type of background, frankly, I think it should be in the statement of considerations at that time. Okay?

Now, with regards to the immediate problem at hand, though, what I think we need to do here again is have

them describe, you know: Is a medical institution applying for the mobile service? Is a private practice scenario applying? Is a corporate entity, commercial entity?

And, for example, if it's a medical institution that's expanding its armamentarium to include mobile imaging, then we should be looking and expecting the radiation safety committee to be providing some oversight for that service as well as part of that institutional service pattern.

It would be just like, if you will, the fact that you have a representative there from therapy or endocrinology. In that committee, they would be exercising some oversight on behalf of the institution over that mobile medical imaging scenario.

By contrast, though, if it was a private practice scenario, which doesn't have a radiation safety committee, that wouldn't happen. It would be the radiation safety officer management that would be overseeing the mobile scenario.

So I think if we avoid these definitions, ultimately fix these definitions but avoid them for purposes of this guidance document but focus upon getting a clear delineation on the applicant as to who's applying, and then bringing to bear some of these things we have talked about, that's probably a better approach.

MEMBER WAGNER: I think that approach is much

better. The issue I think should be the fact that we have to remember this is all diagnostic --

MR. CAMPER: Well, it's diagnostic and limited therapy.

MEMBER WAGNER: -- and limited therapy, all of which can be done on an outpatient basis anyway.

MR. CAMPER: That's right.

MEMBER WAGNER: So it really shouldn't play into a big problem until you go to therapy.

CHAIRMAN SIEGEL: I withdraw my comment about: What do lawyers know about the definitions of medical institutions?

MEMBER WAGNER: Yes.

MS. TAYLOR: Stuart was exactly right.

MR. CAMPER: Made you a believer.

MEMBER WAGNER: He did a fine job.

MR. CAMPER: Well, you know what I think, in all fairness, too, to OGC. I think what may have happened here is that, as often is the case, you get a complex legal answer. Then you try to extract from that key operational line items. It gives you a working model, which is what's reflected here.

And I think Lou has kind of pegged it pretty well. If one looks at this, this has a lot to do with just institutional size, fees, so forth, and not so much about radiation safety. And that's probably a mismatch.

But it was, as Janet said, an attempt to have a working model at this point in time. You know, we've got this house on shifting sand right now because of these fee changes and so forth.

CHAIRMAN SIEGEL: All right. Well, fine. We've dealt with the definition -- that's big progress -- and came up with a better term. I hope you like it.

MR. CAMPER: That's the non-institutional medical practice.

MEMBER WAGNER: That's much better.

CHAIRMAN SIEGEL: And the fact that we called it a medical practice is not a problem because, I mean, basically this has to be -- is that a problem? No. Wait a minute. Commercial service that is in no way, shape, or form a medical practice be licensed to provide mobile medical services. I mean, that's the other problem.

MR. CAMPER: Well, can you have that by definition? I mean, how can you -- restate that. How can you be providing mobile medical services if you're not involved in some --

CHAIRMAN SIEGEL: By having only authorized users at the resident facilities.

MR. CAMPER: That's right. Yes, you could be a commercial entity. And a good example of that is a scenario you described early on, where I have camera on truck, travel

to institution.

CHAIRMAN SIEGEL: But that's not even a licensing issue as long as I'm not possessing byproduct materials.

MR. CAMPER: That's what I'm saying. They're not licensed in that case. Okay? You can have --

CHAIRMAN SIEGEL: Can a commercial entity possess byproduct material --

MR. CAMPER: Sure, by using an authorized user at the site only; right? I can come in and get a license --

CHAIRMAN SIEGEL: Is that a non-institutional medical practice that commercial -- actually --

MEMBER WAGNER: Why don't you call it --

CHAIRMAN SIEGEL: Actually, it's a third --

MEMBER WAGNER: You have commercial.

CHAIRMAN SIEGEL: Never mind.

MEMBER WAGNER: Would there be any reason to change "practice" to "service"?

MR. LYNCH: At this point we're just giving examples.

MR. CAMPER: That's fine, yes. We're just going to --

CHAIRMAN SIEGEL: I don't care what we do as long as we get rid of the word "non-institution."

MR. CAMPER: We're going to rewrite this, take this --

MS. SCHLUETER: You don't like that word?

CHAIRMAN SIEGEL: We don't know what it is, but we know it's not an institution.

MEMBER WAGNER: Right. Take this approach or we --

MR. CAMPER: Well, what we'll do is when we rewrite this and tell them to describe what it is, you know, describe: "Is it a medical institution that's providing? Is it a non-institutional medical practice that's expanding to include mobile medical? It is a commercial -- for example, is it," dot dot dot dot dot dot.

MEMBER WAGNER: Good. I like that better. Good. Okay.

MR. CAMPER: I had one more comment here, too. On Page 6 under the definition of commercial facility, I was struck by something. If you look there, it's the paragraph that says, "In some cases a mobile service" blah blah blah.

CHAIRMAN SIEGEL: Yes.

MR. CAMPER: You get down to the point where it says, "Submit documentation of the agreement between the client and the mobile service in the event of disharmony between these two entities. It is essential that the mobile service have access to the facility in the event of contamination." Really? Why?

You're telling me that I couldn't handle

decontamination on a mobile van if I had appropriately trained individuals? I don't need to get into the hospital. What are they going to give me, material to clean it up, swabs, decon. material?

I mean, I could certainly do that. I mean, a mobile service could certainly do that.

MS. TAYLOR: I think this is more in the situation where they would be in the hospital and have a spill and they need to be able to get into the hospital in the event of disharmony if the work was being done inside the hospital versus the van.

MEMBER WAGNER: I took it to mean that if your van is on their property and there's a problem and then there's --

MR. CAMPER: Right.

MS. TAYLOR: Well, it could say that, too, actually.

MEMBER WAGNER: And they didn't want you to come on their property.

MS. TAYLOR: Right.

MEMBER WAGNER: They wanted to ban you from their property. You've got to be able to get back to your --

MS. TAYLOR: Yes, you can take it that way, too, exactly.

MR. CAMPER: Well, in either case what I think

what's important is that we get some clear understanding that the mobile service has the capacity to deal with a spill, contamination.

And you can certainly do that as a self-contained entity. I don't necessarily need to get into the Nuclear Medicine Department in the hospital 10 feet away to do that.

In fact, I mean, I should be prepared, the mobile van should be prepared, to deal with a spill immediately.

MEMBER WAGNER: To contain it, of course, and so on.

CHAIRMAN SIEGEL: Let me ask you a question. If I give I-131, less than 30 millicuries, to a patient for therapy, 29.9 millicuries, the patient leaves my hospital, walks outside into the parking lot -- no, not the parking lot -- walks outside onto the public sidewalk, --

MR. CAMPER: Throws up.

CHAIRMAN SIEGEL: -- and proceeds to throw up, what is my responsibility, if any?

MR. CAMPER: If you have released them, then they were released.

CHAIRMAN SIEGEL: Correct.

MR. CAMPER: You may have a social responsibility, but you don't have a regulatory responsibility because the criteria has been established.

CHAIRMAN SIEGEL: So now let's say I am a mobile

service and the patient walks out of the van and has been released from my service, walks into the hospital, which is attached to the van by a little bridge, and throws up in the hospital and the hospital also happens to have a license. Still nobody's responsible for cleaning up that spill; right, other than the social responsibility?

MR. CAMPER: That's regulatorily correct.

CHAIRMAN SIEGEL: Because we would hope that both of them would have enough sense to clean it up.

MR. CAMPER: It's good for business in either case.

CHAIRMAN SIEGEL: Well, I mean, you don't want a pool of vomit sitting on the floor in a hospital.

MR. LYNCH: There is also the ALARA principle as well as reasonable and achievable. And that would kick in at that point, too.

CHAIRMAN SIEGEL: But you could argue that it's better for your --

MR. CAMPER: Good health physics practice would mandate that you bring ALARA into bear, but, again, if you're looking at it from the letter of the regulations.

MEMBER WAGNER: I had the terrible problem of where the patient went home in their house with their children there and threw up. And I was notified about it.

And I wanted to go in and help them clean it up

in there, and they wouldn't allow me in their house. They banned me from the property. They wouldn't allow the state or anybody to come in and talk to them. And so, yes, you've got no control over this.

MR. CAMPER: No. You've got no control. That's one of the assumptions, the licensee, when you release them, you lose control. You cannot control the patient to make them do anything.

MEMBER WAGNER: Therein lies a lot of the problem. When is the patient released? When is the patient released?

CHAIRMAN SIEGEL: This is getting complicated for me.

MS. TAYLOR: Okay. So what do you want us to do with that sentence?

MR. CAMPER: Well, I'm saying that it is essential that the mobile service be prepared to deal with any decontamination scenario.

MR. LYNCH: The problem here is access to the facility. The beginning of the paragraph says, "If a mobile service leases a permanent or a semi-permanent space on client property."

And it's just later saying that that service should have access to that facility. They can't lock the door and kick them out. If they want to go in and clean something

up, they should be able to get in there.

MR. CAMPER: It may not be a condition of the contract.

CHAIRMAN SIEGEL: It also says "may or may not be a mobile service," too. And I didn't understand that distinction either.

MS. TAYLOR: Well, we had one case where they really were not a mobile center. I didn't bring those TARs with me. They weren't considered -- the scenarios did not make them a mobile service because they were --

MR. LYNCH: Scanning?

MR. CAMPER: Well, they put a scan van on a property.

MS. TAYLOR: They were there. And they provided service.

MR. CAMPER: They leased the space from the hospital on their parking lot. They set up a scan van.

MS. TAYLOR: But it was permanent. I mean, they didn't take this van and move around. And our clients brought patients to that van.

CHAIRMAN SIEGEL: So you viewed that as contract services being provided to a medical institution and forced the institution to have the license?

MS. TAYLOR: No. The mobile service had their own license, too.

MR. CAMPER: The mobile service had a license, but the point is it's not --

CHAIRMAN SIEGEL: It wasn't mobile.

MR. CAMPER: -- a mobile service in the classic sense.

MS. TAYLOR: Right.

CHAIRMAN SIEGEL: I see.

MS. TAYLOR: It stayed put, and people came to it.

CHAIRMAN SIEGEL: In other words, a mobile service that doesn't move.

MS. TAYLOR: Right.

MEMBER WAGNER: It has the ability to move, but it doesn't move.

CHAIRMAN SIEGEL: What we would call a mobile non-service.

MEMBER WAGNER: Well, I mean, once we put in the definition about whether it's a mobile service would mean whether or not it's -- if it stays in a certain area for more than two months, it will not be considered mobile or something. I mean, that's the other kind of --

MR. CAMPER: You mean define the box --

MEMBER WAGNER: Yes.

MR. CAMPER: -- for when it's mobile, when it's not.

MEMBER WAGNER: When it's mobile and when it's not. But as far as it's essential, I think what's appropriate here is it's essential that the mobile service have access to the facility in the event of contamination. That's too broad a statement.

The question is: Do you mean contamination in the mobile facility, on the property leased by the mobile facility, or in the facility in the institution that's next to that mobile area? What types of access are you talking about here?

CHAIRMAN SIEGEL: Yes, yes.

MR. CAMPER: Well, the trend today is towards scan in van. I mean, the old, you know, pull up with the mobile camera and roll it off the truck and go indoors, I mean, that's pretty much gone. I mean, it may be going on in rural areas, out West in particular, but I think pretty much that technology has passed. It's scan in van type of thing at this point.

So the contamination is either going to occur primarily within the van, conceivably the vomiting scenario just outside the steps of the van or something like that, but then we've already got that regulatory problem we've talked about.

But, I mean, the thing that I was thinking about with it was that we make the sentence here that it's essential

that the mobile service have access in the event of a contamination. That seems to me to apply from a radiation safety standpoint that I've got to have access to their decontamination equipment, I've got to get their radiac wash, I've got to get, you know --

MR. LYNCH: That wasn't the intention.

MR. CAMPER: Well, then if a spill occurs in a van, why is it essential to have access to the facility in the event of --

MS. TAYLOR: We've hung up on the word "facility." Let's get rid of that word and come up with something better, then.

MR. LYNCH: Well, we're talking about a mobile service leasing space on client property.

MS. TAYLOR: And it may actually involve a small, little area within the hospital.

MR. CAMPER: Let me think. Do you mean, then, by this sentence, do you mean that this sentence says, then, that in the event of a spill the personnel of the mobile medical service has to be able to get into the van? You're saying that there might be a problem because it's leased to the institution that they can't get in there?

MS. TAYLOR: No, no, no. There are two scenarios. You can have a mobile service that has a van that has leased property in the parking lot of the hospital, is

right next door to it, and the hospital provides patients and surrounding other facilities provide patients and they do their mobile service.

You could also have the scenario -- and it hasn't come up, but I don't see why --

MR. CAMPER: Wait a minute. Let's stay with that, then. Let's say under that first scenario, now, contamination occurs in the van.

MS. TAYLOR: A hospital could feasibly say, "You can't come on our property any more," and they need to have access to that van like --

MR. CAMPER: Okay. So you're saying, then, that, even though they've entered into a contract to lease the space, that the hospital could say, "You can't come into your scan van?

MS. TAYLOR: If there's been disharmony and the contract doesn't allow them to, yes. That's what we're looking for. If you two have a fight and you have legal problems and they kick you off their property but your van is still there, maybe you haven't been paying your rent.

And if they kick you off and say "You can't come on until you pay all this back rent or we're taking possession of your van," you've got to have some kind of thing there so they can get in. And it probably isn't just contamination, I could have said, but they need to have access to get to the

material and get the waste out and --

MR. CAMPER: Okay. Right. I see what you're saying. Your point is they have to have access to any material, they have to have access to the van in the event of contamination.

MR. LYNCH: Well, they're the responsible party here for the health physics involvement.

MEMBER WAGNER: Yes.

MR. CAMPER: Well, that's an interesting question because if they were doing one of the services that the institution is licensed to do --

MEMBER WAGNER: If the institution is licensed -- if it is not licensed, then they're responsible for it.

MR. CAMPER: Clearly.

MEMBER WAGNER: Yes.

MR. CAMPER: But if the institution, if the hospital, is licensed, let's say 35.200 again, for sake of discussion --

MR. LYNCH: But we're talking about commercial facility here.

MEMBER WAGNER: This is under commercial facility?

MR. LYNCH: Yes, it is.

MS. TAYLOR: Yes.

MEMBER WAGNER: Okay. So if it's commercial

facility --

CHAIRMAN SIEGEL: This is interesting because this is really a contract issue, isn't it?

MR. CAMPER: Yes, it certainly could be.

CHAIRMAN SIEGEL: I mean, this really is an issue of --

MR. CAMPER: Well, yes. But in this case the mobile service is a commercial entity. Okay? But they have an arrangement with the hospital. The hospital has a license.

