

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

PUBLIC MEETING ON IMPLEMENTATION ISSUES
RELATED TO THE PROPOSED RULE ON
GENERALLY LICENSED DEVICES

U.S. NRC

Two White Flint North
Auditorium

11545 Rockville Pike

Rockville, MD

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The above-entitled meeting commenced, pursuant to
notice, at 8:41 a.m.

P R O C E E D I N G S

[8:41 a.m.]

MR. CAMERON: If we could all take our seats, we're going to get started here, finally, and we're fortunate enough to have Dr. Don Cool with us this morning, who's the division director where this work is taking place, to give us a nice welcome.

Don?

DR. COOL: Thank you, Chip, and good morning.

I do want to welcome all of you to Rockville. I'm very pleased that you've been able to join us today and help us understand a little bit more carefully all of the implications of the activities that we're looking at.

This is an area which I think, as you may well know, has a lot of attention from our commissioners, a lot of attention in the wide varieties of the communities, not only you folks as vendors and producers but the folks who use gauges and other devices out there in the public sector for a wide variety of uses -- steel manufacturers, recyclers, and others, who, in times past, have had situations where sources have shown up where they didn't want them to be, and as a result of a relatively long history and process, we are now at the point where we are considering a proposed rule-making which would impose a number of new requirements with regard to try to gain further control and understanding of where these devices are, assuring their accountability at different stages of the process, assuring that they don't, in fact, get into the public sector in a way that was not intended.

That rule was proposed a couple of months ago.

Part of what we will do today is to review some of the provisions of that, and the real reason for this is not a one-way flow of communication.

What we're really looking for is a very much two-way and multiple-way flow of communication to help us further understand the implications of what was in that proposal, the implications, both pro and con, of how that would be implemented, how we would all carry about duties and responsibilities that would come with that, so that we can then go and use this, along with the other comments that have been received in writing and other meetings, with the agreement states and others, to prepare a proposed final rule-making which we would need to send back to our commissioners for their consideration just in another couple of months.

Really, the purpose here today is to have that interchange, and I want to encourage all of you to actively participate, not only in the what-you-think comment per se but getting into the rationale and the processes, the why's that go underneath it, because that really becomes very important to my folks in terms of what we modify, how we would modify it, the implications to be able to understand all of those.

You might find this surprising, I suppose, but it's actually fairly easy to write down rule language.

It's much more difficult to understand the implications of that language and to explain it to ourselves and to everyone else, to put together a really coherent package that makes sense, that accomplishes the purpose without undue burdens or other activities on any of the parties, because really, I think, in one sense, we have to very much look at these

activities as part of a coordinated set, where there is a role and responsibility in a number of places, with the agency and with the states as regulatory authorities, with vendors associated with the production of these devices, with users in terms of their use and control and accountability.

So, again, I would like to welcome you.

I'm going to apologize in advance that, because of some other issues, not the least of which was the event that occurred yesterday in Japan for which another inter-agency call will be happening in just a moment or two, I'm not going to be able to be with you for the majority of the day, but I really look forward to discussions that you're having and the good information that we're going to glean from this.

Thank you very much.

MR. CAMERON: Okay. Thank you, Don. Thanks for just taking that amount of time to come down and greet everybody, and I'd also like to welcome all of you around the table and in the audience.

My name is Chip Cameron, and I'm the Special Counsel for Public Liaison within the Office of General Counsel here at the NRC, and I have the pleasure of serving as your facilitator for today's meeting, and as Don mentioned, the objective of the discussion today is to develop information on vendor implementation issues in the proposed rule so that the NRC staff can be better informed as they proceed to prepare the final rule, and to that end, we have assembled some representatives of various companies, vendors, around the table to engage in a discussion of the rule-making issues, and my job as the facilitator for the meeting will be several-fold.

One is to try to help us to keep the discussion relevant and focused and not only relevant to the broad topic of implementation of the proposed rule but also relevant to whatever particular agenda item that we're on, and comments may not always fit nice and neatly into the agenda items, so that if we identify something that should be discussed later on in another topic, we'll put that up here on what some of you may be familiar with as a parking lot, which I call a paddock.

So, we'll put that up there, and another aspect of keeping focused is to try to develop some what I call discussion threads rather than the unrelated monologue that jumps from one subject to another.

So, we'll try to keep some discussion threads going today.

Another aspect of my role will be to make sure that everybody understands information that's presented and to help clarify any ambiguities either with the NRC staff presentations or what someone around the table might be saying.

Third, to make sure that everybody has a chance to talk today, and lastly, to try to keep us schedule, and we're already 20 minutes late, so I'm already in the C category on that one, but at any rate, the ground rules are simple for today's meeting.

If you wish to say something, please put -- these are called name tents.

Put that up like that in front of you, and I'll be able to keep track of who wants to talk and you won't have to keep worrying about raising your hand, and this also helps us to get a clean transcript that will be useful for the NRC and for

all of you later on, and Jon, our court reporter, will make a note of where you're sitting and who you are so that, at least after our beginning discussion, you won't have to worry about stating your name or affiliation, but we're going to go around in a minute and do introductions, so that we'll get that information from you at that time.

The focus of the discussion are the people around the table, but that's in order to provide sort of a sharper point on the issues.

We're going to go out to those of you in the audience at the end of each agenda item to get your comments on that particular issue, and that's where we will go to -- Joe, are you still there?

MR. CLINGER: Yeah.

MR. CAMERON: Okay.

We'll go to the agreement states that are on this line for any comments that they might have.

What I'd like to do now, before I just briefly go over an agenda check with you, is to go around the table and have everybody introduce themselves.

I think we have few enough people out here in the audience that we might also go to them, but for those of you around the table, when you introduce yourself and what your affiliation is, if you have one or two issues of interest or concern, state them at that time, and I'll start keeping track of these so that we can begin an agenda check, because there may not be some items -- and I know there's one important issue that we may not have on the agenda, and I want to make sure that we schedule it for some place, and let me start with Suzanne.

MS. WOODS: Good morning, and welcome. My name is Suzanne Woods. I work in the Office of Nuclear Materials Safety and Safeguards as a health physicist, and specifically, I work in the Division of Industrial/Medical Nuclear Safety.

Most recently, my work has been focused on the general license registration project and implementing that particular rule that we're all here to talk about today, and the implementation procedures.

Specifically, I would like to share with you that there is a team of individuals, many of which are here in the audience, as well as in the regions, who are working together to try and implement this, and myself as well as they are very interested in hearing what you have to say.

We are interested in your insights and specific knowledge of the general licensees, and we're anxious to hear what you have to say about the implementation issues.

MR. HICKEY: Good morning. I'm John Hickey, Chief of the Materials Safety Branch.

I have been in this particular position, responsible for this program only a few months. However, I've supervised licensing for NRC for 20 years, including general license programs. So, I have been familiar for a long time with the general license issues, and I appreciate your all's coming today, and I think we'll have a good meeting.

MR. ALLGEIER: Good morning. My name is Joe Allgeier. I'm with ABB Automation in Columbus, Ohio.

I thank you folks, the NRC, for this opportunity today and for the invitation to be here, to be with you and share our thoughts and our concerns.

ABB Automation in Columbus is a supplier and manufacturer of gauging devices for sheet industry. So, we do have an interest in this topic, because we do supply significant numbers of seal sources to general licensees.

Thank you.

MR. FORTKAMP: My name is Jonathan Fortkamp, and I am also with ABB Automation, and I serve as the radiation safety officer for the company.

MR. BENNETT: Hi. I'm David Bennett with Hewlett Packard in Wilmington, Delaware. We manufacture gas chromatographs and a device with that is a nickel-63 electron capture detector. I'm the radiation safety officer for that facility.

MR. HEYER: Good morning. My name is Ralph Heyer. I'm with TN Technologies and also representing K-Ray Sensal. We're a manufacturer of process measurement equipment predominantly using cesium and cobalt-60, but we also have cadmium in our sources that are generally licensed.

MR. NORBURY: My name is Mike Norbury. I represent Radiometry Corporation. We manufacture process and measurement equipment for both the metals and non-metals industries.

MR. CAMERON: Thanks, Mike.

Let's go over to Jack.

MR. RAMSEY: My name is Jack Ramsey, and I'm the radiation safety officer at Neles Automation. We distribute generally licensed devices to the paper industry.

MR. CAINES: I'm Gary Caines. I'm radiologic operations manager for Honeywell, Incorporated. We're a

distributor of generally licensed devices to different industries, and we also perform significant third-party service work on general and specific licensed devices.

MS. NIMMO: Hello. I'm Elsa Nimmo. I'm with Honeywell Measurex. We're also a manufacturer/distributor of generally licensed devices and also a service provider to generally licensed devices throughout the United States.

One issue I'm particularly concerned with is the level of compatibility on the general license in 31.5 and specifically some probably unexpected or unintended consequences of the relatively low level of compatibility being requested.

MR. FITZ: Good morning. I'm Chris Fitz with NDC Systems, Irwindale, California. We are also a manufacturer and distributor of several general licenses.

MR. PATTERSON: Good morning. I'm John Patterson. I'm with Metorex in Ewing, New Jersey. We're a distributor of generally licensed devices for chemical XRF, mainly.

MS. BROCK: Good morning. I'm Candy Brock with the Ohmart Corporation in Cincinnati, Ohio. We also are a manufacturer and distributor of generally licensed gauges. I am the customer support manager there and deal directly with customers for startup of generally licensed gauges.

MR. BROWN: I'm George Brown with Ohmart Corporation. I'm radiation safety officer.

Areas of concern that I have are the compatibility issues and the labeling issues, definitions of permanent, those kinds of things, because we can end up with a lot of -- nothing with radioactivity in them that are labeled. That's a problem.

MR. CAMERON: Okay. Thanks a lot, George, and

hopefully we have our audio system working a little bit less annoyingly now.

Let's quickly run through the audience so that we know everybody that's here. Just state your name and affiliation if appropriate.

MS. MATTSSEN: Cathy Mattsen, NRC.

MS. HANEY: Cathy Haney, NRC.

MR. SHAPIRO: Daryl Shapiro with the law firm Morgan, Lewis & Bachius, Washington, D.C.

MS. ROUGHAN: Kate Roughan, AEA Technology.

MR. SMITH: Don Smith, consultant.

MR. CAMERON: Okay. Let's go back to these two.

MR. HARMON: Larry Harmon, Safety Light Corporation, manufacturer of commercial exit signs and aircraft signs, generally licensed devices, and I brought the boss, Nancy, with me.

MR. CAMERON: Okay. We're going to go to the boss now.

MS. HARMON: Nancy Harmon.

MR. CAMERON: Let's go to these guys in the back here.

MR. PEARSON: Jim Pearson, NRC.

MR. JACOBS: Frank Jacobs, NRC.

MR. CAMERON: Okay, Jim and Frank, thank you.

MR. HOSEY: Charles Hosey, NRC.

MR. CAMERON: All right. We'll come back up here.

MS. DANDOIS: Diane Dandois, Licensing.

MR. CAMERON: Okay.

MS. JACKSON: Jackson, NRC.

MR. GOTSCHALL: My name is Glen Gotschall. I work for Environmental Technologies Group in Baltimore, which is part of Smith Industries. We have a sister division called Graysby Dynamics. We both manufacture items with nickel-63 sources.

MR. RADDATZ: My name is Mike Raddatz. I'm going to be the senior project manager for the general licensing projects.

MR. CAMERON: Thanks, Mike.

MR. STIR: I'm Fritz Stir, section chief in the Materials Safety Inspection Branch.

MR. CAMERON: All right. Let's go over to Doug.

MR. BROADDUS: Doug Broaddus. I'm with NRC, also. I've also been involved with the general license project the last several months.

MR. RICH: Tom Rich, NRC. I'm with the OCIO. I'm responsible for the development of the application for general license tracking.

MR. CAMERON: And OCIO is Office of the Chief Information Officer.

MR. McGRATH: John McGrath, NRC, Region I.

MS. SWARTZ: Maria Swartz, Office of the General Counsel, NRC.

MR. JAMES CAMERON: James Cameron, Senior Inspector, Region III.

MR. RAKOVAN: Lance Rakovan, Office of State Programs, NRC.

MR. MESSE: Maurice Messe, NRC Licensing.

MR. CAMERON: All right. I think you can see that we have various NRC staff here from legal, licensing fee, the

region, whatever, for their information and for you to interact with them.

I would just encourage all of you who are here from the industry to interact with these people during the breaks, and it may be useful for you to do that.

MR. HICKEY: Illinois, could you introduce yourself, please?

MR. CLINGER: Sure. This is Joe Clinger with the State of Illinois. I've got Mike Ewing with me.

MR. HICKEY: Can you hear Chip okay?

MR. CLINGER: Yeah, pretty good. Some of the people we couldn't hear very well out in the audience, but overall, it's not bad.

MR. HICKEY: Who else is on the line besides Illinois?

[No response.]

MR. HICKEY: Okay. Thank you, Joe.

MR. CAMERON: Okay. And I would just ask everybody to try to speak up a little bit so that Joe can hear us.

You have an agenda in front of you, and it begins with the overview of the proposed rule that Cathy Haney is going to do for us, and we can take clarifying questions at that time.

I don't want to use Cathy's presentation to launch us on a discussion, but you may have questions for her, and we're going to bring her up here in a few minutes.

The first substantive topic is ways to increase general licensee regulatory awareness. We take a break. There is reporting information issues. After lunch, we continue with

that. The next topic at two o'clock is standardized -- the whole standardized report issue.

At 2:45, we're going to talk about what we've termed compliance issues, and George and perhaps others brought up the whole issue of the level of compatibility. We're going to talk about timing of compatibility at that time.

We may want to put the compatibility issue in terms of the level on earlier, before that.

We take a break then.

We're going to talk about the national database at 3:45, and at 4:15, a bunch of other issues, authorized disposal, definition of transuranics, movement between jurisdictions, and for each of these agenda topics, I'm going to ask Suzanne Woods to tee the topic up for us, to give us just a brief context of what we want to talk about during that particular topic and why is this particular issue a problem, and I would ask the NRC to try to give us a little bit of the rationale for why some of these requirements are in the proposed rule.

I've spoken with some of you about the issue of what devices are required to be registered and possibility of exemptions from those requirements, and I think that that's probably another issue to put up here for discussion at some point, perhaps early on, before we get into some of these other topics, but before we go to Cathy Haney, let me ask any of you around the table, any thoughts on the agenda, any suggestions?

[No response.]

MR. CAMERON: Do you think it would be useful to talk about this issue of what I'm shorthand calling exemptions before we get into the first item on the agenda, not before Cathy

but before the first discussion item?

[No response.]

MR. CAMERON: Okay, John.

MR. PATTERSON: I think it would be helpful to spend some time fairly early on the whole issue of agreement state compatibility, as well.

MR. CAMERON: All right.

MR. PATTERSON: Instead of putting that at the end of the day.

MR. CAMERON: Okay. We'll definitely do that.

Well, let's go to Cathy for her presentation at this point.

MS. HANEY: Good morning.

Hopefully you all have copies of my view-graphs. We'll also put them up on the screen to make them a little bit easier for you to observe.

As Chip said, what I'd like to do today is to do a brief overview of the two rules that have to do with this project.

The specifics of the rule I think we'll get into -- more into detail during the day under the different topics, but as I said, I will just try to do a brief overview.

There are two rules. One has already been made final. The other one is in the comment period right now, and one of our objectives was to hold this meeting during the comment period, so a lot of what we heard today would hopefully give you some thought for some of the comments that you'd like to send in to us on the specific rule, what we refer to as GL-2.

To go through, first, a little bit of history on

the rule, it really -- you know, if you say why are we in this project, why are we doing this, it goes back into the early '80s and maybe even earlier than that, but NRC has been concerned about occurrences where generally licensed devices have not been properly handled or disposed of. So, that's really our fundamental concern, and how we deal with that.

In the 1984 to 1986 timeframe, there was a project where we looked at the effectiveness of the general license program, and there were two thoughts that came out of that review.

One is that many general licensees were unaware of the regulations and what they needed to do and also that many of the general licensees were unable to account for their devices.

The next big milestone for this was in 1991, when we issued a proposed rule that dealt with the accountability of general licensees.

This particular proposed rule really is close to what we refer to as GL Rule 1 that recently became final, and what it did is it -- it was the first test toward establishing a registration program.

We went ahead and took the comments on that proposed rule, prepared a final rule. However, we did not go forward with the final rule at that time period because of the resources that would have been needed to implement the program.

However, in 1996, we hit the next big major milestones where we came out with a report that was the result of a joint NRC-agreement state working group that looked at this particular area, and as a result of the recommendations coming out of that report, we decided that we really did need to go

ahead with the rule-making in this particular area and that we should establish a registration program for general licensees.

However, it would not be -- the registration program would not pertain to all general licensees, just a select population.

On December 2, 1998, we issued what we refer to as GL Rule 1, which basically put a placeholder in the rules to allow NRC to request information from general licensees. This particular rule just became effective -- well, actually, I should say just. I'm stepping ahead of myself. It's effective on October 4th.

Then, on July 26, 1999, we issued GL-2, which is the proposed rule that I mentioned earlier. This -- the comment period on this particular rule closes October 12th, and this rule really, again, went back and looked at a lot of the recommendations that came out of the report, the NUREG-1551.

To give you an idea again, just a little bit, next tier down on the GL Rule 1, we believe that this rule will enable NRC to gather information needed for tracking and for working with the general licensees.

Again, the focus is that we, as well as the licensees, do our part to assure that the devices are properly handled and properly disposed of, and again, it sets the stage for the registration process that really is discussed in detail in the second rule.

As I said, the rest of the information on this view-graph I think I've mentioned already. It basically -- if there's any information that we need from general licensees, we'll really fall back to this rule to get that information.

The second rule, as a quick overview on that, as I say, it was published July 26th, comment period closes October 12th. It does four big things, four major things.

One is it, hopefully, clarifies which sections in Part 30 apply to all the general licensees. Again, we're trying for clarification in our rule. We have an effort underway to make our regulations much easier for licensees to use. I mean it's referred to as the plain English directives.

So, we're trying to be user-friendly, if you want to use that type of word.

Also, it does add some requirements for the vendors, and obviously, a lot of those requirements are what we'll be talking today throughout the whole day.

To get at the next tier of level on this particular rule, there are a set of requirements that would apply to all general licensees, and those are listed on your next view-graph.

It would require general licensees to appoint a responsible individual.

The thinking here is that, if there is one individual that we can go to that is named on a document, that the licensee has had to name, there's a greater assurance that this individual is going to know what's going on with this particular gauge.

Then there are some requirements have to do with change of address, company name changes. Again, this information would be needed for us to track the general licensees, as well as heightened awareness that these licensees are in possession of devices.

It also -- again, there are -- you can read through my view-graphs as well as I can read to you. I'm trying just to hit the top points. I'm doing my best to get Chip back on schedule.

But the next big thing is it does restrict the length of time that the device can be kept in storage. Right now, that's specified as two years in the rule. During that two-year period, if it is in storage, there's no additional testing that needs to be made on the device, but if it comes out of storage and is going back into use, then that testing would need to be done before the device is put back into storage.

The next view-graph gets a little bit more into detail on the registration process, and the registration process -- I'll start out at the bottom since everyone is always interested in the money. It would require general licensees to submit a \$420 fee to NRC.

This \$420 was established based on what we believe the cost of the program for NRC to maintain would be and also looking at the number of general licensees that would fall under this particular registration program.

There are a large number of general licensees in the United States, and the consideration is how far do we take this registration program, and again, NRC has a big effort underway looking at risk-informing our regulations, making decisions based on the risk of the particular uses of the material.

Looking back at the report of the joint NRC working group, we only wanted to make the registration process apply to a subset of the general licensees.

So, we did establish some criteria. This criteria is in the proposed rule that's out for comment now.

So, obviously, you are able to comment on whether we've used the right thresholds, right criteria for the registration process.

But just to let you know what we considered when we arrived at these numbers, it fell down to -- we looked at the hazards from the external and internal exposure associated with the devices, the typical quantity of the radio-isotope or radio-nuclide in the device, the cost and availability of disposal, the half-life of the material, and then the last thing was the cost associated with cleanup and disposal if there was an accident that involved the devices.

So, as a result of that, we did arrive at the criteria that you see on this view-graph, as well as what's presented in the rule.

Then the last view-graph that I'd like to bring to your attention would be that of the specific revisions in the rule that apply to the vendors, and this is probably the area where most of you are most familiar, but it does -- the Rule 2 does propose a revision to the contents of the quarterly material transfer reports.

This would be the information that you would be providing to NRC.

Again, what we're looking at is better tracking, better accountability for these general licensees.

There are some additional labeling requirements that were added, and I believe that was one of the topics that came up earlier this morning that will get discussed in greater

detail as we go into today's agenda, and then, also, it -- another big thing is that it revises the material that the general -- I'm sorry -- the vendor must apply to the general licensee.

Under the current requirements, a copy of the regulations, specifically 31.51, has to be provided to the general licensee when the transfer is made.

This proposed rule would change that and you would need to provide a copy of the regulation before the transfer is made.

Also, you'd have to provide copies of the applicable rules to the licensee and some information on disposal options and costs.

This is really getting at -- from our standpoint -- is what information does NRC believe at this point is needed for the general licensee to have beforehand or when they do get the gauge so that they are aware up front of what provisions they need to comply with.

With that, I think I'll turn it back to Chip. As I said, my objective here was just to do a very quick overview of both rules.

MR. CAMERON: Okay. Thanks, Cathy, and I think it might be useful to see if anybody has any questions around the table and then to keep Cathy here a little bit more to just give us a summary of the compatibility levels to kick off a discussion about compatibility, and we'll start off with that.

Are there any questions for Cathy, and if you could use your name tent, we'd appreciate that.

[No response.]

MR. CAMERON: Okay. There may be questions throughout the day, and we have the staff here to do that.

Cathy, what are the compatibility --

MS. HANEY: I'm going to defer to Suzanne on the compatibility, because there are different levels of compatibility associated with the different requirements, and I think she might be a little bit better to give the reasons for why -- we're spread between B, C, and -- I guess it's B, C, and D, right?

MS. WOODS: There are two areas for compatibility level B and C, and I'll explain those in a moment.

For vendor requirements in the rule, those specific to vendors -- in other words, the manufacturers and distributors -- we consider that a compatibility level B, and that is that they're essentially the same for agreement states as well as they are for NRC.

Compatibility level C, however, would be the 31.5 requirements, those that apply to general licensees. What that specifically -- and if you need to follow along, it's on page 40296 of the proposed rule, and it just says the essential objectives of the regulation should be adopted by the state to avoid conflicts.

So, B would be a strict compatibility, they'd be essentially the same, and the basis for that was that there are trans-boundary implications. Essentially we have agreement state vendors and NRC vendors distributing to both types of jurisdictions.

So, that's the trans-boundary implication there.

MR. CAMERON: Okay. Thank you.

Let's go to Elsa.

MS. NIMMO: Yeah. I think there's been the fact that the general license itself, 31.5, has very significant trans-boundary considerations, and I think that's been overlooked. Let me explain -- and this applies to a lot of us.

Most of us don't just manufacture and distribute devices. Essentially all of my colleagues are in that position.

If a device is a generally licensed device, we don't have to apply for a specific license in those states to do service.

In the NRC regulations, under reciprocity, it explains what you need to do to apply for temporary use in a state, and then, underneath that, it says "notwithstanding the above provisions," and I don't have the wording exactly, but manufacturers and distributors are permitted to do service in the state and are exempt from reciprocity, exempt from getting specific license in that NRC region or state if they already have a license from an NRC region or an agreement state.

With compatibility levels not being set high, what happens is some states -- one example right now is New York -- decide to take this list of devices of highest concern and make them specifically licensed devices. When they do that, our provision to go in that state and to service the device goes away.

You have to get either a specific license or we have to apply for reciprocity.

So, just for example, in the State of New York, which elected to not follow these proposed rules but to make those devices specifically licensed, I am in the process of

getting a specific license in that state to do service to our strontium-ameridium gauges.

That's not simple, and I would argue it's not productive.

I have a license in California already to do service throughout the United States, and dealing with each individual agreement states that chooses to differ from the NRC and not keep certain devices as generally licensed is not a productive activity.

So, I am very concerned with keeping the compatibility level high so you don't have states who decide that they feel the rules are not strong enough and therefore they want to go one better and decide that certain devices are specifically licensed or completely have a different set of requirements.

MR. CAMERON: Okay. So that the focus of that concern is on the compatibility requirement --

MS. NIMMO: For 31.5, yes.

MR. CAMERON: -- of 31.5, and I think you've shown us what your rationale is there.

Let's pick up a couple more company representatives on this same issue before we go to Suzanne. We'll go to Ralph and then come over to John.

Ralph?

MR. HEYER: Ralph Heyer, TM Technologies.

I echo essentially what Elsa said.

In addition to New York, we have states, many -- Louisiana, for example, Illinois -- who may not have it in rule, for example -- New York does have it in rule, there will be no generally licensed devices out there, but we have many states out

there that are saying this is the way I want it.

That's been the response from at least seven different agreement states, and unfortunately, I'm in the position that I'm -- even though I'm not from Missouri, I'm going to say show me where it says -- it's in rule, and I'm trying to abide in due diligence in providing all information to our end users, our general licensed customers.

When providing them the information and they say can we have this device as a generally licensed device, I say yes, you can, however you must now notify the regulatory agency in that respective jurisdiction, and you may have to proceed with getting a specific license.

So, even though there are states that have gone forward, such as New York, in doing diligence and changing the compatibility to point of being more compatible, if that's a case that the Office of State Programs wants to develop, it's still a problem for the manufacturers to provide critical information to our customers, and we're trying to do so in this process and recognizing full well, as Elsa said, that New York limits certain activities within 180 days in a year -- 30 days, excuse me, and so, I'm submitting fractions of days of work that I do there, if I'm there a half-a-day.

If I exceed 30 days of work providing a service to a customer, I have to apply for a specific license in that state.

MR. CAMERON: Okay. Thanks, Ralph.

We're going to go to John and then Suzanne, and then I want to specifically on this issue ask Joe Clinger in Illinois for his views on this, and I guess a question to consider for all of you, is the simplest or the only way to solve

this problem just by changing the compatibility level? But maybe we can find out a little bit in a minute what the rationale is for the existing compatibility level.

John?

MR. PATTERSON: Chip, I just want to echo a lot of the things Ralph said. He made most of the points I wanted to.

The only -- the point we just ran into is Louisiana has said rule-making, what's that? You know, we want it this way. And we had to get a license to do service of an installed device in Louisiana.

The other thing that I've seen happening is more and more states -- we build a portable gauge, as well. People take it around -- and you do, too, Ralph, and that's getting to be more and more of a problem.

Different states -- the craziest one I've heard is Arizona says you don't have to have a license to use this device if you're an Arizona resident.

If you're an out-of-state resident, you have to have reciprocity, and if you don't have a specific license in the state you're in, then you've got to get a specific license in Arizona.

This is getting ridiculous, personally.

MR. CAMERON: Okay. Thanks, John.

Suzanne, do you want to comment on this, and then we'll go to Joe out in Illinois, and then we'll come back to George.

MS. WOODS: I would just like to say that I believe I need to explain a little bit more about compatibility, and then I'll invite the representatives from Office of State

Programs, perhaps, to clarify what the meaning of compatibility is.

Essentially, agreement states can meet at minimum what we set as the standard for compatibility, and they can exceed that, as well. So, I think that is part of what you're explaining and experiencing, and I just wanted to share that with you.

I'd also like to invite anyone to come up -- did you want to say a few words, Lance?

MR. CAMERON: Let's go on to Joe.

Joe, you've heard the conversation on this issue, and I believe Illinois was offered as an example, perhaps not of the issue of not having a, quote, "requirement," unquote, in the regulations but at least on the issue of setting more stringent standards, I take it, than the NRC's standards.

Joe?

MR. CLINGER: Yes, Chip.

I think, in Illinois, we're consistent with the proposed NRC rule. I don't know what you can do about these other states.

Like somebody else has already said, if they want to be more stringent, I think they can be that way, and if you force them to put it in the rule, they'll probably put it in the rule.

I think everybody's trying to accomplish the same thing, it's just that people have different viewpoints on how to get there, but as you're going to have people register, we've been doing that in Illinois for many years, and we don't see ours as being incompatible. It's very consistent with your proposed

rules. In fact, we applaud your efforts to do so, and we would like to other states, all the states do it.

In fact, as chair of the orphan source committee for the Conference of Radiation Control Program Directors, that's one of our initiatives, is to get more control over these radioactive devices but do it in a consistent, comprehensive manner is what I would like to see, and I know that's what the vendors would like to see, too.

So, I empathize with those frustrations out there.

I hope that we're not part of the problem there, because I think we are consistent with your proposed rules, and with the other states, I don't know, you just have to deal with those individually, and maybe through the conference and stuff we can try and get more uniformity, and maybe with the NRC rule, that will help facilitate more uniformity.

MR. CAMERON: Okay, Joe.

Let me just ask you one question there specifically, and it may be that there needs to be some work with the conference or Organization of Agreement States, but what do you think -- what would the Illinois reaction possibly be if the NRC designated this a compatibility level C rather than B? The other way around.

MR. CLINGER: I think, as far as we're concerned, we wouldn't have a problem with it, because we are consistent. So, we wouldn't have a problem with it.

Now, the other states -- they may. I can't speak for them.

MR. CAMERON: Okay. Thanks, Joe.

Lance?

MR. RAKOVAN: Yeah. Lance Rakovan, Office of State Programs.

I think the reason that we've designated most of these as category C is we're looking at the program on a national level and we realize that there's states that have been doing these kinds of licensing for years, and we're coming into this kind of new.

So, we're looking at it as we don't want to step on anyone's toes right now, and that may be the best way to do it, that may not be.

Part of the reason that we're having this meeting is to hear your concerns. So, you know, please continue to share this with us, and once we get all the comments and we can move forward with this, we might have to change some of the compatibility categories.

We can always break up the rule in a different way and enforce different compatibility categories for different sections of the rule.

You know, we can take this to more detail if necessary, but right now, we're just kind of coming in, this is what we're thinking, you know, please let us know what you think.

MR. CAMERON: Okay. Thanks, Lance.

We're going to go to George and then to Elsa and over to Ralph again, but does everybody -- perhaps either Suzanne or Lance could say -- I think, Suzanne, for the vendor requirements, you gave the rationale of trans-boundary implications for why compatibility was set at that level.

Do we have a rationale for the 31.5?