XYZ Mobile Imaging Service, which is a commercial entity, if they go to the hospital, the hospital has a license, the same criteria in 35.29(d) applies.

It doesn't matter whether it's a hospital that's doing mobile imaging, a private practice scenario that's doing mobile imaging, or a commercial entity, you know, Acme Imaging Company. If that hospital has a license, the criteria in 35.29(d) still applies.

CHAIRMAN SIEGEL: (d), about ordering?

MR. CAMPER: No. "Mobile nuclear medicine service may not order" -- excuse me. (c), "If a mobile nuclear medicine service providing services to clients is also authorized to provide a client with responsible" blah blah blah.

MEMBER WAGNER: Yes. But doesn't that set up two situations? Doesn't that just simply set up the scenario

where if they're supplying services to a licensed institution, then they simply have to have access to their leased property in the event of a spill?

MR. CAMPER: Right.

MEMBER WAGNER: The responsibility falls over to the licensed institution to clear up any problems that occur in the institution. But if the hospital doesn't have a license, if it doesn't have a license, --

MR. CAMPER: Right.

MEMBER WAGNER: -- then you have to have access to the hospital itself in the event that there is a need for radiation safety services inside the hospital.

It's just those two situations. So just ask them to clarify each situation and how they're going to handle it, what the contractual arrangement is.

MR. CAMPER: Oh, you're saying, for example, if the institution doesn't have a license and they're injecting a patient --

MEMBER WAGNER: Sure, right.

MR. CAMPER: -- floor, for example?

MEMBER WAGNER: Sure.

MR. CAMPER: You're saying they have to have access to the institution --

MEMBER WAGNER: Right.

MR. CAMPER: -- for decontamination purposes?

MEMBER WAGNER: Right, right.

MR. CAMPER: Sure. So we need to clarify what we mean here.

CHAIRMAN SIEGEL: When a mobile service adds a site of use, that requires a license amendment?

MR. CAMPER: Yes.

CHAIRMAN SIEGEL: Okay. And do you normally require to see the contracts between --

MR. CAMPER: No. If you look --

CHAIRMAN SIEGEL: -- mobile services --

MR. CAMPER: No.

CHAIRMAN SIEGEL: -- and their clients?

MR. CAMPER: No. We look to see the letter that's referred to. Mobile nuclear medicine services under 35.29(d), "The licensee shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years."

MR. LYNCH: So we won't see that, but we do look at that.

MR. CAMPER: No. And we do look at that. And we do look at that, but we don't see the contract.

CHAIRMAN SIEGEL: But the letter doesn't specifically tell you that --

MR. LYNCH: No. It just says, "Acme Mobile Service is authorized to do" --

MEMBER WAGNER: You could ask for that in the letter.

CHAIRMAN SIEGEL: Well, not without changing Part 35.

MR. CAMPER: That's correct.

MEMBER WAGNER: Would you have to change Part 35 to do that?

MS. TAYLOR: To look at the contract.

MR. CAMPER: Oh, yes, if we want to see the contract, I mean.

MEMBER WAGNER: No, no. You don't have to see the contract. What I'm saying is you could ask for the statement in the letter from management that they will provide access for the appropriate services.

MS. TAYLOR: Well, that's what we've asked for, "Submit documentation of the agreement in the event of disharmony." So we've asked for that in this paragraph.

MEMBER WAGNER: Oh, okay. Well, that's it, then.

MR. CAMPER: Yes. In implementing --

CHAIRMAN SIEGEL: Although Part 35 doesn't really give you the right to ask for that; correct? It's sensible that you want to know how that would be handled.

MR. CAMPER: I would put it a little -- I can see

why you would say that. What I would say, I would put a little differently, though. Clearly in the implementation of regulations you ask for things, you review things that one cannot find a specific reference to in the regulation.

CHAIRMAN SIEGEL: Right.

MR. CAMPER: But that's part of implementation because obviously if you covered every possible factual scenario in the regulation, it would be voluminous. So it becomes an implementation interpretation issue on our behalf.

CHAIRMAN SIEGEL: I guess I'm still a little stuck here in terms of -- so what do you want to do with this? You want to --

MR. CAMPER: Well, what I'm saying is I think we need to be a little bit more specific in that, on the one hand, from a pure radiation safety standpoint, if a van is going to an institution and it's going to do scan in van, that mobile service should have the capacity to properly manage a decontamination event. Okay?

You should not have to run into the hospital and get their radiac wash and so forth, plastic bags to contain the chair that you use to clean up and so forth.

By the same token, as Torre has pointed out, there is a need to ensure that that mobile service when it's in a contractual arrangement with a medical institution, that it always has access to the material and to the van. And that

can be just deal with control of materials or it could also deal with the contamination scenario. And there may be others we haven't mentioned.

But the point is you've got to be able to get in that van.

CHAIRMAN SIEGEL: Have you all ever encountered a situation in which the client did not permit --

MR. LYNCH: Didn't one of the technical assistance requests deal with --

MS. TAYLOR: Well, it dealt with this scenario. This is where it came up in the sense that it was leased property. It wasn't leading and going to different clients. It was staying there, and clients were coming to them.

CHAIRMAN SIEGEL: But you've never had an incident that involved --

MR. LYNCH: Disharmony?

MS. TAYLOR: I'm not aware of any. I wouldn't get that information.

CHAIRMAN SIEGEL: A spill with concomitant disharmony. I've been wondering whether we're doing a thought experiment or whether we really have any experience to draw upon.

MS. TAYLOR: To be honest with you, the client and the mobile service probably would have such a detailed contract to allow for all of these scenarios anyway just for

legal reasons that --

CHAIRMAN SIEGEL: Well, I would hope so, but, you know, they may not be as clever as we think they are.

MS. TAYLOR: Yes.

CHAIRMAN SIEGEL: I mean, I know that if Washington University were doing this, the contract would make the NRC license look small by comparison because our lawyers are pretty careful, very plodding, and think of everything.

And I think most hospitals these days are smart enough to know that when they hire independent contractors to do these sorts of things for them, that they think carefully about OSHA requirements and EPA requirements and local safety requirements and a variety of things and NRC regulations.

And they build that onto the contract and figure out a way to make sure that neither party is going to be in violation, number one; and that, number two, that it clearly spells out whose rear end is on the line in the event there is a violation. And that's always pretty carefully subdivided.

I see this as less of a real issue than it seems to be. And I guess the sentence "in the event of disharmony," would it be better just to figure out a way to say "Describe the arrangements for dealing with incidents"?

MR. CAMPER: Yes, access and control of material and incidents.

CHAIRMAN SIEGEL: Right, that occur on either

leased property or in the client's facility.

MS. TAYLOR: It might work.

MR. CAMPER: Yes.

CHAIRMAN SIEGEL: Just kind of make it one neutral.

MR. LYNCH: Well, we already do that. We say, "Include provisions for access of decontamination by the mobile service."

MS. TAYLOR: Yes, but he's wanting to get rid of that description of "in the event of disharmony."

MR. CAMPER: Right, right.

CHAIRMAN SIEGEL: Because that's a very theoretical sort of "Now, what would I do if I wasn't talking to my landlord?" It's hard to write that when you're currently talking to the guy.

MR. LYNCH: I don't think we lose too much if we just strike that sentence out.

CHAIRMAN SIEGEL: I agree.

MR. CAMPER: And, again, that keeps us focused upon the radiation safety issues.

CHAIRMAN SIEGEL: The radiation safety issue. Okay.

The term "base hot lab," the main facility from -- I'm looking at the definition now, "the main facility from which the mobile licensee operates." What does that mean?

MR. CAMPER: Well, I can tell you what it means historically.

CHAIRMAN SIEGEL: I'm at the glossary in the back now.

MR. CAMPER: What it means historically is that these mobile imaging scenarios have typically had a fixed office, often in an industrial complex, sort of a low-lying industrial complex. They do all their administrative billing, et cetera, from that point. And they have a receipt scenario set up.

They have prescribed their procedures for receiving their doses and so forth. At that facility sometimes they have generators, they're preparing their doses there.

And they then load the material onto the van. And they depart from this base hot lab operation and go out and about and service their client.

CHAIRMAN SIEGEL: Is that common practice in 1995 or is it more common for the van to move around while Syncor is delivering the doses to the client?

MR. CAMPER: I think it's still common practice, but I think it's becoming complicated by the fact that commercial radiopharmacies are increasing their delivery networks and are better positioned to provide materials to a van.

Let's say, for example, a van leaves its base hot lab operation, drives 20 miles away to a town populated by, let's say, 8,000 people. It's now there. It's providing services to the hospital in that town. It wants to stay there overnight because the next day it's going to provide services.

What we're finding is that the commercial radiopharmacies are now better capable to deliver materials to that town, that population of 8,000, to that van.

Then you get into a situation. Let's say that that van is going be there for 2 or 3 days because 4 miles away there's a town of 3,000 people and patients are being ambulance-brought to the van.

Now, under that scenario with the van sitting in that town of that population for three or four days, it becomes a lot like a base hot lab.

CHAIRMAN SIEGEL: Yes.

MR. CAMPER: It's still got its primary corporate facility back here somewhere. So it's changing. And the reason it's changing is because of the network deliver for radiopharmaceuticals is different today than it was 10 years ago.

CHAIRMAN SIEGEL: So what is typically happening with waste disposal in the scenario where the van sits at this place for three days?

MR. CAMPER: Well, that raises another

interesting question because you start getting into the question: Now, what do you do about waste? For example, if I --

CHAIRMAN SIEGEL: Put it on the back of a truck on the highway.

MR. CAMPER: Right. Put it on the side.

So if I make two or three injections during the day and I now have a couple, two or three, spent syringes and I want to keep it on the van overnight because the next day the commercial radiopharmacy is going to come and pick it up, is that temporary storage? Is that classical disposal?

I mean, as you know in a medical setting, in an institution setting, we do that all the time. Spent syringes sit there. The next day they come and pick up the suitcases and take it away. We haven't disposed of it, haven't necessarily stored it either. It's just it's part of the use cycle.

CHAIRMAN SIEGEL: They're being held for disposal.

MR. CAMPER: That's right, being held for disposal. So you can argue that's part of the use cycle.

MEMBER WAGNER: But I think that we have to consider on those things -- go right back to the radiation safety issues. I mean, these do not constitute a tremendous radiation safety issue.

MR. CAMPER: No, of course not.

MEMBER WAGNER: I can't see that there's a problem.

MS. TAYLOR: And we got into that when we got a little further. And we also have allowed several exemptions to --

MEMBER WAGNER: And now you want to make sure that they don't leave the daggone thing open overnight for anybody to come in and --

MR. CAMPER: It's a control issue.

MEMBER WAGNER: Sure.

MR. CAMPER: It's a control issue.

MEMBER WAGNER: Sure. It's very simple to deal with.

MR. CAMPER: And, as Torre said, we do grant exemptions to allow this type of thing to take place.

CHAIRMAN SIEGEL: I understand.

MR. CAMPER: But, anyway, getting back to his, I was just trying to explain this base hot lab, what has classically and historically been, but you can see that, again, the way things are changing --

CHAIRMAN SIEGEL: So maybe is the base hot lab concept now an archaic one? In a way, isn't it really better?

MR. CAMPER: No, it's not archaic. It's still being done in a lot of the scenarios.

CHAIRMAN SIEGEL: But wouldn't it be better to say for each site of use of byproduct material proposed by this mobile service, which could include a base hot lab as well as each and every client, describe how byproduct material will be received at that site, how byproduct material will be used at that site, and how byproduct material will be disposed of at that site?

MS. TAYLOR: I don't think we get that specific.

CHAIRMAN SIEGEL: But I may be suggesting that in order for you all to evaluate whether this license arrangement is a good arrangement. Now, you could say, I mean, that could be collapsed to one paragraph that says "The way we do it is we receive everything at Point A, we carry it to Points B, C, D, E, and F, and at the end of the day we carry it back to Point A and that's where it's disposed of."

And then you've done, you've captured what I just did in one paragraph. But if there was a different arrangement at each of nine different client sites, you'd want to know what each of those arrangements are.

MR. CAMPER: Well, let me just bring to bear a point I made in my opening remarks with regard to a couple of big issues that I see. And one is this idea that if you ask someone to describe what you just said, they may well describe a scenario which would warrant an exemption to either 35.29(b), which says "The mobile nuclear medicine service may

not order byproduct material to be delivered directly from the manufacturer or distributer to the client's address of use," because you might as a mobile service be able to describe an arrangement whereby your van would be at Hospital A. Personnel would be there to receive.

An arrangement could be put in place with the hospital that when the material is delivered there, it's clearly instructed the security guard picks it up, signs for it, takes it to your van. Your personnel are on site to receive it and so forth.

In other words, what I'm saying is that I can imagine a mobile service being able to describe such a scenario. Okay? But that would require an exemption to 35.29(d).

CHAIRMAN SIEGEL: What is the historical source of 35.29(d)?

MR. CAMPER: I think that -- again, it's a little hard to kind of be in the minds of those who went before you, particularly the statement of consideration on a particular -- but I think the thinking at this day and time is that mobile services were sort of a stepchild of medical institutions, if you will.

In other words, the institution was the preeminent -- that and the authorized user were the preeminent entities as far as licensing was concerned in the medical

scenario. Mobile services being provided to it, okay. Yes. You're providing a mobile service, but that institution is still in control.

And, really, a mobile nuclear medicine service is not in the position to be able to describe or create a scenario whereby materials can be delivered to that institution and, therefore, that allow that to happen.

And I think that today those business arrangements and the sophistication of those mobile medical services could put in place such a scenario.

MS. TAYLOR: The other issue is that some of those clients may not have an NRC license. So, obviously, they couldn't receive --

MR. CAMPER: Well, that's a good point. Some of them may not be able to, period, --

MR. LYNCH: A lot of them don't.

MR. CAMPER: -- because they don't have a license.

MS. TAYLOR: I think when this regulation was probably written, that was probably the most typical scenario. And now you've more facilities. And it may go back to that with the cost of maintaining a license.

MR. CAMPER: Right. Well, it certainly couldn't receive it at all. That's a good point.

MR. LYNCH: Previously it was not allowed. If

the institution had a medical license, a mobile service couldn't provide the service to that institution.

MR. CAMPER: Well, the way (d) is written right now, you can't. That's right. Even if the institution has a license, it just simply says, "Distribute to the client's address of use." That can be a licensed or non-licensed client.

Now, in Torre's point, if it's a non-licensed client, they can't receive materials, period. But, by contrast, I mean, a licensed institution could.

MS. TAYLOR: And we get into that a little bit, I think, --

MR. LYNCH: Yes, we do.

MS. TAYLOR: -- when we talk about --

MR. CAMPER: Yes.

MS. TAYLOR: -- provisions if the client hasn't had maybe a formal transfer or what have you. I think we do address that.