MS. WOODS: Lance probably is better positioned to

explain this than I, but essentially there is a listing, if you will, a logic flow that is gone through for each regulatory requirement, and -- such as you get this flow chart, and trans-boundary implication pops up. It becomes a compatibility level B.

There are no trans-boundary implications. There are some other implications that have resulted in a compatibility level C requirement.

I don't know the exact background on the logic of this.

Cathy, do you have any insight, or Lance?

MS. HANEY: When we establish adequacy and compatibility for a specific regulation, there is an internal procedure that we use. It is set by a management directive, and as Suzanne started to say, it is a very structured process that we do go through.

It's a series of questions, and you can come out of the process at various different levels, whether it's A, which would be something like a Part 20 requirement, then you get into your trans-boundary, then you get into whether there would be gaps and duplications in regulations, then there's a final category of whether the safety -- you consider the safety and health implications of the particular regulation.

So, it's not like the group that did the rule-making sat down and said, gosh, this sounds like a B, this sounds like a C.

It's a very formal process that we go through, and in order to change those designations, we really need the reasons for why we'd need to change those -- really, why were our initial

assumptions as to is this trans-boundary, why does it kick out there versus another.

I don't think that we can go back in and just say, gosh, it should have been a C, we made a mistake. It is a very formal process, and it goes, really, outside of this rule-making to just agency policy that we're talking about at this point.

MR. CAMERON: And I think that we are beginning to develop a counter-rationale, at least, for the NRC to consider here.

Lance, do you have a quick clarification before we go back to the table?

MR. RAKOVAN: I just wanted to continue on with what Cathy was saying.

If you'd like, I can make a copy of the general flow chart that we use in deciding what compatibility category comes out. I can make copies and bring that over, if you'd like.

MR. CAMERON: Yeah, I think that would be terrific.

MR. RAKOVAN: Okay. That's not a problem.

MR. CAMERON: Okay. Let's go to George and then I think Elsa probably has some comments on the rationale.

George?

MR. BROWN: Thank you. Just a couple of comments on why compatibility is important.

Number one, states typically, if they change rules, won't notify manufacturers. Texas has a possibility of being able to sign on as a concerned citizen, and we'd get flyers, but like when New York changed the rule, we found out by word of mouth long before, and these are major changes.

Some states have changed significant portions of the fee structures and things like that and get mad at us when we don't know about it.

We've got now 32 jurisdictions that we have to keep track of rules, and that's a tremendous amount of time, and there's no neat way to do that.

Simple things like -- we file for reciprocity -- we pay \$12,000 a year just to do service on gauges that are already in plants, and many of those states require their form.

So, that means, for us, our cost skyrockets, because we can't automate it.

If we could get compatibility that would agree with the safety concerns of the states but allow us to use similar reporting requirements -- like the reporting requirement for the form right now says that it needs to be similar information, but if I end up with 30-some different states that want their information in a particular form, that's a tremendous burden to put on manufacturers with no gain in safety.

Our dollars are as precious as anybody's, and they need to be put -- and the information -- getting the proper information to a customer so they use the rules and the gauges correctly, not spend a lot just trying to make sure everybody's got a form that they want.

That's where a lot of the area of concern comes from.

We see this change from the service aspect, because we have a lot of specific license equipment that we service, so we maintain licenses and reciprocity with every jurisdiction, and if this general license rule is no more

compatible than that, then it's an entire 'nother nightmare for us, and I think that's where the concern comes from.

Thank you.

MR. CAMERON: Okay. Thanks, George.

Are you suggesting that, even if the compatibility level remained the same here, that through some -- the states providing better notice of changes or having similar forms, that that would alleviate some of the problem?

MR. BROWN: Yes. Specifically, I think there should be requirements that they notify registered vendors. I mean we've been in business 50 years, and I can call states and they don't even know we've been around, and there should be a requirement that we have a license and they be -- I don't care how you do it, but if they change rules, they have to notify at least a group of people, at least we have a chance of keeping current, and if that could be expanded to reporting requirements need to be standardized, then at least we have a chance of keeping current with everybody.

MR. CAMERON: Okay. Before we -- if you could just be patient one more minute, Elsa -- Joe, I hope you heard George's explanation of a problem about state notification, and I don't mean to pick on Illinois, but you're the only one around to be picked on.

What do you think of the notification requirement that George was just describing?

MR. CLINGER: I totally agree with him. We're very careful that we notify everybody that comes in under reciprocity, that provide us a quarterly report. Everybody that we're aware of -- we notify them whenever we are changing regs or

changing anything that affects generally licensed devices, and I think that's the only responsible thing to do for these agencies, because just to provide, you know, due process, if you're affecting an industry by changing your rules, you've got to let them have some input in it, and so, I totally agree.

Now, how do you get the other states to do that? I think all you can do is bring it to their attention and try and make them do what I think is reasonable.

MR. CAMERON: Elsa?

MS. NIMMO: Yeah. I'd like to go back to the 31.5 compatibility level just to emphasize, with New York, what they did was they took some of the devices and made them specifically licensed, which I guess any state can do, even with the passing of these proposed rules.

When I took a look at that and I realized the impact on the service organization, I gave New York a call and I said, now, these devices that you're going to make specifically licensed, that means I can't come in and service them in the way we have in the past, and I said, well, look at the reciprocity requirement, and their response was, oh, we didn't really realize that it had that impact, it wasn't our intention to make you get a specific license, and, well, that was a surprise.

So, they had made this change in what a generally licensed device could be and had this unexpected consequence to the service organization which I feel is definitely a trans-boundary situation.

When I spoke to them more, they said, well, you know, it will be simple. You just send in your California license, and if California has approved it, we'll certainly

approve it.

So, we sent in our California license, several binders this thick, and we got back a letter with about 10 points: Your training isn't the way we in New York want to see it. Your badging isn't the way we want to see it in New York.

So, you get the picture.

I think if there isn't a consistent definition of what a generally licensed device is throughout the United States, we're in the position of possibly having to get specific service licenses in 20-plus states, all with their different ideas about what an adequate training program is, adequate badging.

MR. CAMERON: Okay. I think that puts a finer point on some of the concerns.

All right. Let's go to Ralph.

MR. HEYER: My personal opinion, for what it's worth -- I understand fully the Office of State Programs' efforts when performing reviews on 18-to-36-months basis for adequacy and compatibility.

I think what we've heard George and Elsa say, and John, is caution should be made when the NRC goes to review a state program and looks at their program to see whether it's adequate or compatible but also recognizes that sometimes, even though they are as restrictive, they are much more restrictive and they're so restrictive that they're inconsistent, and I think that's the contention we were trying to make.

On another note -- and I don't know if we'll get into that a little bit later -- is the issue of exempt quantities.

The working group made five recommendations in

NUREG-1551, did diligence in providing a good, fine point to what we need to do for accountability issues, yet we see devices were previously exempt quantity-type devices being distributed in process measurement equipment.

One side, we say let's increase accountability. Yet, here we've developed another area that potentially will not maintain accountability for these devices.

So, consistency in application in 10 CFR 31.5 is critical.

MR. CAMERON: Okay.

What I did, Ralph, is I noted for the NRC staff that you talked about review of adequacy and compatibility. That's done through the -- what's called the IMPEP program here at the NRC, and you seem to be suggesting that there may be a way to handle this problem through that route, but it seems like the more direct route would be to change the compatibility designation here.

Do we have any other comments we want to add on the compatibility level?

I think that there's been some good discussion about exactly what problems exist out there, and I would ask the NRC staff whether they have any questions for the panel that would help them to understand this a little bit more if they don't already.

Suzanne, John, Cathy, anybody?

[No response.]

MR. CAMERON: Okay.

MS. WOODS: I have one question on compatibility timing.

MR. CAMERON: Can we address it later on?

MS. WOODS: Sure, that's fine.

MR. CAMERON: Okay. We'll pick that up then.

All right.

Anybody in the -- we might as well do this now.

Anybody in the audience have anything on the compatibility issue that hasn't been said up front here?

Yes, sir, if you could just come up to the microphone, please, and just please, for the transcriber, for the stenographer, identify yourself and company.

MR. HARMON: I'm Larry Harmon from Safety Light Corporation, and I am kind of the oddball in the group here, because you're talking mainly about gauging devices.

We manufacture commercial exit signs, which also fall under 31.5. The aircraft signs, of course, fall under 31.7.

I know that the rule in place here -- Massachusetts, when this proposed rule went out, even though it designated what isotopes had to be registered and what isotopes didn't have to be registered, Massachusetts sent a letter out to everybody, including tritium exit signs. The \$450 fee, of course, is about three times what we charge for an exit sign.

So, I don't know if that's really with the compatibility thing here we're talking about, but at any rate, I just wanted to bring up that there's other devices underneath 31.5 that's affected by this other than gauges.

Thank you.

MR. CAMERON: Okay. Thank you very much.

All right.

Thank you very much, Cathy, for going over the

rule for us, and right now, what we're going to do, we're going to go to the first listed item, discussion item on the agenda, which is ways to increase general licensee regulatory awareness, and you see we listed a number of things there.

I'm going to ask Suzanne to just briefly give us a context for that, and then we'll go to you guys for a discussion.

Suzanne?

MS. WOODS: Okay. A couple of things come to our attention, and we'd like to introduce them just to serve as stimulation for conversation.

The focus of the rule in particular is to increase the general licensees' awareness of devices and associated requirements, as well as accountability and tracking, and what we've found is that, many times, NRC licensees don't know they're licensees, they don't know about maintaining the label, instructions for safe use, proper storage transfer and disposal.

So, the rule, in particular, emphasizes one means of getting this information to licensees, and that is to provide it prior to the purchase. I believe it's referred to as disclosure.

Currently, as just a reminder for those in the audience and others, 31.5 regulations are to be provided by the vendor during the process of transfer.

This provision in the rule would require that this transfer of 31.5 regulations to the licensee occur before the transfer of the device, during the purchasing process.

It also specifies copies of additional applicable regulation -- sections of the regulations, lists of services only performed by specific licensees, info on the disposal --

information on the disposal of options for devices being transferred, including estimated costs, agreement states and general licensees, in particular, for agreement states -- there would be a requirement for 31.5 or comparable agreement state regs to be provided, as well as the name, address, and phone number of the agreement state agency.

What we're looking for here is whether there are any issues that you foresee in implementing this. Are there ways to facilitate this approach?

Are there issues with achieving any type of comparable enforcement-type issues as asked for in the rule, and in particular, the rule also emphasizes what the positives and negatives would be to changing the words in the rule to "prior to purchase."

Also, are there other ways to increase the awareness of general licensees as to their regulatory responsibilities and safety and all those other issues I've mentioned up front as examples?

MR. CAMERON: Okay. Thanks, Suzanne. We'll try to get into other ways, also, in this discussion, but let's go to the basics. Let's go to Elsa, and then we'll go over to David.

Elsa?

MS. NIMMO: I think there's a good reason to avoid the use of the word "sale," and that's because some of the devices are leased. So, the "prior to transfer" -- I don't know how other people feel, but for us, that works.

Actually, most of the information that's described we're already providing, and it may change the point at which that material is sent, but not significantly. So, "sale" would

be a bad -- "prior to sale" would be a confusing term, because it really isn't always a question of selling a device.

MR. CAMERON: Okay. Let's clear that issue now, before we go to other points.

Any other comments on the use of the language about transfer, sale, purchase, lease?

Gary, is that what you wanted to address?

MR. CAINES: A little bit. My comment was on the timing. When we say "before," I think that needs to be specified more tightly. "Before" can be five minutes before the device is installed if somebody wanted to really press the issue.

MS. WOODS: I would like to respond -- to facilitate that question a little bit with some more information.

The Commission has gone to the trouble of describing in here what they intended by "prior to transfer," and while they have specified it's not their intent to get into the business of the vendor-licensee interaction, it was intended that this information would be a matter of knowledge to the licensee before they chose -- or to the customer before they chose to become a licensee.

So, it is somewhat specified in the discussion of the proposed rule, and maybe that can facilitate your discussion a little bit more.

MR. CAMERON: Okay. What we're focusing on is this phrase in the regulation, and Elsa focused in on the aspect of sale versus lease or some other arrangement, and Gary talked about the word "before", "prior." Let's keep going on these issues.

David, did you want to address that particular

phrase, or did you want to get into another area?

MR. BENNETT: Another area.

MR. CAMERON: Okay. Hold on, then, a minute, and let's clear this area first.

John, did you want to talk to that?

MR. PATTERSON: Yeah. One of the issues that most of us have, I think, is when -- I think the wording is "prior to purchase," isn't it?

MS. NIMMO: Transfer.

MR. PATTERSON: No, in the proposed regulation.

MR. CAMERON: Sue, could you clarify that?

MR. PATTERSON: The issue that I have -- it doesn't matter what the exact word is. The issue I have is when does that happen? Most of us take a purchase order, and three months later, we ship the unit, or two months later.

Those are not necessarily exactly happening at the same time. It's not like walking into a store and purchasing a television set.

You know, which of those events triggers the need for information?

For example, the selling process for many of us probably is we have a salesman go out and talk to the customer, the customer says, gee, I'm interested, give me a quotation, we give them a formal quotation that says here is what we're selling you.

Some months later, we get a purchase order which says okay, we want to buy that, and then some months later, we ship it to them.

Which of those events is the one you're talking

about?

MR. CAMERON: Okay. And keep focusing on the -- it helps in terms of, I think, resolving these issues to focus on what the objective of the requirement is, and that might give some guidance as to when the information should be provided, but as John points out, there could be several points here.

George?

MR. BROWN: Another portion of that section that needs clarification is the disposal. If somebody was to ask me what the disposal possibilities for americium is, there are none. It's defined as an orphan. I mean there's just no place.

So, the only thing we could tell them is there's nothing to do with it.

It needs to be clarified that return to a manufacturer or proper end use or something like that.

So, I don't have any problem notifying people that we'd be willing to take them back at some point in the future for a fee, but that's not disposal, that's transfer of material, and just telling someone that's going to buy a gauge that there is no -- the way the low-level waste packs are falling apart, that whole is -- whatever disposal means, we have no way of knowing what that would be in the future anyway.

So, we need to clarify that transfer, because that becomes a big issue.

MR. CAMERON: Okay.

Does anybody have a suggestion on what a better -- what point should be defined as the when that should be used in the rule?

Gary?

MR. CAINES: I would say something like 10 days prior to transfer. I think a time period needs to be put in.

MR. CAMERON: But this is in terms of providing information to the purchaser about their requirements as a general --

MR. CAINES: Yes, 31.5.

MR. CAMERON: -- licensee?

Now, if that's 10 days, has the purchase already been --

MR. CAINES: Yes.

MR. CAMERON: -- made at that point?

Is the intent to get them to consider this before they decide to buy them?

Suzanne?

MS. WOODS: Maybe it would be helpful if I just read the words right out of the rule.

MR. CAMERON: All right.

MS. WOODS: "The Commission's intent that 'prior to transfer' would be before a final decision to purchase so that the information can be considered in making that decision."

MR. CAMERON: Okay.

So, 10 days may or may not be within that framework.

Elsa?

MS. NIMMO: I think probably some of the reaction from the people sitting around the table -- we're in radiation safety, and if I had a way of guaranteeing that the salesman would always give that information, I'd love that, but short of requiring -- the NRC requiring the customer to sign that they got

that information, I can't make that happen.

So, if you do something like 10 days prior to transfer, I can make that happen, but if you wrote in "prior to the decision to lease or purchase," some mechanism -- some rather strict mechanism would have to be set up.

I think, for a lot of us, we're not talking about small companies where we personally are interacting with the salesman who's based in the office next door. It's a big organization with salesman that we haven't met, who are very, very difficult to control.

So, I think that's part of what you're hearing from us.

I would personally love to see that information be in the hands of the person making the decision to lease or purchase, but doggoned if I can figure out a way to guarantee that that will happen.

MR. CAMERON: Okay. Let's stay on this issue of when and how to make that happen.

John, did you have a comment on that?

MR. HICKEY: Well, just a followup. I think the points are well taken. We need to think about -- I don't think specifying one number would necessarily do it. It may be a time range.

If you're going to specify a minimum time, it seems like you may also want to specify a maximum time, and I think Elsa's point is also well taken about it's hard to control how the decision point factors into this, as opposed to just the -- providing the information.

So, that's something that we need to think about,

but I agree their point's well taken, that the proposed rule, as written, needs more thought.

MR. CAMERON: Okay. Let's finish up on comments on this issue of timing, and then we're going to go to David, who's been waiting patiently on another issue.

John, do you have anything on -- is this on timing?

MR. PATTERSON: Yeah, this is one timing again.

MR. CAMERON: All right.

MR. PATTERSON: One of the other issues that you have to understand is many of these systems are specifically built for a specific order.

Ten days in that case is not nearly good enough, because if you send this out to -- the intent is you're going to tell the customer you've got these responsibilities and give him the option to say, oh, gee, I didn't know that, I want to cancel the order. It's much, much too late 10 days ahead.

So, I think it depends a little bit -- you've got to look at what the sale cycle and the build cycle for a particular product is, as well.

So, it's unique to each particular company, I'm afraid.

MR. CAMERON: So that maybe what you're suggesting is that it would help the NRC in making this decision if they really understood, perhaps, a little bit more about how the actual business end of this is operated from the sales on down.

Questions or comments on timing?

Ralph, do you have one on timing?

MR. HEYER: Yes. We've got in 10 CFR 31.5 already

a timing issue that the general licensee notify the regulatory agency within 30 days, and we know that's not been real effective.

The point I'm trying to make is, sale and lease, let's not have our regulators get into that business.

I think the term "end user" would be appropriate, thus avoiding the term of third-party contracting that we have sometimes, and perhaps an issue of the time the end user receives that device, then -- what we've tried to do over the past year is, at the time the unit is installed, in those cases where they're fixed units, we have hand-delivered the general license package information, because we've had problems where we've tried to, at the time of purchase, mail a package and it goes to a third person or someone who is not directly involved, goes to everyone else except to the end user, and I think the Commission is trying to make the objective to get all the information to the end user in a timely fashion, and that's the focus we need to stay on.

MR. CAMERON: Okay. Thanks, Ralph.

Jonathan, do you have a timing --

MR. FORTKAMP: Yes. Two comments.

First, at least in our company -- I mean when you talk about prior to the decision to make a sale, from radiological operations, we're at the very end of the sale process.

The order has already been processed months, perhaps years in advance of when we're notified to get the source ready for shipment, and it's not really reasonable, in our system at this time, to distribute that type of information prior to the

decision to buy or lease.

As well, you're dealing with two different groups. The group that's really going to be interested in the information for the disposal and the regulations is not the group that's -- generally is not the group that's making the decision to buy or sell the device.

They are the radiation safety person at the mill, in our case, you know, at a paper mill, is not the person who's buying -- the decision whether they want to buy this whole measurement system, this whole measurement platform that ABB would sell.

They are told the decision's been made, we're buying one.

At that point, you know, the way the regulations are written, the decision was already made and the information at that point probably would not have gotten into the hands of the person in the customer's end who would need to know or who would understand how to use the information.

MR. CAMERON: So, there's a disconnect on the purchaser's end as well as perhaps on the sales end.

MR. FORTKAMP: Very much so. You know, especially with the bigger companies, you know, ABB and Measurex. Some of the smaller companies, I can't speak for, but at the larger companies, you know, it's a huge institution. All the groups work pretty independently, and they have to as far as the business side goes.

MR. CAMERON: Okay.

I think we'd better let David get on-board here, and then we may come back with Doug and Elsa and Chris to see if

there's anymore on the timing issue, but go ahead, David.

MR. BENNETT: Touching on the timing issue, our system is fairly simple.

When customers call our order processing center and order one of our devices by part number, within the computer system a flag comes up and directs that regulatory information must be sent to the customer prior to the sale being completed.

A package is faxed to them, including a general license registration card that states on the card I have read and will agree to the regulatory information that's provided.

The person that's responsible for the device, the end user, has to sign that card. It can't be a member of their purchasing group.

That information is then faxed back to us before the sale is completed.

The RSO office has worked very closely with the order processing center in developing procedures to make sure that every time a customer requests one of our devices, that the computer system is set up for it, they have all the paperwork that's necessary to fax a copy of 31.5, plus a copy of the registration card.

They are required to complete that information, sign off on it, put their signature on it, and send it back to us.

So, it has been working very, very well for us to make sure that they get that information.

I can't swear that they're reading it, but they are at least signing off on that card.

If there are no responses to that --

MR. CAMERON: At some point, I think it would be useful to see if other companies have the same type of system or whether it would be feasible to implement that type of system. Let's get some comments on that now before we go on.

Gary?

MR. CAINES: Honeywell has something similar, but this is not done before the sale. When the device is being transferred, we have a similar card that the customer is required to sign stating that they have read and received all the materials, read it, and fully understand everything.

MR. CAMERON: But not before sale.

MR. CAINES: Not before sale.

MR. CAMERON: Okay.

Chris?

MR. FITZ: Yeah. Chris Fitz from NDC.

One of the problems that we have would be with -- we sell to a lot of OEMs. OEM is an original equipment manufacturer, so that we -- that is our customer, and we don't even know who the end user is until maybe 30 days prior to shipment.

What Ralph was talking about, the third parties -- we would be supplying the OEM with the information, who is responsible for providing it to the end user.

MR. CAMERON: Okay. Thank you.

David, let's go back for your next point.

MR. BENNETT: Just a quick response.

Our OEMs have specific licenses, so they are authorized to receive those devices and then transfer to a general licensee. We have distribution centers that have

specific licenses to receive -- purchase and receive our general licenses, generally licensed devices, that they, in turn, sell.

Going on with the question that you had asked earlier, the concern I have with providing information to customers up front is the volume of information that we provide to them.

Thirty-one point five is like three pages printed out, just by itself. I don't have too much trouble with three pages, requesting that they read three pages and signing it off, but the proposed rule includes requirement for other information, as well, regulatory information, as well.

So, we're looking at, what, six pages, seven pages of information that these people are going to be required to read.

My proposal would be that we continue requiring 31.5, which is the guts of the thing, but to include in our information provided to them that other very important regulatory information will be provided, say, along with the product or at some other time, it's very important to comply with it, as well, and be familiar with it.

I'm just concerned that, if you throw a book at them and they're trying to close a sale, they're just not going to read it. It's hard enough to conceive that they're going to read three pages, let alone six to 10 pages of regulations.

Secondly, we're not seeing too much of a problem with the original purchasers receiving and understanding information.

Our greatest concern is that, with the turnover of companies being so great, turnover of personnel being so great,

that the information is discarded and lost along the way.

We're trying a couple of things like, in the booklet that we provide to the customers, to describe a documentation process for them to follow to ensure that that information gets passed on, safety checks and things like that, and that's helping, and another thought we're having -- we're looking into the possibility of including a corporate web-page address on the metal tag that would identify all of the regulatory requirements for the device, in case the paperwork gets lost, and that's what we typically see, is that a laboratory two or three sales down the line of the history of the device has no documentation whatsoever.

So, we thought, well, if we put a corporate web-site on there and indicate, for critical regulatory information for this device, contact this web-site, that way we could provide up-to-date information and guidance for the customers at all times.

Continuing on, I question the possibility, if we're really interested in getting people to read this stuff and comply with it, is there any possibility of looking into identify penalties in the event these regulations are not followed?

We provide all of these regulations up front, at whatever point in the sale, and so many times, the chemist mentality of the person using our device versus the regulatory mentality of the radiation safety office is totally different.

The lab chemist, bench chemist, very, very often, especially if they're in R&D -- and this is not a slight, but very often, their level of concern over regulations is just not there.

The regulations office is very concerned about this. The chemist is concerned about his project, and so, their level of concern for complying with regulatory issues is very low, and I just wonder, possibly, of identifying what sort of penalties might be included in the case of failure to comply with them.

MR. CAMERON: Thank you. You raised a number of important issues, and I don't want to forget Doug from our staff -- has your point been covered? All right.

John, you had a question?

MR. HICKEY: Just on the question of penalties, the suppliers and the users are licensees of NRC, or if it's in an agreement state, the agreement state, and there are penalties, and they can be severe. It depends on how severe the infraction.

So, merely because you're a general licensee does not mean that you are not subject to penalties for violations of our requirements.

MR. BENNETT: I understand that. I'm just suggesting that we identify the possibility of penalties and how severe they might be.

MR. CAMERON: And on whom, I guess, was part of your point.

MR. BENNETT: For the customer, for the person purchasing the general license device.

MR. CAMERON: All right.

Jonathan?

MR. FORTKAMP: Along these same lines about material to be included prior to transfer or whenever, you asked for an estimated cost of disposal.

I think the way the final disposal options are right now and the way they're laid out to be in the future, it's so unpredictable that I think it's unrealistic to give a realistic number to a customer about what disposal cost is going to be.

The lifetime of some of these devices can be upwards to 30 years.

Thirty years -- I mean, you know, over the last 10 years, disposal costs have jumped up and down and all around, and in 30 years, it's impossible to predict what they are or what they are going to be or even if there is going to be the possibility for disposal.

I think that's a difficult thing to include, and by having us as vendors pin down a number, an estimate, I just don't want to get into the case of being tied down to a number that we can't realistically stick with.

MR. CAMERON: Okay. And this was raised earlier, a similar point by George, I believe, not on the cost, necessarily, but on specifying some -- the mechanism of -- what the actual mechanism for disposal might be.

Do you want to say anything in regard to Jonathan's point?

MR. BROWN: I think the cost issue is the same. My point was the law says disposal. I can only tell a person that a transuranic has no disposal. I mean what do you do with a transuranic?

In certain cases, it could be you send it to a certain jurisdiction that may not have -- North Carolina -- they don't have access to Barnwell. Other people may not have access

to other sites.

So, my problem was using the word "disposal." It should be clarified that a vendor -- that we can agree to take them back if the laws allow it at that time.

The cost issue -- we can make estimates of today's cost, but they do bounce around a lot.

I imagine Barnwell will be closed by this time next year, and where do we go with even sealed sources at that time? So, there is no disposal.

MR. CAMERON: Okay. Thank you.

Elsa?

MS. NIMMO: I was going to echo the comments of John.

I am not sure quite what the NRC was looking for.

I think many of us could say it's our corporate policy that, if we've shipped a source, we will take it back, and we wouldn't have a problem saying what the 1999 fee for that return would be, but we do have a problem predicting what the fee in the future is or, as George points out, what the disposal -- what other options they would have.

We could certainly say that they are free to consider other people licensed to do disposal, and we could direct them in that way, but we couldn't give really useful specific -- here are your options, here are your estimated costs, when the gauge might be out there for 30 years or more.

MR. CAMERON: We're going to go out to Safety Light in a minute for comment, but let's get some clarification, if we can, from the NRC staff on Elsa's point.

MS. WOODS: It appears to me from reading the

proposed rule that the intent is that there be a knowledge that there is some fee, there is a process by which they're going to have to follow for disposal, and that perhaps sharing the current free structure for disposals of the sources and devices that they would be procuring might in one sense educate them.

It seems to me that the emphasis has been throughout this rule that they be knowledgeable about such things.

Did you have anything more to add, John?

MR. HICKEY: Well, I was just going to say I think Elsa summed it up nicely.

What we need to think about is whether what we really want is for the manufacturer to say this source -- this device will only be able to be disposed of by a transfer to an authorized person. We are such an authorized person for you to return it to us, and this is what our current charge is, and we need to decide whether we wanted to say more than that.

MR. CAMERON: Okay. The gentleman from Safety Light had something to offer on this?

MR. HARMON: I had written a comment to the proposed rule back in '91 where I didn't think commercial exit signs should be a part of 31.5. Hearing what I'm hearing today, I know it shouldn't be.

I don't know how we get that changed, but some of our signs go out within five minutes of the date of a sale, because a fire marshal walks in and says you need a sign here, it's out.

Sometimes the owner of the building -- you're talking about transferring buildings and that type of thing --

the owner of the building might be a guy in New York City that has a spec building that somebody else is ordering a sign from.

So, we have that issue to deal with, and I just wanted to make that comment.

I forgot what the other comment was I was going to make. It had to do with that gentleman's --

MR. CAMERON: When you say "that gentleman" --

MR. HARMON: The one in the plaid shirt.

I forget what the other issue was I was going to make, but at any rate, I don't think that commercial exit signs are falling in the same program as all these devices, even though they are under 31.5, and I think the regulations that the NRC is making for gauging devices, where they take months to be able to get these to the field and all this other kind of thing, does not apply to commercial exit signs.

I think we have different things that the NRC has to think about regulating commercial exit signs.

That's the other point I was going to make. We have to send out the same regulations that the gauging people have to send out. A lot of times, the responsible party for our devices is a janitor in a school, for instance, or someone like that.

We have to send out about the on/off device, we have to do all kinds of things which doesn't even apply to our sign. These people don't even understand what they're reading.

If we are stuck within 31.5, my suggestion would be -- is rather than put anything that the NRC writes out to the public, is have us write something that you guys can approve that puts it in simple English and says this is what you do if,

instead of all the garbage.

MR. CAMERON: Is that term "garbage" -- is that a regulatory term?

Okay. We'll put that up there.

Let's finish up with some comments in the audience, and then let's take a break.

Mike.

MR. RADDATZ: Good day. I'm Mike Raddatz.

The one thing I'd like to emphasize to everyone here is that, if you were buying a condominium today and you moved in, they'd disclose the fee structure, and if you find out the last day, when you were attempting to move out, that, oh, by the way, you owe us 25 percent of the original purchase price and you can't leave until it's paid, this is the same structure that we're getting into now, is the devices are there, they exist, you sold them.

The end user cannot be forgiven their lack of knowledge of what to do with it. It's our responsibility to try to find a way to get there.

To say, well, the gentleman can't -- does not understand what they're reading -- that's true. A lot of our regulations do need to be written in plain English, and we're going to try to do that, but the reason we're here is that you cannot be absolved from responsibility by saying, hey, we tried.

But you did sell it. You made a profit by selling it. It's our responsibility to regulate it. We're looking for your help.

We need to find a path forward. A lot of hand-waving saying, well, hell, I can't do anything about it --

there was an honest suggestion, okay, if we tie this stuff to a web-page, where somebody can go up and find the life-cycle history on a permanent labeling -- these are good suggestions.

These are things that we can use to feed back into it.

As we progress through the day, a solid thought, an idea saying we could do this, and that way these end users would know, you know, with a little skull-and-crossbones, don't open it up, don't throw it away, don't put it in the trash, that we need to get there, and that's the type of things I hope to hear, because we're going to do feedback on these regulations.