CHAIRMAN SIEGEL: Can a mobile nuclear medicine service under 35.29(d) order byproduct material to be delivered directly from the manufacturer or distributer to the mobile service's address of use at a client site?

MR. CAMPER: No. It requires an exemption from 35.80. It requires an exemption from 35 --

CHAIRMAN SIEGEL: So the way this is currently

set up, there either has to be either the client has to have a license or there has to be a base hot lab?

MR. CAMPER: Either that or an exemption.

MR. LYNCH: Or an exemption.

CHAIRMAN SIEGEL: Or an exemption.

MR. CAMPER: See, to do what you just said --

MS. TAYLOR: Which we have allowed to have material delivered to the van.

MR. CAMPER: That's right. To do what you just said requires an exemption of 35.80(a), which says, "The mobile nuclear medicine service shall transport to each address of use only syringes or vials," blah blah blah. And the reason it specifies only syringes or vials, because you can't do it with generators, although we will grant an exemption for that as well.

But the point I was --

CHAIRMAN SIEGEL: Going across Montana you really have to drive fast.

(Laughter.)

MS. TAYLOR: Well, those exemptions are --

CHAIRMAN SIEGEL: And with 0.15 water, it's even tougher.

MR. CAMPER: But the point I was making was -- and we kind of got into some basement-level details. What I was really saying is if it's appropriate to ask for some of

the descriptions that you were suggesting, --

CHAIRMAN SIEGEL: Yes.

MR. CAMPER: -- which I think is a good idea, by the way, but if you do that, I think that part also needs to bring to the attention of the applicant that some of these receipt scenarios may require you to obtain an exemption of 35.29(d) or 35.80(a) because if they're going to scribe in the detail that you were suggesting, some of those things will absolutely mandate an exemption.

On one hand, you have a good --

CHAIRMAN SIEGEL: But that's okay.

MR. CAMPER: Well, no. It's okay. It's fine. I'm just --

CHAIRMAN SIEGEL: I just think that in a way it's better to just be very direct and say, "Just tell us how you're going to do it."

MR. CAMPER: I agree. And all I'm saying is that someone out there today if an applicant --

CHAIRMAN SIEGEL: At the risk of trying to achieve clarity of thinking.

MR. CAMPER: Yes. But, I mean, if you're, on one hand, going to describe clearly what it is that you're going to do, which is obviously a good idea, I'm only saying to make them aware of that. And guess what? In doing that good idea and giving us that good detail, you might have to exempt, seek

an exemption, which is fine.

CHAIRMAN SIEGEL: Well, that --

MEMBER WAGNER: I had one issue with the issue on base hot labs. It's Number 4 on Page 8. I put a bunch of question marks by this one, "Submit confirmation in the form of letters from local agencies that operation of the base hot labs does not conflict with local codes and zoning laws. Include confirmation in the form of a signed statement by the licensee that police and fire departments with jurisdiction in the area shall be notified of byproduct material content initially and at 12-month intervals."

MS. TAYLOR: This is under a residential --

CHAIRMAN SIEGEL: I thought physicians are required to do essentially the same thing.

MS. TAYLOR: This is under a residential use. If you look up at (c).

MEMBER WAGNER: (c)?

MS. TAYLOR: There have been requests to operate from a residential location.

MEMBER WAGNER: Right. This is a residential location.

MS. TAYLOR: So this is information that we would want applicable to that scenario. And we really don't --

MR. LYNCH: If you're doing this out of your house, --

MEMBER WAGNER: Yes, right.

MR. LYNCH: -- we want to make sure the zoning is appropriate for it and --

MEMBER WAGNER: I understand. I understand the reasons for the request. I also can perceive of it being difficulties with some of these things. I'm not sure, "Include confirmation in the form of a signed statement by the licensee that police and fire departments with jurisdiction in the area shall be notified of byproduct material content initially and at 12-month." What kind of notifications do you want them to have?

MS. TAYLOR: Well, the nuclear pharmacies do this. You sign a letter saying that they have been notified of what you have in that facility in the event of a fire.

MEMBER WAGNER: Yes.

CHAIRMAN SIEGEL: Your institution does it, too.

MEMBER WAGNER: I know that, but I'm thinking of these small fire departments out in certain facilities. I can tell you they don't know anything about radiation. I've talked to them. They know nothing about radiation.

MR. LYNCH: Well, the intent is to inform them that "We have hazardous materials in my basement here. Should there be a fire at this address," --

MS. TAYLOR: Yes. "Beware of that."

MR. LYNCH: -- "here is what you need to do.

Here are the numbers to call."

MEMBER WAGNER: All right.

MR. CAMPER: Yes. We don't get into: How qualified is the fire department to deal with --

MEMBER WAGNER: No. I understand that.

MR. CAMPER: Our approach is to make them aware of that.

MEMBER WAGNER: I was just trying to get at what we're trying to achieve by all this notification and stuff because --

CHAIRMAN SIEGEL: Have there really been requests for residential --

MS. TAYLOR: Right.

MR. CAMPER: Yes.

CHAIRMAN SIEGEL: -- base hot labs?

MS. TAYLOR: One that I'm aware of.

MR. CAMPER: Yes.

CHAIRMAN SIEGEL: And it was permitted by the local zoning laws?

MR. LYNCH: There's one in St. Louis.

MS. TAYLOR: Probably your next-door neighbor.

MR. CAMPER: It's next door, yes.

CHAIRMAN SIEGEL: It's my house.

(Laughter.)

MR. CAMPER: It's your neighbor, your next-door

neighbor.

MS. TAYLOR: Well, I think most of them are set out probably in --

CHAIRMAN SIEGEL: One block away from Washington University's temporary decay and storage facility, but they do a good job. So it doesn't bother me.

There's a residential base hot lab in St. Louis?

MR. LYNCH: Yes, yes.

CHAIRMAN SIEGEL: Incredible. Okay.

MEMBER WAGNER: "Verify that restricted areas should not include residential quarters." I hope so.

MR. CAMPER: While you're at that part there, too, I had a question on 3, just above that, again this idea -- and, Jim, maybe you can shed some light on this -- "Submit an evaluation demonstrating compliance with 20.1301." So we're saying we want somebody in a residential scenario to do that.

My question was: Do all licensees have to do this? Because if you go look at 20.1301, 20.1301 is an absolute regulation standard. This is the one that says, "You will limit your doses to members of the public to 100 millirem. And doses in the unrestricted area will not exceed 2 mr."

MR. LYNCH: Yes. Commercial pharmacies have to deal with that question. Who's on the other side of the wall?

CHAIRMAN SIEGEL: So does everybody.

MR. LYNCH: We're going to put a TLD on the wall to ensure that the dose on the other side is below regulatory limits, that sort of thing.

MR. CAMPER: So that's the evaluation that we're referring to.

MEMBER WAGNER: Or you could have a survey done by some --

MS. TAYLOR: Right.

MEMBER WAGNER: You can come in and do a quick survey and to verify that the exposure rates are so low that no one could possibly --

MR. CAMPER: Well, that's fine. I understand.

CHAIRMAN SIEGEL: So you're saying this is redundant here?

MR. CAMPER: Well, it's either redundant --

MR. LYNCH: It is required on any license application.

MR. CAMPER: The impression I had was we seem to be asking for something. When we say "Submit an evaluation demonstrating," we seem to be asking for something here that's different or above what we're routinely expecting to see licensees demonstrate to show compliance of 20.1301.

MS. TAYLOR: We could just say "Demonstrate compliance or describe how you're going to demonstrate

compliance" or --

MEMBER WAGNER: But don't they already have to do that in Part --

MR. CAMPER: But we're just pointing --

MEMBER WAGNER: Why is it being singled out for residential and not others? Why is it --

MR. CAMPER: Well, that's another interesting point.

MEMBER WAGNER: Why is it being singled out for residential and not others?

MS. TAYLOR: Just to make sure.

MR. LYNCH: I mean obviously in a residential situation you have potentially on the other side of a wall somebody spending a great amount of time, 20 hours a day, as opposed to a commercial facility, where that would likely be limited to less time than that. So it was an attempt to bring out that concern a little bit here.

CHAIRMAN SIEGEL: Now, Paragraph 2 probably should be altered along the same lines that we suggesting altering it for client. It's dealing with a fairly uncommon scenario.

I guess this is where you're talking about you're leasing an apartment in an apartment building as your base hot lab.

MS. TAYLOR: I don't think we can do that.

CHAIRMAN SIEGEL: I just can't imagine. I can't imagine the tenants in the apartment building sitting still for that.

MS. TAYLOR: That probably wouldn't be authorized.

CHAIRMAN SIEGEL: Well, it says "residence owner and licensee." I guess it could be a man and a woman living together who are not married and one of them runs the base hot lab and the other is the residence owner.

MEMBER WAGNER: We had a physician who wanted to rent the apartments in a -- or, actually, motel rooms --

CHAIRMAN SIEGEL: You've thought of everything.

MR. CAMPER: We try.

MEMBER WAGNER: -- as his place to put his therapy patients. He wanted to rent a motel and put patients in the motel for confinement.

CHAIRMAN SIEGEL: Oh, God. All right.

MEMBER WAGNER: We had that situation.

MR. LYNCH: So I don't know. Why did we decide with 1301 there? Do we want to --

CHAIRMAN SIEGEL: I'd be inclined to delete it since it's part of every license application unless you meant that it was --

MR. CAMPER: Well, that's the thing I was --

CHAIRMAN SIEGEL: -- at a higher and higher

level.

MS. TAYLOR: Okay. I don't have a problem with that.

MR. CAMPER: Well, as I read it -- and maybe I misread it, but I got the impression that we were seeking some evaluation demonstrating compliance that's distinctly different than what we would expect under normal circumstances.

MR. LYNCH: No. It's just that in a residential setting, it has a little different flavor.

MR. CAMPER: And even then we're looking for presentation in a program that demonstrates compliance with 20.1301, not necessarily an evaluation demonstrating compliance. In other words, we're looking to see that they're going to give us a program that would appear to meet the intent of 20.1301 that the operation will not cause an exposure to greater than 100 millirem.

MR. LYNCH: You're right.

MEMBER WAGNER: But I believe the evaluation --

MR. CAMPER: But we don't say, "Show us that you evaluated your program so that that won't happen."

CHAIRMAN SIEGEL: You could change this to say something like, "Submit a description of your program demonstrating how you will achieve compliance with 20.1301" --

MR. LYNCH: We do that elsewhere.

CHAIRMAN SIEGEL: -- "in a residential setting." And you're just trying to emphasize that it's more difficult to do so in a residential setting.

MR. CAMPER: In a residential setting. That's true.

CHAIRMAN SIEGEL: That would be okay. I don't mind the emphasis here. I'm actually flabbergasted that anybody is going to do this in a residential setting.

MR. CAMPER: Yes.

MEMBER WAGNER: I think that's a good point because I think evaluation, I think evaluation, if I recall this correctly, can be calculations.

MR. CAMPER: Yes, it can.

MEMBER WAGNER: And so here you may be wanting to ask --

CHAIRMAN SIEGEL: Well, until you're licensed, it has to be calculated.

MEMBER WAGNER: Correct, correct. But it still may be ongoing calculations that you can present without any real measuring data. And it might be here in the residential setting that you may actually want to measure, have some real data that you would evaluate.

MR. LYNCH: Well, certainly our inspection process would look at that. I mean, that would be a key aspect of the inspection to determine whether the 1301 is met.

CHAIRMAN SIEGEL: All right.

MR. CAMPER: So we're flipping to Page 9.

CHAIRMAN SIEGEL: Temporary job sites. Oh, I actually have a question about two jargon terms, "base hot lab" and "scan in van."

MR. LYNCH: Those are all but --

CHAIRMAN SIEGEL: Is "hot lab" really the term we want to be using in a regulatory document?

MEMBER WAGNER: Why don't we take out the word "hot"?

MR. CAMPER: Yes, I can see your point. You mean as in "base hot lab"? That's common nomenclature.

CHAIRMAN SIEGEL: As in "base hot lab."

MEMBER WAGNER: Yes. I know, but that -- I know it is.

CHAIRMAN SIEGEL: I mean, it's an inflammatory word.

MEMBER WAGNER: Really, I agree.

CHAIRMAN SIEGEL: No pun intended.

MS. TAYLOR: What's the other lingo out there?

MEMBER WAGNER: Base laboratory.

MS. TAYLOR: Base laboratory?

MR. CAMPER: Well, is it a base radiopharmaceutical laboratory?

CHAIRMAN SIEGEL: That would be okay.

MS. TAYLOR: Let's do that.

MEMBER WAGNER: That would be fine.

CHAIRMAN SIEGEL: And then if you're going to do that, make it "laboratory," instead of "lab," which is also jargon.

MEMBER WAGNER: Yes, right.

CHAIRMAN SIEGEL: I just think a non-pejorative word. "Hot" implies --

MEMBER WAGNER: I agree.

CHAIRMAN SIEGEL: -- by in these formal regulations that we're making a judgment about them.

MR. LYNCH: This is a regulatory guide. This is not a regulation.

MEMBER WAGNER: Still.

MR. LYNCH: It's meant to speak to the --

MEMBER WAGNER: Sure.

CHAIRMAN SIEGEL: And then this "Jack in the box service" we're talking about --

MR. CAMPER: But the point, though, even if it's a guide, there's a way to describe what it is and not do it in an inflammatory manner.

CHAIRMAN SIEGEL: You could --

MS. TAYLOR: Politically correct; right?

CHAIRMAN SIEGEL: -- have "highly dangerous base hot lab" while you're at it, too; right?

MEMBER WAGNER: We have those. We have different --

MR. CAMPER: And by definition it is a radiopharmaceutical laboratory.

MEMBER WAGNER: Right, right.

MR. CAMPER: It is based in nature. So that's the kind of thing.

CHAIRMAN SIEGEL: "Scan in van service," is there a better way to describe?

MR. CAMPER: "Scan in van"?

MEMBER WAGNER: You could put it -- well, I think that's a term that's used --

CHAIRMAN SIEGEL: Mobile imaging service or --

MEMBER WAGNER: No.

MR. LYNCH: Well, see, it's not --

CHAIRMAN SIEGEL: "Scan in van" is such jargon.

MR. LYNCH: It is a --

CHAIRMAN SIEGEL: It's Jack in the box. It's right at that level.

MR. LYNCH: Yes. We didn't like that either.

MS. TAYLOR: Well, maybe we could just say "Indicate if only imaging service will be provided with" --

MEMBER WAGNER: Why don't we just say "in-van imaging service"?

MR. CAMPER: "In-van imaging," yes.

MS. TAYLOR: Oh, that's good.

CHAIRMAN SIEGEL: Bless your heart, Doctor. So leave the hyphen with the word "in-van."

MEMBER WAGNER: "In-van imaging."

CHAIRMAN SIEGEL: "In-van imaging service." Thank you.

MR. CAMPER: Texas is heard from.

(Laughter.)

CHAIRMAN SIEGEL: You can have "imaging non-service." I'm not going to let you escape on that one.

MS. TAYLOR: I'm glad I didn't have anything to do with that one.

CHAIRMAN SIEGEL: Okay. Good.

MEMBER WAGNER: It will have to be changed throughout the document, too.

MS. TAYLOR: Yes. I'm glad for the REPLACE feature.

MR. CAMPER: I'm showing about 9 after 10:00. Do you want to break at about --

CHAIRMAN SIEGEL: Yes, I do.

MR. CAMPER: -- 10:15 or something or do you want to break now or --

CHAIRMAN SIEGEL: Yes. Let's do it.

MR. CAMPER: You want to go now?

CHAIRMAN SIEGEL: Yes.

MR. CAMPER: All right. This is a break.

(Whereupon, the foregoing matter went off the record at 10:05 a.m. and went back on the record at 10:32 a.m.)

CHAIRMAN SIEGEL: We are on temporary job sites. Are we okay? I didn't have anything there other than the "scan-in-van" jargon.

MR. WAGNER: I guess we were on page 9 and 10.

MS. TAYLOR: Right.

MR. WAGNER: Temporary job sites, okay.

CHAIRMAN SIEGEL: Was there anything substantive on either of those?

MR. LYNCH: If you will note, in here we bring up the paragraph about 1301 again, 20.1301, Item 3.

MR. WAGNER: Right.

MR. LYNCH: Again, we're just trying to be --

CHAIRMAN SIEGEL: Reemphasize.

MR. LYNCH: Reemphasize.

CHAIRMAN SIEGEL: Well, maybe you ought to just add a similar parallel phrase.

MR. LYNCH: Well, we are saying it's outside the van.

MR. WAGNER: Why in the world don't you just take this and put it at the beginning?

MS. TAYLOR: Because --

MR. WAGNER: Just put it at the beginning.

MR. LYNCH: Well, the point is we could not include it at all, if that's the desire.

CHAIRMAN SIEGEL: Well, I don't mind seeing it reemphasized.

MR. WAGNER: It's a minor point. It's not important.

MS. TAYLOR: Oh, you're saying at the very, very beginning?

MR. WAGNER: It doesn't matter.

MS. TAYLOR: Chances are, that might be addressed in the body of 10.8 already. I'm not sure, and these are specific things --

MR. WAGNER: Just reemphasis. That's fine.

MS. TAYLOR: Yes.

MR. WAGNER: That's fine. It's not a problem.

MR. CAMPER: I had the same concern here that I've expressed several times before, and it's this 35.29(c) issue, if they are doing the same services, so forth and so on. It may be that we'll cover that somewhere up front, as sort of general administrative guidance.

MR. WAGNER: I have a lot of problems on page 10, Number 4. Did I interrupt you there?

CHAIRMAN SIEGEL: That's what Larry is talking about, yes.

MR. CAMPER: Also, back on page 9, though, the sentence where it says "Indicate if 'scan-in-van' services will be provided. Note that your service may not be considered licensed activities if you are only providing services for scanning patients." We could say that more clearly.

MR. WAGNER: Imaging. Well, I guess you want to say scanning, imaging or -- I guess it could be more than just imaging.

MR. CAMPER: Well, it may not be considered licensed. It may not be considered licensed activities, if you are only providing... --

MS. TAYLOR: Well, and then we go on to say, "In situations where radioactive material is not handled by the mobile medical service an NRC license may not be required." Instead of saying handled, we may want to say possessed and used.

MR. CAMPER: Yes. We need to be a little more explicit about what we are getting up there.

CHAIRMAN SIEGEL: Some sort of clarification on that. I don't know exactly the words, but --

MR. WAGNER: Although I can't imagine that being the case, because they would have to have -- They would have to have a Cobalt 57 flood source. They have to do some kind of --

MR. CAMPER: We don't regulate it.

MS. TAYLOR: We don't regulate that, but there are probably other sources they would need also. Do we have anyone like this? The other thing is, if they go to the facility with their van in which they could use those sources under their supervision and do all their QA -- So they wouldn't have to possess the sources.

MR. WAGNER: Yes, they could do that. If they just have the camera or they have a thyroid uptake probe or they have -- It just doesn't have to be imaging either. That's the other caveat here, is that it doesn't have to be just imaging. It could be quantitative studies.

MS. TAYLOR: That's true.

MR. WAGNER: You could have quantitative studies. It isn't just limited to imaging.

CHAIRMAN SIEGEL: Do we know if anybody is doing that, if people are transporting any. Thyroid uptake probes are sufficiently inexpensive that, if you really want to provide this service, it's not that big a deal for the hospital to do it, unless it's a matter of not wanting to have a license at all. Okay.

So are we aware that scan-in-van exists with no licenses of any sort, simply transporting camera from site to site?

MS. TAYLOR: Well, I'm thinking it must, because

this is information that came from the current policy guidance directive that's being used with this year's --

CHAIRMAN SIEGEL: Well, I'm sure scan-in-van exists. The question is whether it exists unlicensed, because the mobile service never actually has anything other than a radioactive patient who walks into the van.

MR. CAMPER: Let's say -- That's an interesting question for sort of a different reason. Let's say someone was very astute, who really understood the regulation, and they recognized they could do that absent the license. We wouldn't know it unless the licensee, the hospital, had indicated in their application somewhere that patients were being scanned on this van and that they wanted to inform us, you know, that this was another place of use, not within the boundary of the building but otherwise. We might not literally know it.

CHAIRMAN SIEGEL: Well, no, you might know about it, though, because someone who is doing it might be clever enough to pick up the phone and say, this is what I'm planning on doing, and I want to make sure that you all don't see any problems with it.

MR. CAMPER: Right, or he might be very clever and decide he didn't --

CHAIRMAN SIEGEL: They might be exceedingly cover and say, the hell with you, I don't have to have it. Okay.

MR. WAGNER: On Item Number 4 --

CHAIRMAN SIEGEL: Are we on page 10 again?

MR. WAGNER: Yes. Is the intent of this rule to say that the client is responsible for the radioactive materials on their site or does it really mean that the client is responsible for radiation safety on the mobile van itself, in addition to the mobile people being responsible for what's going on in the mobile van?

MR. CAMPER: Well, it's saying -- If you go back to 35.29(c), it's saying that the institution, the hospital, is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile medical service is under the client's direction. In other words --

CHAIRMAN SIEGEL: It's setting up a hierarchy, really.

MR. CAMPER: It's saying that you're going to ensure -- you're the hospital, and you're going to ensure that the regulatory conditions are met while that van service is at your facility providing those services.

MR. WAGNER: So, basically, what it's saying is, if I as the hospital -- If I go in and I say, okay, you people are here to do this scanning, but I have to make sure you're doing this in compliance with the regulations, what are you doing. What are your practices? Do I have to verify that

they're going to be doing things appropriately? Do I have to go down there and inspect them. What do I have to do, because they're the ones that have been doing this all the time. Presumably, they have a license.

CHAIRMAN SIEGEL: Well, that's exactly what it means, because this is -- The mobile service is functioning as an independent contractor providing service to a licensed institution. Therefore, the institution's management has the ultimate responsibility for the licensed activity.

Actually, even though I can think of objections from a purely business point of view, I think from a safety point of view, this is a better hierarchical structure. It puts the ultimate responsibility on sort of the bigger organization, what would generally be the bigger organization, what would generally be the organization with a broader set of overall responsibilities, deeper pockets perhaps.

MR. LYNCH: If you look at 35.25, which the hospital would be required to follow, it says periodically review the supervised individuals, use of byproduct materials and the records kept of that use. So that regulation is going to require some --

MS. TAYLOR: Well, that's true.

MR. CAMPER: The answer to your question from a practical standpoint is that, yes, they are going to have to go out there and keep an eye on what's being done. They're

going to have to monitor it. They're going to have to take a look and see if appropriate records are being kept, so forth and so on.

CHAIRMAN SIEGEL: Now again, is this a big problem? Are there lots of these arrangements?

MR. CAMPER: Well, let me just put it this way.

CHAIRMAN SIEGEL: Where both have licenses?

MR. CAMPER: We just had -- The answer is, no, there are not lots, but we just had an exemption request from a mobile medical imaging situation. They requested an exemption to 35.29(c), and their rationale for it was that we are offering this as a business service; we want to and intend to control all aspects of the radiation safety program associated with this service, all aspects of its use, and we don't want to be in a situation where we find ourselves either in conflict with the medical institution which we're providing service or an absence of an adequate level of service or support or monitoring by that licensee. We want to control it. We want to oversee it.

MR. WAGNER: I agree totally with that.

MR. CAMPER: And we granted an exemption.

MR. WAGNER: Okay. They granted the exemption?

MR. CAMPER: Yes.

MR. WAGNER: To me, that would be a sensible way to do it.

MR. TAYLOR: I haven't been to OGC yet.

MR. CAMPER: We intend to grant the exemption. I'm sorry.

CHAIRMAN SIEGEL: Why does that medical institution have a license?

MR. CAMPER: Because they either have historically wanted to use material. Again, let's take 35.200 as an example. They have wanted to do that for whatever reason. They may still have a license, but have decided to use the services of a mobile service, because maybe it's cheaper or maybe their operating parameters have changed. I don't know.

MR. TAYLOR: They may not have a user.

MR. CAMPER: They may not have a user, but they want to keep being able to image patients, but the question that it raises in my mind --

CHAIRMAN SIEGEL: But if they don't have a user, they don't have a license.

MS. TAYLOR: Well, they still need it.

MR. CAMPER: They could still have a license. They could be --

CHAIRMAN SIEGEL: Well, it can't be an active license.

MR. CAMPER: That's right. They're in a stage of flux. They still have a license, though, by definition, but

getting back to the point you were raising, the thing that I'm struck by as I was looking at all this, you know, the question is, if you're going to issue a license to a mobile medical service -- We have historically sort of had this -- If one reads these regulations, you get this parent/child feeling -- right? The medical institution is the parent. The mobile is the child.

I guess the question you have to ask yourself is, if you assume that in 1995 mobile medical imaging is changing, provision of service are changing and so forth and so on, is it appropriate, is it necessary for us to place the same level of responsibility and burden on a mobile medical imaging service that we expect of an institution with regards to radiation safety and control and use of materials and so forth?

That's something I think we need to explore, as we revise Part 35. Obviously, that would require a rule change, but it's something we need to ask ourselves as we look at it.

MR. WAGNER: I mean, I can see this going both ways. I can see where a small service company would come in, and they would want the radiation safety services of the larger institution when they get on their site. I mean, I can see where they would want that, because they are a small company, and they don't have the depth to manage some things

or the other situation is where they want to be independent of the person because of this very problem.

This could be a terrible conflict.

MR. CAMPER: Well, sure it could. Let's imagine that you're -- Let's say you're a very sophisticated physicist and in a very sophisticated position. You and Barry decide to perform, you know, mobile imaging. Now you are both very conscientious.

You understand radiation safety, understand the regulations, but now you're going to go provide your services to a hospital in a very small community in a very outlying area that's not terribly sophisticated when it comes to radiation safety.

MR. WAGNER: But they got a license.

MR. CAMPER: But they got a license. You may well want to control and be able to monitor all aspects of radiation safety.

MR. LYNCH: I think in most cases, the mobile service does follow all the way through.

MR. CAMPER: Yes, I think you're right.

MR. LYNCH: But if they are coming into your institution, do you want to have any control over them?

CHAIRMAN SIEGEL: Sure you do. Of course. I would.

MR. WAGNER: If they are coming into my

institution, that's one thing. If they are providing services within their van, and it's confined to the use inside their van, that's another issue. As soon as the patients walk out of there, I'll take responsibility for them, although I don't have any legal requirement to do that, because they are all diagnostic patients; but I expect them to manage the things inside their van.

If I go in there and try to tell them they're not doing something right, and they are doing the services and they are in conflict with me, I can see where that creates a problem.

CHAIRMAN SIEGEL: Well, we're stuck with this right now.

MR. WAGNER: Yes.

CHAIRMAN SIEGEL: We're stuck with this Part 35. We're stuck with it right now.

MR. WAGNER: Yes, we're stuck with it, but I think that's the reasonable way of dealing with it, is asking them for the information and then making the decision based upon the individual request. So I don't see any problem.

MR. CAMPER: Well, and at this point, I mean, the best we can do is get a clear delineation of the arrangement.

MR. WAGNER: Yes, right.

MR. CAMPER: Who's doing what.

MR. WAGNER: Right.

CHAIRMAN SIEGEL: The simplest solution to this problem for a small medical institution that uses a mobile service is to get rid of its license and not have a license. Right? Then the mobile service is responsible for the entire service.

MR. CAMPER: Yes, and again it would not surprise me if we see that happen. There's two movements that I sense going on. One is I see a consolidation of licenses among small entities that have some corporate arrangement. Possibly some nuclear medicine department is closing, using a more central location, and I also see mobile services as emerging.

MR. LYNCH: Then there's a fee issue.

MR. CAMPER: Right.

CHAIRMAN SIEGEL: Okay. Page 11, transport of radioactive material and purpose. In the middle of that paragraph it says, "Transportation of generators is not authorized by 35.80, other than for base hot lab locations."

MS. TAYLOR: We missed that.

CHAIRMAN SIEGEL: That's not English, is it?

MS. TAYLOR: No. We must have had two thoughts going and didn't fix that. We just need to say transportation generators is not authorized, period.

CHAIRMAN SIEGEL: Because a base hot lab, presumably, is not mobile, is it?

MR. WAGNER: Could be.

MS. TAYLOR: Could be, but normally they still wouldn't be able to transport generators --

CHAIRMAN SIEGEL: But then you still can't transport it. Okay. I got it. Fine. I didn't have anything else in that paragraph. Yes, this next thing, 35.25. Tell me a little bit about how you guys are handling 35.25 these days. Bring me up to date.

To me, 35.25 is the full employment regulation for NRC inspectors into the next century, because 35.25 theoretically can be taken to extreme limits and, in fact, anything that is sort of off base in a radiation safety program could be interpreted as a violation of 35.25. Don't you agree?

MR. CAMPER: Well, I look at it a little different than you. I don't quite look it as the NRC full employment thing, and the reason I don't is because the truth of the matter is I think that the degree to which we are scrutinizing supervision today is fairly lax.

CHAIRMAN SIEGEL: Well, that's why I asked the question.

MR. CAMPER: What I mean is this. Let me tell you what sets this up, and this is part of an even bigger issue that we've, you know, talked about a little bit, you and I, and we talked a little bit about within the ACMUI itself.

That's this whole question of what is the role of

the authorized user in 1995? The way Part 35 is structured today, if you go back and look at the supervision issue over time, you'll find that there was a time when supervision had specifications associated with it, like being physically present or available within one hour or 15 minutes. Some states, by the way, require that today, but in 1987 we relaxed, if you will, the term supervision.