We're going to take everything you say and we're going to feed it back into the process, and all of you, when you look at any of the regulations, look at those statements of consideration, the statements of consideration for the proposed rule.

They tell you not just what the rule says but what we were thinking when we put it in there, and they do have weight and they do have standing.

Thank you.

MR. CAMERON: Okay. Thanks. And I think that we have been hearing a number of recommendations for how to approach this around the table, and I think we're going to be hearing more of them, also.

David?

MR. BENNETT: Just had a comment.

I don't necessarily see it as garbage, but I do see it as very, very confusing information for the majority of our customers, and the thought I had was that, instead of sending

the entire regulation, that we would be able to extract out pertinent information for our particular products, and even if it means passing it through the NRC and getting approval, it would certainly lessen the level of frustration that our customers face in dealing with a product such as ours that is of very, very low health risk, a very bad agent, if you will, compared with higher levels of concern.

There's much in 31.5 that is just not applicable, and rather than smash them in the face with all this material, where they need somebody to walk them through by the hand and say, well, this is what you need, you don't need this point, this is not applicable, this is applicable, these are the things that you need, I would prefer to be able to extract out word for word portions of the regulation that are pertinent for our individual customers, and not only on an individual but I mean on a device-related basis, and provide that to the customers, instead of the entire package.

MR. CAMERON: Okay.

We are getting a little bit more support for this idea of somehow tailoring the information. There was a suggestion that maybe the NRC needs to look at this, but that's also another alternative. We do need to get to a break soon, and I would like to give Elsa and John a chance to speak, and also Doug.

Doug, why don't you go ahead right now, and then we'll come back to the table, and please introduce yourself for the stenographer and the audience.

MR. BROADDUS: This is Doug Broaddus, and as I mentioned previously, I've been working on this project for quite

some time, as well, and I wanted to give a little bit of insight into the purpose for the provision for the disposal and to throw out some ideas that you may want to think about.

Disposal was not the only intent, as you say, George.

It was, in fact, more of a disposition, trying to find out -- trying to provide information about how the general licensees could get rid of the material in the end, and I agree with you that disposal does convey one thought only and that's putting it in the ground, but the intent was, in fact, more than that.

The other part to the rule is the general language that is in there -- that is, provide information on disposal, and the reason it was left general was to provide some flexibility for the vendors to provide that information in a variety of ways.

As George pointed out, disposal is not the only option for many devices and sources. There's recycle. There's disposal. There's return to the manufacturer, as well as if you wanted to provide information about what the costs are for today as well as what they are in the future.

You have that flexibility, but the intent is to get that information to the end user so that they have that information available to them so that they can make a decision about whether they want to really purchase this and take that responsibility for the ultimate disposition of the material.

Also, just to let you know, as well, there are a number of different options for transuranic materials. Transuranics are only -- can't be disposed of if they're not accepted by disposal facilities, and generally that's greater

than Class C materials, but there are a number of programs out there for recycle, as well as return and reuse for transuranics, as well.

So, it's not just -- just returning it to the vendor is not the only option for that.

MR. CAMERON: Okay. Thanks for that on the disposal issue.

Let's go to Elsa, and then we'll come down to Candy and across to John, and then we will take a break.

MS. NIMMO: To respond to Mike's comments, the transfer of information to a potential customer, the items that are listed -- is that intended to be something that the NRC would inspect against, to be able to look and see that we had provided that information in advance of transfer or decision to buy, decision to lease?

MR. RADDATZ: If the regulation says that the material has to be in their hands prior to -- if that's what we end up -- in final language, then it's inspectable, but they -- see, anything that's in the regulations becomes an inspectable, enforceable unit.

If it's not implicit in the regulations, then it's not necessarily inspectable.

What we're trying to do right now is give you the information on our intent. Our intent is to educate the people that are purchasing any device, that their responsibilities fall beyond it.

Unfortunately, we don't get to speak to all of them, nor do they listen to us all the time. You do.

At some point, the vendor, your sales staff,

someone in your organization is interacting with the final purchaser, what you've called the end user. So, we are going to have to rely very heavily upon you to ensure that this information gets into the right hands.

That's why we're here. Part of it is to find out what's the best way to carry out the intent of the Commission, not just the letter of the law, not just as it reads today but to carry out the intent, and we're looking to you to say, you know, NRC, this will work, NRC, it won't.

We need concrete suggestions for -- if we have explained our intent, that you can tell us, look, here's a method that may work, and with the number of people here at the table, I think we can find that method.

MR. CAMERON: Okay.

MS. NIMMO: Mike, if the regulation read something like that the distributor had to have records that demonstrated the material had been made available to the purchaser or lessor in advance of the decision and you put it in terms of we had to have records showing that, probably it would happen.

MR. CAMERON: Okay.

Let's maybe come back to that when we revisit compliance issues, but I think, just to put a little discussion footnote on that exchange, that if these regulations are to be inspectable and enforceable, the NRC has an obligation to make sure that they're understandable and that they make sense in the practical world, and I think that that's part of at least what we're all about here.

Let's take two more comments, Candy and Jonathan, and we'll take a break.

Candy?

MS. BROCK: In my role, I deal with customers on a daily basis for source return. So, this is a subject very near and dear to my heart.

A lot of those conversations start out with how much are you going to pay me to buy this back from me? So, I understand the need for disposal information, and I understand your analogy of the condo owner, but with a condo owner, it's that condo owner who is selling the condo at the end of that period of time.

Unfortunately, in our industry -- or fortunately, depending upon your viewpoint -- the gauge is out there for 30 years, and the person who has originally signed off and said yes, I understand that there will be a disposal fee has long since retired, dead, moved on to other endeavors.

So, that transfer of information does not go from that original person who set out to buy the gauge to the person who, 30 years from now, is going to be dealing with disposal issues.

So, the intent doesn't follow all the way through.

MR. CAMERON: Okay. Thanks, Candy.

Jonathan.

MR. FORTKAMP: Along these same lines, you know, it is great that we get the regulations out and it's important that we get the regulations out, but in my experience, whenever one of our customers has a question about something, he doesn't go back and look up his regulations, he gets on the phone and calls us, and I want to tie this back in with what we started this morning with, and that's a compatibility issue.

When it comes to -- these guys are calling us. For us to respond to them, are we going to have to go and look up one of 32 different sets of regulations that we need to evaluate?

If we can reach a level B compatibility, we are much more familiar with the regulations, whether it be the NRC or any agreement state, and then we can relate that information to the customer, no matter where he is, or if he spans many states.

You know, we have many customers that are in multiple states across the agreement states, NRC. We can relate that information to a single person in charge and give them correct and accurate information.

Generally my first response now with many questions in agreement states is, well, let me get the information and go look up the regulations and get back to you, and it's not a productive effort.

With the level B compatibility, we could -- it would be much more homogeneous for us as vendors and generally as the primary consultant to the end customer.

MR. CAMERON: Okay. Thanks, John.

Joe, I don't know if you want to say anything at all before we break, but I didn't want to forget the invisible people out there. Do you have anything to add?

MR. CLINGER: I agree with most of the comments I've heard out there. There is some confusion sometimes on the part of the vendors, as well, in terms of the general license.

We've had a couple of instances recently, and one resulted in a request for a hearing and is taking up a lot of legal time, and that is the customers out there, the general licensees, feel like they are working under the vendor's general

license, and they don't realize that they themselves are general licensees and have to comply with a lot of requirements.

So, even though we've been doing this for many, many years, there's still some companies out there -- and I think it's the salespeople that are putting out some erroneous information that causes problems.

So, once we get in touch with the radiation safety officer, they're able to straighten it out.

With all these problems, with the differences in the regulations between all the different states and then confusion on the part of the salespeople, I can see why the general licensees are having problems.

MR. CAMERON: Okay. Thanks, Joe.

We're going to take a break and try to be back around 10 to 11. That gives you a little bit more than 20 minutes.

Just one caution for all of us is that we're walking sort of a fine line between -- it's really good to have examples from your experience about why things might not work.

If those examples involve anything that might suggest a violation of the regulations, let's please keep it in the hypothetical framework so there's no misunderstandings, and if there are other people out there from the vendor community who want to be up at the table, please see me during the break.

[Recess.]

MR. CAMERON: Okay. To just sort of do an agenda check here, the staff, NRC staff from our licensing fee section is with us, and we wanted to make sure -- we know that there could be no problems with these, but --

[Laughter.]

MR. CAMERON: -- we thought that we might have a little discussion of that now, get that off the table, so that they could go back to assessing other licensees.

[Laughter.]

MR. CAMERON: So, we want to do that, and also, the one issue from this morning that we didn't talk about that I think that we need to at least get on the table, this whole idea of criteria for registration, potential exemptions, competitive effects, etcetera, etcetera, I'd like to do that before we pop back onto the published agenda.

Suzanne from the NRC staff has some information about agreement state compatibility issues for you, and before we do that, though, we have a new member up here at the table, and I'm going to ask her to introduce herself.

Kate?

MS. ROUGHAN: Kate Roughan, AEA Technology, formerly Amersham.

We do distribute a product line to general licensees, but primarily we distribute sources that get used in the gauges that then ultimately go to general licensees, and we're at the receiving end, also, of, hopefully, disposals.

MR. CAMERON: Okay. Thank you very much.

Suzanne?

MS. WOODS: I just wanted to point out that, during the break, OSP arranged for us to get the flow chart that we referred to for compatibility levels, and what I'd like to do is -- while we'd like to move forward on our agenda, we'd like to invite you to review this and use it with the proposed rule in

hand, and identify those areas of the rule that you feel might well fall into this flow chart in another area, and to give us an area of the rule, specific requirements you're talking about, and give us something to go on, the basis that we might use to use a new compatibility requirement.

So, I invite you to do that. The timeframe for comment, I believe, ends October 12th.

MR. CAMERON: Okay. And keep in mind that, if you have questions about compatibility or any other parts of the rule that would be useful to get answered in preparing your comments, I know the staff is receptive to hearing from you either by e-mail or over the phone to get any clarification of information so that you can do that.

Suzanne, while we have you, do you want to say what the -- do you want to talk about what the -- is there anything to be said about the fee structure to just kick off this discussion of fees that you want to say?

MS. WOODS: Bottom line, there's one fee. Four hundred and twenty dollars is proposed. It is projected that it will be that amount. There are some considerations with regards to the number of agreement state licensees dropping in and out of the program.

The basis of it is essentially the cost that it will be to regulate, to implement a registration program, and provide that to licensees.

So, it is on a per-licensee basis; it is not on a per-device basis.

We are required to have full fee recovery. So, we have implemented and propose that this will probably be the \$420

per licensee as the cost that it will cost NRC to implement a registration program by a licensee.

With that, then, if there's any further clarification from the fees group --

MR. CAMERON: Okay. Let's go to discussion here, and if there are any needs for clarification, just step up to the microphone.

Okay. Chris.

MR. FITZ: Yeah. Just one clarification on the fee proposal. You said per user?

MS. WOODS: Yes.

MR. FITZ: Now, if they have several different sites --

MS. WOODS: So, we're relying on the definition of what a general licensee is.

So, I think what you're hitting on -- let me guess.

MR. FITZ: Go ahead.

MS. WOODS: I think what you're hitting on is an individual corporation may have various different locations of use, and we'll be hitting on that when we discuss locations of use in the next agenda item.

MR. FITZ: Okay.

MS. WOODS: But specifically, the current definition would provide that one license would be per location of use, so that it is conceivable an individual corporate structure, for example, might have multiple licensees and a few associated with each license.

MR. CAMERON: Okay. Other questions of

clarification on this?

Let's go to John, and why don't you step up to the mike, too?

John?

MR. PATTERSON: Just real quickly.

My understanding is it's regardless of how many units are at a given location.

Second question: The responsible individual for one location could be the responsible individual for another location -- i.e., RSO for a company could be responsible individual for multiple locations?

MS. WOODS: With regards to the first question, which is could there be multiple devices under a particular license, the answer is yes.

MR. PATTERSON: Okay.

MS. WOODS: With regards to the responsible individual, provided that they can meet the outlined responsibilities for that individual, for that corporation and corporate structure, I don't see anything in the rule that prevents that.

We'll discuss that a little bit later, and we can come back to that definition.

MR. CAMERON: All right.

Yes, sir, and please identify yourself for the transcript.

MR. GOTSCHALL: My name is Glen Gotschall. I'm from a company in Baltimore called Environmental Technologies Group. We market a device -- we have a specific license agreement with the State of Maryland, and we market a product

under a general license to various customers.

I'm not sure I understand this, but all those customers that we sell this device to under our general license will be required to be licensed under our general license.

MR. HICKEY: What I understand the question to relate to is your customers that are in states that are under NRC jurisdiction, who are already general licensees of NRC -- am I right so far?

MR. GOTSCHALL: Yes.

MR. HICKEY: Okay. If those devices have the radio-nuclides in the quantities that we have outlined, they would be required to register and pay a fee.

MR. GOTSCHALL: Okay. For those devices that do not fall in those groups?

MR. HICKEY: They would not have to register or pay a fee.

MR. GOTSCHALL: Thank you.

MR. CAMERON: Okay. And we are going to go to the criterion in a minute, as soon as we're done with the fee.

Is there any problems that anybody sees with the fee, you know, amount, who it's assessed against? We had some comments on, is it per user, etcetera, etcetera.

John?

MR. PATTERSON: There was a suggestion somewhere in the documentation there might be a small business -- difference for small businesses. Was that a question, or was that a proposal, or what's the status of that?

MS. WOODS: That was part of the discussion as to why a sliding scale was not used, the discussion behind why it

came down to on a per-license basis rather than per device, and specifically, I believe the area you're talking about -- I can find it in here for you, but I will paraphrase.

It references the differences between a small business and a large business, number of devices and so forth, so that there would be no fairness and equity attributed to a small business as opposed to a large business, and it is required for us to provide that fairness and equity.

MR. CAMERON: Any questions on that sliding scale business or any clarifications?

Do you want to come up and speak to that, and just give your name for the transcript, please.

MS. JACKSON: My name is Glenda Jackson. I work for the NRC in the Office of the Chief Financial Officer.

Just a clarification on the small entity. We do provide in our annual fee structured reduced fees, reduced annual fees for businesses that qualify as small entities.

We have a lower-tier small entity fee which is \$400, and in our reg analysis -- reg flex analysis with this proposed rule, we determined that the \$420 fee was not that much greater than that lower-tier small entity fee that we provided in our annual fee structure, and we solicited comments from those businesses that felt that there would be a significant impact on them of this proposed \$420 fee, that they could specifically submit comments on that issue.

MR. CAMERON: Okay. Thank you, Claudia. The reg flex analysis that Claudia referred to is -- Glenda, sorry -- is the requirement under the Regulatory Flexibility Act, where we're supposed to take into account impacts on small businesses.

John?

MR. PATTERSON: Just a question. The lower-tier small business fee is against a much higher specific license fee, though. I mean your smallest business tier on the specific license, which is normally thousands of dollars, drops down to 400.

So, you know, this starts at 400. Is it absolute dollars or it's a proportional? I'd argue it ought to be proportional.

MR. CAMERON: Glenda?

MS. JACKSON: The \$400 lower-level fee for our annual fees is really not a proportional fee, but it was a determination of a fee that would give those smaller gross receipt businesses a break on the annual fee. It's a true dollar amount, and we probably will be even looking at that amount in the future to see if that should be changed, but it is not a proportional fee.

MR. CAMERON: Glenda, why don't you just stay up there for one more minute, because -- I don't know if Chris' comment will require an answer or not.

MR. HICKEY: I'm sorry, Chris, but I would add, to follow up on John's comment, that that is the type of comment we are seeking, that it should be proportional in this case.

MR. CAMERON: All right.

MR. FITZ: Yeah. I think you may see more review of that, because as NDC's customers are -- tend to be smaller businesses that purchase one or two gauges, a lot of those businesses may look at what's going to happen if this regulation goes through as is and will decide to return those gauges.

If the program is going to be self-funded, then you create a lot more -- quite more burden on the licensees that are still out there.

MS. JACKSON: And again, those are the kind of comments that we are looking for, but again, we do have to recover the cost of the program, so are sort of in conflict with different requirements, and we try to weigh those varied requirements that we have to look at.

MR. CAMERON: All right.

David?

MR. BENNETT: I have a question about restructuring the fee program away from the specific licensees, and I don't know if that's appropriate at this moment.

MR. CAMERON: I think it's directly -- it's a fee issue.

MR. BENNETT: It is a fee issue.

MR. CAMERON: Glenda, do you want to come up to the table?

[Laughter.]

MR. CAMERON: And I'll be back in about two hours.

[Laughter.]

MR. BENNETT: My comment is, as I read through this, I see that the burden for paying for controlling general license program is going to be shifted away from the specific licensees to the general licensee.

Now, our product contains a nickel-63 source, which is not on the list of those that are going to be registered. So, those customers are not going to be picking up for that.

We have specific licenses and we're paying upwards to \$30,000 a year for those licenses.

Now, does that mean, by transferring that fee structure away from the specific licensee, that those people holding specific license for non-registered material such as ours are going to see a reduction in the specific licensees, as well?

[Laughter.]

MS. JACKSON: If all things were to remain equal, I would assume that that would be an outcome.

Given that the fees that we would be transferring are relatively small, I'm not sure we'll get to that point, whether we will actually see a reduction in fees or not, but the specific licensees you have on your nickel-63 device, for example, would still be paying a fee for that specific license.

It's just that currently, because we're getting the program developed for the general licensees now, we do not have applicants for general licenses to charge in today's structure and we do not have people who are registrants to charge at this point in time.

So, that's why, in our current fee structure, specific licensees are paying, but it's all specific licensees paying for that program. But in the future, we would recover those costs from the registrants.

MR. CAMERON: Okay. Thank you.

Other comments on fees, or questions?

Daryl.

MR. SHAPIRO: Daryl Shapiro of Morgan, Lewis & Bachius.

Did you consider the competitive impact on -- and

this goes to registration but it's also fees -- the nickel source that doesn't have to pay the fee versus, for instance, the americium that does and what -- how that affects the balance of competition in the industry?

I hear that the \$420 fee is perceived as small and not of great impact, but knowing a lot of these competitors, their sources are 10 to 20 or 40 thousand dollars for maybe a 30-year life source. Multiply that 420 times 30 years, I think that may put them at a pretty significant competitive disadvantage.

Lastly, did you consider making the registration process other than every year? Certainly the first year to get them in, certainly notice of transfer and other requirements, but if they're just using it as is, why do they need to renew it each year and pay that fee?

I think, in the proposed rule, you compared it to either a driver's license or an owner's certificate. Some states, I understand, do have a yearly requirement. Others -- I think Maryland -- doesn't. You have to renew it every three or four years.

What impact do you think that would have on the fee, and is it something you considered?

MR. CAMERON: And let's -- we'll confine this to the fee aspects of the question, but there is a larger question, as Daryl points out, that we're going to go to right after we're done with the fee discussion.

Glenda?

MS. JACKSON: I will address the competitive nature.

The NRC is required by law to recover 100 percent of its budget, and part of the requirement of that law is that we do assess fees for services and also the annual fees, which the general registrants would not be subject to under this proposed rule.

They would only be subject to the fees for services, and in applying the requirements for fees for services, we're required to charge those fees for the cost of providing those services, and that is what we looked at in determining the \$420 fee, would be our projected budgeted cost for this program, and we would be required, then, to recover those costs from the people who receive that service, which would be the general licensees.

So, we would not be able to look at the competitiveness between those general licensees and another class of licensees, for example.

MR. CAMERON: Okay. And there may be a larger point that drives this.

Are there questions on fees, again?

MR. HICKEY: Well, Mr. Shapiro also asked about what were the thinking of making it an annual versus a one-time fee.

MR. SHAPIRO: Or every four or five years.

MR. HICKEY: Yeah, whatever. Could Suzanne or Glenda --

MS. JACKSON: I will talk to the fee aspect of that. I will have to turn it over to Suzanne on the other aspect, but because of our fee structure, recovering costs, we've always considered the license or the registration or the approval

to be the basis for a fee, and in the rule-making process, they have determined or are proposing to do an annual re-registration.

Therefore, there are costs associated with that. That is a service provided to the registrant, and therefore, there is a fee associated with the cost of processing those re-registrations.

So, the fee sort of follows the licensing or registration process, if you will, which I will have to get Suzanne to address that part of it.

MS. WOODS: The annual cycle for registration and re-registration is determined to be in line with the control and accountability and tracking issues and the knowledge that would be attributed to licensees being aware of where their devices are, what they have, and so forth.

I believe that it was originally proposed during a stakeholder -- by a stakeholder during the working group sessions. The original proposal on which much of this registration program is structured, I believe, was even the six-month cycle. So, it has expanded from there.

MR. SHAPIRO: You don't have a registration process now. You're going to go to one, and you think it's going to work. Would it not make sense to go an every-four-year once you get people in the program and see if it works?

If it doesn't, maybe there is the need, but if you require registration in the first year, you put general licensees on notice that I think address all the concerns you have about transfer, disposal, etcetera, and then only require them to update or re-register if they change and then, every four or five years, sort of verify that things haven't.

Maybe that's a first step, maybe that works, and maybe then you don't have to do it every year and have a fee of 420 each year.

MR. CAMERON: I have a suggestion here. Since we're really getting into the registration program, which largely can drive the fees, let's come back to this issue, and I know that Mike wants to say something on that. Let's finish up with the amount of -- the direct issues on fees before we get into this.

Chris, is yours fee-related?

MR. FITZ: Yeah, it is. I would just like to find out, will there also be an inspection fee, and what will be the frequency of inspection of general licensees?

MS. JACKSON: The \$420 proposed fee was to cover the cost of the entire general license registration program, including any inspections that might be conducted. It's similar to what we do for the specific materials licensees. We no longer charge a separate fee for each inspection that we conduct.

MR. CAMERON: Okay.

Mike?

MR. RADDATZ: To finish that up, to echo what Glenda is saying, remember, it's the whole program, which includes all the FTE, our employees, to do the inspections, to do the paperwork, and do everything. Instead of going after individuals for, let's say, an inspection of 20 or 30 devices on a site, it's covered by the one-free inspection spread over the entire program.

So, there's more to it than just getting one piece of paper and being done, because they will not bill individually

for inspections, it's covered in the entire fee, and what we're doing differently that we're not doing now is we're going to go out and start inspecting, and that has to be recovered.

MR. CAMERON: Okay. Thanks, Mike, for that clarification.

MS. WOODS: With regards to inspection, presently the inspections that are being planned are those that are followup, in short, and in reactive.

In short, a reactive inspection if we are aware of an event; a follow-up inspection if we are aware that a licensee has fallen off our scope, we aren't hearing from them, they've moved, the address has changed, the name of the company, the responsible individual which is now under the current rule, contact individual, all those things have fallen off the scope and we've lost touch with them.

Those are the two planned inspections at this present time.

MR. CAMERON: Okay. Thank you, Suzanne, and thank you, Glenda, for coming up and answering some questions on this.

Let's move into what we've been talking about, registration.

Now, Daryl brought up the question of who, who has to register, what's the rationale for that, and I'm going to just ask Suzanne to just give us, you know, a brief context on that, and then we've been discussing the issue of how often, so we'll get into that, but let's get into what the criteria are for who has to register.

Suzanne?

MS. WOODS: The registration criteria are based on

the quantity of the isotope and the isotope type. So, there is a listing in here, and I'll run through it very quickly.

For cesium-137, 370 mega-bacarals or 10 milli-curies; strontium-90, .1 milli-curie, 3.7 mega-bacaral; cobalt-60 is 1 milli-curie; and transuranics are 1 milli-curie.

So, if they have these amounts, or exceed them, in the device, then it is required to submit for registration.

MR. CAMERON: Okay. Well, let's open that up for discussion. I think we've already heard about the aspect that there may be negative competitive implications from this, but does anybody have any comments on the criteria that were used to set who has to register?

I mean do we have a good rationale for that? Are there other isotopes, additions, deletions, whatever? Anybody have any comment on it?

David.

MR. BENNETT: Just a quick comment, question.

Nickel-63 isn't on this list, and I'm sure there are others. Why am I paying \$30,000 a year in licensing fees? Why have these others that are not as great a concern?

Why are we going to have to continue paying license fees and go along with all the other regulations in here -- the record-keeping, the reporting, and on and on and on? It costs us a tremendous amount of money to operate.

I think that they should either all be in there or take a look at these things and say, hey, you know, maybe this is just too much, this is overkill for this stuff.

MR. CAMERON: So, you're, first of all, questioning whether there should be a selected group at all

rather than all, and secondly, you're saying that -- questioning whether the criteria -- if there is going to be a selected group, whether the criteria are related to public health and safety?

MR. BENNETT: No, I'm just wondering why, if nickel-63 and others that are not on this list are going to have to be regulated, why do we have to follow all the other things if it's a safety-related situation or issue?

It seems like you have this tremendous structure here for all devices, and then a portion of those, we're going to go the extra extent and make you register, and we expect it, but the rest of them still have to follow some other stuff.

It's really safety-related. Should we re-evaluate the needs or the requirements that you're placing on the people that are not a part of that list?

MR. CAMERON: So, your point is, if they don't -- if there are certain devices that don't have to be registered, maybe they shouldn't be subject to the rest of these regulations.

I guess I'll ask Sue.

MS. WOODS: NRC relies you as a specific licensee to follow those procedures and put in place those practices that are specified in the regulations to assure that a general license is issued to nickel-63 users, as provided in the regulation.

That is what your specific license does, and I can't speak to the fee amount, but it is those provisions in the regulations for the specific license that does allow us to provide a general license to your customers.

MR. BENNETT: That's not answering my question.

MS. WOODS: Okay.

MR. CAMERON: Okay. I guess it also points out

the fact that the competitive effects may not be as stark as perhaps they would look, since even those who aren't subject to the registration program still have a large body of regulations.

Doug, do you want to also speak to David's concern?

MR. BROADDUS: Yes. One thing I want to point out is that the registration is not saying that any other device that is not subject to registration is not subject to a general license anymore.

What we're saying is that all the other devices are still subject to the same requirements. We still think they need the same level of oversight.

What we're saying is that those that are subject to registration require an additional amount of oversight. So, those are what is being charged a fee for that additional oversight, and they've been selected based on a risk, the cost for disposal or cleanup if they get out into the public domain, the direct exposure risks.

There's a number of different risks that were looked at when determining the criteria for those, and what we're saying is that nickel-63 is below that level, but it's still subject to general licensing requirements.

So, that's why you would have to continue to still have your license to distribute that generally licensed device.

MR. CAMERON: Okay. Thank you.

Let's go to this issue of who's in the lucky group to be registered. Any comments on that?

Daryl, do you want to restate your concern?

MR. SHAPIRO: Now I have a new question.

MR. HICKEY: Okay.

Let me at least come back to your question about the competitive issue, and I want to hear more comments about our criteria, but the principle is that the people who supply or use the riskier devices impose a higher burden on society and there's more regulatory effort on our part to regulate those devices.

So, people who have chosen to use the riskier devices are going to have to pay a higher price than the people who choose the devices that are a lower risk.

So, that's the principle, but we're open to comment on how we apply that principle.

MR. CAMERON: Okay. Let's go to Daryl, and then we'll come back to George and Elsa.

MR. SHAPIRO: Well, that's right.

The problem is, as a customer, you know, your annual fee is borne by the producer, the distributor. That doesn't enter into my calculus, but as a customer, if I have a choice between device A that meets the requirements and device B, this may push that decision quite clearly to the other side.

While we're talking about registration, you certainly use quantity, type, ergo risk. Did you consider use?

Did you consider the difference between a fixed source in a manufacturing line versus a portable source? Did you consider a company who sells a source that commits to taking it back for disposal or transfer versus one that doesn't?

Trying to marry up the registration, the fees with the underlying purpose -- and I think we all share the concern about lost and orphan sources, but if there are some sources that, even though the type itself provides a risk, if they way

they're used, the way they're taken back somehow nullifies that, did that enter into the registration calculus?

MR. CAMERON: I want to make sure that everybody, I think, understands.

The suggestion is -- and I think that it's the type of comment that the NRC is looking for, whether they have considered it or not, but going to John's underlying risk objective, are there other criteria besides just the isotope involved that should be considered in setting that registration criteria?

John, I don't know if you want to say anything at this point or whether you want to hear some other comments first.

MR. HICKEY: Let's hear a couple more comments.

MR. CAMERON: Okay. George and then let's go to Elsa.

MR. BROWN: I wanted to address the one question that might cause some confusion about whether there is a need for compatibility of isotopes, if you compared a nickel-63 to a cesium, let's say, that, really, it's going to be a competitive issue, because the application defines what isotope that you use.

So, it doesn't really make any difference, for instance, in measuring density and level gauges, a lot like Ralph and I do. We're going to have to use higher-energy, cesium, cobalt sources when measuring inner, lighter materials.

You can use strontium, something like that, or krypton, which isn't on the list, which a lot of the paper industry use.

So, the fact that we have a pretty defined list I don't think creates a competitive disadvantage. In the working

group sessions that we had in '96 or whatever, we did a lot of discussion of this to make sure that we don't have a competitive disadvantage.

On the idea of competitive disadvantage, I want to point out the need for a general license is a competitive -- or the lack of not having a general license would be a competitive disadvantage, because there are non-nuclear alternatives out there.

So, it is imperative for us to compete with non-nuclear sources to have a safe means of making, distributing, and using GL devices.

So, having -- because the question came up in those groups, should we eliminate the GL device altogether for this group, and that would be -- competitive-wise, it would be quite a burden on us, with no real gain to the industry.

For most of our devices, somebody can get a specific license if they want, and still buy them -- the fees become a little higher, they can do differentiate things. So, it doesn't have to be just a GL, it can be both.

MR. CAMERON: George, just as a point of clarification, when you say non-nuclear, what do you mean by non-nuclear?

MR. BROWN: It could be a microwave. It could be an x-ray device.

MR. CAMERON: It could be non-Atomic Energy Act material.

MR. BROWN: Right.

MR. CAMERON: Okay.

Else?

MS. NIMMO: I had some question about -- the devices -- or the isotopes that are on the list, the ones that tend to be more of concern for toxicity, for contamination, tend to be ones where the sealed sources are more robust than, say, a krypton-85 source would be, and frankly, I'm a little surprised at the low level that is set for, say, strontium-90.

Strontium-90 is clearly a problem if it's loose in the environment. On the other hand, the encapsulation that's used in practice is a lot more robust than would be in some other source, and I don't know how much that played in.

I certainly was there when a lot of the discussions of the criteria were set. I don't remember much discussion of encapsulation.

And I have a second question that has persistently come up during the working group sessions, and that is we're focusing very much on the GL devices for this list of isotopes.

We have specific licensees who may be renewing their licenses at rather infrequent cycles -- four years, seven years. We're not asking them to inventory and report back to the NRC that they have their strontium-90, their americium, their transuranics.

I still see a discrepancy. I fail to believe that the GL devices are the entire problem.

MR. HICKEY: I still want to hear more discussion on the first point, but the second point is that the specific licensees have applied directly to NRC, and in many cases, they do have requirements to conduct periodic inventories and report to NRC if the devices are missing. So, the general principle is the specific licensees have a direct relationship with NRC.

MR. CAMERON: Okay. That's the rationale for the second point.

The first point, the encapsulation issue, I think, goes to the general point that was raised earlier about criteria that don't involve the toxicity of the isotope, should those be factored into the process, is a suggestion that you're making, also, Elsa?

MS. NIMMO: Well, just that I don't recall that there was much discussion of the encapsulation and how that plays into deciding which isotopes and at what levels.

MR. CAMERON: Okay.

Any other comment on the criteria?

Suzanne, John, do you have any questions you want to ask about that?

We do have -- still have this question about -- that we should deal with about how often, before we go on.

Doug?

MR. BROADDUS: I did want to make a comment about sealed/unsealed sources and the criteria.

Both americium and strontium, you know, are not high direct radiation hazards when you're talking direct exposure. I mean they're not high hazards from that standpoint.

However, when you do remove the encapsulation, they do become much greater hazards, and one of the items that we are very concerned about is that, if we don't have control and accountability for sources in these devices, that they can get into the public domain and get anywhere, including scrap recycling facilities and to general members of the public, where they can very easily become unsealed.

So, that is something that we have considered, is members of the public, you know, getting access to these sources and making them unsealed and looked at it from that standpoint, and in addition to disposal for americium -- americium is definitely a disposal problem, as well, but strontium is definitely a problem if you -- if we get it unsealed.

MR. CAMERON: Okay. Thanks, Doug.

Let's go to Suzanne, then we'll go over to Kate.

MS. WOODS: I think Doug is hitting on what I wanted to emphasize, that much of what I understand the working group -- and I was not part of it -- did and the criteria they established was based upon real events that occurred, and so, there are opportunities, once a device and, in particular, the source is available to the public or out in the public domain, for either smelting it or grinding the source and so forth.

Additionally, there are devices which remain in place, and those buildings get sold, and those devices could become open and provide exposure to individuals who unknowingly know that that is a radioactive device, regardless of whether the source has become separated at that point, and the source, of course, would have to be inside, but those types of circumstances do still occur.

MR. CAMERON: Thank you, Suzanne.

Kate?

MS. ROUGHAN: Just a couple of comments.

I mean one of the reasons the NRC has a general license is that the device and the source basically is inherently safe; people can use it without specialized training. So, even if it does get into the wrong hands, supposedly you cannot get

excessive exposure from it.

The second comment is that the source encapsulations -- most of the sources that we manufacture either are double or triple encapsulation. For someone to get access to the actual radioactive material, they'd have to basically un-weld the capsule. These aren't screw-top capsules in most cases. They're triple or double encapsulation.

You can't inadvertently open them up and they stay contained. So, I think that should be a consideration in what does need to be registered, because a lot of them also meet ANSI requirements, special form requirements.

MR. CAMERON: Okay. That's a suggestion that should be considered. There may be other aspects of encapsulation other than how easy it is to get off, but that needs to be considered.

Do we want to finish up on this -- how often the registration should be?

Daryl, are you suggesting that it should be every three or four years or what? Do you want to just briefly put a fine point on this, and let's go to David for comment.

MR. SHAPIRO: It relates directly to the fee, and as I hear today, the fee includes the paperwork, the processing, the maintenance of the file, plus the inspection of new events, reactions, or maybe not filing the registration.

All of that seems to be easily reduced by extending the period of time. Once you get a general licensee in the system by a first-time registration, I don't understand or I haven't heard the need to re-register every year versus every, for example, four years.

You could put general licensees on notice in the initial or original registration that, should you transfer you have to notify us, should you dispose of it you have to notify us, if you take it to another location you have to notify us, if you change your responsible individual you have to notify us, and by doing away with annual and going to some period of time, can you substantially then reduce the fee and, therefore, the impact competitively on both the vendors and the purchasers?

MR. CAMERON: Okay. So, initially and then on the occurrence of specific events.

Sue, do you want to ask any questions on that or provide the rationale for the annual fee, or Doug?

Go ahead, Sue.

MS. WOODS: I guess the questions that come to mind when I'm listening to changing the cycle are some real-world kinds of things that we've encountered and that is falling off our scope.

Licensees move devices, especially portable devices move. How do we track them?

We have an issue right now -- and it's on the agenda to discuss later -- about intermediate persons. We've heard discussions of how a device transfers from a distributor to an intermediate person. That person may have it in their stock for however long -- we want to discuss that with you -- and then it transfers to someone else, and it may actually even transfer to another person before a year is over with.

How do we track those individuals? Those questions come to my mind.

We have a mailing that has gone out to individuals

recently -- here's a real-world example -- where somebody had the device only for three months, they were in our system for about three months, and they no longer had the device anymore when we went sent them the mailing, the mailing being the proposed rule that you have before you.

So, that's how quickly this stuff happens. How do we deal with that?

MR. SHAPIRO: I'm not suggesting that any of those examples should be exempted from the rule, but those are all triggering mechanisms that should require a report. But for a general licensee who simply keeps using it year after year, does not transfer it, does not change the responsible individual, does not dispose of it, why go through the process each year? Why re-register them?

It would seem to me, by registering them initially, you get them in your system and you put them on notice of their regulatory responsibilities. You know, if someone's going to violate it, someone's going to violate it. If someone wants to purposely drop off the face of the earth, they will.

I don't know that re-registration every year is going to help you much there.

MR. CAMERON: Okay. Let's go up to the table here, to Chris on this issue. You heard from Suzanne that the rationale for annual registration is tracking. So, in your written comments on this, you might want to focus on whether the rationale of tracking can be satisfied in some other way than annual registration.

Chris?

MR. FITZ: Yeah. I think what we're doing is

we're basing the new regulation on history, how it's happened in the past, and what we're trying to do with the new notification, the new responsibility that the vendors have to take on, is to increase that oversight.

Right now, currently, as John pointed out, specific licensees have an obligation to report if they lose a device. Don't the general licensees have that same requirement currently?

MS. WOODS: Yes.

MR. HICKEY: They have a requirement. It's not the same. The specific licensees have to take an inventory every six months, and if they're missing it --

MR. FITZ: So does general licensees.

MR. HICKEY: The point I was trying to make is the specific licensees, in order to get that specific license, have to apply and go through a certain process to establish the relationship with NRC, and that was the difference.

MR. CAMERON: Okay. Let's go to Jonathan and then David.

MR. FORTKAMP: The rule is already in effect that the general licensees are required to report transfers, to report movement or change of name.

Those rules are already in effect, and if they aren't being followed up now, I guess I'm not sure that the intent of the rule is going to be followed through with just new rules.

MR. HICKEY: I think that's a reasonable comment, but I think if they have to write a check every year, they're going to think more about it than they're thinking about it now.

But I think your comment is reasonable.

MR. CAMERON: Let's go to David.

MR. BENNETT: We have the same process in-house that we're talking about with registration and annual registration.

We do it on a monthly basis, and there's a big difference between telling our internal users that you have the responsibility for notifying us when you change or do something versus our going to them on a monthly basis and saying tell us that you still have this.

The customers -- historically, the customers are not paying attention to the regulation. If the regulation says you've got to notify us of the change, they're not listening to it.

Going to an annual program where the NRC contacts the customer and says verify that you have these things and that it's still under the control of so-and-so and so-and-so is a very different impact. I'm 100 percent for an annual program.

I wouldn't be complaining if they did it on my nickel-63 customers a bit, because historically, we see the high turnover of businesses, and we see a very great lack of understanding of requirements trailing down the line of the history of the product.

It's not the same as telling a customer, well, when you change, notify us of it, because they're not going to do that, but if you go to them on an annual basis and say here is what you're responsible for, here's the people that it's assigned to, and here's the location where it's supposed to be, verify it, and having to pay the fee -- to me, the fee is not the issue. To

me, the issue is the traceability, and an annual program such as this provides it for them.

MR. CAMERON: Thank you, David.

I think we probably have exhausted this, but apparently not completely.

[Laughter.]

MR. CAMERON: I think we're getting comments on both sides of this, and before we go, I'd at least like to get us to the discussion of the next agenda item before we break for lunch, and I wanted to ask Joe Clinger from the State of Illinois -- Joe, do you have any comments at all on the fee and registration criteria discussion that you've been listening to?

MR. EWING: Joe had to leave. This is Mike Ewing. Can you hear me?

MR. CAMERON: Yeah. Hi, Mike.

MR. EWING: Our program is a little different than what you envision, but we have found that an annual contact of some sort is very important to keep up to date with what the general licensees are doing.

MR. CAMERON: Okay. Thank you very much. I think that sort of follows on on what David was saying.

Final comment from Jonathan?

MR. FORTKAMP: Just to follow up on what I said before, that it hasn't been done previously, I think we're really stepping up the burden on both the NRC and agreement states, and I just have real doubts that it's going to be followed through, that the annual reports are going to be cross-referenced to our quarterly reports of distribution, cross-referenced with receipts, transfers out are going to be cross-referenced with

transfers in. I just don't see it happening. It's a real novel concept, but in effect, I don't see it happening.

MR. CAMERON: Okay.

Sue, did you want to lead off the next topic for us?

MR. HICKEY: To tell you the truth, Chip, I'd like to talk more about this, and I want to bring in the issue that people brought up earlier about exemptions, because I think it also -- it gets us to the comments on the types of things that people feel that either it would be additional exemptions or changing the criteria.

So, maybe we should just go ahead and break for lunch and then come back.

MR. CAMERON: Let's try to finish this off.

MR. HICKEY: Okay.

MR. CAMERON: Okay?

MR. HICKEY: Some people had some concerns -- or if there are any additional comments on exemptions other than the comments that have already been made about if the sealed source is robust -- are there anymore comments about -- where the proposed rule captures your device but you have a reason why you don't think it should be required, registration, other than the reasons that have already been brought up?

MR. CAMERON: I think we probably had a pretty good discussion on that, but Suzanne, you had one final comment you wanted to make?

MS. WOODS: I actually think this feeds into a good deal of the discussion for this afternoon, so I would like to address a little bit what you've said.

It has been our concern, too, that we can track all this. So, we have put into place a new computer system.

Presently, we have something called the general license database, and when you all submit your transfer reports to us, quarterly and annual reports, we enter that into our general license database, and that, hence, is then where we've had our mailings that have gone out to people and been returned to us.

So, we had a one-time-only notification of a device going to a general licensee and going into our system. That is where we are now.

Where we're moving to is a general license tracking system. The general license tracking system will take all of the transfer reports, just as we do now, and enter them in. It will create a table of information, and we will have an automated form that will go through a scanning process and be automatically entered into our database.

When that form is mailed out to your customers, to our licensees, it will have in it all the information that you provided to us on the transfer form, transfer report, and it will be filled into the appropriate blank on the registration form.

The licensee will then be asked to either verify that information be true and sign to that effect or provide the correct information.

So, this afternoon, one of the topics we'll be getting into is discussing how we're going to deal with all that and the phone calls that both you and I are going to get over it, okay?

But I would like to assure you that we have put in

place an automated system to try and track all of this and cross-reference it, being able to even so much as do specialized reports, that we might have specialized queries of things we think would help us, also to help us with event searches and so forth.

So, this is a sophisticated system.

MR. CAMERON: I don't want to get us into this afternoon's subject, and I think John may have had a good idea about maybe this is a logical time to break for lunch and come back and do the -- start off the reporting issues, but let me ask you about that, and Jack, did you want to talk about this tracking system that's been brought up?

MR. RAMSEY: I just wanted to ask one question, clarify something in my mind.

MR. CAMERON: All right.

MR. RAMSEY: Is this tracking system -- are we talking about both sources and devices or a combination of sources and devices or just sources or just devices?

MS. WOODS: It's the information required for transfer reports in the proposed rule. There are some -- there is some information in there on sources. Am I correct? No, there is not. No. So, it's just the information that's come to us during the transfer reports we've already received and those that we'll be receiving as a result of this rule, as it's proposed, if it were to go final.

MR. CAMERON: Let's revisit that to make sure that that's clear when we get to that discussion.

Are you ready for a break before we start reporting? Want to take a lunch break? Okay. Let's do that and

be back at one o'clock, and we'll go into reporting information issues.

[Whereupon, at 11:55 a.m., the meeting was recessed, to reconvene at 1:00 p.m., this same day.]

A F T E R N O O N S E S S I O N

[1:07 p.m.]

MR. CAMERON: We're going to go to the topic of reporting, reporting information issues, which you see at 10:45 and at 1:00 on the agenda.

Now, the first issue we wanted to address is location of use, and I'm going to ask Suzanne to give us some context, and I know that one issue -- I talked to some of you -- that fits in here that isn't on the agenda in this whole topic of reporting is how do you define replacement.

So, let's make sure that we get all the issues out here, because we're hear to listen to what your concerns are, and we don't want to drive this too much.

Suzanne?

MS. WOODS: Location of use, on the surface, seems like a fairly simple concept, but when we've tried to deal with some of these issues that I'm about to highlight, you'll see where we could use some assistance and insight from you.

Specifically, we'd like to establish a unique address or a unique mailing address for each location that is associated with the license. So, each license would have a separate address.

The proposed rule states the general licensee -- or general license address is specified as the mailing address for the location of use of the generally licensed device.

The issues associated with that is that, for example, you could have a corporate structure where the mailing is in, you know, city A and the device is actually located and used in city B, and yet another device is in city C.

So, you see that both of them would have the same mailing address, and it may go as far as city A and B, where the devices are actually located -- they may be on such things as pipelines or in particular locations where there is no actual deliverable mailing address.

So, you can see how this starts to become a little bit more complicated. Let me go on.

If you look at our current system, the general license database, we have these two types of information that I've just specified -- we would have a location where it's actually at and a mailing address for it, and then we also have another piece of information.

For example, if it's on a campus, it may be building X, floor seven, laboratory nine. We have some very detailed information.

So, we go from the very detailed or more -- or less -- rather, less detailed.

That detailed information is useful for things like inspection and event response. We certainly need a mailing address that we can correspond to licensees with, but we also need a unique address for the license so that we don't double-bill anybody.

We send a fee along with the registration form. It's a request for payment that goes along with the registration form. So, we want to make sure that we can cover all these areas and do so within the definition of location of use.

I'm going to add a little bit more complexity to that.

It's come to our attention that fixed gauges are

on mobile devices. So, how do we determine the location of use?

By definition, location of use is, for a portable device, the place of permanent storage. Other than that, it's the place where it's used. It's a fixed device. So, how do we reckon that issue in this discussion of location of use?

Additionally, if we're going to talk a little bit about fixed gauges, we're also interested in knowing how often this occurs, how much of an issue is it with the fixed gauges on portable -- on mobile devices -- trucks, boats, and so forth, and do we actually need to clarify what we mean by portable and what we mean by fixed?

So, these are all related issues. I threw them all out here at once, so you can consider them and provide us some insight as to what you see will work. We'd appreciate hearing from you.

With that, I'll open the discussion.

MR. CAMERON: Okay.

I asked George Brown to sort of lead us off with at least some of these examples of these types of problems from at least one or several industries that he might work with.

George?

MR. BROWN: Well, a couple of specific industries that fall into the questions you have, that we have questions about how to handle -- the mining industry, for example, you'll have one mining -- maybe one engineering shop that is the headquarters for seven or eight mines in one location, and you'll have devices at all of those locations.

You will also have issues with those mines, that the mines will not always be used. They may shut them down for

an extended period of time and then start them back up again.
So, the storage at a location issue could come up.

On the mobility issue, probably the most extreme example would be on a barge used for dredging, dredge barges.

They used to have a dredging company that owns the barge, who bought the gauge and put it on the barge and then leases it to people to do canals, channels, whatever, and that company could easily be in Alabama and the barge could be on the inter-coastal waterway, just about anywhere, moving from jurisdiction to jurisdiction.

So, those are some locations of things that -- basically the kind of questions you brought up, and how do we handle those?

One regulator I talked to in a state said we'll make it a specific license. Well, it doesn't solve the problem because it still is moving around in whatever jurisdiction it's in. So, you can have a lot of problems with moving.

As far as how we as a manufacturer look at the issue that you've questioned about mobility and portability, I've always taken the stance that a fixed gauge, when mounted in position, maintains the same geometry between the detector and the source, so it can be surveyed and inspected to be safe in that location.

So, you can't change the source detector location. A portable gauge you would move the source detector around, and then a portable gauge could be on a mobile device, which could be a truck or a barge, but it could also be, within a plant, a belt scale on a crane that moved back and forth. Something like that is mobile also.

And those are -- when pressed by -- and it happens. I mean, you know, people go to get inspected and then they say, gee, you know, how come you solved it like that and they say, well, this was my interpretation of what fixed and what mobile is.

So, that's how we've addressed those issues, at least.

The issues of mining are just pipeline, kind of pin each one of those down, and most of the time, by today's rules, we get the address of the person, the engineering office, where somebody will be, because that way, when they call for inspection or information, there will be somebody here.

So, a maintenance shop, which might even be closer but if isn't manned all the time is not the location to put, because the people want to have a location that you can contact.

MS. WOODS: So, what would be the location for a barge?

MR. BROWN: Yeah. The places that have those now, the company that leases the barge, who is operating the barge, the operating company for the barge, who has control of the device, is how that was handled with the agreement states, not the person who -- that comes to some of the issues of all this reporting and time.

You know, this company builds a device to use a GL gauge on it, and you ship it to the barge manufacturer. I mean they are the purchaser. You know, they are the people that you need to notify or the person that they lease it to, and then is that lease a transfer? Ownership didn't change. The name changed. It can become kind of a nightmare.

On the barge issue, we try to go with the operation company, the company that's going to have operation and control of the device.

The mining industry, it's pretty simple, because they tend not to move around much, they stay pretty put, but they change names a lot.

MR. CAMERON: Let's hear from John and then we'll go to John Patterson and Ralph.

John?

MR. HICKEY: Ralph was first.

MR. CAMERON: Okay.

Ralph?

MR. HEYER: To add to what George was saying, we have two units that we consider portable units that are fixed on pumper trucks or dredges. The pumper trucks become mobile. Yet, it doesn't affect the geometry of the particular source head configuration.

We have discouraged companies to purchase these units as generally licensed devices.

We've encouraged them to be specifically licensed, because in essence, they're attaching those particular units onto a mobile operation, whether it's a dredge or a pumper truck, that goes from one location to another or may be sold as part of equipment to another company, and I personally have defined that as a GL redistribution which is not allowed by the end user.

So, we've gotten large companies to agree with that, for that reason, the accountability, location of use, and traceability.

For those companies that prefer not to go that

route, we've asked that they give us the responsible individual who is tracking that -- in essence, a utilization log.

Where is that particular unit on that dredge, dredge number such-and-such or barge number such-and-such, and that's the information that we try to obtain at that point.

Whether it works in a real-world situation, it hasn't often, but it does give a starting point.

And the last comment that I have is the issue of general licensed devices and a little known fact that they are not exempt from transportation responsibilities, and so, when those particular units are put on a pumper truck or put on, you know, a dredging operation that becomes mobile, they have to abide by the DOT bill of lading and shipping and posting requirements, and our little 10 CFR 31.5 exempts them from everything except that little part on transportation, and with the agreement between the NRC and DOT, that's becoming more and more an issue where the Department of Transportation is enforcing that in the field.

So, we have a training issue, an issue that needs to be conveyed, that I believe NRC needs to take a leadership role on that.

MR. CAMERON: Okay. And let's make sure we come back to that particular issue.

Let's go to John and Gary and then come back up to the NRC staff for a question.

MR. PATTERSON: Yeah, I guess one of the questions I had, Suzanne, is you're worrying about the address of the device, but the new regulation has this responsible individual clause, which is really a new addition.

Isn't it that individual's address that you need, because -- I mean some of our generally licensed devices are portable. It's that individual who ought to know where it is.

I mean that's asking a lot, I do understand, but you know, theoretically, at least, and in practice, I would hope, that's how you find out where the device is at any given time.

MR. CAMERON: Is that a potential solution, to focus on the responsible individual, rather than the location of use? Is that what you're suggesting, John?

MR. PATTERSON: Yeah. I mean that's why you've added the responsible individual, isn't it?

MR. CAMERON: Okay.

MR. HICKEY: I was going to make the same comment, that there's two aspects to this.

As far as accountability, what we really want is the responsible individual who, in turn, can tell us where the devices are, whether they're at his site or her site or at some field location in a barge or in a mine.

The other aspect, though, to this is the collection of fees, and I think we're going to have to give more thought to how we define a location for the purposes of assessing a fee.

MR. CAMERON: So, there's two purposes to the location. One is tracking and one is assessment of fees. All right.

MS. WOODS: Location of use essentially equates to this is a license, and now, when you've done that, now there's a registration.

MR. CAMERON: Okay.

Before we go to you, Suzanne, I want to give you an opportunity to react to a lot of what was heard.

Let's go to Gary and then to Elsa.

MR. CAINES: A little bit more extreme situation where you have fixed gauges mounted on a mobile unit -- we sell a lot of devices that are mounted on aircraft.

These not only move between jurisdictions in the United States but internationally, as well, and lots of times, the ownership of these airplanes -- there's a lot of holding companies, a lot of people in between. Sometimes it gets really muddy as to who actually is responsible for some of these things.

MR. CAMERON: Would John's suggestion about responsible individual -- would that help in that circumstance at all, or would it just be as difficult?

MR. CAINES: It might. I'd have to think about that.

MR. CAMERON: All right.

Elsa?

MS. NIMMO: 3M couldn't have a representative here today, but they're one of our major customers, and I guess I'm trying to speak to their concerns.

They have a very strong corporate radiation safety office, as you probably know, in the Minneapolis-St. Paul area, and I looked very carefully at this responsible individual and the fact that the NRC said they didn't need to necessarily be physically present at the location of use, and I know that that's something that 3M would be extremely concerned with, but I do see the one problem.

If their responsible individual for all of their

U.S. plants is located in Minneapolis, when you're trying to, for the purpose of fee collection, figure out the different numbers of general licensees, there are going to be a number of them who all have the same, presumably, responsible individual who's located in the corporate location.

I think, from my standpoint, having worked with 3M over a number of years, I think they have one of the better radiation safety programs, and I'd hate to see the rule not allow it to have a centralized corporate safety department the way 3M does, because I think it's highly effective, but it does leave you with the -- okay, now you have many general licensees with different locations of use, perhaps reporting to responsible individuals much smaller number, possibly even one person.

There are no solutions in my comment. I just want to make sure that the situations that have a corporate individual like that -- that it doesn't get undermined, because I think it would be detrimental to their safety program.

MR. CAMERON: Can you explain why you think that that centralized program would be undermined because we focused on -- because of focusing on the responsible individual? I wasn't sure if everybody had that.

MS. NIMMO: If you said you must have the responsible individual be linked physically to that site, they must be physically at that site, then the correspondence between the NRC would go out of their corporate headquarters and go to the individual locations, and it leaves that corporate office out of the loop. That corporate office is extremely effective in dealing with their locations, and I think it would be a shame to undermine that program.

MR. CAMERON: Is the idea of the responsible individual either in our proposed rule or in the concept that John was putting forth -- I don't know if they're different -- is that assumed that the responsible individual would be physically at the same place?

MS. NIMMO: No, it does not.

MR. CAMERON: All right.

Suzanne, I'll turn it over to you. You've heard a lot of things. You must have a lot of questions, comments.

MS. WOODS: I think you make a good point. Regardless of whether it's the responsible individual or one central mailing address, how do we identify location or unique something that we can tie as a general license so that we can say this is a license here, this is the license here, and so forth?

How do we gather that information, as well as all the information that you -- some of you have been providing, you know, the details, lab number nine on floor seven. How do we gather that information?

How do we structure this definition so it's clear to you and something that will facilitate your efforts in gathering this information for the transfer reports? It has to be clear to the licensees.

MR. PATTERSON: The problem I have is your floor five, lab seven is not the definition of a license. That's a definition of the location of one instrument covered by a license.

MS. WOODS: That would be on a campus setting. The locations of use are referred to as a campus setting, where there are a number of facilities and a number of devices,

particularly in a campus-type setting. That would be one location of use, considered one license, under the proposed rule.

A corporate structure with multiple devices used in various locations, whether those are fixed devices, those locations would be considered separate licenses, and if they're portable, it would be the place that they're stored on a permanent basis.

So, those are the three types of structures fore equating a license to, but how do we prescribe an address to them so we can communicate to them and so that we can identify them uniquely as, in fact, a general license, so we don't cause our system to send out multiple registration requests with attached fee requests for one license.

MR. CAMERON: Anybody have any suggestions on that?

MR. PATTERSON: Doesn't it come down to a judgement call? I've got a specific example.

We have two buildings that are half-a-mile apart. You know, people walk back and forth between them. Is that one facility? If I have generally licensed devices in both buildings, is that one license or two? You've got to put some human judgement into this thing, I think.

MS. WOODS: Is the definition in the rule clear enough to support that type of judgement call?

MR. CAMERON: While people are thinking about that, let's hear from Kate.

MS. ROUGHAN: We have more experience with industrial radiography, and it's kind of a similar situation, where they have a specific license, but they can go out to

temporary job-sites and they can have multiple storage locations on their license. There's one annual fee for that, and there can be 60 devices on that license. There's one person responsible. It seems like it's a very similar situation.

MR. PATTERSON: In that case, it's up to the end user to define it.

MS. ROUGHAN: That's right, yes.

MR. PATTERSON: I guess, going back to my judgement, it's the end user that makes the judgement.

If I were submitting the application, I would say those two buildings a half-a-mile apart are one facility. I guess you get to review it and say, hey, wait a minute, you know, they're 10 miles apart, that's not one facility, you know.

MS. WOODS: Okay.

So, what I'm hearing is, for those types of things that are fixed, that are falling within the definitions of the rule, are things like it would be a judgement call, the rule language would support that judgement call, and that judgement call would have to be made by the licensee in providing that information to you for the transfer reports that are provided to us. Is that a correct characterization?

MR. CAMERON: John is still thinking about this, I guess.

Do you want us to go to George?

MR. PATTERSON: Yeah, go to George.

MR. CAMERON: Okay.

MR. BROWN: The uniqueness of a general license is the end user relies on us, the manufacturer, for almost all of his input.

To say this is going to be the responsibility of the person buying the gauge -- and I am opening up more work for a manufacturer, but the chances of having them understand the rules clear enough to know this location issue -- it's going to be up to us, the manufacturer, to specify to them what it is, and what will happen is they will ask us, the manufacturer, us, okay, you're going to sell us a gauge, what do we have to do, and you have to notify.

Well, do we notify for one location or two locations?

So, the judgement call, I think, is going to come down to the manufacturer. It's not going to be the user. The distributor of the general license gauge is the person that's going to have to be familiar with the rule and make the judgement call.

Now, I don't know how that relates with enforceability, whatever, but it's going to have to be the distributor who decides what they tell the person to fill out.

MS. WOODS: How difficult would it be to provide all three types of location information as I described up front, the real specific stuff about a lab on a certain floor, which is the actual place -- let's just, for sake of discussion, call it the actual location of use, and then have a mailing location of use, and then, if it is a campus-type setting, that would be the licensed location of use. Could you collection that information? How could we best facilitate getting that information?

MR. CAMERON: Does this go -- picking up on something in response to that, what George said and what Ralph said earlier about company-by-company agreements -- I mean is

that the way -- is that the only way that this can be done? In other words, leave it up to the discretion of the manufacturer?

MS. WOODS: Well, I just broadened it out to not only be what George was referring to as location of use and having to make a judgement call but that we found these other pieces of information are useful, as well, and I'm asking would it be difficult to collect all of the information.

MR. BROWN: The gauges that we sell, a mailing address of how to get hold of the person and a plant location, a plant address should be relatively easy, but to pin it down to a use location, that could be a problem, because it's very tough to define a use location inside a facility.

I mean how do you define, you know, a gas pipeline, you know, I mean high caustic return line or something like that between two vessels? So, it's not like a lab, you know, location.

Yes, a fixed location at a plant, they could find it, but I don't think -- and I don't think you need the detail.

The reporting requirement is going to come from us anyway. I mean we're the people that are going to have to submit in the quarterly report that information. So, it's going to be up to us, really, to find where it goes.

And I don't think -- as long as it's clear, I think the information can be relatively easy to get, because right now, I mean we list end user and interim user, that kind of stuff.

So, it would just require a little more work on, actually, the sales end of the game to make sure that they understand when they sell these things who it's going to have to

be, and that, in itself, can be a hard time, but getting that tied back before it ships -- in the realm of undue burdens, I don't think it's an undue burden, and I do think it will help strengthen the accountability, but it should, I think, be mailing address and location, or mailing address of the person and location.

I think keying it to the responsible person is real important.

MS. WOODS: Mailing address and then the actual location.

MR. BROWN: Mailing address of the responsible individual and location of where the gauge will be, and I think those devices -- because then it's very clear to us, to our people -- and we can tell, you're the responsible person, and this is the location we're putting it. If you move it from that location for any reason, you're the person that has to notify, because once they get the gauge, they may not talk to us again. Generally they do, but sometimes they don't.

MR. CAMERON: Okay. Let's go to your colleague Candy for some amplification on that.

Candy?

MS. BROCK: No, no amplification, further question.

Can you not create an economic hardship for a company that orders on an agreement state who has no fee for general license gauges?

In Michigan, I'm required to pay \$420 but my plant extends into Ohio, and the Ohio gauges are not paying a fee, therefore, I'm going to shut down this little town in Michigan

because I'm going to move my whole operation to the State of Ohio.

It seems like we've got some trans-boundary issues there, too, on these locations of use.

MR. CAMERON: Well, that takes us back to an earlier discussion, I think.

MR. HICKEY: We're aware of that issue. That's a broad issue, because there are some states that charge lower or higher fees or no fees compared to us, and that we just live with as, you know, the difference between having state authority versus Federal authority.