What the Statements of Consideration basically says is that we don't -- we remove the physical requirement, the availability requirement, within some defined period of time, because -- because of the various medical practice statutes within the various states and so forth and so on, and differences in institutions and what goes on in institutions, that the physician is in the best position to determine the degree of supervision that is warranted in their setting.

Now from a regulator's standpoint, from our standpoint, that really causes a significant problem for our inspectors, because what it translates into is that our inspectors really don't become overly concerned about supervision issues from authorized user's standpoint until you get into situations like places where the doc flies in once a week, but in the meantime while he's not there, injections are occurring. Scanning is going on.

Sometimes that raises problems as to whether or not adequate supervision is taking place, but as you know, --

I mean supervision, you can put in place a mechanism, a system for instruction and monitoring. You don't necessarily have to do it yourself. You as a physician can make sure that your chief technologist is properly supervising and monitoring and instructing, and then you're monitoring how that's going on.

So it's very wide open today, and one of the things I'd like to see us do when we revise Part 35 is take a close look at what should supervision be today. What's the role of the authorized user today?

I would argue that the authorized user in 1995 is not the same thing as it was in 1965 or 1975. You know, back in those days, and you know very well yourself, the AUs were in there working with the technologists closely, hand in hand. You were developing radiopharmaceuticals, new procedures.

You know, has the modality matured today to a point where physicians who just want to use materials in the course of the practice of medicine -- are these AUs like we had classically known them; and if they are or they are not, what's the appropriate level of supervision?

So supervision is not something that gets dinged too often in violation space. Probably the most striking example is where -- when the QM rule came along and people weren't instructed in the quality management rule, and that became a violation associated with 35.25(a)(1), failure to instruct in QM rule.

MR. LYNCH: Or extreme situations.

MR. CAMPER: Or extreme situations where it becomes clear to us that supervision is not occurring. Technologists have not been instructed. Then you get into supervision violations, but they're usually pretty striking cases, actually.

CHAIRMAN SIEGEL: Is there an appendix in 10.8 that gives examples of 35.25((a)(3), that periodically review the supervised individual's use of byproduct material and the records kept to reflect this use? I've always been troubled by not quite knowing exactly what the right paper trail is for that paragraph.

MR. CAMPER: No, there's not such an appendix. You know, there's appendices in there to describe the various records that need to be kept. You get examples of the kinds of records you should be keeping.

MR. LYNCH: Training. Training is described, how often it should occur.

MR. LYNCH: Training.

CHAIRMAN SIEGEL: The training is in there.

MR. CAMPER: Let me tell you, the best description, I think, that you would find would not be in Reg. Guide 10.8. It would be in the recent Reg. Guide on management of radiation safety programs in medical facilities.

We talk a lot in there about reviewing supervised

individuals, reviewing the records and that type thing.

MS. TAYLOR: The NUREG?

MR. CAMPER: The NUREG, NUREG 1560, but not as an appendix in 10.8. No.

CHAIRMAN SIEGEL: Okay.

MR. WAGNER: The biggest problem with a lot of these guidelines is the fact that, although these are guidelines about what the person should submit, they aren't guidelines as to what would be adequate. The reason is because you're going to run into such variabilities that you don't really know what's adequate until you see what they're doing and then try to assess whether or not what they're doing is adequate for the situation they have.

MR. CAMPER: That's a good point, and also even before that, if you take a performance mentality approach -- You know, you really want to have some fairly general concepts and guidelines about supervision, because in theory the user or the radiation safety officer is in the best position to reach that level of performance for their institution.

So you don't want to intrude too much.

MR. WAGNER: That's right.

CHAIRMAN SIEGEL: Then this next page gets us to the point where I think you may be intruding too much. How did you decide that --

MR. WAGNER: When you indicate the next page,

what page?

CHAIRMAN SIEGEL: Twelve.

MR. CAMPER: Let me -- Can I insert a thought here?

CHAIRMAN SIEGEL: The authorized user at least once every 30 days.

MR. CAMPER: Let me make a comment on page 11 before you do that, if I may, Barry. When you get into a discussion of Item 8, "Individuals Responsible for the Radiation Safety Program," we then move into a discussion of supervision.

There is a lot more about the individual responsible for a radiation safety program than only the supervision. There's probably a lot more things that we should be saying about it.

MS. TAYLOR: The intent was you only bring in specific things into these modules that are specific to this type of modality. The rest of it's covered in the main body of 10.8. So that is in 10.8, and then they are directed -- That would apply to all uses of byproduct material in the medical users, and then we are supposed to address specific things in this guideline, instead of reiterating everything that's in the body of 10.8 into this -- each module.

So the purpose of this module is just specific to mobile medical. There is a lot more, but they are told up

front at the very beginning. There's a paragraph. There are other things that apply.

MR. CAMPER: Yes, you're right.

MS. TAYLOR: And you should refer to that and address those issues also.

MR. CAMPER: Where are we telling them that?

MS. TAYLOR: At the very beginning.

MR. CAMPER: What do we say?

MS. TAYLOR: On page 1.

MR. WAGNER: Yes.

MS. TAYLOR: If you look at the first paragraph.

MR. WAGNER: In addition to the more general items identified.

MR. CAMPER: Well, the only thing I would say, though, is it might be worth a sentence or two in here, specifically drawing their attention to those key items. I mean, the responsibility for the radiation safety program is a big deal, obviously, and it might not be a bad idea to ponder putting in just a sentence or two in there that would draw their attention to specific parts that they need to consider with regard --

MS. TAYLOR: Then I think we need to do that for all the other items, too, then; because all of these items do not go into all the information needed for each of those specific -- There's a lot more under radioactive material and

purpose. There's a lot more --

CHAIRMAN SIEGEL: Well, except the only argument in favor of what Larry is saying or an argument in favor of what Larry is saying is that, because of the physically distributed locations of use in a mobile service, the individual responsible for the radiation safety program has to be able to get around.

So if you are going to institutions that have their own licenses, then it's the local radiation safety officers who are going to take the responsibility. If you're going to places that don't have licenses, there has to be a mobile medical service radiation safety officer equivalent who takes over all responsibility, and we need to know something about what it is that individual does to evaluate safe radiation practices, both through supervision and through other things, the necessary environmental monitoring and things of that nature at each site of use.

So I think the mobile service does point out a need for that.

MS. TAYLOR: So what kind of sentence are you looking for?

MR. WAGNER: It seems to me like what you want to point out what's specific. You want to bring to their attention that in addressing the more generalized items of regulatory guide 10.8 that the applicant must keep in mind

those issues that are particular to this mobile program in addressing those radiation safety needs.

MR. CAMPER: For example.

MR. WAGNER: For example.

MR. CAMPER: Very articulate.

MR. WAGNER: So it's just a matter that you're just calling the attention to it, calling their attention to the fact that they have to specifically design their responses to 10.8 around their mobile --

CHAIRMAN SIEGEL: Do you have regular old 10.8 there?

MR. WAGNER: -- situation.

MS. TAYLOR: No.

CHAIRMAN SIEGEL: Does anybody have it?

MR. CAMPER: Just one more quick thing, since we're back on page 1. I want to mention as an editorial comment, we're referring to Reg. Guide 10.8 revision 3. So this will be the next revision?

MS. TAYLOR: We're working with revision 2, and this revision will be revision 3 Reg. Guide 10.8.

MR. CAMPER: These modules will go into the existing Reg. Guide.

MS. TAYLOR: But they're modifying that, too, and it will be revision 3.

MR. CAMPER: Right. That's what I'm saying.

Currently, it's revision 2 is what exists. Right? Okay.

CHAIRMAN SIEGEL: Okay. Next page. How do you get to this every 30 day thing?

MS. TAYLOR: History, I guess.

CHAIRMAN SIEGEL: But where? What's the regulatory basis for that? Help me out here. I mean, if someone is doing --

MS. TAYLOR: I think that was probably policy when this thing was first issued.

MR. WAGNER: Thirty days rolls around real quick. In some small situations, 30 days rolls around real quick.

CHAIRMAN SIEGEL: I mean, I can think of circumstances of very limited use where once a year is probably too frequent.

MR. WAGNER: And other circumstances where once a week is not frequent enough.

MS. TAYLOR: We're asking them to indicate a frequency, and we can evaluate that on the scope of the program at the time.

MR. WAGNER: I think what you should do is you should tell them that the frequency of the supervision must be consistent with the volume and type of practice, and that's what it should be, and that they should have the rationale for saying what the time interval should be; but they should specify a time interval for themselves.

MR. CAMPER: Yes. I think that's a good suggestion.

MS. TAYLOR: I like that.

MR. LYNCH: And I think we're trying to provide license reviewers with a little better -- what would be --

MR. WAGNER: I think that's very fine, because now it will have to be spelled out by the user what he's going to do. So he has to meet what he says he's going to do, and it has to be approved.

CHAIRMAN SIEGEL: If you imagine a van that's traveling around and they're doing bone scans, liver scans, and gated blood pool studies in the van, and that's all they do, what are you going to look at every 30 days to find out whether they're doing it right?

MR. LYNCH: It's the same old stuff.

MR. CAMPER: Well, let me be the devil's advocate. Barry, let me be the devil's advocate for you. I understand what you're saying when you say it's only nuclear medicine, so forth and so on, but imagine a scenario, if you will, where the van is going out and about. You have a driver and a technologist on board.

The technologist will decide to do things like soup up the doses, get the scans done quicker, which has happened even in institutional settings, would decide that, as has happened even in institutional settings, look, all these

records every day, these daily surveys and so forth and so on -- this is nonsense. This is small mass material. These are low exposure levels, and I'm just not going to do it, and I'll come back in later on and kind of fill it in.

These things happen, unfortunately. Now --

CHAIRMAN SIEGEL: But I don't think that mobile is any different with respect to that.

MR. CAMPER: Well, it's only different in the sense that the technologist is yet one more step removed physically from the presence of the authorized user. I mean, in a --

CHAIRMAN SIEGEL: Unless the authorized user is a radiologist right there in the hospital who is reading those scans as they are coming off the machine.

MR. CAMPER: Or unless that radiologist is also walking through the van looking at the books from time to time. I mean, the point is that in a fixed setting, the users, as you know, are moving about in the department. It's much easier to look over and see what kinds of doses are being assayed. Does the dose log look like it's right, and so forth, look at the count rate on the camera, where is it.

If all that is occurring out somewhere in a van, the user is not in the van. It's just the potential for that to happen is greater, but again that doesn't necessarily imply that it has to be every 30 days. I'm just saying, it's that

kind of possible scenario that makes us wonder whether or not some defined period of time is not appropriate.

CHAIRMAN SIEGEL: I got the picture. All right. I didn't have anything else bothering me on page 12.

MR. WAGNER: Can I get back to that then? I mean, if that's the case, here you specified 30 days. Is there any guidance that can be given to the user to say should be reviewed over intervals not to exceed such and such, but variable according to the needs; and you wouldn't want to say 30 days, but I would disagree that once a year was enough.

CHAIRMAN SIEGEL: Oh, I didn't say that was enough either.

MR. WAGNER: But I think six months might be.

MS. TAYLOR: Then we have no regulatory basis. I mean, that was one of the comments that came out, was the 30 days. We have no regulatory basis for a frequency --

MR. CAMPER: Yes, this is a "should."

MS. TAYLOR: This was policy from previous TAR from the past.

MR. WAGNER: But you can make a recommendation in a guideline that -- to tell people that, if they're only going to say they are going to supervise it once a year, you're not going to consider that adequate. You know, you can give an upper limit, and I think my recommendation would be not to exceed six months, but must be -- but may be required to be

less, depending on the use and what you're doing, the scope of what you're doing, but it gives them some guidance.

I mean, these are people who are going to be writing these things, and Lord knows what they're --

MR. LYNCH: One of the things that we wanted to do right in the Reg. Guide is write the Reg. Guide with as much information as we can put in, to make the licensee very clear on what we expect and what we will accept.

MR. WAGNER: Right. I think, if you just say something, that it shouldn't exceed six months, but it may be required to be less, depending on the scope and use of the material, and that the user should make a specification as to the intervals he feels most appropriate.

MR. LYNCH: Is six months too long?

MR. WAGNER: I don't know. That's very had to say, depending on what -- I can see where six months probably is adequate.

MS. TAYLOR: If we say six months, everyone is going to come in and say six months, and then we can't argue with it, if the program seems very huge and it seems like they should be looked at every quarter.

MR. WAGNER: Well, you could give an example. You could give examples where in this situation an interval of six months might be required, but in another situation an interval of 30 days may be required.

You might be able to do that when you give your examples. You're going to be making up examples for this. Right? Isn't that one of the things that we're going to be doing later on, giving examples?

So in the license examples you could say that, what the NRC would approve in this situation, this is a reasonable time; in another situation, it's not. You might not have to write it here, but somewhere you got to have some guidance as to what kind of times you're going to require and not require. I think some examples would be worthwhile. It's got to be variables, and their judgment isn't going to be the same as your judgment.

CHAIRMAN SIEGEL: The other question -- Actually, while we're on this, it says the authorized user should review the supervised use. That's actually not what 35 says. Thirty-five says, "The licensee shall..."

MR. CAMPER: Well, I was just pondering the same thing, because what if you have a situation where you have a commercial entity and your AU functions as a contract employee of the commercial mobile lab for purposes of image interpretation?

Now the licensee is the mobile entity.

CHAIRMAN SIEGEL: There has to be a prescribing physician somewhere in the loop, does there not? There has to be someone who wrote the procedure manual. There has to be an

implicit prescription to give the drug for the practice of medicine in the state.

MS. TAYLOR: But that could be at the client hospital where they are just coming in and --

CHAIRMAN SIEGEL: That's correct. I really think it's the licensee. Let's say that the way you've got -- You've got a mobile medical service that doesn't have any physicians in its employ, but has a terrific health physicist who runs the program.

MR. CAMPER: Right. Exactly.

CHAIRMAN SIEGEL: And that's actually the preferred person to be reviewing the use, rather than the radiologist, who couldn't care less. All he wants to do is look at the pictures.

MR. CAMPER: Right.

MS. TAYLOR: So throughout Item 8, change that to licensee.

CHAIRMAN SIEGEL: It wouldn't be a pathologist who became a nuclear medicine physician -- a radiologist. Okay.

MR. WAGNER: So it's going to say that the licensee should review the supervised individuals' use of byproduct material on a periodic basis, depending upon the scope and use of --

CHAIRMAN SIEGEL: Well, does a mobile service

have a radiation safety officer?

MR. CAMPER: A radiation safety officer is designated, yes.

CHAIRMAN SIEGEL: So then, really, up above shouldn't we indicate the frequency with which the RSO or AU?

MR. CAMPER: Well, licensee is a better term, because the licensee can be the users.