So, the industry just have to live with that. In some cases, it's an advantage; in some cases, it's a disadvantage.

MR. CAMERON: We heard the interchange between John and George and Suzanne on this. Does anybody have anything to add on that?

Suzanne, do you want to sort of summarize what you've heard?

MS. WOODS: I think what we just shared with George is what I'm hearing sort of culminated into responsible individual, would be a mailing address to them, and a unique address could be associated with the actual location of use.

It does not necessarily have to go down to the floor, the lab, or the pipeline, you know, the operation line that it's on.

That information -- that the definitions that we've talked about here for location of use and -- actual location of use, as I've referred to it, and a mailing address

for responsible individual would be definitions that a general licensee could work within providing that information to you, that it would be clear to them.

You believe that to be true is what I'm hearing. Somewhat? Okay? I see a shrugged shoulder, so I'll open it up for discussion on that if you have something more you'd like to add.

MR. CAMERON: John, are you reaching for your card?

MR. PATTERSON: Yeah.

That also helps you with the 3M case, and I work very closely with a guy at Merck, and he's got the same issue. He's got lots of different locations, but he's the responsible individual.

So, he's the mailing address and he's probably the one that's going to be responsible for paying the damn fee, but they're all over the state. Well, actually, in this case, they're all over the country.

MS. WOODS: I'd like to revisit my subtopic of fixed gauges on portable devices for just a minute, and I think that, using this structure, is it possible -- the structure we just outlined -- would that work in those scenarios to identify a unique address for the license, as well as a mailing address?

MR. CAMERON: You meant unique address of the --

MS. WOODS: Actual location of use and a mailing address for the location. I may be mixing semantics.

MR. HEYER: Maybe.

MS. WOODS: Maybe? Okay.

MR. HEYER: I see no problem in doing diligence

and providing to the NRC this day forward that information, responsible individual and location of use. However, know that perhaps the physical location of that particular device may change, and we have no control over that.

It's an initial notification. I think the term initial address, initial location of use is something that we can document and have documented as other manufacturers have in our quarterly reports.

No one says it's going to be valid five days later, and you even mentioned yourself you sent out something, three months later it's gone. Well, guess what? There's devices going in and out in 30 days that you're never going to see.

It's just one of those things. If it's a temporary use location or something like that, you're going to have these built-in factors, but we can do diligence in providing that information. I don't see any problem with that, speaking personally.

MS. WOODS: The transfers that occur in those cases, though, would be reportable issues to us.

MR. HEYER: Within 30 days?

MS. WOODS: When it moves from one location to another.

MR. HEYER: I'm talking portable units that may go out to a general licensee and then come back within a 30-day period. We'll report that. However, when you get the information and then you tally it up and you contact them, they contact me and say how come -- you know, I sent this back to you, you know.

That's just an example of the 30-day window that

sometimes applies, because we're saying they have 30 days to notify, and what happens within that 30 days -- you used 90 days, I believe, in one scenario. There are those types of situations.

We can do diligence, I think, in providing that information that you need for responsible individual, physical address to go to. The actual location of each device, when it's a portable device or a mobile device, may be difficult, but that's something that we can convey to our customers as best we can.

MS. WOODS: I'm curious to know if these fixed devices on mobile units -- have they been evaluated for the types of vibrations and all the different factors that go into those things? Have they been noted as mobile devices?

MR. HEYER: They are so denoted on the sealed source and device registry system and have met the criteria set forth at that time.

MS. WOODS: So, if we called them something like mobile devices, that would be a clear definition to people? How would we reference those kinds of devices?

MR. HEYER: I have no problem if you call it a fixed device. I'm just letting you know it's fixed on a mobile unit.

I mean I don't -- my peers here have mobile devices, but they're fixed also, but may -- George may say it's fixed, because it doesn't break the beam geometry. It stays on a pipe saddle. That pipe saddle can physically be removed without affecting the beam geometry, but it's on a truck or it's on a dredge, and that's how it was evaluated on the sealed source and device registry system, is all the criteria used to evaluate the

source head configuration, limitations and conditions of use specify what it is used on, whether it is an oil field application or whether it's used on that.

MR. CAMERON: How important is this -- is the geometry of the source affected? I've heard that a couple of times. Does that make our job easier or more difficult, or is that important to us in terms of this whole framework?

Suzanne?

MS. WOODS: Source geometry refers to the alignment of the source, whether it's with regards to the shielding, beam detection, geometry.

MR. HICKEY: I think it's only relevant in characterizing the device, but it doesn't really help as far as describing where it's located.

MR. CAMERON: All right.

MR. HEYER: It also describes the limitations of what a general licensee can and can't do. If it maintains it's fixed configuration, it's not physically removed, relocated, or the beam geometry broken, then that's not a general licensed activity.

MR. CAMERON: Okay.

It seems that what we came up with here -- and Jonathan, I'm going to go over to you -- is that responsible individual, mailing address for the responsible individual, and physical location, as opposed to perhaps actual location, physical location within a plant -- is that the suggestion that we have on the table for this?

MS. WOODS: I thought I heard actual location.

MR. CAMERON: I thought that George started to

make -- or made the point that we may not be able to tell you where the actual location is within the plant, but we can give you the physical location in terms of being in the plant, and I thought that's sort of the thing that Ralph was picking up on there, and Ralph's shaking his head yes, but -- George, are you and Ralph on the same wavelength here?

MR. BROWN: I think we are.

I mean the idea is a general licensed gauge can be shipped to a plant and be used in one location, one process in that plant for several months, and then they'll have us come in, take it down, and move it to another one at the same location, and it will be in two spots in the same physical plant, and I think this -- addressing the mailing address of the responsible individual addresses specifically the issue of mining installations, which have a lot of unmanned sites, pipelines, which will have locations that don't have a mailing address.

I mean it could be defined as the mile 173 pump station of several run of pipe as the location, which means something to them, and it means something to you, because when you ask him where that gauge is, it pinpoints it.

So, I think the combination of those two should meet both of the requirements and be well within the realm of us being able to handle it easily, on initial notification.

MS. WOODS: I think that I was just getting the terms mixed up. I think I was in line with what you were talking in terms of definition of which location we're talking about. So, I think we're all talking on the same page.

MR. CAMERON: Okay.

Jonathan?

MR. FORTKAMP: I think it's probably resolved at this point, but just a comment, as well, that it's going to affect the burden on the licensee and the regulators for reviewing, because if you're getting down to a very specific location, you know, a particular pipe, and it's moved on a -- not a regular basis but on a frequent enough basis, and if that's the identified location, then every time that moves, there's going to be another report of transfer, and so, that's not only a burden on the licensee but it's a burden on the regulators for review of that.

If you can, you know, expand that to just a site location, you know, it's in this building at, you know, 650 Ackerman Road, say, for ABB, and then, within that, the responsible individual needs to know where it is from there.

MR. CAMERON: So, you're basically being consistent with Ralph and George. Okay.

Illinois -- I don't know if -- Joe or Mike, any comments?

MR. CLINGER: No. I think generally what I'm hearing sounds like what we do. I think I agree that they key is the responsible individual, though.

MR. CAMERON: Okay. Thank you.

Anybody in the audience before we move on to the next segment on reporting?

John.

MR. HICKEY: I just want to add one final comment. We will think more about the issue of designation of location, both for accountability and assessment of fees, but I want to emphasize one thing. There is an advantage in knowing

specifically where the device is in a plant.

If a device is found in a scrap-yard and our database shows that it was registered at General Motors in Detroit, Michigan, we will send out the inspector and he will go and drive and park in the parking lot, which alone is one square mile, and then he'll go to the responsible individual and say we found a device in a scrap-yard and it caused a \$5 million contamination incident and it was registered to you, and he'll say, well, our computer system on that went down six months ago and we don't have the data on those devices.

It would be useful if our database said that it's located in building 123-A in the northeast corner, installed on such-and-such a device. So, that is where that could become an issue.

So, that's just something that we -- that's one of the issues we have in mind when we're looking for a description of where the device is.

MR. CAMERON: So, you're saying that you can't assume that -- we should hope that the responsible individual will know the actual location, as opposed to the physical location.

MR. HICKEY: Correct.

MR. CAMERON: But that that reality may not occur, I guess.

MR. HICKEY: Correct.

MR. CAMERON: Ralph, do you have a comment on John's point?

MR. HEYER: Yes. Would not the six-month physical inventory address that issue that's required currently under the

rule?

MR. HICKEY: Well, you know, I was talking to my staff. That's the first I've heard. I have to read the regulation. I wasn't aware general licensees had to take inventory. I'd forgotten about that if that's the case. I know they have to do leak testing in some cases, but I'm talking about the case where we have a real problem and the responsible individual falters.

If we had the record of where the thing was installed, we could have him take us to that location, rather than having him or her search through his records to figure out what's going on.

MR. CAMERON: I think Elsa had something to say on that.

Elsa?

MS. NIMMO: It seems like, if the responsible individual has faltered on that, they probably would have faltered on updating you when it moved to the most recent location within the facility.

You know, it seems like a situation where probably a fine is in order.

MR. HICKEY: I'm not talking about the penalty. We have real cases where sources get melted down and crap up facilities, but the faster we can find out where they came from, the better.

MS. NIMMO: Yeah. It seems like the type of situation where you're likely to have both problems rather than -- they kept you perfectly up to date where the device was, but on the day you visit, the responsible individual doesn't happen

to know.

MR. HICKEY: But if we never got the initial report of where it was installed, then it's more difficult to find out about it later. But if they told us initially where it was put, then people can forget about it, but we still have the information.

MR. CAMERON: Okay. I think Doug has a comment, and Glen might have a comment on that, and then let's close up on this one.

Go ahead, Doug.

MR. BROADDUS: One of the things I think we're doing here is we're kind of mixing the registration -- people that are subject to registration and those that are not subject to registration.

Those that are subject to registration every year -- we're going to contact them and they're going to tell us where the device is. We're going to ask them. You tell us -- you reconfirm with us where the location of use is.

Those that are not subject to registration, the information you give us is all we have, that's all we'll ever have, because we're not going to contact them, you know, on a periodic basis unless we know of an incident or something like that and we go through our database and find out that, in fact, the device we found in the scrap-yard, you know, belonged to this particular licensee.

That's the only time we may be contacting that general license at that point.

So, the information you give us at that point, you know, with the initial transfer report, is the best information

we have, and if you can tell us the exact location at that point, you know, that gives us more information to try to find it then.

MR. CAMERON: Okay. Thanks, Doug, for pointing that out.

Going back to -- on a related point that I think should be clarified, Ralph's point about the six-month inventory -- is that applicable to both devices that need to be registered as well as devices that do not need to be registered?

Ralph suggested that the solution to John's concern might be the required six-month physical inventory, and going back to your point about the distinction between registered devices and non-registered, I wondered if the six-month physical inventory applied to both of those situations or only to registered.

Ralph, I'll ask you first.

MR. HEYER: My understanding of 10 CFR 31.5 is that six-month physical inventory, six-month shutter check, and six-month leak test wipe, unless otherwise specified, must be performed by a general licensee. Three things are required to be performed by a general licensee under 31.5. That's always been there.

MR. CAMERON: So, it has nothing to do with whether it's a device that needs to be, quote, "registered," unquote, or not.

MR. HEYER: Not to my knowledge.

MR. CAMERON: That might solve the problem. I don't know.

Elsa?

MS. NIMMO: I think maybe the confusion -- it's

not a called a six-month inventory. It's just you have to do the shutter test and the warning lights test, and if it's a solid source, you have to leak test it.

Well, at the same time, you're recording the serial number. The data are meaningless without the serial number.

So, it, in effect, ends up being a physical inventory, just not called that.

MR. CAMERON: So, this is something, at a minimum, the staff should consider whether this resolves some of their concerns that were raised by John.

Doug?

MR. BROADDUS: Yeah. Doug Broaddus again.

Point of clarification: 31.5 does not require an inventory. What it requires is a leak test, as required on the label, and that leak test may be anywhere from not required to required every six months, every 36 months. Thirty-six months is the longest time period that we will allow currently.

It does also require a shutter frequency test, which is six months, unless, again, the device has been authorized for a longer period for testing. So, that could also be as long as 36 months.

So, in general, the default is six months.

MR. CAMERON: Okay. Thanks.

Well, at least I think there is some food for thought there for the staff, and why don't we move on to the other reporting information issues?

Two things identified here are identification of the responsible individual, who has already come up, and taxpayer

ID number.

Suzanne, do you want to give us some context?

MS. WOODS: The issue here that we would like to raise is how can we make it a clear definition, once again, that the licensee can provide you with a responsible individual that you can report to us?

We presently have a definition in the requirement for a contact person. That could be anyone, as you've mentioned today, from a purchasing agent to any point -- anyone, a receptionist, a point of contact. We don't want that to continue to happen.

The intent is that this individual, under new 31.5(c)(12), as proposed, would be a designated person who ensures that the general licensee is aware of its regulatory responsibilities, has the authority to take required actions for complying with the applicable regulations, discusses the possibility of a back-up -- excuse me.

We'd also like to discuss the possibility of a back-up responsible individual, and how could we get this information clear -- clearly from a licensee to you and to us?

MR. CAMERON: Any comments on responsible individual?

George?

MR. BROWN: A couple of things.

As far as the scenario where we have a person at a plant, if we had, essentially, as you defined it, that kind of guidelines, we could pass that on to the customer and ask for that information.

As the form of more of a question, the way I read

the rule, it says that a person has to be on-site. The question, then, do they have to be an employee?

For instance, could that person say Ohmart is the responsible individual and contract with us, and then we would maintain responsibility of that gauge for them, because there are a lot of general licensees that would -- some would do it, some wouldn't, but would that responsible individual have to be an employee of the company or a contractor could do it, and would they need a specific license if they were going to, or could it be a maintenance group, something like that?

So, you, I think, define whether it has to be an employee of the company.

MR. CAMERON: Are there any comments on that same issue, does it have to be an employee of the general licensee?

MR. RICH: Tom Rich here.

In one of my previous lives, I was responsible to do GL inspections, and it was kind of a nightmare at the time. I do believe that the responsible individual has to be in that company.

For example, some of the places you go, they use devices in a secure area, a gold room, for example, in AT&T, and it took almost a day just to get a clearance to get in there.

The responsible person at that time was just a maintenance, had no rights to go in that place, didn't even know who was in that room and so forth.

The second thing is, a lot of times these devices -- like you said, they could be a half-mile apart, but an inspector then trying to track that thing down is almost impossible.

So, if you do use a responsible person and their address, make sure that the responsible individual is clear on his requirements, that he does have authority to go in all those places, and that he does know at any particular time where that device is.

If we're trying to follow up on incidents, we need to know where that device could have been or where it's gone.

MR. CAMERON: You're raising a larger issue but relating it back to George's point. The implication is that if it wasn't an employee of the company, that responsible individual would have to be able to go anywhere in the company.

MR. RICH: That's correct. Naval shipyard, for example, you know, outside contractors usually can't get in without a clearance. So, it wouldn't do much good to have that as a responsible individual if you're doing an inspection or need to find out where the device is.

MR. CAMERON: Okay.

David, do you want to continue on this trend, or did you have a different point?

MR. BENNETT: Different point.

MR. CAMERON: Suzanne, what do you have to say on the discussion? Did you have something on this discussion?

MS. WOODS: Yes. I think what Tom is hitting on is the second part of the definition provided in the proposed rule that specifies what we want to see in a responsible individual, and that is someone who can take -- has the authority within the company to take action to make sure that compliance occurs.

So, in these scenarios, I think that's what Tom

was hitting on.

MR. CAMERON: Okay.

MS. WOODS: I'm not certain that hiring someone from outside the company -- we would want to assure that that second part of the definition were to be in place.

MR. CAMERON: George, just because you raised the possibility of a contractor, in your experience, would -- if your company or a -- if your company, for example, was the responsible individual, would you have the authority to do the types of things that Tom and Suzanne were talking about?

MR. BROWN: Well, generally, if somebody contracts with us to do things like that, we specify that up front. I mean you're required to maintain other safety-related issues that we have to have responsibility for and be able to enforce.

So, it's not uncommon, if we have a field service person at the plant, to tell them that something isn't right. He'll padlock it off, lock it off until shields are put in place or something's done.

If you had a contract to do that, that responsible person would have to have that authority. The authority is going to come from the plant manager.

You're not going to get any grassroots people be able to make those decisions and enforce anything unless you have the management-level responsibility, because these things will have sometimes significant financial impacts to a plant.

These people don't put these gauges in because they want to. They save them money or allow them to run, and if you're going to take a process or a device out of service because of a problem or something that needed to happen, there's

significant financial impact to most companies, and they will respond pretty quickly if it's clear.

I don't think it's an issue that a non-contractor person -- they're also going to have a lot of issues -- instrumentation in a lot of plants -- the entire maintenance is contracted to another company, and that still might be the best person to have in charge.

So, it's not just us. It could be just an electrical contract company that has 15 people working in there and they do all the maintenance and repair of all the devices.

MS. WOODS: I think you've brought up a very good issue, and I think we have to decide at NRC if we're comfortable with that, as it's been laid out for what we see as the responsible individual.

MR. CAMERON: Let's go to Chris and then over to Kate.

Chris?

MR. FITZ: Yeah, I was just going to say it seems like, there again, we're looking at it from a risk base, these are inherently safe devices. We allow medical institutions to have a consultant radiation safety officer. It seems like the burden on the general licensee is much higher.

MR. CAMERON: So, the RSO analogy from the medical area?

MR. FITZ: Yeah.

MR. CAMERON: Kate?

MS. ROUGHAN: It's not clear to me how we as distributors are going to determine how this responsible individual is and if they have any proper authority. We can't

assess that. The general licensee themselves would have to identify it, and that would have to be consistent. They notify the NRC of who the responsible person is. They should also notify the manufacturer, so we have that information, also, because we can't assess that with what we ship. We're given a name. That's all we have.

MR. CAMERON: So, is this something that -- the implication, I guess, is that when you transfer -- or whatever the word we're going to be using -- that device, that that would be another detailed piece of information that you would have to ascertain, is that -- do these -- the people who you're giving us as a responsible individual have the authority?

What do other people think about the reality of having to do that?

Elsa?

MS. NIMMO: I think all we can do is notify the general licensee what the requirement is and what kind of authority their contact person has to have, and after that, all we can do is report the information that's been passed on.

We're not going to be assessing their corporate structure. We just don't have that kind of knowledge about the site.

MR. CAMERON: And is that a consensus around the table, that understanding? I see a lot of people are shaking their heads. And does that sound right to the NRC?

MS. WOODS: Yeah, and that's why we brought this to the table, because we see that this is an issue where it really is going to rely on the general licensee to fully understand it. So, we're asking, is it clear the way it's

written?

Are they going to take hold of it and answer to you with a name that meets these criteria, or is there some other suggestion you have for how we can word this so it is clear, or what we can do to facilitate your efforts to collect this information?

MR. CAMERON: The question is, very simply, is the language that's specified in the rule sufficient to let the general licensee, purchaser, whatever, know what types of authority the responsible individual has to have?

John, what was your comment?

MR. PATTERSON: I was going to go back to something I think George started, and that is the issue of a non-employee being the responsible individual.

Don't forget, some of these devices get sold to -- we sell to inspection companies that are, you know, two or three people.

You're probably better off, in that case, if they go out and get a knowledgeable individual to be the responsible individual than try and do it themselves, because they're doing 58 other things, and they're not going to pay attention in some cases.

And I'd just like to echo Elsa's thoughts. There's no way we can evaluate the name we're given. You know, we're going to have to say here is what that individual is going to be responsible for, tell us who it's going to be, and we're going to get a name back, and we'll give it to you, you know.

Again, if it's one of these two-people operation and it's the president of the company, let's hope not, but

hypothetically, he could be say, oh, yeah, it's another regulatory thing, I'll ignore it.

MR. CAMERON: Okay. Let's hear from Jack, and I would just like to touch base with Elsa again before we go on.

MR. RAMSEY: It seems to me that, if you let the responsible party be someone who's not an employee of that company, although he may be able to handle the regulation better than anybody else in the company and do everything that needs to be done, you're still kind of defeating the purpose of the original intent, and that's to get someone in the company to take responsibility for their gauge.

Now, if they take responsibility, they may go out and hire someone to do all that stuff, but there still has to be that person who is an employee of the company who says, oh, yeah, I know.

If he says, oh, no, you know, there's the fellow, you know, take him to jail, I think you're kind of going to defeat the purpose.

MR. CAMERON: So, you're drawing a distinction between the responsible individual is someone within the company, but they may go out and hire someone to help them implement that responsibility, but they are still the responsible individual.

MR. RAMSEY: Exactly.

MR. CAMERON: All right.

David?

MR. BENNETT: I didn't think the intention here was to educate -- necessarily educate the company. The proposed rule states the name and phone number of the person identified by the general licensee. The interest here is in providing better

tracking, and whether that's by an individual in the company or a contract service shouldn't really matter.

I understand the concern with people from outside of the company having less access to those areas where the instrument would be. I mean that's very valid point. But the interest here is in being able to track the devices. The rule is it's the person identified by the general licensee.

MR. CAMERON: Okay. Let's go Suzanne for a comment, and then we'll touch base with the agreement states and the audience.

MS. WOODS: I think your comments have been very helpful. You are, right now, our best source for -- your experience as well as your specific knowledge of general licensees and what they can and cannot understand, which is where a lot of these questions are coming from.

You've had a good deal of interaction with them to know that something like this will work or not. So, I appreciate your comments and how it will be incorporated within their structures of very small business situations to very complex, such as 3M.

So, those things are very valuable.

The other issue that I raised was a back-up responsible individual, and I'm wondering, could we hear some comments on how you think that might be of value or otherwise?

MR. CAMERON: David?

MR. BENNETT: That's where I do not agree. I don't think it should be forced on companies to have backups for people. If an inspector is going to show up at a facility and this person is out on vacation or away on a business trip, that's

too bad.

We're already forcing these companies to pay somebody to become familiar with these requirements. You know, all companies have to do this, not just those on this list, but all companies have to abide by this section of the regulations.

So, if you have a company that is, number one, having to pay to train an individual and maintain that person's training level and then, secondly, having to force that \$420, but now you're adding another person to this puzzle, I think it's too much.

I think one person being responsible for that information should be adequate.

MR. CAMERON: Okay. Thank you.

Chris, more on that same point?

MR. FITZ: Yeah. Just to echo the analogy to the radiation safety officer, the NRC does not recognize assistant radiation safety officer. It's kind of the same point.

MR. CAMERON: All right. Thank you.

I should ask, does anybody around the table want to speak in favor of the need for a back-up responsible individual?

[No response.]

MR. CAMERON: Okay.

State of Illinois -- responsible individual discussion, including the back-up responsible individual -- any comments?

MR. CLINGER: I don't think we have a position on whether the back-up responsible individual has to be an employee. Excuse me, the responsible individual.

As far as the back-up responsible individual, we're against that, also.

MR. CAMERON: Okay. Thank you.

Let's go quickly to the audience on the responsible individual discussion. Anybody have a comment out there?

Glen, you had something to say previously. Maybe you want to come up and put it on the record.

MR. GOTSCHALL: Glen Gotschall from ETG.

This is a little bit different scenario from the rest of you, but just to be aware of it, my company is a defense contractor.

Our customers are typically other government agencies, various government agencies, quasi-government agencies, sometimes with covert operations. Sometimes it's all I can do to get a point of contact name. I have to call them and say, hey, I can't ship this unless you give me a point of contact, phone number.

To go back to them and say, hey, now I want somebody who's going to be the responsible individual, you know, I might get a name, but you know, who knows whether that person exists.

So, you know, that's another scenario.

MR. CAMERON: Interesting problem. Okay.

Daryl?

MR. SHAPIRO: Not nearly as interesting as that, but it may be helpful to think about how I might answer that question.

If a general licensee came and asked, I'd like to

hire a consultant to be my responsible individual, is that a good idea, the first answer is, if they're better able than you, probably, but you as the licensee are ultimately responsible. The NRC will look to you.

If there's a failure on the part of the responsible individual, the NRC may consider action against that person, but it's your license, it's your ability to do business, to possess licensed material, in this case generally licensed material.

That ought to be a pretty good forcing mechanism for general licensees who want to go outside and have an RI who is not an employee.

MR. CAMERON: Okay. Final comment, Jonathan.

MR. FORTKAMP: I think it's good to give them the option -- the customers an option for -- to bring an outside individual, someone whose primary purpose is to look over their devices and to help them meet the regulations, but I think it does need to be clear in the contract that, if an outside contract person is hired, that they do have all the authority required under the regulations, just as a contract RSO would have to have all the authority that an in-house RSO would have to make decisions and to put, you know, unsafe practices to a stop.

MR. CAMERON: Okay. Thanks, Jonathan.

How about taxpayer ID, Sue?

MS. WOODS: The Commission has asked us to consider, in a staff requirements memorandum, which is a memorandum to the staff in response, generally, to a Commission paper -- they asked us to consider the issue of taxpayer ID and collecting that for general licensees for the purposes of

tracking them.

There's a lot of issues surrounding that, but while we have you here, we would like to ask you, is this something that we could do? Who would collect it? When should we collect it? What other issues and alternatives do you identify with it?

For example, here's a possible scenario of how the logistics might play out.

You provide us a transfer report and report to us a new general licensee, and under the proposed rule, we would go out and provide them registration in an appropriate timeframe.

That registration request might go out, be responded to. We have a certain cycle that's being discussed as far as those that are not responded to, going out and requesting it again and so forth.

There might be as much as nine months, maybe a year from the time that you have notified us on a transfer report to the time where we actually put an inspector out there because we've made all the efforts to contact this individual and they are gone, and we've discussed issues today where three months, 30 days, various things where it is easy for these certain individuals, different types of users, to fall off the scope of the radar screen for NRC to track them, and the tracking and accountability purposes is the initial intent of this registration and this proposed rule.

So, there is some discussion on this taxpayer identification as a means for getting that information. It's been discussed as to what point it should be collected. Should it be collected as soon as we know about the licensee? Do we

collect it from them? Do the vendors collect it?

There are a lot of issues in the forefront on this, and we'd like to hear from you on them.

MR. CAMERON: Is the purpose of the taxpayer ID to provide greater assurance that we will be able to find the individual? I mean is that the essence?

MS. WOODS: It's been asked that we consider collecting it for the purposes of tracking these individuals more closely.

MR. CAMERON: Okay. So, looking at it from that's the purpose, taxpayer ID, does it accomplish that purpose, and how difficult is it going to be to get that type of information from the general licensee, for you guys to get it from them?

Elsa?

MS. NIMMO: I guess I was just -- Suzanne, was the intent for us to get that information and give it to you on the quarterly reports of distribution?

MS. WOODS: There was no intent, no direction. It's just consider this issue, and we're asking how, when, who, all of the five W's on this, and I played out one scenario as a possibility.

Certainly, one of the issues could be for you to collect it. You know, what do you recommend? If we were given this as a tracking mechanism, what do you think of it as a tracking mechanism, and if we were to implement it, how and when would we implement it?

MR. CAMERON: Let's address the first one you brought up. Is this going to provide a lot of or a little value added to tracking, first of all?

MR. PATTERSON: Corporate identification number, not individual identification number.

MS. WOODS: The licensee, which is the corporate structure.

MR. PATTERSON: Okay.

MS. NIMMO: I guess, since it wasn't in the proposed rules, I hadn't given a lot of thought to us as distributors getting that number and forwarding it to you. My first reaction is sort of, wow, that sounds like a pain, and it sounds like information that might -- I don't know. I don't know how difficult that would be to get. Offhand, it sounds kind of scary.

MR. CAMERON: Anybody have an opinion on how the general licensee would -- whoever collected it but how the general licensee would react to giving a taxpayer identification number?

Ralph?

MR. HEYER: In Texas, a specific licensee has to provide franchise tax information, and in that, they ask for corporate tax ID, and that's strictly from the regulatory agency.

I personally, as a company, would not ask that of our customers.

MR. CAMERON: Because you think it would be looked on as too intrusive?

MR. HEYER: That's correct.

MR. CAMERON: All right.

Jack?

MR. RAMSEY: I'm just not sure I would understand the value added from a tracking standpoint, because you're going

to get a tax ID number, but that -- you know, they may relate to the facility, it may relate to all the facilities in the United States.

I'm not sure how the corporate structures of all these companies are set up.

So, yeah, you might get it, but it may not really be of any value. Yeah, you can identify somebody up the line that owns this, but I'm not sure it's going to tell you anything about where the device is.

MR. CAMERON: Suzanne, let me ask you.

The implication here is that, if you can't find -- that there could be all these different ways that you could find this company individual and therefore check on the device, but if all else fails, if you can't find them through that, you're always going to be able to go to the taxpayer ID and, therefore, somehow magically locate the person and where the device is. That's the idea behind this, right? Okay.

I don't know if we're coming up with any good ideas about whether the taxpayer ID number is something that's going to be the -- sort of the sure-fire way to always find out what's going on.

Does anybody have any -- Jack indicated some skepticism about that, and I would like to see, is there any support for, yeah, the taxpayer ID is always going to get you where you want to go or not?

Ralph?

MR. HEYER: More a question than an answer.

Has the Organization of Agreement States talked about this? I mean I think a lot of them have perhaps looked

into that issue as part of their own previous experience.

MR. CAMERON: Let's go to not the Organization of Agreement States, but let's see if our agreement state has any experience with this or any comment.

Illinois?

MR. CLINGER: Yeah. I don't know about the Organization of Agreement States, but here, we've not had -- we've not had a great deal of difficulty in making contact with the general licensee as we've received a report of a distribution.

MR. CAMERON: Do you require in any way taxpayer identification numbers?

MR. CLINGER: No, sir.

MR. CAMERON: Elsa.

Thank you.

MS. NIMMO: Taxpayer ID numbers aren't generally required for specific licenses, are they?

MR. CAMERON: So, in other words -- Ralph, in Texas, franchise -- what you called a franchise tax is required, but the question for the NRC is do we require taxpayer ID numbers for specific licensees?

MS. WOODS: I don't believe so.

MR. HICKEY: No, we don't. The comments -- I'm gathering that the tax IDs are not already in play in your transactions. So, you wouldn't be interested in bringing them in play.

Potential advantage, though, for us to ask them directly from the general licensees would be, one, if we have duplicative information where we have three reports, all that

have the same taxpayer ID number, but the names are GM Incorporated, General Motors Incorporated, and General Motors Corporation, we would see that they all the same taxpayer ID. That would be one example of how that might be helpful.