CHAIRMAN SIEGEL: But that doesn't work for the previous sentence. "Indicate the frequency with which the licensee is physically present..."

MR. CAMPER: Or the licensee's representative.

MS. TAYLOR: Well, we're going to be changing this whole thing. That will fix itself out.

MR. CAMPER: The licensee's representative is physically present.

CHAIRMAN SIEGEL: Okay, got it.

MR. WAGNER Then the theory is that it will be consistent with the scope of use radioactive material, and then maybe within the examples that you give somewhere, they can go back and see the examples for examples of periodicity.

CHAIRMAN SIEGEL: Boy, is this complicated. Remind me never to open --

MR. WAGNER Yes, these things -- well, they have some very sticky, very sticky kinds of issues that you an get involved in with crossing state lines as one of them we

haven't even addressed yet.

CHAIRMAN SIEGEL: Right. Okay. Anything else on page 12? Protected from the elements, up to and including what?

MS. TAYLOR: Apparently, someone in --

CHAIRMAN SIEGEL: Given the fact that we know that tornadoes are attracted to mobile units of all sorts, it's a well known fact. So how do we think that a mobile nuclear medicine van can be protected from a tornado?

MS. TAYLOR: Magic. Well, this came about from talking to someone in Region 2, who apparently had experience with a licensee that had a garage that was pretty rundown, and it really wasn't very secure and what have you. So -- You can't protect them from a tornado.

CHAIRMAN SIEGEL: Doesn't say tornado. It says high winds.

MS. TAYLOR: Right. Okay.

CHAIRMAN SIEGEL: Tornado is a form of high wind. Okay. That's fine. Page 13. On the third line of 10.2.1 and 10.3, "...and check all other transported equipment for proper function before medical use at each address of use..." Although that's good practice, it's not Part 35. Part 35 doesn't require me to make sure my camera is working. It's good medicine.

MR. WAGNER: What do they mean, "all other

transported equipment"? Do they want to make sure the toilet flushes?

CHAIRMAN SIEGEL: Camera works, toilet flushes.

MR. CAMPER: The cameras, dose calibrators.

CHAIRMAN SIEGEL: No. Dose calibrators are specifically required. "All other transported..." -- Although I agree with you, you've gone a bridge too far in terms of what -- because the problem is -- and here's the problem. If I put that in a license, even though you don't have the right to force me to put it in a license, it just became a license condition.

MR. LYNCH: Well, see, that's what it says in 35(a).

CHAIRMAN SIEGEL: What?

MR. LYNCH: 35.80(b) says, "Check survey instruments and dose calibrators, as described in 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use."

MR. WAGNER: What does that mean, "all other transported equipment"?

CHAIRMAN SIEGEL: So you did that to --

MR. CAMPER: We have a regulatory basis. The question is, why do we have the regulatory basis?

CHAIRMAN SIEGEL: Because you snuck it in, and nobody caught it.

MR. WAGNER: It would be --These are the kinds of problems, though, that gets the users angry a lot of times, because it's so generalized.

CHAIRMAN SIEGEL: Right, but again the camera has to be checked.

MR. LYNCH: Well, it says for medical use. So that rules out your toilet scenario.

CHAIRMAN SIEGEL: And you don't have to check the spark plugs and carburetor in the van.

MR. CAMPER: That's an interesting point. I mean, that would seem to get at the gamma camera.

CHAIRMAN SIEGEL: It sure does.

MR. CAMPER: But you know that we don't require quality assurance, for example, on a gamma camera.

CHAIRMAN SIEGEL: Well, from a practical, medical point of view, it's logical that if you're moving gamma cameras around, you want to check them before you use them, because road bumps are more likely to do that, and that may have been the way you snuck it in here.

MR. CAMPER: I think the logic was exactly that. I think that there was assumed a higher probability of failure of imaging cameras and so forth because of the transporting. Therefore, this --

CHAIRMAN SIEGEL: But it would be interesting to know how you have evaluated whether those checks that have

been written in licenses in the past are adequate.

MR. LYNCH: We would just ignore, basically, gamma camera checks, even if a licensee --

CHAIRMAN SIEGEL: Even though you have the regulatory authority to do it that you didn't know about until I opened my big mouth.

MR. CAMPER: Let's adjust that TI. Just kidding, for the record.

CHAIRMAN SIEGEL: That's fine.

MR. LYNCH: I think we have historically stayed away from it.

MR. CAMPER: That's right.

CHAIRMAN SIEGEL: Well, though, it actually is important. It's just good medicine to not give a dose of something until you're sure that the camera is going to be able to take a picture.

MR. CAMPER: We don't get into that.

MS. TAYLOR: That's interesting. I didn't realize that.

MR. LYNCH: The states.

MR. CAMPER: That's a good point. Now the states, in many cases, do have specific requirements.

MR. LYNCH: Right. In most cases, I would say.

MR. CAMPER: And they do inspect them, but we do not.

CHAIRMAN SIEGEL: This is a clear example of Parkinson's Law, but we're keeping busy here.

MS. TAYLOR: As a comment, I notice in 11.9 and there's one beforehand, some of these things we've talked about needing an exemption, I haven't actually quoted the regulation in the exemption. So we'll put a generic, "this will require an exemption from such and such, and you should submit it for whatever." This particular one is delivery to the van.

CHAIRMAN SIEGEL: Okay.

MR. WAGNER: It's interesting that it does say all other transported equipment, but your second sentence there says, "Describe your procedures for taking survey instruments and the dose calibrator." That, you specifically want.

MS. TAYLOR: Yes, but we were just quoting 8ED, and then we want to get into the stuff on the survey meter and the dose calibrator.

MR. CAMPER: Yes, we're clearly focusing on the first part of 8ED which draws you with distinction to 35.50-.51.

CHAIRMAN SIEGEL: Interesting. Okay. Page 14. I guess you're stuck with therapy not being permitted because of current Part 35.

MR. CAMPER: That's right.

CHAIRMAN SIEGEL: But you would grant an exemption for therapy if confinement was not required.

MS. TAYLOR: Right.

CHAIRMAN SIEGEL: Is that correct?

MR. CAMPER: Correct. Well, we would consider such an application. We have not granted one yet.

CHAIRMAN SIEGEL: Because it's interesting that you would allow -- This allows someone to be given 10 millicuries of I-131 for whole body imaging of thyroid carcinoma for imaging in a van, but doesn't allow someone to get 10 millicuries of I-131 for treatment of hyperthyroidism, which is a little bit silly, if you think about it; because the radiation safety considerations are identical.

MR. CAMPER: Yes. Currently, if you go back to 35.29(a), Barry, it says that the Commission will license mobile nuclear medicine service only in accordance with subparts (d), (e) and (h). So that gives you (d), which is 35.100, (e) which is 35.200, and then (h) which is your --

CHAIRMAN SIEGEL: It's probably bone densitometry. Is that what that is?

MR. CAMPER: Yes.

CHAIRMAN SIEGEL: Which is no longer an issue, since everybody is using X-rays. Yes, that -- I mean, that's something for a fix in Part 35 next time around. right?

MR. LYNCH: And we're trying to say that we would

allow it, but should we go further than we've gone here?

CHAIRMAN SIEGEL: Well, I wouldn't necessarily encourage applications. I think there many reasons why getting treated by a mobile service is not the optimal medical arrangement in that the follow-up arrangements are not likely to be real terrific.

MR. WAGNER: Screening for pregnancy.

CHAIRMAN SIEGEL: Yes. There's a lot of good reasons why it's not the best way to do it, but I think it should be allowed, but --

MR. CAMPER: I have a question. I'm reading here. I'm wondering something. Torre, maybe you can help me out. (d), (e) and (h) -- (d) is uptake dilution and excretion. (e) is unsealed byproducts materials for imaging and localization. (f) is radiopharmaceuticals for therapy.

CHAIRMAN SIEGEL: Correct.

MR. CAMPER: (f) is not cited under 35.29(a).

CHAIRMAN SIEGEL: Correct. It's excluded.

MS. TAYLOR: That's why they need an exemption.

MR. CAMPER: I understand. So are we clear that that requires an exemption?

CHAIRMAN SIEGEL: Yes. Oh, yes. In fact, the first line on page 14 in that paragraph.

MR. CAMPER: So the idea is that, as we would give it to them, it would clearly require an exemption. Good.

Good.

MR. LYNCH: But we wanted to point it out as, you know, it is an exemption. We don't necessarily encourage it, but we'll consider it.

MR. CAMPER: And the rationale is that it's -- Even though it's therapy, it's a releasable -- patient releasable amount. So we've chosen to draw the distinction to that particular category there, as opposed to not considering the other more complicated modalities at this point in time.

MR. LYNCH: Somebody could come with an exemption request saying, I want to do CA therapy, 100 millicuries --

CHAIRMAN SIEGEL: Which is when you're looking to drive them around in a truck for a week until --

MR. CAMPER: Now at some point, we're going to have to come back with guidance, if we ever do move toward licensing, say, a mobile HDR. We'll have to come back and create a separate guidance. Mobile HDR has been licensed by the state of California.

CHAIRMAN SIEGEL: Page 15, the second paragraph. When 35.75 becomes revised, you'll need to update that language.

MR. CAMPER: That's right. I had the same note.

MS. TAYLOR: When will that become final?

MR. CAMPER: Well, it has gone to the EDO this week. It will be --

MS. TAYLOR: So it will be final before this goes out?

MR. CAMPER: Yes, it could.

MR. WAGNER What is it going to say?

CHAIRMAN SIEGEL: Well, unless John has pulled a fast one on me in the last 10 days, it's going to say that exposure has to be less than 500.

MR. CAMPER: Right.

CHAIRMAN SIEGEL: And that you have to instruct people if it's more than 100. That's a simple version of what it says.

MR. CAMPER: With some particular instruction.

MR. WAGNER And nothing about quantities?

CHAIRMAN SIEGEL: Well, no -- Yes and no. There's the 500 milligrams as the simple regulation, and then there's the no-brainer regulatory guide approach that says, if you're below this number, you an be assumed to be in compliance.

MR. CAMPER: But the language in the rule itself does not say 30 millicuries. Dose driven.

CHAIRMAN SIEGEL: It's actually a little more than 30 millicuries, the way it recalculates that, 36 millicuries. Okay.

MR. LYNCH: Back to 29.9.

CHAIRMAN SIEGEL: Yes, that will give you 36.5.

No, actually, those will be less of a problem now, because by calculation there's going to be 80 millicurie administrations in people --

MR. CAMPER: Let me ask a question here. I have a note in the margin. Bottom of page 14 says, "If you wish to perform radioactive drug therapy procedures, you must request an exemption from this regulation and provide a detailed explanation as to why an exemption is needed. Such requests will be reviewed on a case by case basis."

What about I just want to do it for this purpose. I want to provide that service. Is that a reasonable explanation for granting an exemption to do up to 30 millicuries of iodine therapy?

MR. LYNCH: Because I'm going to provide a service to someone and make it more convenient for them, provide them the service?

MR. CAMPER: What I'm saying is we've seen -- Obviously, we now know we're treating this category of therapy --

CHAIRMAN SIEGEL: I don't think that's a problem. I understand what you're saying, but since it requires an exemption, can you imagine asking for an exemption and not saying why you want the exemption?

MR. CAMPER: I understand. What I'm saying is that, let's say I come in and I say in my application I want

to provide the service of up to 30 millicuries of iodine therapy as a service.

MR. LYNCH: To make more money.

MR. CAMPER: No, I want to -- Well, you wouldn't say that. You would say, I want to make this service available to my clients. Is that an acceptable reason for the exemption?

One gets the impression from reading this that, you know, if you're going to seek an exemption, there has to be a pretty good reason for doing it because of therapy procedures, and is the availability of the service, in and of itself, an adequate reason? I'm not saying it's not. I'm throwing out the question.

CHAIRMAN SIEGEL: Given that mobile nuclear medicine services generally provide services to the kind of less sophisticated clients that you've been discussing, I think that's a reasonable answer to the question.

On the other hand, if someone says they want to do mobile nuclear medicine and want to provide it at hospitals in the city of St. Louis, then -- I mean, I can't imagine why anybody would want to compete with Washington University and St. Louis University to provide that service in the city, because of all the hassle that goes with providing that service, the quality management program, the other rigmarole.

So I think -- I mean, just say my clients need

this service; I want to provide the service. That will be an acceptable reason.

MS. TAYLOR: And I'm sure the reason would be it's rural areas, and they don't have access.

CHAIRMAN SIEGEL: I assume that the service in St. Louis is not currently pursuing therapy, are they? I don't care. I mean, seems like everybody else in town has stopped doing therapy, and I'm so tired of seeing every hyperthyroid patient in St. Louis, I could scream.

MR. WAGNER: Regulatory guide -- Are we on page 16?

CHAIRMAN SIEGEL: We are trying to get there, yes.

MR. WAGNER: Item 2 on page 16, last sentence. "If you determine that bioassays are not required, provide justification for this conclusion." Are there any other guidelines the NRC can give people to give them guidelines as to what justification will be required, what circumstances they accept as being justification not to have to do a bioassay, anything more specific somewhere?

MR. LYNCH: The Reg. Guides.

MR. WAGNER: Are there Reg. guides that you can refer them to?

MR. CAMPER: I understand your question. Let me think for a minute.

MS. TAYLOR: It isn't only Reg. Guides per se. There's been a couple of TARs we've been working on.

MR. WAGNER: Well, there might be some guides in some other modules, because this only refers to mobile. There might be guides in some other modules saying, if one is making out their license, what would constitute a requirement --

MR. CAMPER: An adequate justification.

MS. TAYLOR: Well, Sally's guide is pretty much going to require it, because patients covered under her guide are probably going to have to be hospitalized, and bioassays are required under 3.15(a)(8).

MR. WAGNER: See, I mean, if you're -- therein lies the rub here. I mean, clearly, if you're going to have patients who are going to require hospitalization, okay, bioassay is probably going to be required. We're talking about all diagnostic here.

MR. CAMPER: Yes. When you're above 30, it gets a little simpler, except when you doing capsules, there's some interesting discussions going on today.

MR. WAGNER: Of course, but I'm trying to get you to think about whether your guidelines -- what will you accept, and what does a person really have to say here?

CHAIRMAN SIEGEL: But that's based on the probability of exceeding X percent of the annual limited intake.

MR. WAGNER: Correct.

CHAIRMAN SIEGEL: Isn't that what the Part 20 guidance is based on here?

MR. CAMPER: Yes. That's correct.

CHAIRMAN SIEGEL: Okay. So the way you do that, and this is a health physicist calculation -- this is not something you pull out of a table. As you look at -- or maybe it is, and I just don't know those Reg. Guides, but you look at the total amount of I-131 used and the number of people who are going to be using it, and over what period of time, and --

MR. WAGNER: Right. That's my whole point, though, here.

CHAIRMAN SIEGEL: But that is literally the calculation that is required as part of any license application.

MR. WAGNER: I don't disagree with that. My only point here is to tell the person what he's got to do. Here, it's very general. It says, "If you determine that bioassays are not required, provide justification..."

CHAIRMAN SIEGEL: Well, don't you think Reg. Guide 8.20 tells you how to go about it?

MR. CAMPER: It does. It talks about activity levels, the form in which it exists, and it may be that --

CHAIRMAN SIEGEL: And 8.9 is even more detailed.

MR. CAMPER: Right, and you're not exceeding

those thresholds in terms of quantities or form, as described in those guides, then you can explain that you're not doing that.

MR. WAGNER: But you can tell the person. I mean, if you determine that bioassays are not required -- All I'm asking you to do is give the person who is going through this thing, saying, how do I determine that, and go back to here. Well, just be more specific in the statement.

MR. CAMPER: Okay. So clarification as to what is acceptable.

MR. WAGNER: Yes. If you determine that bioassays are not required, as determined by whatever is in those regulatory guides, provide the information. You're saying provide justification. It's like you're trying to provide something over and above what they've already done.

MS. TAYLOR: I'm not really sure what we can put in there. There's so many variables as to why they could determine it's not necessary. I mean, we could just say, please describe how you reached this conclusion, and make it sound a little less harsh.

MR. WAGNER: Yes. Yes, you could do that.

MR. CAMPER: You could do that. You know, how you reached this conclusion; for example, a discussion of the evaluation.

MR. WAGNER: Right.

MR. CAMPER: Yes, something like that.

MR. WAGNER: The way it's written, it just tells me --

MR. CAMPER: It's harsh.

MR. WAGNER: And I would sit there and struggle with that, I've got to justify this now after I've gone through all this. Just asking to clarify that.

MR. CAMPER: It can be made a little less punitive.

MR. WAGNER: There you go. There you go.

CHAIRMAN SIEGEL: Okay, next up, emergency procedures. This is another one of these "should equals three hours." how did you get to that number?

MS. TAYLOR: I'm sure OGC had a comment on that, too. We didn't get to incorporate all the OGC comments, because we didn't get them, and she was commenting on the basis for these numbers.

MR. LYNCH: They didn't comment on that.

MS. TAYLOR: They didn't?

MR. LYNCH; No.

MS. TAYLOR: They did on the 30 days.

CHAIRMAN SIEGEL: What did they say about the 30 days? They just said how did you get that number?

MS. TAYLOR: What's the regulatory basis.

CHAIRMAN SIEGEL: I mean, I can -- it's hard for

me to understand if unit doses of technician are all that are being used by a mobile service, why are a response time of under three days is necessary. What can happen?

MR. LYNCH: Adverse reaction?

CHAIRMAN SIEGEL: That's a medical issue.

MR. CAMPER: People walking through it, spreading contaminants.

MS. TAYLOR: Well, let's not put the time in. Let's just see what they say. There again we get back to the reasons. They're going to come back, well, give us what's acceptable. Is one hour acceptable?

MR. CAMPER: Well, I mean, if you just leave tech lying about, syringes spilled.

MR. LYNCH: If it's in the hallway and the waiting room, that's not an acceptable situation.

MR. CAMPER: That's right. So I'm saying, you have the spread of contamination issue.

MR. LYNCH: At least, this limits --

MR. WAGNER: But the issue here is quite clear. Why does it have to be the radiation safety officer or the authorized user that's got to show up on the scene? If it's contamination in the area, the chief tech ought to be able to go down there and take care of that issue. Why does he have to respond within three hours, because somebody did that? This happens frequently. They got to clean it up. They know

they got to clean it up.

MR. CAMPER: Yes, it should be -- or their designee, for one thing.

MR. WAGNER: Or a responsible designee. Yes, there you go.

MR. CAMPER: That's right, because as a practical matter you've got the one tech out there somewhere, and they had that instruction theory.

CHAIRMAN SIEGEL: Well, that person obviously can respond within three hours, because that person is there.

MR. WAGNER: Right, and if they just tell you that this person is trained to clean up -- this person as a tech is trained to clean up every kind of isotope we use and that we can't think of anything more serious than what we've got, this is how we're going to do it.

MS. TAYLOR: Do we need to segregate out the accidents and spills from the misadministrations and such, because I mean, you're right, an authorized user really is only going to show up in the event of a misadministration.

MR. CAMPER: Well, you know how this is written. What was in the mind when it was written was, it wasn't so much that the technologist wouldn't be there. We're not clear about that, by the way, and we need to clarify that the designated responsible for that; but I think what's happened here is the idea that, even if that occurs, that the RSO is

going to play an active role in monitoring the situation.

MR. WAGNER: Right.

MR. CAMPER: And that such active role would dictate that they would be there and see what's going on at least within three hours. Now that raises a question. Couldn't the designated responsible individual go through the appropriate steps to decontaminate, contain the spill, etcetera and through telephone communication with the RSO be providing him with input, you know, like I've cleaned it up, I'm getting, you know, survey meter measurings now of thus and so. I've done wipe tests. They demonstrate thus and so.

I mean, does the RSO have to drive all the way across Montana to the van, when telephone communication with a trained, responsible individual could suffice.

MR. WAGNER: But then if you give them an exemption for therapy, now you've got a little bit different situation, and then they've got to address that issue, and that comes under quality management program anyway. So I think we have to take the three hours off.

MR. CAMPER: Well, it has to be -- The response has to be commensurate with the level of the problem.

MR. WAGNER: Level of activity of the individual. They have to be prepared to respond to whatever they do. If they're dealing with just simple diagnostic tests and stuff, then the chief tech is there on site all the time, and he's

going to be trained to do these things. So we don't really need to have anybody respond in three hours.

CHAIRMAN SIEGEL: Well, I mean, couldn't you even make it more generic than that? Procedures should be submitted -- this first sentence now -- to indicate that the radiation safety officer and/or authorized user will be available to direct the response to incidents.

MR. WAGNER: Yes.

CHAIRMAN SIEGEL: And that could be telephone. That could be five minutes away and physically present, as opposed to -- You don't want a mobile service being run by a technologist when the only RSO is canoeing up in the Yukon and is not reachable. So there has to be a way to reach someone responsible to figure out how to handle things.

MR. CAMPER: But, you know, in this day and time, they could even be reachable while canoeing in the Yukon.

CHAIRMAN SIEGEL: If they choose to be.

MR. CAMPER: I mean, today pretty much, with telecommunications, satellite link-ups, mobile FAXes, etcetera.

MS. TAYLOR: I would worry about somebody who was communicating by satellite.

MR. LYNCH: Do we want to give examples here, that three hours would be a reasonable or --

CHAIRMAN SIEGEL: Yes, I kind of prefer the

example approach as opposed to the "should" approach.

MR. WAGNER: Right.

MR. CAMPER: The time frame as an example.

MR. WAGNER: As an example for a given situation.

MR. CAMPER: But, again, it has to be specific to the situation, an iodine scenario.

MR. WAGNER: That's entirely different. Right.

MR. CAMPER: So we'll do that, Barry. We'll use that timeline as an example, but point out that it must be specific to the event at hand, for example, iodine spill, much more close monitoring, and so forth.

MR. WAGNER: It depends on what quantity of iodine, too, you're talking about here.

MR. CAMPER: Right. Quantities and isotopes.

CHAIRMAN SIEGEL: Yes, I mean, because I -- I'm just thinking. If we had a technician spill occur in the middle of -- while a tech was doing something in the middle of the night and I got a phone call, I can tell you, I'm not going to go to the hospital. I would say, clean it up, tape off the room, post a sign, and I'll see you in the morning.

MR. LYNCH: But if you dropped 30 millicuries of I-131 --

MR. WAGNER: Of course, you have a different story.

CHAIRMAN SIEGEL: I would say, call the radiation

safety officer. It's too dangerous.

MR. CAMPER: Clean it up, contain it, and call me in the morning.

CHAIRMAN SIEGEL: Take two aspirin. Take two potassium nitrates and call me in the morning, immediately. How about that?

MR. CAMPER: And put all your swabs in a plastic bag, and call me in the morning.

CHAIRMAN SIEGEL: Okay. We're getting punch here.

MS. TAYLOR: Yes.

MR. CAMPER: Where were we, transportation?

MS. TAYLOR: Yes.

CHAIRMAN SIEGEL: Transportation.

MR. CAMPER: That's pretty straightforward, really. The quarterly audit -- Is that a clear requirement in 49, Item b.

CHAIRMAN SIEGEL: Where?

MR. CAMPER: B, Item b.

CHAIRMAN SIEGEL: What page are we on?

MR. CAMPER: Seventeen.

MS. TAYLOR: Do you know, Jim?

MR. LYNCH: I don't know. That's not from 49 CFR.

MS. TAYLOR: Is that from Bob Gettone? Right?

Would it mean 71? It wouldn't mean 71, would it?

MR. LYNCH: No.

MR. CAMPER: As I read it, at least as written, one gets the impression that that quarterly audit requirement is contained within 49 CFR.

MR. LYNCH: I don't believe it is.

MR. CAMPER: I'm not certain that it is.

MS. TAYLOR: Well, I'll check it.

MR. CAMPER: Now we do say "should," but again it would be interesting to know why we're settling on a quarterly.

MR. WAGNER: Is that another place where we put in periodic?

MR. CAMPER: I'd like to know more about how we arrived at quarterly. I'd like to know about what 49 says exactly.

MR. WAGNER: Right.

MR. CAMPER: All right. So 18?

CHAIRMAN SIEGEL: This storage now -- Again, if the client facility has got a license, does 35.80 preclude --

MS. TAYLOR: Yes. You have to bring into each address of use and remove it at the end of each day. So you have to bring it back into your control.

MR. CAMPER: Yes, you have to remove it. Currently, as written, you have to remove it. Bring it in,

and remove it.

MR. WAGNER: Even if they have a license?

CHAIRMAN SIEGEL: What if the --

MR. CAMPER: Well, someone could --

CHAIRMAN SIEGEL: Let's say, a hospital has its own nuclear medicine department, one camera, and they order stuff from Syncor. They have their own waste stream, but because they've got unusually busy, they requested that a mobile service comes and provides them with an extra camera, and before they decide whether they're going to buy another one.

So they've got parallel operations going on. So, literally, the stuff that was used by the mobile service cannot enter the waste stream of --

MR. CAMPER: That's correct.

CHAIRMAN SIEGEL: Okay, that's fine.

MR. CAMPER: Now one could pursue an exemption.

MS. TAYLOR: It's not just because of this. I think it would be the wastes.

CHAIRMAN SIEGEL: Could doses be transported from one licensee to the other?

MS. TAYLOR: You can't have wastes at other licensee facilities.

MR. CAMPER: right. You have several things going on. You have the restriction here, but you also have

the consolidating and integrating of someone else's waste into your waste stream. You can't do that.

MS. TAYLOR: You can't do that, because you have to be responsible for it to the end.

CHAIRMAN SIEGEL: Can doses be transferred from licensee A to licensee B?

MR. CAMPER: Oh, yes, sure. Sure, as long as they meet the criteria. They're either a manufacturer, according to Part 32. They're prepared by an ANP or an AU or someone under the supervision. Yes.

MR. WAGNER: That's the way to do it, just transfer it into their storage facility and let it sit there for a few days.

MS. TAYLOR: You can't with the waste.

MR. WAGNER: You can transfer it over if they're authorized to have it. Sure.

MR. LYNCH: Not waste.

MR. WAGNER: Why can't -- They're authorized to have that isotope. What does it matter whether you transfer it?

MR. CAMPER: Not waste.

MS. TAYLOR: They're classified as a waste broker.

MR. CAMPER: You're getting to be a waste broker, if you do that.

MS. TAYLOR: You're responsible for your material from beginning to end.

MR. CAMPER: That's right. You want to collect your waste. If you want to accept waste, you need to be in the waste business.

MS. TAYLOR: There's a business out there for you.

MR. WAGNER: It seems to me it would be a little bit expensive, but unfortunately, that's the way it is.

This next issue on page 18 and 19 is an interesting issue, and I must admit, it's one that sort of really boggles my mind.

CHAIRMAN SIEGEL: Which one?

MR. WAGNER: The one with excreta. I mean, this is a --

MS. TAYLOR: This is the result of a TAR.

MR. WAGNER: It's a really difficult issue, because we run into this problem in a different fashion in the state of Texas. What's happened is we had a situation where one hospital injected a patient for a bone scan. It was an elderly patient that was incontinent.

The patient had a diaper. The patient was --

CHAIRMAN SIEGEL: I had the same note. That's interesting. Go ahead.

MR. WAGNER: The patient released -- was released

from the hospital, went to an outlying clinic. At the outlying clinic, the patient changed diapers. One of them ended up in a trashcan, which was immediately picked up and taken to a dump site where it set off the radioactive monitors, which caused one heck of a stir and a lot of people's time and effort over this one issue, and then how to resolve it; but the state, unfortunately -- the inspectors were focused on the idea of how do we cite the individual rather than cleaning up the problem, taking care of the issue.

It was the contention of the hospital that their responsibility for that radionuclide stopped after the injection of the patient, because that was the legal dissemination and disposal of the isotope, and it's documented on their forms that this is how I disposed of this patient, whatever, and it's done for.

Now I was thinking about that. I was thinking, well, what if the patient didn't go to the other site? What if the patient went up to another room, was an inpatient and went to another room, and now you have excreta, and that situation?

CHAIRMAN SIEGEL: Let me make sure I understand this. If a patient is not required to be confined under the conditions of 35.75, then you don't really need to do anything --

MR. CAMPER: That's correct. You do not.

CHAIRMAN SIEGEL: -- to monitor that patient so long as you maintain within the overall environment compliance with Part 20. Correct?

MR. CAMPER: That's correct. NCRP has recommendations about diagnostic patients, you know.

CHAIRMAN SIEGEL: Right, but diapers are an interesting problem, because they don't end up in the sanitary service system.

MR. CAMPER: But from a regulatory standpoint, they're not confined under the least criterion of 35.75, you do not have to do anything about that.

MS. TAYLOR: But also, excreta of the medical patients is excluded from anything anyway.

CHAIRMAN SIEGEL: No. Excreta goes into the sanitary sewage system.

MR. CAMPER: Only if it's into the sanitary sewage system.

MR. WAGNER: And that's wherein, I think, lies the rub here on this guideline, in that you're trying to distinguish excreta going into the sanitary sewer line versus excreta going and being disposed in a toilet in a mobile van.

MR. CAMPER: Well, the reason is -- Well, the patient excreta is exempt, because it's in a dilution, infinite dilution, whereas in the case of the holding tanks, you do not have infinite dilution. You now have contained

radioactivity in a holding tank.

MR. WAGNER Well, I think if that's the case, then that's what this guideline should be addressing. This guideline should be addressing that kind of dilution and that kind of problem, if that's what you're trying to get at.