Another might be where a company disappears and we can't find them. We could see whether the taxpayer ID was active, whether there was any activity going on against that taxpayer ID.

MR. CAMERON: Okay.

Let's go to Candy and then John, and then we have a triangle of NRC staff here.

Candy?

MS. BROCK: I see taxpayer ID numbers often on purchase orders. They're really not as hard to get as you think they are, but I don't think it's going to be of great value to you, because the people that are going to abandon gauges are also the same people that -- people that are looking for that taxpayer ID number.

I mean, you know, the government -- they're just going to drop out of everything. They're not going to drop out of just the gauge.

MR. CAMERON: So, if they drop out, they're going to drop out entirely and the ID number is not going to be much help.

MS. BROCK: Right.

MR. CAMERON: All right.

John?

MR. PATTERSON: I just want to react quickly to what you said, John. There may be cases where you have the same

taxpayer ID number on multiple licensees, you've got multiple locations for the same corporation. General Motors is probably a good example.

MR. CAMERON: Okay. Thanks, John.

Let's go to Cathy and then to Doug and then come back to the table to Suzanne.

Cathy?

MS. HANEY: We don't use it in licensing, but the CFO's office does that information. But it's only to be used for the purpose of collecting fee.

MR. CAMERON: If you don't mind, just lower that mike a little bit and repeat that for all of us.

MS. HANEY: We don't use the tax ID number in licensing, but the CFO's office does get that information from specific licensees. But it's only to be used for purpose of collecting fee, and we can go to IRS if we lose track of someone to try to see if they could help us.

MR. CAMERON: Okay. CFO is our Chief Financial Officer, and that's who implements the license fee.

Doug?

MR. BROADDUS: Yeah, Doug Broaddus again.

I was going to echo what Cathy said, that, yes, in fact, we do collect taxpayer identification numbers for collection of debt, but I also wanted to add an additional comment that, you know, the fees group, this OCFO, does have some success in tracking down licensees for the collection of a debt when they do drop off of our scope, at least, and typically, when they just go away completely, in many, many cases it's because they're going into bankruptcy or they're moving to another

jurisdiction where we no longer have a way to get in contact with them.

A taxpayer identification number would allow us, you know, in both of these cases, to find out either where that person was filing for bankruptcy or if they had, in fact, moved to another jurisdiction, and even if it was for a corporate taxpayer identification number such as General Motors, at least we can go to General Motors and say what happened to this particular facility that was, you know, at one point, on this particular date, at this location.

So, we still have a way to find out what happened to the device or the facility or that particular licensee with the taxpayer identification number. It gives us some additional means to do a search.

MR. CAMERON: Okay. It seems that there needs to be, obviously, I guess, more exploration about how much value taxpayer ID gives you, and John certainly gave some other instances where it may be helpful. I guess we have had some experience with it being helpful.

On the second point about how it's collected, it seems like there may be some reluctance on the part of the vendor community to ask for this information. So, that's another issue.

Suzanne, do you have something else on this?

MS. WOODS: Very quickly, yes.

Rather than repeat what Doug and Cathy have said, I'll just say that that information -- I'll just emphasize that that information is for the purposes of fees and not to necessarily track down a licensee, and so, therefore, we wouldn't be able to do it for licensing/inspection-type purposes.

With regards to why are we in this issue, I think that would probably be helpful. I'm seeing some puzzled looks.

We've sent out a lot of mailings, and again, we talk about an annual registration, so we have an annual upkeep on certain individuals who are our registration populous, but for general licensees, where we receive the information only once on transfer reports, on those quarterly reports that come in from you to us, that's it, and based on our experience most recently as we tried to send out first GL-1, as Cathy referenced it, the first proposed rule, and then, most recently, we sent out the mailing of the final proposed Rule 1 and the proposed -- excuse me -- the final rule and the proposed Rule 2, in all those instances of mailing out and as much information as we've collected from licensees over the years, we still lost a number of places to mail to.

So, a taxpayer identification in those cases would perhaps help us.

We have Oak Ridge looking into -- our contractor looking into how to find these individuals. You've got letters, probably, in your offices where we've requested your assistance for those efforts, where Oak Ridge wasn't able to locate these individuals through the normal tracing methods.

So, there are still going to be a number of licensees that we need to find, and in those kinds of scenarios, taxpayer ID might be the one and only thing that we can -- maybe the name of the company just simply changed and so forth, but it might be a way of finding an individual who could give us information to close out the issue.

It seems like taxpayer ID is not going over very

well. That's my impression. But I will say that I will open it up very carefully before we move on to something else and just say is there anything else that would help us track individuals besides taxpayer ID?

[No response.]

MR. CAMERON: We're not going to put a beeper on every responsible individual.

Before we go to the standardized report, are there any other issues related with reporting? Elsa brought up one about what's the definition of the term "replacement," and Elsa, maybe -- I don't know enough to explain it. Maybe you could ask about that.

MS. NIMMO: I had two questions on replacement, and one is there are a number of places where it will say something like report is not required if the device is transferred in order to replace -- to obtain a replacement device from the same specific licensee, and my question is, with a replacement device, we may have a model number of a device, and that model number can have different isotopes or, for that same model number, one isotope that has a range of activities.

Say we initially shipped a Model 2201 and it was a 500-milli-curie krypton-85 source and the customer says to us we are going to return that, would you now send us one that is a 1-curie krypton-85 2201?

Is that a replacement that doesn't require reporting? How identical?

MS. WOODS: You've hit on a couple of issues and anticipated an agenda item. So, yes, we wanted to talk about this.

MS. NIMMO: Okay. That's coming later?

MS. WOODS: No, we can talk about it now.

MR. CAMERON: Oh, it isn't coming later.

MS. WOODS: It's coming later, but you've described this in such good detail, I would hate to lose the opportunity to talk about it now, if that's all right with everyone.

MR. CAMERON: That's fine with me.

MS. WOODS: Okay.

Essentially, the rule talks about replacement device, and it's my understanding from reading it that, when you say replacement device, in the past -- the discussion here talks about the past and the present intent.

The past intent was that you have a general license with a general licensee for a device, because they possess that device. If they replace the device, they still have the general license, okay? It's not tied to that particular model number or that particular isotope.

You've hit on an issue that we have with regards to labeling, and we wanted to bring it up. If you change the source, if the model is authorized for a range of different source quantities or source isotope types and you change it and you don't change the label --

MS. NIMMO: You have to change the label.

MS. WOODS: Right. If you don't change the label but if you -- you can go back and forth into a registration compatibility issue. So, yes, we do have to make sure that happens.

Did I answer your question on replacement device,

what they were talking about in the past, that it sticks with a general licensee, the general license stays with the general licensee regardless of whether or not the device is the exact same model number or not.

MS. NIMMO: So, even if the activity were different, it would still be considered a replacement device.

MS. WOODS: It's my understanding that it would be so long as it's within the parameters of the original device.

MS. NIMMO: What if it was a different model number?

MS. WOODS: Then, as long as that device was authorized for those isotopes and quantities, it's considered a replacement device. Even though it's a different model number now and it might be --

Go ahead, Doug.

MR. BROADDUS: If I could provide a little bit of clarification here -- Doug Broaddus again -- from the standpoint of -- you know, we're going to have information that's in our database, it's going to say what that licensee has -- model number, serial number, isotope, activity.

You change the label, you change the information from what we have in the database. So, we don't know what that licensee has anymore.

So, if you change the information that's on that label, we need to know that. That's not a replacement device.

If you stay within what -- the information that's on that label -- for example, we recognize that isotopes -- you know, radioactive material decays. Your label says that you have 1 curie of a certain isotope, cobalt-60. It decays down. It's

below that.

Well, the label, you know, is not always correct in that standpoint, but the amount that was transferred, you know, was -- that's what it was when it was transferred.

You put a replacement source in there, so long as it's not above 1 curie, that's okay. That we're not concerned about.

MS. NIMMO: New serial number.

MR. BROADDUS: Well, the source has a new serial number, not the device, though, unless you use the source for the serial number of the device. In that case, we would need the new serial number.

Now, your replacement device, as defined in the regulations, is you have to tell us what the model number and the serial number of the device that you're replacing, as well as the model number and the serial number of the new device.

So, if you were doing that, putting just a new source in there, and your serial number is -- you know, the serial number for the source -- you'll provide that to us as a replacement device, but if you put a different isotope in there, it's not the same information that was on the label, so it's not a replacement device at that point.

MS. NIMMO: What about the customer? It says the customer shall furnish a report to the director of NRC within 30 days after the transfer of device, and then it says it's not required if they've obtained a replacement device.

So, now we've given them a new serial number, which is on the label, and given them a new set of labels.

MR. BROADDUS: They would have to report that the

previous one was returned, I mean as it is written right now, because it's different than what we have in our database, it's different from what you've reported to us previously.

MR. HICKEY: Could I ask Doug and Cathy to both stay at the microphones, because I don't think we've fully brought this out.

What we need to explain is what does the statement mean about not having to file a report? What are the circumstances under which you do not have to file a report?

MS. HANEY: What we're trying to do is, in the situation where the vendor is in a position to give us the information about what he got back -- because he has to include the information about what he sent out. We've added that to the vendor report, that he has to give us the information about what he got back that's being replaced, and by replacement, I think we mean pretty much anything that's taking its place to do the same thing and not necessarily the same model.

So, in that case, the same -- the general licensee doesn't have to report, but the vendor would have to include it, because he's sending out a new device, and we're going to include in that the replacement, meaning information on the device he took back.

MR. HICKEY: Let's walk through a specific example for the attendees.

We have in our hands a registration sheet that identifies a device by model number and serial number. The general license sends that back to the manufacturer and obtains a replacement device, and so, now the model number and the serial number on our registration sheet don't match what the general

licensee does.

What is the general licensee's obligation under the proposed rule?

MS. HANEY: If he happens to be a registrant and we sent out a form with different information, he'd have to update it.

MR. HICKEY: Is that consistent with what the propose rule says about not having to file a report for a replacement device?

MS. HANEY: Yes.

MR. HICKEY: Okay. Can you walk us through that?

MS. HANEY: Because that's done in the context of the registration, verifying and updating the information in the registration process.

MR. HICKEY: Okay. So, the 30-day report would not be necessary, but the next time the registration came around, the registration would have to be updated?

MS. HANEY: Right. But for all the devices, the vendor would be updating our information. When the general licensee gets rid of a device some other way, only he can tell us.

MR. HICKEY: But that's not a change from the current rule, right?

MS. HANEY: No.

MR. CAMERON: Okay. Well, I guess now that this is all clear --

[Laughter.]

MR. CAMERON: It sounds like people were saying that maybe the NRC needs to more clearly explain how this works,

at a minimum, in the supplementary information, at least, to the final rule.

MS. NIMMO: It gets kinds of worse.

MR. CAMERON: It gets worse.

MS. NIMMO: Yeah.

John, the scenario you just described where the general licensee returns a device and gets a new one to replace it isn't what I experience and probably not most of my colleagues.

What happens is they're running and they say maybe, okay, this source that we're using is getting -- you know, it's getting weak, we're going to need a replacement, but they run until the day they have the replacement device, and they install the replacement device.

So, at the time we do the shipment, we don't have anything back from them, and the truth is, getting the device back is not immediate and usually takes some time.

We, and I suspect some of the other manufacturers, chase devices as best we can to try to get them returned, but it might be six months before we see that back.

So, we've done something that we believe to be a replacement, but until we get the other one back, we don't know exactly what serial number we're going to get back, because it's not a they send it back, then we send them a new one. It's the opposite order.

MR. HICKEY: Right. But was your question about what the obligation was on the vendor or what the obligation was on the customer?

MS. NIMMO: Oh. It was twofold. I don't

understand when the customer has to report, and then I also have a problem with us saying what we've replaced. It's complicated, both questions.

MR. CAMERON: Let's take a final -- against my better judgement, Doug do you want to chime in on this issue?

MR. BROADDUS: There was one other item that I wanted to make sure was brought up.

Because we do have registration -- we have certain licensees that are going to be subject to registration, keep in mind that putting a new isotope or a new activity source in the device may change their status from they're no longer subject to registration to now they are subject to registration or vice versa, they were subject to registration previously, now they're not.

So, it's important that we know so that we can register those that should be registered, we know the information, you know, for what the device is and what the device contains, the isotope and the activity.

Elsa, I had a question for you on your scenario you just talked about.

Did the device that they were replacing -- or that you were replacing, the one that was still there, that you took six months -- it took six months to get back -- did it still have the source in it?

MS. NIMMO: Absolutely. We, each year, are taking back some hundreds of devices, some of which are just out-and-out retirement but many of which are being replaced, and so, this isn't like a single case. This is a constant fact that we're sending replacement devices and then, some weeks or months later,

the item that got replaced comes back with the source in it.

We're never shipping anything that -- they're not transferring the source in the field. It's a GL device.

MR. BROADDUS: I would say in that situation -- I mean it's really up to the vendor to say how you want that to be reported, because you're the driving factor in that situation.

If the licensee doesn't return it to you, he's got two generally licensed devices, and they are then -- at that point, they have two of them.

MS. NIMMO: And they've got the storage thing that kicks in.

MR. BROADDUS: And you can tell them, so long as you have that second device, you know, we're going to treat this as an initial transfer, it's not a replacement, but you have to report it to us anyway, whether it's replacement or not.

The difference is you're reporting it to us as an initial transfer and then they are required to report it back to us.

If they don't give it back to you right then and there or within -- before the next report comes in, it's an initial transfer. They are required to report back to us that they got rid of it.

MS. NIMMO: You know, actually, I think you've sort of hit on the solution, that if we don't have the other one back, we should treat all of them essentially like initial transfers.

MR. BROADDUS: And they would be required to make a report back.

MS. NIMMO: Yeah, I think that's it.

MR. CAMERON: Thank you.

Cathy, one final comment before we go to standardized reports?

MS. HANEY: Well, a question, really. Would it be just as easy or easier to report to us everything you get back, all the detailed information, regardless of whether you replaced it or not?

MS. NIMMO: Are you asking like on quarterly reports?

MS. HANEY: Yes.

MS. NIMMO: That we would tell you what we shipped out and what we got back in from NRC sites or something.

MS. HANEY: Would that be easier compared to what it says now?

MR. PATTERSON: That wouldn't be hard.

MS. HANEY: We may get duplication. It might be easier for you, I don't know.

MR. CAMERON: Okay.

David, did you want to say something about that?

MR. BENNETT: Quick response to that is that, number one, that's what the proposal says anyway, that the NRC believes that it should include this additional information in the quarterly reports.

The thought I had in addition to that is that we could inform the customers up front that, if they wish to transfer the device to another general license holder, then they would have to go through the notification requirements themselves.

If they wanted to channel it back through the

vendor, then the vendor would be able to handle all the paperwork.

That would give encouragement to the general licensee to use the vendor or the manufacturer as that channel, which is what I would prefer.

So, you give the customer the option. If you want to transfer your ownership to another company or whatever, you can notify them of that transfer or allow the vendor to.

MR. CAMERON: Okay.

Is this an issue that can be dealt with under the standardized report also?

Ralph, go ahead. I want to make sure everybody gets a chance on this.

MR. HEYER: I was trying to understand what David was saying, that I always thought -- and if I'm wrong -- I've been wrong before -- that a general licensee cannot transfer a general license device without being re-distributed by someone who is specifically licensed.

MR. BENNETT: No, that's not true.

MR. CAMERON: Does anybody from the NRC want to offer an opinion on this to the extent that we understand --

MR. HICKEY: Well, let me just ask, are you talking about the narrow cases of they remain in the same building or something?

MR. BENNETT: Yeah.

MR. HICKEY: Okay.

MR. BENNETT: Same location.

MR. CAMERON: All right.

Chris, quick comment?

MR. FITZ: I just wanted clarification on that.
Was it to a new location?

MR. CAMERON: Okay. So, you've got that.
Candy?

MS. BROCK: What happens in instances where a customer sends a generally licensed gauge back to someone other than the manufacturer? We as a vendor get sources back from -- we get TN sources, we get Ronan sources, we get competitor sources.

How would we know if that was on a general license report, and we now put it on ours? Is the burden on us, or is the burden on the end user?

MR. CAMERON: Any opinions on that?

MR. HEYER: At the risk of opening my mouth again, it's my understanding that another company can't do a redistribution of another manufacturer's device.

MR. HICKEY: I think she's talking about the case where the customer disposes of it by transferring it to another manufacturer.

MR. HEYER: Then it's disposed.

MR. HICKEY: So, the -- I think the burden there is on the customer that got rid of it, reports to NRC that they got rid of it.

MR. CAMERON: Okay.

MS. WOODS: It would be a transfer report from the general licensee. If it was a registration licensee, for example, they would be indicating that it would be for the purposes of disposal or final disposition.

MR. CAMERON: Okay.

Suzanne, do you want to talk a little bit about standardized reports for us?

MS. WOODS: We are putting out a draft NUREG licensing guidance, and in that, there is a draft transfer form, and this is what it looks like.

We'd like to know if it's clear to use, the content is the type of content that you're comfortable with, and ways to make the form easier to use and adapt, because it is our goal to have everyone use this as a standardized report.

We've talked with the agreement states during an agreement state workshop this summer, and it appears to us that not only using this form -- could it be used for the agreement state reporting and would meet with their requirements but it would also facilitate our efforts that we could have a standardized way to process these things.

We've talked about a general license tracking system, an automated system. We've set it up now for OCR, which is an automated forms processing and reading and scanning and data entry into the database, but it's going to be set up for registration forms.

It would be nice to be able to do the same thing for the transfer reports, quarterly and annual reports that come from you.

Standardizing this form means that we don't have manual entry of the data that comes from you.

So, we are interested in making this as user-friendly to as possible, and we'd like to hear how we can do that, and the NUREG is proposed to be used not only by you by also by general licensees.

So, one of the questions related to this is not only, one, is it user-friendly to you and how can we make it so, but also to general licensees. In fact, should it be a separate form for them?

And then I will have a specific question once we've talked a little bit about this, and that's with regards to intermediate persons. Did we put enough blanks on here?

MR. CAMERON: Let me ask a process question for the group.

Unfortunately, I don't think we had hand-outs of this form, but it sort of underlines the issue of are people going to be able to comment on this form in some other forum, either as a part of this rule-making or because the NUREG will be out for comment or whatever?

In other words, is there -- can they -- people sit down and study this at some point and give us their comments on it?

MS. WOODS: Yes. The draft form will be in the draft guidance sent out for comment. However, we are developing this computer system as we speak. So, the time delays would not allow us to meet that.

We can do it as a future modification, but we are interested in knowing if this is even a usable type of scenario.

MR. CAMERON: Okay. So, the general question is, is standardized reporting a good idea?

Mike, do you have a quick comment right now on this, to aid in people's understanding?

MR. RADDATZ: Yes, I do, and I have a way to focus it, just to give you an idea of what we're looking for.

What if -- this is a proposal now, just for discussion.

What if that form were available in three different forms -- or four different formats, one that you could just print out because you got it out of the back of one of our books; a second is you can download the PDF, you know, format off the net; third, I supply you with a Word Perfect or a Word template that you could download and fill out.

Our goal is to get the information in a clear, concise format that we can easily scan, and at this point, some of you have heard the discussions that we're going to be paper-based to start, and then we're going to evolve from there.

We need to be able to get it so that it scans in quickly and easily and we keep our costs down.

That's what I would like to throw out as a proposal, four different formats. You could copy it, you can download the PDF, or you could download a Word Perfect/Word template that allows you just to fill it out.

MR. CAMERON: Okay. That's useful. Thank you.

And let's consider both issues here.

John?

MR. PATTERSON: Absolutely, positively, as quickly as you can get to electronic input. Absolutely, positively provide it as a Word Perfect or Word template. I do not want my people to have to sit down at a typewriter and fill this damn thing out.

MR. CAMERON: And the "damn thing" for the transcript's sake was the --

[Laughter.]

MR. RADDATZ: Oh, there is some emotion here.

Okay.

[Laughter.]

MS. WOODS: The intent would be to provide it electronically, in a format that we have already established for scanning.

MR. CAMERON: Maybe being against standardized reporting is like being against motherhood, but are there any negative implications that people can see from standardized reports? Any concerns along those line? Maybe that's a way to start.

Elsa, and then we'll go to John.

MS. NIMMO: I think probably any format that you give us, if you give us time, we can use that format, any electronic format, but if you give it to us and say, okay, within the next quarter, it must be done in a format, we might have some difficulty meeting that.

You need some lead time to convert -- many of us have computer-based systems that spill out our annual report or quarterly reports, and we do other things but just not overnight.

MR. CAMERON: Okay.

John?

MR. PATTERSON: The other comment that I thought of after I made that first emotional comment is also get the states to accept the same report.

MS. WOODS: We've discussed it with them, and it's -- they like the idea of a standardized report, as well.

MR. CAMERON: And I know the State of Illinois can see the chart, but do you guys have any comments on standardized

reporting?

MR. CLINGER: No. Sorry.

MR. CAMERON: Okay.

So, we heard -- one concern is lead time. There has to be lead time, and people will need some time to look over the specific information fields and comment on it.

Mike.

MR. RADDATZ: One more question. This is from my electronics people that are going to be implementing this. I'm looking for a consensus. Do all of you have access to the internet, or is there anyone here that does not have access?

[No response.]

MR. RADDATZ: Generally, would you consider that all vendors generally have access? Is that a fair statement? Thank you.

MR. CAMERON: All right.

George.

MR. BROWN: In looking at this form, this is the form we would fill out for the quarterly reports?

MS. WOODS: Yes.

MR. BROWN: So, we would need one piece of paper for every licensee?

MS. WOODS: Yes. There's two there, but you'd have one piece of paper like that. You'd have to use multiple sheets of paper.

MR. BROWN: The people that you didn't ship anything -- you still have to notify? States require you to notify them that you did not -- for this quarter, we didn't ship any gauges.

MR. BROADDUS: The form right now provides two places for -- where you can indicate transfers to two different general licensees, basically. That's what it allows for.

You could also use the same form and just write on it no transfers if you wanted to do that.

I don't believe there's any particular place on there where there's a spot for it, but you could, in fact, just send it in and just indicate, you know, no transfers this period, because you still have the reporting period, still have your information that you have to provide, the license number, and then your name, just write across there "none" or something like that. But the reports, yes, are required to us as well as to your state as to whether you did or did not report any. So, you would have to send one of those forms in or something to us every month -- or every quarter, I'm sorry.

MR. BROWN: If that's the case, there ought to be someplace on there that says who the report's being sent to. I didn't see that.

MR. BROADDUS: Well, we looked at it more as a generic -- you would put that on -- you know, on the envelope you put on it or something, you know, that you put it in, basically.

If it becomes a -- something where, through the internet, you can do the filing, as well, then you'd be sending it directly to the person that you're making the filing with.

Again, it is generic in nature, so that it can be used by anybody, used by anybody, and it can be sent to any regulatory jurisdiction.

MR. CAMERON: I guess another process question for the group, since you probably need to spend some time looking at

those fields, I mean actually trying to fill it out, are comments going to be taken on the NUREG before the final rule is developed?

MR. BROADDUS: No.

MR. CAMERON: No. Okay. It's not necessarily bad. It's just how much of a connection there is between what's in the proposed rule and this form. All right.

David?

MR. BENNETT: I was just concerned that right now I generate maybe 52 pages of information, and I'm going to be going to three to four hundred pages. I'm not too crazy about that.

MR. CAMERON: Does this increase the reporting burden on the vendor?

MS. WOODS: Yes. That's one of the issues I wanted to highlight.

MR. CAMERON: I know you have some other things that you want to talk about, Suzanne. So, let's hear Jonathan, and why don't you go back to your specifics?

Jonathan?

MR. FORTKAMP: Just one comment on the form in general.

If it's supposed to be generic enough that general licensees can use this, as well, to me it's -- this is more of a -- just a critical comment on it -- it's not clear if the devices are coming to or from or who they're going to.

It ought to be more delineated as who's the report by, devices returned from general licensee to vendor, because the term "transfer" is used a lot, but that goes both ways.

Just a comment on that. And it does increase the burden on us.

MR. CAMERON: Okay. Thank you.

I assume -- again, another process question for the staff -- that this form will need to be evaluated from some sort of an estimated reporting burden standpoint to try to get a handle on what the reporting burden is.

Mike, you look like you're shaking your head yes.

MR. RADDATZ: The answer is yes. Anytime we request information, the burden -- although a lot of this has already been done.

What we're looking for, what would be helpful is suggestions for -- you know what you've been reporting, you understand, hopefully, by now, what we're trying to do with the intent, not just what we've said but the intent of what we're trying to do -- a suggestion for how that information could best be transferred is what we're trying to achieve here.

We put this up for discussion purposes, to say, in a paper-based system, here's the type of information we're looking for.

We know you have a lot of material to do, but we have a certain responsibility, we're trying to find a faster way to do it that does not -- well, you're going to have some burden, that's reality, but that decreases the burden as much as possible and, at the same time, increases the likelihood that the information we get is correct and, you know, is quality information.

MR. CAMERON: Okay. Thanks, Mike.

Before we go to Glen out here and then back to the

table, Suzanne, did you want to add anything at this point?

MS. WOODS: I'm hearing about the page numbers, and that was one issue we had discussed as the staff, as well.

Is it possible that we should wait until it can all be done electronically, until the NRC accepts electronic signature? Is it possible? I'm trying to open up the discussion. What is possible? If this isn't going to work, how can we change this to make it work?

MR. BENNETT: I think that, as long as you go by what the proposal states, a form will be provided for us in making these reports, however the use of the form would not be required, as long as the report is clear and includes all the required information. That would do it for me.

MR. CAMERON: Okay.

MR. HICKEY: I just wanted to comment that, if the number -- first of all, we shouldn't focus on what that form looks like, because again, we're going to go to electronic forms where nobody is actually going to see anything other than a computer screen.

If the number of pages is because we're requiring you to provide more data, then there's nothing we can do about that, but eventually you'll be submitting zero pages but you'll be submitting an electronic report, and it will take somebody more time to enter in more data.

If it's just a question of we laid the form out so it takes more pages for the same amount of data, then yes, your point is well taken. Our intent is to get the data, not how many pages it takes to print it out.

MR. CAMERON: Okay. Let's go to Glen and then to

John and then over to the gentleman from Safety Light.

Glen?

MR. GOTSCHALL: Glen Gotschall from ETG. Just another comment.

Looking at one field there, it says check if replacement. Typically, the units that we get back are sent back for repair, and we repair those units by replacing some sieve filter elements and return it with the same source back to the same customer. So, in those cases, in the next quarterly report, you'll see that we're sending the same serial number again to the same person, and this may happen two or three times.

So, in the past, I have no way of knowing if that customer had notified you that they had sent it back to us. There's no field up there for check if repair, something like that.

MS. WOODS: That's a good point.

MR. CAMERON: Okay. Thank you.

John?

MR. PATTERSON: Is this time to ask specific questions about that form?

MS. WOODS: Yes, and I also wanted to emphasize that we recognize it is a voluntary, but we want to make it as user-friendly as possible so that there is an incentive for you to use it.

MR. PATTERSON: Candy and I were sitting here trying to fill it out. Type of device and, in case of replacement, provide the following for devices received -- would you explain those two fields to us?

MS. WOODS: I'm going to defer to Doug and Cathy

on this. They worked on the form.

MR. BROADDUS: Type of device is consistent with the principle use code that's on the registration certificates. So, it would be -- like if it's a self-luminous light, it would be -- the code, I believe, for that is "W".

Fixed gauge -- fixed gamma gauge -- for fixed beta gauges are "D" and "E". So, I mean that's the type of device.

You could either write it in as what it is called -- I mean typically when you send them to us, you say, you know, we transferred a gamma -- an Ohmart model so-and-so gamma gauge to so-and-so, and that's the type of device.

That could be -- it's generic, and you could provide that to us.

As for in case of replacements, what they're saying there is -- you've got to go back up to the top. The rule requires that you tell us the type of device, the model number, and the serial number of the one that you're replacing, so that it's referring to the headings above that, the one that you're replacing.

However, the problem is there's only space provided there, so --

MR. PATTERSON: I didn't understand either of your explanations, and all of us on this side of the table don't know what you meant by device type.

MR. HICKEY: The type of device is the shorthand term for the device -- gauge, self-luminous exit sign.

MR. PATTERSON: Oh, okay.

MR. HICKEY: Okay.

The replacement information is -- the general term

and the model number and the serial number. What do we want on the replacement information?

MR. BROADDUS: There's a line there, and above that, the line, is the heading. It says type of device, model number, serial number.

What it's saying is, for replacement devices, ones that you are replacing, you have to tell us the type of device that you're replacing, the model number and the serial number that you're replacing. That's what's in the rule.

The rule says you have to tell us the type, model number, and serial number of what you're replacing.

So, it's referring back to the headings above that. It's saying provide that information.

MR. CAMERON: Can I make a process suggestion or ask a question of John and the staff?

Is it possible to give people a copy of this form before they leave, and is it possible or is it valuable for you guys if they took the time to look at it and e-mailed in questions or comments on it at this point?

Because I assume that the NUREG probably has explanations of what these fields are, and it's a little bit unwieldy to go through the explanation of all of that, and I think it's useful that you get an idea from people about what is needed here, but I'm not sure that we're really using our time most efficiently by discussing what are in the fields.

And John, I'll ask you. Is there some further process that could be gone through on this form?

MR. HICKEY: Well, let me check, and we can -- we have information on who's here, and we could get the form to them

separately.

This thing is a work in progress, and we haven't announced it in the Federal Register, so I'm reluctant to say how we're going to handle it right off, shoot from the hip.

MR. CAMERON: Okay.

Mike?

MR. RADDATZ: What we really could use comments on is not the form itself but on what the content of the form should have, based on the information that you have, because possibly, possibly it may be easier for you to download a simple ASCII file of the information that you would be putting in your quarterly transfer report, sending that to us, and we can just put that into our database directly, easier for you, easier for us, but the information that we need is not what you see there but an idea of what you have and what you would currently be getting.

Don't focus on this but focus on the intent of the rule. Here is the information we think you should have. We could use that in a comment.

MR. HARMON: This is Larry Harmon from Safety Light.

I think Mike might have answered some of my questions.

I think it's good that there's a standardized form that we could transfer the stuff over the web. We do now probably about 350 pages of quarterly reports every quarter. So, it would greatly increase ours.