The safety issue, as I see it -- Anybody who has a toilet on a van with patients coming in, they're going to have a contamination problem all around that toilet, if they permit the patients to use that toilet. It's going to be there, period.

MR. LYNCH: As it is in most nuclear medicine departments.

MR. WAGNER: Yes. I mean, it's definitely going to be there, and I can see where the concern is, but I have a hard time seeing that it's going to be --

MR. CAMPER: Well, let's take a look at the first on there. We're saying, describing the structure of the holding tank and so forth. How would you spin that differently?

MR. WAGNER: I have no idea. I mean, I have a lot of problem with the whole thing.

MS. TAYLOR: Do you think they shouldn't allow it at all? We have a TAR in with that right now, and these are the issues that we've come up with between two of our branches.

MR. WAGNER: I don't think it's a problem to allow it. The question is what kind of quantities are we talking about? What kind of quantities are they talking about? I mean, this -- To me, this should represent a non-problem. It should be a non-hazard, because (a) what are you usually concerned about?

First of all, let's look at internal contamination. It doesn't represent a risk for internal contamination, period. What it does maybe represent a risk is risk from gamma radiation that might emanate from it, but what kind of activities are we going to require for gamma radiation in a holding tank of this facility? Is the holding tank underneath the driver's seat?

MS. TAYLOR: Well, these are the questions we've asked.

MR. WAGNER: I think that's a reasonable question. Maybe it's underneath the driver's seat or something, just to make sure.

MR. CAMPER: Well, we do. We say, you know, we ask, tell us about the structure of the holding tank.

MR. WAGNER: Right. Right. Right.

MR. CAMPER: Where is it in regard to the public, workers on the van, driver of the van?

MR. WAGNER: But are they really responsible for the -- legally responsible for the activity after it's been

injected into the patient?

MR. LYNCH: Oh, yes. I mean, if the excreta is collected.

MR. CAMPER: In this case, they are, yes, because excreta is being collected. It is not being released into the --

MR. WAGNER: Where in the regulations would it say that they would be responsible for that? Where in the regulations?

MR. CAMPER: Well, I would -- The regulations are explicit. It's the other way. The regulations are explicit that excreta is exempt --

MR. WAGNER: That's correct.

MR. CAMPER: -- if it's going into the sanitary sewage system.

MR. WAGNER: But that doesn't mean -- Yes, that's correct. That, I understand.

MR. CAMPER: Well, if I'm not putting excreta into the sanitary sewage system, then I still have responsibility for it. It's not exempt.

MR. WAGNER: But they've already injected it into the patient and disposed of it in the patient.

CHAIRMAN SIEGEL: I know, but I mean, it's the same thing as if --

MR. CAMPER: Well, let's take another example.

Let's take another example. Let's take the old studies we use to collect stool. Okay? We were responsible for it.

CHAIRMAN SIEGEL: But you can flush it down the toilet when the study was over.

MR. CAMPER: Sure. I'm simply saying, though, there was an example where that same stool introduced directly into the sanitary sewage system would have been exempt, but it was not. In that case, we were holding it for purposes of conducting a study. In this case, we're holding it for purposes of convenience to the patient, because patients have to go to the bathroom, but we have the need to hold it until we can release it into a sanitary sewage system.

During that holding manipulative process, it's not exempt.

CHAIRMAN SIEGEL: So the correct way to handle this is to set up a little outhouse a block away from the van.

MR. WAGNER: You don't even need an outhouse, just a little park.

MR. CAMPER: All you need is a long tube, a long tube into the nearest toilet.

MR. WAGNER: I mean, presumably the excreta from the patient is out of your responsibility, once the patient leaves the van, but it's not out of your responsibility while the patient is in the van. Correct?

MR. CAMPER: Right.

CHAIRMAN SIEGEL: Say that again, slowly.

MR. WAGNER: Your responsibilities leave with the patient leaving your van. You're not responsible for the patient's excreta once he leaves your van.

MR. CAMPER: That's correct.

MR. WAGNER: And you are responsible for the patient's excreta as long as they are inside your van. I don't know where it says that in the regulations, but -- or where you would find that, if there was interpretation of the regulations. That's fine.

Actually, I agree with it. I mean, it's not -- As a radiation safety issue, it's quite clear.

CHAIRMAN SIEGEL: It really is clear.

MR. WAGNER: It's quite clear.

CHAIRMAN SIEGEL: Why don't we break for lunch, since we've been having this lovely conversation.

MR. CAMPER: I do have one more. One more thought, real quick. That is somewhere in here, and I don't know just where it should be, but I would like to include a paragraph or two that talks about these reciprocity issues. Someone while ago mentioned this idea of crossing state lines.

What we need to do is draw to their attention that reciprocity does exist and that they will need to check specifically with the state in which they wish to go to provide services for what is necessary in that state, whether

it's a license or whether or not there's some reciprocity arrangement.

Most of the states have a reciprocity arrangement with a following need to get a license.

CHAIRMAN SIEGEL: Yes.

MR. CAMPER: And the time frame for that license requirement is variable. So they're going to need to be aware of that.

MR. LYNCH: That's a good point.

MR. CAMPER: The fact that you get an NRC license doesn't mean you can go into North Carolina.

MR. LYNCH: And we've had that problem already.

MR. CAMPER: Yes, that's right.

MR. WAGNER: You also said something about talking about therapy exemptions and how does a user go about getting an exemption for therapy. You said you wanted to discuss those things, too. Did you want to give guidance inside here for that? You had mentioned that at the beginning of this morning. I wrote that down in some notes.

MS. TAYLOR: Oh, for HDR concerns?

MR. WAGNER: It's therapy exemptions. How does a user go about it? I presume what we were talking about is in stages. The first stage would be exemption for therapy under 30 millicuries, over 30 millicuries, and how does a user -- What guidance do you give the user about applying?

CHAIRMAN SIEGEL: Over seems out of the question.

MR. WAGNER: That's out of the question.

CHAIRMAN SIEGEL: I don't see how you would physically do that.

MR. WAGNER: You couldn't do that. That would be inpatient.

MR. LYNCH: If you had an arrangement with the hospital right there.

MR. CAMPER: Could you administer in the van and then take them into the hospital?

MR. WAGNER: I guess you could.

CHAIRMAN SIEGEL: Are you supposed to be moving the over 30 millicurie patient through unrestricted areas from the point of administration to the point of confinement? I don't think you are, and nearly all therapy is actually given in the room.

MR. LYNCH: No. Some therapy is given in the nuclear medicine department, and they walk in the halls going up.

CHAIRMAN SIEGEL: Cancer therapy?

MR. LYNCH: Yes.

MR. WAGNER: Yes, some people do it backwards.

MR. LYNCH: I mean, they do it where they have the hood.

MR. WAGNER: It sounds like a really bizarre

situation, though. Do we really need to give them guidance about this? I mean, is this really an issue that you see?

MR. CAMPER: Well, I think -- I don't recall that exactly, but I think what I was referring to was the guidance with regards to an exemption for under 30.

MR. WAGNER For under 30. I think maybe we discussed that already.

MR. CAMPER: I think we have, yes. All right. So we've discussed that issue.

CHAIRMAN SIEGEL: Were there any other comments that came from these letters that were sufficiently important that we should look at them?

MS. TAYLOR: Well, we pretty much --

CHAIRMAN SIEGEL: Or have we hit them?

MS. TAYLOR: We pretty much hit them or we've already included them and talked about them.

CHAIRMAN SIEGEL: Well, I guess --

MS. TAYLOR: I'm looking through to make sure there wasn't anything.

CHAIRMAN SIEGEL: -- another way to handle it is, if Lou and I see something on the airplane on the way home, we can send you an E-mail message, since you are accepting written comments post-meeting. Right?

MR. CAMPER: See, Barry, if you go back to the question you were raising a moment ago, if you go over to

35.315, safety precautions, it says, "For each patient or human research subject receiving the radiopharmaceutical therapy and hospitalized for compliance with 35.75 of this chapter, licensee shall provide a private room with a private sanitary facility" as opposed to administering only that private room.

Now, you're right, most folks do it that way, but some do administer in the nuke med department and wheel them back upstairs to the private room.

CHAIRMAN SIEGEL: The problem is, though, that that patient instantaneously makes unrestricted areas into -- in violation of the 2 mr per hour limit when walking from point A to point B.

MR. CAMPER: By definition, you're right.

CHAIRMAN SIEGEL: So you really -- although we might look the other way, it really shouldn't be. Right?

MR. LYNCH: Well, then you assess that. If they're using a hood situation in the laboratory, that limits exposure to the people that are delivering the dose. They take them up the back way in the freight elevator and whatever.

MS. TAYLOR: One comment we received --

CHAIRMAN SIEGEL: Well, I mean these get sometimes a little bit crazy, as you know.

MS. TAYLOR: We received two comments about

delivery of material to a van, and we said it had to be with the presence of mobile service personnel. We received a comment from Region 2 and one other region and asked why we wouldn't allow it, if the van was not occupied, because we do in fixed facilities.

I think part of our reasoning was that it was a fixed facility within a building. It's not going to so easily disappear and what have you. So that is in a couple of these comments, and we decided not to include that; because we didn't want that.

That's really the only one we didn't talk about.

MR. WAGNER: Well, there's an issue here on item 5 of delivery to a van without the presence of mobile service personnel should be acceptable if the licensee has established adequate security and implemented delivery procedures to ensure the material will only be delivered to their van. If the van is not found, delivery driver will take material back to the supplier.

MS. TAYLOR: That's what I was just talking about. We were just concerned --

MR. WAGNER: Makes sense to me.

MS. TAYLOR: I mean, it would require the pharmacy to have a key to the van.

MR. LYNCH: But now you're talking about a vehicle.

MS. TAYLOR: Versus a permanent facility.

MR. WAGNER: Well, if they have a secured area, I mean, where they store things overnight or whatever, what's the problem? They take it into the van. The driver delivers it to the van. They put it in there. It's inside there. It's a locked door. They come out of the van. The door is locked and they leave. What's the problem? We're talking diagnostic materials, for the most part.

MR. CAMPER: It depends upon the security arrangements.

MR. WAGNER: Oh, of course. Of course. I mean, the driver would be escorted to the van, open up the van for him. He puts the case inside the van at the designated position. They walk outside. They lock the van, and they leave.

MR. CAMPER: Is that adequate in a situation where a van could easily be broken into?

MR. WAGNER: Well, not, not if it's easily broken into, but it depends on the security arrangements.

MR. CAMPER: Well, I'm saying, it's a van, though, arguably.

MR. WAGNER: But it's located on private property. It's at a hospital.

MR. CAMPER: So then that depends upon what kind of security arrangements exist for oversight of the van while

it's on those premises.

MS. TAYLOR: Well, now we've got one TAR in with an exemption that they're going to have to park the van in the street, public street, because the van physically will not fit, and that would be a concern; because you're much more --

MR. WAGNER: Of course. Why can't they put that in their application?

CHAIRMAN SIEGEL: There's not a real big black market out there for stolen technetium.

MR. WAGNER: No, there's not.

MR. CAMPER: No, but the idea that technetium, a case of technetium, finds itself in the public domain because some kid breaks into a van and steals it is a problem. At the very least, it's a public perception problem.

CHAIRMAN SIEGEL: It's a public perception problem.

MR. WAGNER: Yes, right.

CHAIRMAN SIEGEL: It has a lot less to do with reality than anything else. Stealing cobalt 60 pieces of steel is one problem.

MR. CAMPER: Oh, I understand.

CHAIRMAN SIEGEL: Just, you know, put a lot of word salad in. It will be fine.

MR. CAMPER: No, you're right. Even in the worst case scenario, if the kid steals and injects himself with it,

big deal. Right? It's like having a nuclear medicine procedure, but by the same token, in terms of the eyes of the public, the idea of this case of radioactive materials in the public domain is not acceptable.

MS. TAYLOR: You'll have a pharmacy that, oh, I forgot the key or this key is not working for some reason, well, they leave it in the hall overnight, leave it with the van, that's going to be more -- You can't trust completely or put the onus completely on the pharmacy that they will take that material back and not just leave it at the doorstep, because they were told this is an urgent delivery, we absolutely have to have this.

MR. WAGNER: In human society, we're never going to have 100 percent guaranty of anything, but I still think we're talking about tornadoes here. We're talking about rare instances, things that are highly unlikely, and there's a certain level of security you can supply, but you will never be able to supply absolute 100 percent, guaranty that something won't happen somewhere.

MS. TAYLOR: And that's part of the reason with this facility you're not so concerned, because it's within a building in a hallway versus a van, it's just sitting on the step in the parking lot.

CHAIRMAN SIEGEL: Tornadoes are increasing in frequency.

MR. CAMPER: In mobile home parks especially.

CHAIRMAN SIEGEL: No, no, seriously.

MR. CAMPER: No, I know they are.

MS. TAYLOR: Well, I guess this is a policy issue, Larry, that we need to talk about inside.

CHAIRMAN SIEGEL: In yesterday's New York times there's an article, an extension of this thing that says that there is no pretty clear evidence that the greenhouse effect is really occurring, and one of the things they have observed is that precipitation is now occurring with increasing frequency as huge dumps in large storms of over two inches of precipitation, rather than the more gentle types of rainfall we've had in the past.

MS. TAYLOR: Yes, I read that.

CHAIRMAN SIEGEL: It said that the greenhouse effect is increasing. I mean, why do you think we've got up to Hurricane Marilyn this year? It's clearly because of the greenhouse effect.

MR. WAGNER: Obviously.

CHAIRMAN SIEGEL: All right. So I think we're not certain about --

MS. TAYLOR: We'll take this up with management.

MR. WAGNER: I just have a level of uncomfortableness.

MS. TAYLOR: With it being in a parking lot.

MR. WAGNER: I've seen these sorts of operations, and I think it has to be taken on a case by case basis.

MR. CAMPER: To a point, we certainly have a concern about security when this stuff is out on the parking lots or even on the street, and you're right, though. What we should be looking for is what security arrangements exist. What is the mechanism that the van operator or the van operator in concert with their client are going to put in place to adequately secure the materials against theft, loss, etcetera.

MR. WAGNER: One of the things -- They actually may have a camera out there which is monitoring the van from the security desk, you know. That's one thing that you might have, and you certainly wouldn't want to have that if it was in a residential area. You had the van located in a residential area, you know.

CHAIRMAN SIEGEL: Are we finished?

MR. CAMPER: Well, we're still having a bit of discussion. Is that it?

CHAIRMAN SIEGEL: Are we still on the record or off the record?

MR. CAMPER: We're still on the record.

MR. WAGNER: Well, in any event, I understand your concerns.

CHAIRMAN SIEGEL: Shall we adjourn the morning

session.

(Whereupon, the Committee recessed for lunch at 12:01 p.m.)