What we're in the process of doing, however, is having our database -- we have an order entry system, of course, where customer and curies and all the other kind of stuff gets

put into our shipping documents now, and we're trying to pull them out by writing another program that we can put them in, so I don't have to have a girl typing them all the time.

If we could somehow -- and I don't have my information guide here and I don't know if it can be done, but what I'd like to do is be able to use that form, if I could, be able to modify it, to be able to grab information off of a couple different other places in my system that fill in that information automatically, so we don't have to type it in. That's the only thing I'm concerned with.

MR. CAMERON: Okay. Thank you. That supports electronic.

I think that there is a lot of support for the concept, but there needs to be more information in terms of meaningful comment.

Let's finish this off so that we can take a break, and then we can move on to the next topic.

Jonathan? And then we'll go to Suzanne.

MR. FORTKAMP: Just real quickly, and perhaps this is what everyone's saying, but I just wanted to make it clear that I agree with the way the proposed rule reads, that a form be provided but that as long as the information is in a legible format otherwise, because I know a lot of us have databases, and instead of trying to match these databases to a particular form, that we can just spit out the same information in a clear and legible form, just make that clear, though.

MR. CAMERON: Okay. Thanks.

Suzanne, anything else that you want to elicit on the standardized form issue?

MS. WOODS: With regards to comment on this and getting it before it goes out in draft, the necessary items that we are interested in addressing today are those things that we're going to have to incorporate in our system as it's being developed now.

Other than that, this form can wait. Your input can be used, to the extent possible, before it goes out in draft, and thereafter, as it finalized, but it may be okay to just wait for your comments until this is actually out for draft public comment, with the exception of one issue, the number of intermediate persons.

We were going to bring this up here because we actually have one blank here, but it's come to our attention that the numbers of intermediate persons can be quite lengthy. We need to be able to program our database to handle those numbers.

For example, a recent scenario is the vendor provided company X with a device, company X provided that device to a general licensee for the purposes of demonstration for a period of a few months, and the device was returned back to the distributor.

It can be redistributed again. It could have been returned back to company X and sent out as a demo for somebody else.

There are electrical contractors who have numbers of these and are intermediates.

There's a number of intermediates. How many should we plan for, quite frankly? What is your sense of how many we should plan for in our database? We wanted to get a feel for that today.

MR. CAMERON: All right. I guess the answer is between one and --

MS. WOODS: Is it typically, you know, five or less? Ten or less?

MR. CAMERON: Chris?

MR. FITZ: Once we transfer that device to -- whether it's an OEM, a customer that's going to be using it for a short period of time, how do we keep track of where it's going, and are we responsible for reporting that? It sounds like that's what you're recommending, or am I missing that?

MS. WOODS: Well, there are intermediate persons and then there are final end users, and both of them are general licensees to be reported to us. I guess it sounds like there might be an issue. Is that clear? But that's something we could handle after the break.

And then what numbers of intermediate persons should we plan for?

MR. CAMERON: John, Mike, do you want to add anything to this conversation?

MR. HICKEY: Well, my interest is not what happens after it reaches an end user, but I'm interested in knowing how often it's going to happen that there's going to be more than one or two intermediate users at the time you file the quarterly report.

At the time you file the quarterly report, you're going to have to know who the end users are and how many intermediate users there are, and I'm interested in knowing how often it's going to be more than one or two people, more than one or two intermediates.

MR. CAMERON: That may help to know that.

Anybody want to offer any opinions from their experiences about -- is that a rare event?

George?

MR. BROWN: Well, it's not uncommon to have an intermediate user, and if you wanted a number, I would probably say two. It's common to have one and not totally unreasonable to have two. I don't remember many cases that we ever got to three.

That's a lot of shuffling around, and somebody in there is a redistribution -- in my opinion, would end up being more of a redistribution, which wouldn't require a specific license.

For instance, we sell a lot of things to Measurex, and they redistribute them, but we transfer them to them as a licensee, and they do the quarterly reports.

So, from a lot of things the manufacturer does, I think two would be a good number, if you want a number.

MR. CAMERON: Any other opinions around the table?

Jonathan?

MR. FORTKAMP: I guess my comment is more on the term intermediate user. These individuals are not really users of the device in the typical sense of a user of the general licensed device. I mean we talk about an end user as the person who actually uses the material.

MR. HICKEY: You're correct. I'm sure George is talking about what's common is there is a construction company that's building the building or remodeling the building for a tenant, so they are the ones that actually initially take possession of the device.

So, they don't use it, but they're responsible for it. That's what we mean by an intermediate possessor.

MR. CAMERON: Is it clear to everybody what John's explanation was about what we mean by intermediate user?

MS. WOODS: The term is actually intermediate person.

MR. CAMERON: Intermediate person. Okay. We heard that two might be a pretty good rule of thumb on this. Anybody disagree with that or have wildly different experiences in terms of numbers?

MR. HARMON: This is Larry Harmon from Safety Light.

We probably have three to four people probably touching the sign before it actually get installed. We have a person that buys it from us, we then ship it to -- sometimes to a distributor, who then takes it to a contractor, who we often don't know -- in fact, we never know who the contractor is. We ship it -- they ship it to the end user, the end user that's on our report. So, we have three or four intermediaries there that -- I don't know how far you're going to go with this.

MR. CAMERON: Is that unique to your particular --

MR. HARMON: Yeah, it is.

MR. CAMERON: -- business? Okay.

MR. HARMON: To the self-luminous business.

MR. CAMERON: All right. Thank you.

Let's have a comment from Mike, and I think we'll take a break.

MR. RADDATZ: I'd like to close out the discussion of the form and give you what our feelings are.

One, we're trying to keep this as cost-efficient as possible. Ultimately, you know, the user field is going to be paying the cost for us to do this. So, our thoughts are that we'll either have a standardized form or a standardized format that you could download your databases into.

Any of your people -- your database people can, you know, parse it into a specific report format, you know, put it in an ASCII file, and either send us the disk or send us -- you know, e-mail it, or however we end up doing it.

If you have comments or suggestions, you don't like that, do like that, we need to know, but that's basically what we have right now. It's either going to be a standardized piece of paper or a standardized format to download your databases into.

We seek comments on that approach. If you have a third, we'd like to hear it, but those are the two that we can think of.

MR. CAMERON: Okay.

Let's take a break to a little bit after 3:30 and come back and get the compliance issues, and I know some people have airplanes, whatever, to catch. So, we're going to try to get you out of here right around five o'clock today.

So, see you in about 15 minutes.

[Recess.]

MR. CAMERON: Let me cover just quickly a couple of things.

I think we have addressed every issue on the paddock. We have a new one here.

One point that I just wanted to make for the NRC

staff and the agreement state folks was the suggestion that John Patterson had earlier, where -- when we were talking about consistency, lack of notification of new state requirements, and all this, that John was suggesting that maybe there would be a benefit if the NRC, the agreement states, at least a good representation of them from the Organization of Agreement States or whatever, companies, sat down for a day to just discuss some of these issues, not necessarily related to this rule-making but the whole idea of uniformity.

So, I'll just put John's idea on the table for you for some consideration.

Suzanne, agreement state compatibility -- we have talked about that, but now we want to focus on the timing of that under compliance, and if you could just briefly tell us what the issue is here with timing.

MS. WOODS: Specifically, agreement states and their timing of when they actually come into compatibility with new requirements is specified under a particular directive that NRC has, and there is a time gap between the time in which NRC puts in place its rules and regulations that go into effect and that time delay between then and when agreement states will then put into effect the same requirements or those at the appropriate compatibility level.

In this case, with you, vendors, compatibility level B requirements will be delayed for agreement state vendors to follow in accordance with agreement state requirements, and that time delay between NRC implementing it and requiring it of the vendors in NRC states and the vendors in agreement states and the vendors requiring it is going to be significant.

What we're going to ask you to do is to volunteer to provide that information to fill in that time gap. There's quite a number of benefits for everyone here to gain from doing that.

Specifically, it will facilitate NRC general licensee compliance.

It will better assure that the information that we print out of our system onto a registration form and send to them is accurate in the sense that it will have filled in those blanks, we won't be giving you as many phone calls, and so forth.

It will be less calls not only to you but to us, as well, and the same information that you would put on this form or provide to us during that time period, you could go ahead and provide to the agreement states and still meet their requirements.

So, providing it early doesn't lose you anything but does gain something for you, and it certainly does gain something for us. It better assures that our NRC licensees are in compliance with our requirements.

An example of the kind of information I'm talking about is responsible individual, serial numbers and model numbers of the devices, location of use, and associated addresses, as we've discussed today.

With that, I'd like to go ahead and open it up, and the paddock issue is the next subtopic on this category of compatibility.

MR. CAMERON: Okay. Great.

First of all, do you all understand or does anybody have any questions about what Suzanne just explained, the

agreement state compatibility time lag and what the NRC is asking of you in terms of complying with the rule, those of you who are in agreement states?

I'm not sure how that works, but are there any questions about that?

Elsa?

MS. NIMMO: I think most of us, expecting our agreement states to adopt it, would be moving towards that as quickly as we could, of course hoping that they adopt identical language.

MS. WOODS: At the compatibility level B, they would have to not necessarily adopt identical language, but it would be explicit that they do have to be -- how does the wording go? -- as restricted.

MS. NIMMO: Yeah, but we've been -- the requirements for manufacturers -- oh, yes, excuse me -- requirements for manufacturers are compatibility level B.

MR. CAMERON: And just keep in mind, though, this is a proposed --

MS. WOODS: Essentially identical.

MR. CAMERON: -- and the comments that you've provided, plus the written comments, on compatibility levels will be considered.

So, they won't necessarily be the same after the staff --

MS. WOODS: Correct.

MR. CAMERON: But I guess the main point is -- that Elsa is making -- is that the vendor see some -- there's some incentives to trying to come into compliance as soon as

possible.

MS. NIMMO: That's my personal remark. Other vendors might not -- they might want to wait and see what their particular agreement state adopts. My guess is we would just sort of move in that direction as quickly as we could.

MR. CAMERON: Okay. Well, let's get some other feedback from people around the table.

Kate, do you have any opinions on that?

MS. ROUGHAN: Well, we'd probably move ahead as soon as possible, too, once the NRC adopted the regs. We have three years for the State of Massachusetts, but they tend to follow very closely NRC anyway. So, we would start going that way, make it as standardized as quickly as possible.

MR. CAMERON: Does anybody else want to express an opinion and, again, take the caveat that Elsa offered to heart, that this is a opinion of a particular person for a particular company. We don't know what the vendor community generally will think about it.

MS. WOODS: Again, also, the words I was looking for and escaped me were "essentially identical" for compatibility level B, so they would have essentially identical requirements.

That means the type of information that we're asking you would be the same type of information they would be requesting. So, whether they request more information is up to them.

MR. CAMERON: I should also ask the agreement state representative who's on the line what their feelings are about the vendors in agreement states voluntarily moving to comply with the NRC requirements before the state -- a state has

its regulations in place. Are there any problems with that?

MR. CLINGER: I don't know. I'd have to talk to our licensing section about that. I probably shouldn't speak for them. Probably not, but certainly wouldn't want to twist their arms very hard, because you know, it's a new requirement, and to ask them to do it on some kind of accelerated basis -- you typically try not to do that to them.

MR. CAMERON: That's an interesting issue, I think, about what the agreement states think and whether there is any value to agreement state discussions with the vendors in their state on implementation, immediate implementation.

MR. CLINGER: Could I say something else?

MR. CAMERON: Sure.

MR. CLINGER: We commented on the proposed rule already, and I think, on this issue, we said that we didn't think that the information, although very desirable, is absolutely necessary to running a registration program. In other words, we couldn't see the need for urgency in it beyond -- ahead of the normal three-year implementation period.

MR. CAMERON: Well, that's a point that we should put before the group, too. Is there a need for urgency in terms of the registration program?

MR. HICKEY: I don't know if I would use the word "urgency."

I think that it could run into problems with customers if they start running into compliance problems, if their suppliers are in agreement states and the suppliers aren't doing -- are not out ahead of the agreement state, the customers could run into problems and start complaining to the vendors

about it.

MR. CAMERON: John, comments on this or another issue?

MR. PATTERSON: I don't know exactly -- this is more a logic problem in my mind, and it's a competitive issue if it comes out the wrong way.

A vendor resides in an agreement state and distributes according to the agreement state's regulations. I'm in the NRC state. I've got to do it tomorrow. He has got three years before he's going to send out notification to you so you can license, register the device in an NRC state.

The end user is in an NRC state. I'm in an NRC state. The other company's in an agreement state. That end user -- when does he start paying the fee?

MR. HICKEY: He'll have to start paying the fee at the same time. The information we need to find out if they need to be registered is already required to be submitted to us. There's just a few other things I think we're adding, like do we require -- maybe Cathy knows.

Do we require the responsible individual now or the intermediate people now?

MS. HANEY: Intermediate people are already required. We ask for a contact name only right now. The new rule would be a responsible individual and phone number, and we've also added serial number.

MR. HICKEY: So, we're already getting the essential information, and everybody will have to pay the fee at the same time.

MR. PATTERSON: So, the registration will come

into effect --

MR. HICKEY: -- for everybody.

MR. PATTERSON: -- in the NRC state. The end user in an agreement state may not have to pay a registration fee until that state becomes in compliance.

MR. HICKEY: Right. And the state may never require it, and the state may not allow general licensees to exist at all.

MR. PATTERSON: Yeah, but that's going to be the same regardless of where the device is sourced from.

MR. HICKEY: Correct.

MR. BROADDUS: Can I make a point of clarification?

One of the items that we haven't asked for previously was serial number.

We are now asking for that, and when we register, we will be registering and sending out information to those that are -- when we request registration, we'll be sending out information to the general licensees saying, you know, we understand you have model number so-and-so, serial number so-and-so, and they have to provide that back to us, you know, provide back to us whether they have that or not and verify it.

If we're not getting the serial numbers, then we're just going to have to say we understand you have 20 of these devices, and they may or may not.

So, it becomes -- it reduces the accountability that we have for the devices by not having immediate compatibility.

We don't have that accountability for individual

devices. We only have the number of devices that we think they have, and whatever they come back to us and tell us is what we have to -- it reduces our ability to register as well as keep accountability for individual devices.

MR. CAMERON: Suzanne?

Glen, did you have a question before we -- maybe we should explore this source serial numbers, but Glen, did you have a comment, and if you did, please step to the mike. No. All right.

Suzanne, do you want to talk about source serial numbers?

MS. WOODS: The paddock issue. Okay.

Before we go to that, let me just -- you described one scenario where you're an NRC licensee, specific licensee in an NRC state, and you have an NRC licensee, general licensee that you're distributing to, and you raised the issue of are you now in a competitive issue with an agreement state licensee, specific licensee who is -- does not have to require -- is not required to comply with NRC requirements but, rather, the agreement state requirements and that agreement state doesn't have to come into compatibility for quite some time, until after NRC's licensees have to go ahead and implement the rule. So, you see a disparity in time, and you're asking is there a question of competition.

What we see is the issue -- and I tried to elicit this at the beginning, was we see that NRC licensee getting their registration form.

If they are your customer, they're going to have that form filled out completely for them and they're not going to be calling you, and they're just going to sign it and send it

back to us.

However, if that licensee is a customer of an agreement state licensee and that agreement state licensee has not volunteered to provide and meet with the NRC timing of implementation for the rule, then their customer, NRC customer, NRC general licensee customer receives a general license -- or a registration form with blanks in it, and do most general licenses who have two different types of numbers on their device know which one's which? I don't know.

Are they going to fill it out properly? Are they going to likely call you for assistance on it if you're the agreement state vendor? If they receive information that is completely inaccurate, they might ask you how did NRC get this information.

So, there are certainly some issues here that we were raising to your attention in the light of asking for voluntary early participation with the timing of implementation of NRC on this particular rule.

MR. CAMERON: John, do you want to comment on that?

Suzanne has followed up on a good point here about at least -- is it clear how this regulatory framework would work between vendors who are in agreement states transferring to GLs in different types of jurisdictions, and is there any confusion about that that we should straighten out so that you people understand it before you file written comments?

[No response.]

MR. CAMERON: Okay.

We're going to go on to the next --

MS. WOODS: Right. There's another sub-issue with compliance, and I'll run down this really quick, and then I'm going to open the paddock issue, because I think that's going to be more discussion. These are issues we wanted to highlight to your attention.

The source and label changing -- these are highlights.

Changing labels at the time of the source change to facilitate a general license compliance with the registration -- if, for example, you have a particular device that you change the -- it's authorized for two different isotopes and you've changed the isotope or you've changed the quantity of the source, if that puts a person in or out of registration space, we need to know that information and so does the potential registrant.

Labels with sources -- with source information will assist the general licensee with that compliance information.

We're not requiring that you put source information on the label, but it certainly allows them to know what it is they've got and whether or not they have to register and meet our registration requirements.

Also, we wanted to highlight that, in the proposed rule, the timeframe for changing labels on devices, these permanent labels, is one year, and finally, there is a need to change the label or the general license description that appears on the label if the device is moved to a specific license.

It is possible that, under this rule, if a licensee is both a specific licensee and has a generally licensed device, they see a fee attached to both, they may move their

general license to the specific license, in which case there was a label on there that declares this is a generally licensed device and you have to meet the requirements and so forth. So, that label would have to be changed.

John Patterson brought up a particular issue with regards to source serial numbers, and I've hit somewhat on that issue, so I'll defer to him for the remainder.

MR. PATTERSON: I just made the statement that, you know, with most of our devices, the device has a serial number. In our databases, I think most of us have the source serial numbers, as well, and that's probably information you guys ought to have.

You know, I said, the the risk of sticking out my neck and offending somebody -- so, anybody else who wants to comment on that -- I mean, for us, it would not be a big deal. I don't know about the rest of the vendors.

MS. WOODS: So, in other words, besides the serial number and the model number on the device that we're asking for now in the proposed rule, we would have a serial number for the source, as well.

Now, that's a good thing in the sense that, if we find just the source, we certainly can find who owns it. So, it is a benefit.

What are you feelings on that issue? What's your insight?

MR. CAMERON: We're going to go to -- George Brown has an issue that we're going to get to.

Kate, why don't you tell us what's on your mind, and then we'll go to --

MS. ROUGHAN: I had a comment somewhat related, but you're talking about changing the labeling. A lot of these devices and source holders or source assemblies are registered under a sealed source and device registration, and in order to change labeling requirements a lot of time, that would require an amendment to that.

Is there going to be a general authorization that you can change those labels in the regs under NRC, and if so, will the same exemption hold true for agreement state device registrations? Because it takes time to make those amendments. We may not be able to get that done in a year.

MR. CAMERON: Any comment?

MS. WOODS: Are you talking about the change to a permanent label?

MS. ROUGHAN: Yes. There different information that you have to -- you're requiring some additional information.

Right now what may be listed in device registration for labeling the device or source-holder -- you may have to upgrade that or make changes, and on the device registration, that would normally require an amendment change, along with a fee, obviously, and that takes time -- six months, a year, depending on the state or NRC, and right now, we've got a year to implement the labeling changes. We may not have enough time to do that.

MS. WOODS: Okay.

MR. CAMERON: George, was that the issue that you were concerned about?

MR. BROWN: No.

MR. CAMERON: The permanent label? Was it related

to this?

MR. BROWN: It's related to labeling. A question on the serial numbers for sources -- if it's going to be part of the database, some devices that we sell will have more than one source in them. So, you could have more than one serial number for a capsule.

So, that could become a problem as far as reporting. I don't know what the max would be, but four --

MS. WOODS: Thanks for keeping the numbers in mind. That's important to us.

MR. BROWN: My question is -- and we can come back to it later, but I think we really need to discuss that there is a new requirement for labeling -- it says bear permanent, embossed, etched, or stamped label to the source-holder.

I've got some real concerns about that, and I don't know if we want to handle that right now or if you want to get done with the serial number.

MR. CAMERON: Why don't we just wait a minute and come back and revisit that and make sure that some of the issues that Suzanne raised -- that you get a chance to comment on that.

Mike, did you have a few comments you wanted to make?

MR. NORBURY: The only comment I had was that, as far as we're concerned, we already report the source serial numbers anyway as part of our report and have been doing that, so it's not an issue. I think most of us keep isotope source serial numbers anyway, for tracking reasons.

MR. CAMERON: To close that out, does anybody have -- well, George indicated one potential problem with the source

serial number. Is there any other concerns with source serial numbers?

MS. WOODS: But essentially this is information you all have?

MR. CAMERON: Ralph, source serial number?

MR. HEYER: Source serial number -- our specific radioactive material licensees don't always have source serial numbers listed on their licenses. So, are we now imposing something more on general licensees?

MR. CAMERON: Something to consider.

Elsa, where did you want to go?

MS. NIMMO: My only comment was that people in the industry do this differently. We've always used our source serial number as our device serial number. So, if you have both fields, you're going to get the same number, which is fine as long as your program will accept that and not cough it back as being unacceptable.

MS. WOODS: Thanks for that point. That's a good point.

MR. CAMERON: David.

MR. BENNETT: Our source serial numbers are the same as device number, as well, and I just have a concern that it could cause confusion to customers if you require the source number and all they know of is the device number. We don't distinguish between source and device number. We just call it one number. It's only one serial number, and it is the same as the source number.

MR. HICKEY: I guess if we knew in some way that that's common, that could be dealt with, but I'm interested, do

you change sources?

MR. BENNETT: No.

MR. HICKEY: Okay.

MS. NIMMO: We do on occasion, but at that point, they get a new label.

MR. HICKEY: That has a new device serial number?

MS. NIMMO: Yeah. Well, it's just stated as serial number.

MR. HICKEY: What's the serial number on the old source at that point?

MS. NIMMO: The old source -- we ship them a new shielded source assembly, a new set of labels. They send us back the shielded source assembly, which itself is also labeled, and they apply the new label and install the new shielded source assembly.

MR. HICKEY: So, basically, your device doesn't really have a serial number. It just is -- it's a apparatus sitting there containing something that has a serial number.

MS. NIMMO: Right.

MR. HICKEY: Okay.

MS. NIMMO: It's not of interest to anyone if it doesn't have a source, not in that way.

MR. CAMERON: Chris?

MR. FITZ: We're kind of just the exact opposite, John. We have a device number, and inside that is a source serial number. We may change the source number, but the device will stay the same.

MR. HICKEY: I would think of that as the more common situation.

MR. CAMERON: Doug?

MR. BROADDUS: I wanted also to respond to the question or the point of the confusion on the customers.

What we receive on your quarterly transfer reports is going to say that the device model number and the device serial number -- or the device serial number and the source serial number are the same.

So, we'll put that into the database that way, and we can handle any number of sources and serial numbers. I mean we've designed it that way, so that it can accept multiple isotopes.

So, that's -- when we send out the registration request forms, it will indicate on there -- if we ask for source serial numbers, it would indicate the device serial number is this, the source serial number is this, and they would be the same, and so, the person going out and looking at the label would see that serial number and say this is the serial number we have here, and I don't think there would be confusion from that standpoint, because we would be telling them what we have given them, you know, what we have in our database, we'd be telling them, and all they'd have to do is go out and look at the label and see if it's the same, and if they're identical, you know, we're already telling them that, and all they had to do is verify yes, that's the case.

MR. CAMERON: Mike?

MR. RADDATZ: Maybe I could clarify what we're trying to get at here, you know, again, what we want.

What we want is a way of -- if we find a source -- if a source is called in outside of a device -- and you know,

that happens. It's a rare event, but it doesn't happen. We're trying to chase that down. We're looking for guidance.

Obviously, we don't want somebody opening up a device, yeah, I got the source number, I'm reading it right now, and then putting it back in, and I don't feel good, I'm going home now.

We don't want that, but we're trying to find a way that information that you already have can somehow be related to the database.

Our thoughts were that, if there are multiple sources in there, then the source serial numbers can be recorded at the same time.

If you have another idea, we're looking for it.

That's the problem. That's the issue. I offer it up, and if, again -- you might want to think about it, come back with an idea. I offered before standardized labeling as a thought. What if we proposed or, better yet, industry proposed through, let's say, an ANSI standard a standardized label?

You come back at us saying, hey, we think that we can live with this following labeling format, and it all would be the same. That would be much simpler for us, much simpler for you. I don't know if there's a competitive disadvantage or not. I'm not trying to dictate it.

Again, that's the problem. We're hoping for some solutions to it.

MR. CAMERON: Kate?

MS. ROUGHAN: Actually more of a question. We sterilize and label our source capsules, but a lot of times those then go into another holder. I'm not sure if that holder is

labeled on the outside, if there needs to be a requirement for that.

MR. CAMERON: Anybody have any information on that?

MS. WOODS: The proposed requirement is to label the device and any separable housing. So, if the holder is essentially a housing, then the answer is yes, it needs to be labeled.

MR. CAMERON: Okay. Thank you.

Keeping in mind what Mike said, any comments on the -- what the NRC is trying to do here?

Chris, whatever you want to say, go ahead.

MR. FITZ: No, it was just a thought.

MR. CAMERON: Okay.

Are we ready to go to George's permanent label issue? I think we probably are.

Do you want to explain that to us?

MR. BROWN: In the proposed rule, 32.51(a)(5) states each device meeting criteria in the above section of this chapter bears a permanent that is embossed, etched, stamped, or engraved label affixed to the source housing, if separable, and then it has to have certain wording. What I wanted to point out is the wording, the way I would look at it there, would mean that it can't be a removable tag, but yet it must be a removable tag.

For instance, source holders that we have cast may be -- well, they're cast and it goes through about three states before it comes to us as a finished product. From the moment it's cast, it will now have the words on it "radioactive material."

As it goes to the manufacturer that does the machining for us, if he scraps out one because of a machining error, now he has a piece of scrap metal with a label on it that says radioactive material, and you have lots of things with not radioactive material in them but labels on them that say -- which create a big problem in themselves.

I don't have any problem with putting the label on it, but the wording should be durable labeling, something like that, and we've been putting riveted steel labels, stainless steel tags on source holders for 50 years, and they stay there.

Now, they can be removed if somebody wants to vandalize the gauge and take it off, but you could vandalize and take off an embossing, too, if you really wanted to, and my only comment is the wording get changed because it has to have some -- in order to scrap it out when it's done, you have to be able to take the label off. You can't throw away something that says radioactive either.

MS. WOODS: So, it sounds like the words "permanent" imply that it's a permanently affixed label to the device, whereas durable, it talks about the label itself maintaining the integrity of the information on it. Is that what you're getting at?

MR. BROWN: Yeah. I mean somewhere in this wording it should be -- durable with the intent to last the useful life of the device or whatever you wanted.

The issue is brought up in the device registrations now. So, I mean in the device registrations, we have to define how it's labeled and why we think it will withstand in the environment that the device is being used.

So, those issues are there. That's my concern with that, is to make sure that we get that corrected.

MR. HICKEY: I'm sorry. I'm still not clear on what your concern is.

MR. BROWN: Well, two concerns is that you end up with a bunch of things, empty source housings, that have the words "radioactive material" and the trefoil on them and no radioactive material, either in the stream coming into us to be made into gauges or when we're done with them, to try to remove that off.

We don't do anything in tungsten, but some people do, and to engrave and machine tungsten and then to obliterate it to be able to throw it away again would be very hard to do.

So, a durable marking or wording that would require it to be durable -- just the way it's worded, to me, it doesn't seem to me that a riveted label would fit, of any type.

MR. HICKEY: Okay. I understand.

As a matter of fact, in Part 20, we have a requirement to obliterate radiation labels when the radioactive material is removed. So, your comments is that this requirement doesn't seem to be consistent with that.

MR. BROWN: Well, it's also coming in, too, when you buy them from somebody. I mean we have had problems with packages of labels being shipped to us being dropped and broken up and just having labels on the ground that said "radioactive material." I'm sure you've gotten calls, too.

MR. CAMERON: Okay. Thanks, George.

Mike, do you have a comment?

MR. RADDATZ: Real quick. That's a very good

comment, and that can be dealt with easily. Remember, we have the statements of consideration, and I encourage everyone, when you get a rule, to get the statements of consideration and read them, and that's a place where that will be elaborated on, not just saying what we want but what we mean.

MR. CAMERON: And I guess that probably the suggestion would still be to change the wording of the actual text of the rule just in case there are people who don't have the -- that was your recommendation, I think, right?

But supplementary information often explains these, and I think we've heard a number of issues today where we perhaps could be clearer in the supplementary information.

Let's go to Jonathan and then David.

MR. FORTKAMP: Just to follow up on George's comment, there's another situation where we have a device where the device might be labeled that meets the requirements and we have the source that -- the entire device is not transferred out and we just do source replacements within the device, and along the same lines, a permanently affixed label with a source serial number -- that source serial number is going to change each time a new source goes into it, although the device itself may not change, and along the same lines, a permanently affixed label, you know, prohibits us from doing that.

MR. CAMERON: Okay. Thank you, Jonathan.

John, did you have a question?

MR. HICKEY: Well, I was just going to say the wording of the rule is intended so that you could change the label as long as it's durable, but your comment may still indicate we need to make a change but that that was the intent.

MR. CAMERON: David?

MR. BENNETT: I have a question about the additional label on a separable house, source housing. What's the intention behind that?

MS. WOODS: I'm sorry. Could you repeat that?

MR. BENNETT: The proposed rule would amend the existing labeling requirements to require an additional label on any separable source housing.

MR. HICKEY: The intent there is, if it's junked and the -- that somebody would be able to recognize the primary shielding containing a source that had been separated and there would be a label on it. That's what's behind it.

MR. BENNETT: Our situation is one where we stamp "radioactive material" and a radiation symbol and perhaps the radioisotope on the device itself, then attach a metal tag to the device with a wire cable, and all of the other information, then, that is required for general license tags is identified on that label, in addition to a radioactive symbol and radioactive device, but like I say, that metal tag is attached by a metal wire to the device. That tag lays inside of a housing area where the cover is -- the separable source housing is located, but the metal tag is always within view. So, I'm asking whether or not it's necessary to have two tags that are always visible.

If your intention is to be able to identify that there is a radioactive device inside of that housing, we meet that requirement, because the metal tag is there, but it's not -- it sits right inside of a compartment with the source housing, and that tag is attached to the device. So, I'm asking if we need to have two labels that say the same thing in constant plain

view.

MS. WOODS: I think I understand what you're saying in your description, and it sounds like the label is not necessarily visible unless you dismantle the housing.

MR. BENNETT: No. If you're familiar with gas chromatographs, open up the top of the gas chromatograph, and there is sort of a tray, and sticking out of that tray is the housing. Inside the housing is the device. Attached to the device is a metal tag that sits inside of that tray, next to the source housing.

So, the metal tag is just as visible as the source housing is, and so, my question is if we have to have a separate tag on the source housing in addition to the tag that we have on the device.

MR. HICKEY: The intent is, if that source housing is separable, it should be labeled.

Now, maybe there's a comment here that we need to consider, but the idea is, if somebody pulled that source housing out of there and threw it away and somebody else picked it up, would they know there was a radioactive source in there?

MR. BENNETT: I think the source housing would come apart and away from the device. I'm talking about a cover as opposed to perhaps a box that encapsulates the entire thing.

MR. HICKEY: The gas chromatographs did not drive this requirement.

MR. BENNETT: I understand.

MR. HICKEY: It was the 5-curie cesium source in lead that drove it, but I understand your question.

MS. WOODS: I think the separable housing is the

concept that you have a device that you could put a label on anywhere. You certainly have a component that's associated with the source that is in that device.

If the component associated with the source is separable such that you put your label on one place on the device and now the source is apart from that label, then you need to label that separable part, so it's clear to anything who picks up that minimal -- the smallest component with the source in it that is separable.

If that should happen, it's clear to them that they are picking up a radioactive source.

MR. BENNETT: That's what has the label on it now.

MR. CAMERON: Okay. Let's hear from Doug and then hear from Ralph and maybe get to the national database.

MR. BROADDUS: The design that Dave is talking about -- this is Doug Broaddus again. The design that David is talking about would meet the intent of what we're trying to get to, because the label is attached by a -- some type of metal cable or something like that to the separable source housing, but it's also visible at all times when the whole device is installed.

However, it doesn't meet the strict letter of the regulation, because there's no label on the outside of the device itself.

However, as John pointed out, his devices would not be subject to registration.

So, we wouldn't be as concerned about that. We wouldn't say -- only those that are subject to registration have to meet that requirement, and those are the ones that have the

higher risk.

It says right here, "The proposed rule would amend the existing labeling requirements to require an additional label on any separable source housing and a permanent metal label or a permanent label on devices meeting the criteria for registration."

MS. WOODS: That's in the comments. That's not the way the proposed rule reads.

MR. BROADDUS: Well, if that's the case, then we need to make it clear. This is what the intent is saying.

So, from the intent of the rule, you know, this would not have to meet this requirement, but as this indicates, also, we want to be able to identify those devices, you know, that have separable source housing that do meet the criteria for registration if they become separated, because they do require this enhanced oversight or increased oversight and are at greater hazard. We still want to be able to identify what they are in the field if they get separated.

MR. CAMERON: Okay. I think we need to do some clarification on what exactly we mean there.

Ralph, do you have a comment on this?

MR. HEYER: I guess I'm more confused now than ever. A source capsule inside a Type A approved shipping container potentially could be dislocated if subjected to a fire, smelted down, cut through. Does that capsule have to be labeled?

MR. HICKEY: Well, that's not what we're talking about. What we're talking about here is shielding. You have to consider the way the rule is worded.

MR. HEYER: Okay. So, the source housing --

MR. HICKEY: The shielding has to be labeled.

MR. HEYER: Okay.

MR. CAMERON: Can I make sure that this is clear?

The source housing that Ralph asked about does not have to be labeled, correct? It does have to be labeled.

MR. HICKEY: The source housing is a lead-filled cylinder that has a name plate, model number, serial number, isotope, the whole nine yards.

MR. CAMERON: And John's comment about shielding was -- did you get the answer to your question?

MR. HEYER: I believe so. When it was pointed out that you said shielding of the source housing, it's just the source housing, source head, Type A approved shipping container, like a radiographer camera is a Type B approved shipping container. You're not asking for the pigtail, are you?

MR. RADDATZ: This is Mike Raddatz again.

The smallest component that would be a normal piece of the assembly, right? That's what you're looking at. We're not telling you to cut it apart to get it out, but the smallest component that could be found.

So, if you've got a device that the radioactive shielding, housing, source holder is a component. The outside of the device has to be labeled, yes, but the smallest component that could be separated -- like some people said that their devices were replaceable, the device stayed in the field, the source housing went back and forth. The source housing has to be labeled as radioactive.

MR. CAMERON: Is this clear to everybody, or are we creating more confusion? And I won't use myself as a

measuring standard on that.

John?

MR. PATTERSON: The trouble is, if you look at the wording of the actual regulation that's in the back of that thing, the separable housing doesn't fall under the criteria of section 31.5(c)(13)(i). It's simply a label on that piece.

MR. RADDATZ: Send it in as a comment for clarification. We'll ensure that it's addressed.

MR. HICKEY: I agree, it's unclear, and we'll address it.

MR. CAMERON: Good. That's great.

Are we ready to move on to the national database before we all run out of steam? Is that what you're going to talk about next?

MS. WOODS: Yeah.

In the proposed rule -- you may have already read this, so we're going to go ahead with asking you to comment on it -- it specifically says that the Commission specifically seeks comment on the advantages and disadvantages of implementing a national database of general licensees.

Our general license tracking system that we're developing has the robust ability to handle such a thing. So, it is possible, first of all, to do this.

This would involve the expansion of that computer system to do it, and one option for implementation would be to report all the transfers to NRC, including agreement state licensee transfers.

The issues presented are who would maintain this. At the agreement state workshop in July, the agreement states

felt that agreement state licensees should have some part in the cost in it, and the issue of vendors potentially sharing in that burden came up, as well.

Potential advantages of having a national database include tracing found devices to owners, what we've often -- not often but -- not necessarily orphan sources but those that have been found and can be traced to their owners, information immediately that's available.

So, if we find a device or anything, a source, we can find that information immediately and do not have to go through our database, an agreement state database, and have them search their files manually or electronically otherwise, and another advantage is that it has -- we would have a complete general license and device information.

A disadvantage is that we would be maintaining data in each of these databases at different jurisdictions, and there are proprietary issues. Most of you have submitted affidavits to us that request your customer lists stay within our regulatory requirements that would allow us to maintain that proprietary.

Agreement state jurisdictions may not necessarily have that, and we have had some discussion with them. It's still an open issue.

Another potential disadvantage is that the data integrity with multiple users may not necessarily stay quite as intact as if we had one single system and one user. So, there's always that risk when you have multiple users entering information into a database.

With that as the sounding point, can we go forward

with a bit of discussion on a national database and what you feel on this?

MR. CAMERON: Is this going first to the need, to something that is needed?

Elsa?

MS. NIMMO: Back when the NRC working group got started, the intent was to really be able to know where sources were, and at that point, Jack Dukes of ABB put forth kind of a six-point proposal which I think basically all the manufacturers agreed with, and at the heart of that was a national database, and I think nothing has changed.

To a lot of us, the proposed regulations look, frankly, rather weak and ineffectual at getting at the original intent that was discussed during those working group meetings.

So, seeing it as a -- well, the NRC will have a database and the states will have to somehow keep records of their devices that fall in those categories doesn't look nearly as effective as having a single national database. I personally would still really favor that over multiple databases by states.

MR. CAMERON: What is the difference between what Suzanne was talking about and what the six-point program was? In other words, how would you change what's in the rule or what's contemplated now to implement the six-point program?

MS. NIMMO: This rule is for an NRC database, and it doesn't address the devices that are going to agreement states.

So, we would end up with 20-some-odd databases, and these sources cross state boundaries, and where the scrap metal ends up, where an orphan source might end up may have

nothing to do with where that serial number source was originally distributed to.

I see individual databases as being very much weaker than one place that attempts to capture all this information.

MR. CAMERON: Suzanne, is that what you were proposing, is the same thing that Elsa is talking about?

MS. WOODS: I believe that's what everyone has in mind, is that we would be moving towards the discussions in the working group. I have a little bit of information on -- I have, I think, four points here out of the working group NUREG.

I think the wording, as it was described, was a national inventory or database of all devices that would be a semi-annual inventory and reporting inventory and to be repeated, the inventory, on an annual basis. So, both semi-annual and annual were discussed.

Also discussed were reporting transfers and uniform regulation of devices by agreement states and NRC and also using a risk-based approach which is to be included -- which devices are to be included, isotopes and so forth, in the database and that all devices should be in the database.

Those are five of the six points that I had jotted down from that report, if that helps to facilitate the discussion.

MR. CAMERON: It seems that there is support being expressed for this idea, and I just wanted to check in with our agreement state rep, if they're still there in Illinois.

Any views on the national database?

MR. CLINGER: Well, we commented favorably on it.

We have a couple of concerns.

One, we would not want to unplug our database till we were real sure that yours worked, and the second thing would be the cost. It would be difficult for us to ask our licensees to pay for the development of the thing.

MR. CAMERON: Okay. Thank you.

So, some sort of a pilot program to test it out and also the question of -- that Suzanne raised about who's going to pay for the --

MR. CLINGER: Yeah, I think that's essentially it.

MR. CAMERON: Suzanne, were you going to add something?

MS. WOODS: No, that's fine.

MR. CAMERON: What about the cost issue?

MR. HICKEY: Well, if I can be presumptuous and say if I were a vendor, I would say, first of all, enough money is already being paid to NRC and states to pay for these programs, so I don't see why it should cost anymore money.

In fact, maybe it would be cheaper, because all the states have to do is give NRC a copy of their reports and NRC can put them into the system, and then there will be a national database.

[Laughter.]

MR. CAMERON: I don't think that they could have said it any better. Good work, John.

What other feasibility issues did you raise, Suzanne, that you might want to get comments on? The cost issue is still on the floor, too, for people who want to comment on it.

Glen, do you want to make a comment on it up here

at the mike, please?

MR. GOTSCHALL: I was just going to comment about -- for those of us who now want to send in quarterly reports with a request for non-disclosure of our customers, how would you control that in your database?

MR. CAMERON: So, this is the issue that you brought up. How would that be addressed?

MS. WOODS: I'm sorry.

MR. HICKEY: He's asking how would the database be protected.

It would be a proprietary database, and only NRC employees would have access to it, and the state regulatory agencies that already have provisions for protection of proprietary information. It wouldn't be something that's available to the public.

MR. GOTSCHALL: That's what DOD said, and they got sued and lost.

MR. HICKEY: Well, I don't want to get into that now.

[Laughter.]

MR. CAMERON: Let's talk about the comfort level of the people around the table on this issue, proprietary information. Anybody have the same concerns that Glen has over unauthorized access or unauthorized release of the information?

MS. WOODS: Some of the scenarios that were discussed at the agreement state workshop were the following: that there is a difference, potentially, between protecting information that's in the database and generating a piece of paper that sits on someone's desk that could come under FOIA for

us or the other similar type of requirements in an agreement state, how are those things handled.

Proprietary information here is reviewed during a FOIA request, and a determination is made apart from, for example, your affidavits, but the affidavits are considered in that request.

So, we have agreed to maintain that information proprietary. Agreement states may have a whole different regulatory framework for releasing information.

We raised these issues at the workshop and discussed them, but it really would have to be something that we'd have to go into more to find out where we are on it.

To what extent is there a comfort level, I think is what Chip is getting at, with allowing a national database. Every state agency would have access to your customer list, for example. How do you feel about that?

MR. CAMERON: Is that an issue that you have to deal with, essentially, already? Maybe not on as wide a basis, perhaps.

MR. BROWN: From what I understand, you just said that the database would be available to regulators but not part of public record. So, it wouldn't be available in a public document room.

I don't have any problem with regulators having access to a database that has a list of our customers, but I don't think that that should be general knowledge that anybody could say, gee, can we look at the database for the quarterly reports. We would have a problem with that.

The way I think you said is that it's available to

regulators only.

MS. WOODS: Whether there is actual provisions that would limit it to only regulators under all circumstances is yet to be determined, and those circumstances being specific requests from the public for that kind of information.

So, there some things there, but I hear what you're saying in terms of you're comfortable with NRC seeing it and agreement state regulators seeing it but you don't want it to be released. Is that correct?

MR. BROWN: Right.

MS. WOODS: Okay.

MR. PATTERSON: I think that's shared by pretty much all the vendors.

MR. CAMERON: Elsa?

MS. NIMMO: I think all of us who are in otherwise competitive situations wouldn't want the salesmen of our competitors pulling up lists of our customers.

MS. WOODS: So, we would need to explore further that there is -- these assurances would be in place. Is that a fair assessment? Okay.

The other issue I had raised was who would maintain it? There has been a natural assumption in this conversation that it would be NRC. It might be agreement states. It might be agreement state licensees in the case of agreement states where they would be sharing some of the burden of cost on this.

What are your feelings? How would general licensees -- how would specific licensees in terms of vendor-specific handle this? Any thoughts on that?

MR. CAMERON: Go ahead, Glen.

Is it clear to everybody what the term "maintain" means in this context?

MS. WOODS: Maintaining a database is updating the software, the hardware, providing training to users on an ongoing basis or new users, those kinds of things, the day-to-day administrative issues with the quantity of memory being used in the database and so forth.

MR. CAMERON: The database administrator?

MS. WOODS: Everything that would maintain -- just like you maintain a house at home, every, you know, nail that has to go in a hole and every window that needs to be cleaned to keep this going. So, that's what we would have to do, is what what maintenance means.

MR. CAMERON: Glen?

MR. GOTSCHALL: From my perspective, I'd rather see the NRA -- excuse me --

[Laughter.]

MR. CAMERON: Now, there's an out-of-the-box suggestion.

MR. GOTSCHALL: I'd rather see the NRC maintain the database rather than the states. I've been a state employee, and I know states are very political, and I'd rather see it `t a head agency rather than controlled state to state. I think that would be safer.

MR. CAMERON: Okay. Thanks, Glen.

Let's go Illinois about the database maintenance issue. Any comments on that particular issue?

MR. CLINGER: No, I don't think so.

MR. CAMERON: All right.

Suzanne, is that all there is on the database?

MS. WOODS: That's it on the database.

MR. CAMERON: Now, we have --

MS. WOODS: -- disposal cost.

MR. CAMERON: -- a few issues left that we're going to try to move through fairly quickly so that we can come back to all of you around the table to see if there's any final issues that you want to tell us about.

This is the whole issue of penalties, right, and enforcement? Okay.

MS. WOODS: Whether we call it disposal or we call it final disposition or transfer out of the possession of the general licensee, user, whatever you want to call it, we want to provide an incentive to users, to general licensees to take care of these things when they're done using these devices.

That incentive, as it's currently structured and proposed in the rule, would include enforcement that would have a civil penalty structure equating to three times the cost of disposal.

During the interim, as we begin to implement registration and do the kinds of follow-up things we're doing now -- responding to mailings, sending inspectors out -- we're going to be doing that very soon, sending inspectors out to find these lost licensees that didn't respond to mailings or the mailings, rather, were returned -- as we show up and we have perhaps some inspection issues to talk with them about, to find their devices, during that period there's an amnesty. That's what point one up here is talking about.

But once the amnesty goes away, we will have in place an enforcement structure that includes a three-tiered civil penalty structure if the proposed rule goes forward as suggested.

Again, all of this is with the emphasis that this would be the deterrent and the encouragement, rather, to dispose of things appropriately, whether that be returning it to the vendor or otherwise.

Our questions to you are how accurate are these numbers and are they, in fact, three times what it would cost for the three separate tiers of disposal? Are there more tiers than three separate types of -- levels of disposal cost?

And will this effectively encourage authorized disposal or authorized transfer out of the possession of a general licensee at the termination of their license, although we have no official process for that, for license termination.

MR. CAMERON: The three tiers are?

MS. WOODS: Well, they're 5,500, 1,500, and 45,000 dollars.

MR. CAMERON: What does each tier represent?

MS. WOODS: Well, there are different isotopes and quantities. So, certain of them would be less expensive than others.

MR. CAMERON: To dispose of.

MS. WOODS: Correct. And have we captured -- in three tiers, have we captured the range? Is it more appropriate to have other tiers? Are these numbers appropriate?

MR. CAMERON: And will this, in fact, provide an incentive for proper disposal?

Anybody want to take a whack at any of these

questions, including whether it will provide the incentive for proper disposal?

MR. BENNETT: Only if that information is provided to them and they are made aware of it. Only if that information is provided to them ahead of time and they are constantly made aware of it. Again, the issue of communications on an ongoing basis.

Since these do turn over -- since ownership of these things does turn over on a frequent basis and you're going to be contacting them on an annual basis, maybe that's something that should be included in the information that's provided to them.

MR. CAMERON: That's a good question. Is that type of information required to be provided to a purchaser of one of these devices, going back to our first -- you know, one of our early subjects?

MS. WOODS: Well, the disposal costs are in there, but what civil penalties would be imposed if they didn't pay it, no.

It's not required that you provide that to them, but certainly, if I were a vendor, I mean it would be something that I would use as a comparison point. You can either return it to me for this cost, dispose of it properly, or you're going to have to pay a civil penalty over here that's three times my cost.

MR. CAMERON: I guess David is suggesting that it should be a required part of the information.

MS. WOODS: Okay.

MR. BENNETT: When I go through a driver's education program in school, I am taught of the possibilities of

finer if I don't obey the speed limit when I get my driver's license, and I think I see the same situation here.

A customer is purchasing one of my devices, and I'm going to tell them of the disposal and identify a disposal fee. I think it's only right that we would have to provide that information to them.

Again, like I say, I think -- well, two things: number one, that it's provided in some verbiage in the annual interaction, and what are you going to do about situations such as ours where they're not going to be certified or part of the certification process?

How is that information supposed to be provided down-line to these customers?

MR. CAMERON: Let's go to Kate and then over to Elsa.

Kate?

MS. ROUGHAN: We're going through a process right now of trying to get -- we had some polonium-210 sources that went out under a general license over the past several years, and right now, we've determined that there's tens of them out there that are unaccounted for.

We've sent letters to the last known general licensee telling us where they are or when they disposed of it, and what we're finding is they're saying they transferred it but no one has any records of when it was transferred or who received it.

So, in this type of case, you have lost and improper disposal. It's going to be difficult sometimes to find who's at fault. We have the situation where we don't know if the

source was shipped or not. The general licensee can't prove that they shipped it, but they've said they shipped it.

So, how far do you go to determine has it been improperly disposed, and who is ultimately responsible for it?

MR. CAMERON: This goes more to not the question of how much the penalty is but what's the sort of standard of proof to apply the penalty. How do we deal with that issue?

MS. WOODS: Lost during transport, during shipment? Generally it's the shipper.

If you're the specific licensee shipping it to a general licensee, we would go to you, because they are not in possession of it yet, and once it's been transferred from them back to you, it is still theirs until it arrives to you, but that does not necessarily mean the issue of improper disposal would come up. It would depend on the circumstances of the particular issue, the particular circumstances of that case.

MR. CAMERON: If we can't find the device and we're establishing this tracking system, if we can't find the device with the general licensee, do we assume -- and they can't show who it was transferred to, is the assumption that it was improperly dispositioned or disposed of and the penalty would then be applied?

MS. WOODS: I can't speak for the Office of Enforcement on this, but I do believe it would be a case-by-case review. On the registration sheet, we are going to be asking for disposal information. If they have disposed of it, they need to share that information with us and where it went.

So, certainly for registration population devices, we'll have the opportunity to find that out. For general

licensees that are not part of the registration population, we're going to find out if we find the device or the source and trace it back to them.

We might find it on inspection and some other issues, but again, the inspection frequency is not going to be the same as it would be, for example, as you all experience on specific licenses.

MR. CAMERON: Okay.

Elsa, do you still have a comment?

MS. NIMMO: No.

MR. CAMERON: Chris?

MR. FITZ: Just a quick comment on this.

When you were talking about the transport issue, I would assume, since I'm distributing as a specific licensee, I would not be held accountable to these standards if it was lost in transport?

MS. WOODS: These are civil penalties being proposed for general licensees.

MR. FITZ: I thought the question was asked was if they were lost in transport from the licensee to general licensee.

MS. WOODS: Okay. I tried to cover both issues, but apparently it wasn't clear.

If you're the vendor, specific licensee, and the general licensee is not in possession of the device yet, they become the general licensee when they are in possession of the device.

So, it's not with them. I'm guessing it would be the specific licensee, if it's a vendor to GL transport and if

the general licensee -- general licensee transport. If the general licensee is sending it back to the vendor, then it's theirs until they give it to you.

That's the interpretation we've made on these in the past.

MR. FITZ: That makes sense, but it seems like it's going to be -- if a specific licensee loses a source, an americium source that's specifically licensed, are they going to have to pay that much? You said it's a case-by-case basis, and is there going to be a severity level three or two?

MS. WOODS: This is improper disposal. When you talk about losing a device, you're talking about control and accountability, and for a specific licensee, control and accountability is covered under Part 20, and so, there's a whole 'nother structure.

MR. CAMERON: I think that, regardless of what the situation is, I think that we've heard a couple of points made by people today of the comparability between what happens -- what's done to specific licenses and what's done with general licenses under this new registration scheme, and I think that's one thing that -- the suggestion is that you should look at that comparison in terms of enforcement or whatever.

The implication is that it shouldn't be -- that there shouldn't be a big difference -- the specific licensee should still be treated more stringently than the general licensee in these cases.

So, I think that maybe that's a suggestion that sort of runs through all of the provisions of the rule, that we always ask that question, how does this compare to what happens

to a specific licensee.

MS. WOODS: Okay.

MR. CAMERON: I think we're probably -- there's two items left on the -- this part of the agenda, and I think, on the advice of the technical staff on this, if you have questions or comments on those, talk to people afterwards, after the meeting is adjourned, so that we can get to everybody for a final wrap-up here in terms of what happens from here, do you have any final comments on this process that we're going through, and so, I guess I would go to -- start around the table beginning with George and going that way to see if there's any last comments or questions about all of this, and then I would like to allow John, as the senior NRC official here, to sort of close the meeting up.

MR. BROWN: I'd like just to thank NRC for having this and getting this together.

I'd just point out, from a functionality standpoint, meetings like this, I think, are very effective, but in order for us to get approval, we have to have real set topics of what's going to be covered. Sometimes it's viewed by management that, okay, fly to D.C. and what are you going to do?

So, if you want something like this, a little bit of notice, you know, an agenda that you can show them there's some meat to it, they don't mind spending the bills. That's just a comment, because I think it's very functional to get this done.

I'm glad we had a chance to get the comments out, and my concerns, the questions that I had, I think, have been answered, and we still have time to comment, too. So, thank you.

MS. BROCK: I echo George's comments. This is the first of these type meetings that I have attended. It's been

very informational, and I thank you very much.

MR. PATTERSON: I'd echo that. I think this has been a useful day.

Two issues that I haven't heard addressed:

One, what is the specific schedule for requesting information under the rule that was just passed? I believe you're sending letters out to our general licensees in October.

Two, the 30-day response time for the general licensees is going to create havoc in some of our offices because the general licensees are going to call us and say what the hell is going on here and give me some information and help, but 30 days is going to be tough on us, not the general licensee.

MR. HICKEY: Just to clarify, was your first question when is the deadline for commenting on this proposed rule?

MR. PATTERSON: No.

MR. HICKEY: What was your first question?

MR. PATTERSON: My first specific question is you now have the rule in place that says you can request information, and I believe you are about to do so. When are you going to do that and expect 30-day response from the general licensees for those that are going to be registered?

Is that an incorrect assumption, Suzanne?

MS. WOODS: I understand what you're saying. Yes, the first rule goes in effect as of October 4th. When are we going to implement it?

MR. PATTERSON: Yeah.

MS. WOODS: When are we actually going to send out registration forms and request that licensees respond within 30

days? That is currently planned for mid-2000, to send out the first of those. They are not going to be able to go out, all of them, right away.

MR. PATTERSON: Oh, okay.

MS. WOODS: We're looking at several thousand. So, it will probably be the course of yet another year after that for which, at that point, we will go out and request another round of re-registration, and with that, as described in the proposed rule, there will be a fee request with that next round.

So, we've described today ways in which you can facilitate the information that we get from you, one by the requests we have before you now on your desks to help us clean up our current database and the mailing address to licensees and all the information in there, so that when we fill out that information on the form and send it to the registration, it will limit your phone calls, and two, that you, as agreement state vendors, go ahead and start to provide that information to us even before your agreement state requires you to -- in other words, the compatibility timing issue that we talked about.

Regarding the 30 days response from general licensee, we recognize that there is a 30-day time limit for them to respond to us, but we are putting out a lot of mailings to let them know well in advance.

We've gotten a lot of phone calls now. I'm guessing you're getting them, too. These folks are starting to wake up and realize who they are and learn what it is they've got and learn their responsibilities, which is what we want to happen.

This is happening well in advance their getting a

registration form. So, the 30 days certainly begins to look a little bit more reasonable as it falls well outside that October 4th time date, okay?

MR. FITZ: I'd like to echo, also, thank you very much, facilitated very well by Chip, went very well. I just hope, when you take these comments back and you go back and you look at -- you're creating a separate class of licensee, and I hope it's not going to be too strict and cost-prohibitive to those licensees.

Thank you.

MR. CAMERON: Elsa?

MS. NIMMO: Yeah. Thanks to everyone involved. As I have said before, I'm hoping, as we send in comments, that you'll look carefully at the 31.5 compatibility level and a lot of the other issues that were brought up, and I am sure there will be a few new ones in the written comments.

Thanks.

MR. CAINES: I'd like to echo what Elsa said. I think this meeting was very productive, and I would also like to emphasize the importance of having the compatibility level B for the whole thing, not just for the device distributors.

MR. RAMSEY: I think it was a most productive day, as well, and I'd encourage everybody to get comments in in the next 12 days.

MR. CAMERON: Mike?

MR. NORBURY: Well, I think it was also very productive. This was one of the first ones of these forums I've attended, and it was very useful.

MR. CAMERON: Thanks, Mike.

MR. HEYER: My accolades to everyone involved, staff and attendees. I think a professional environment makes it a whole lot easier for us to provide comments up front.

I look forward to providing more comments and looking forward to working continuously with the NRC, since I don't think this will go away.

MR. CAMERON: Thank you.

Kate?

MS. ROUGHAN: Just two comments.

Again echoing the compatibility issues, I think it needs to be consistent for everything across the board, but also to echo what Chris said, it appears we're, in a sense, changing the definition of a general licensee, you're adding additional requirements onto them now, adding additional requirements on the vendor.

So, in a sense, they almost need a license before they can get it. It may not be a license but certain checks that need to be done.

So, I think that that needs to be looked at very closely.

MR. CAMERON: David.

MR. BENNETT: I just want to thank you very much for opening up the subject. I appreciate being able to participate.

MR. CAMERON: Okay.

Jonathan?

MR. FORTKAMP: I'd like to say I think it was also very productive.

I guess I will say I'm a little disappointed that

there wasn't better agreement state attendance. I appreciate Illinois listening, but as much as this is going to involve the agreement states, whether it's a compatibility level B or C, I wish that they would have been in attendance to hear some of our comments, and I hope they do read through the comments as they are published later on, and also, I'd like to acknowledge that the -- I think the NRC acknowledges that the vendors are going to play a big role in this, telling the end users what's going on, and to that end, I think the compatibility -- both sets of rules should be compatibility level B.

MR. CAMERON: Joe?

MR. ALLGEIER: Also want to thank the NRC for the opportunity to participate. I am impressed with the thought that you've already put into it. Sounds like you're trying to do a very good job of eliciting our opinions, and we appreciate that.

MR. CAMERON: Agreement state comment, final comment.

MR. CLINGER: I would just like to agree that it's a shame that more of the agreement states didn't participate in this. I think most of the states do agree with many of the things that NRC is trying to do with this rule, though, and I also want to say it was a very well-run meeting.

MR. CAMERON: Okay. Thank you. And maybe we'll have State Programs --

MR. FRAZEE: Chip?

MR. CAMERON: Yeah.

MR. FRAZEE: Chip, this is Terry Frazee in Washington.

MR. CAMERON: Hey, Terry.

MR. FRAZEE: Hi. How are you doing?

MR. CAMERON: Good.

MR. FRAZEE: I've been a fly on the wall off and on during the day. This has not been the most effective way for me to participate, but I certainly have heard a number of the comments, and I will try to take a look at the transcript from the meeting.

One thing I would like to put in or interject at this point has to do with like the national database issue, trying to keep in mind that what we have to do in this state is keeping track of our licensees, our registrants in this case, and we already have a database.

We are doing not a full registration, but we are keeping track of them, plus we've got it and we're not likely to want to discontinue it. We don't see a lot of need for a national database.

Because of the ability to communicate electronically, a lot of things go very quickly. If we find a source and we want to track it down, I think that putting out the word is very easy and getting people to respond has been very effective.

Having a national database may or may not serve us any better than the way we would do it right now, some concerns about the ability of whoever is going to run the database keeping it up to date, and also the issue of timeliness.

I think the thing that we're most interested in is the what-if. Something goes wrong, we either have a mess on our hands, in which case I doubt that we'll be able to identify a serial number, or we would have a sealed source that's turned up

in a scrap-yard, and by golly, there it is.

We can probably possibly figure out the model and hopefully have a serial number, in which case they it's not a rush job. We can put the word out and hopefully eventually identify who the owner is and go back after them on that score.

A lot of the details that I've heard today have been very detailed, you know, how precisely do we need to know where a particular source has been put in a plant? Well, I'm not sure that I care that much as long as I know who the owner is. Then it's their problem to figure out where it went.

And so, the information that would come to us on transfer or the quarterly reports, for instance, we're interested in knowing as much as we can about the source. Certainly, sealed source serial number would be very useful, as well as the device and model serial numbers, but the transfer, that it came to a particular location -- that's all we need to know. We don't need to know that it's a replacement.

I heard the comment about, well, sometimes it takes six months to have them returned. Well, that's fine. In six months, then the manufacturer sends us another report that says, hey, we got back such-and-such a serial number from a particular location, and that closes out our records.

I will try to pull together some additional comments and send them off to you, but I'll let you get back to the meeting.

MR. CAMERON: Okay. Thanks, Terry. I'm glad to know that you were out there listening to this, and perhaps the -- State Programs can send the transcript to each agreement state or notify them that it's on the web so that they can see these

comments before they make their comments.

Before we go to John for closing, I would just ask, Glen, do you have any final comments for us out there?

MR. GOTSCHALL: Just very quickly, the form that we're going to look at for quarterly reports -- are you going to mail that to us, to the attendees on the attendance roster?

MR. HICKEY: We haven't decided that yet, but if we do it, we'll make sure all the attendees get it.

MR. GOTSCHALL: Okay. And I also appreciate the opportunity to come down here and hear the proceedings, and I thought it was done very well.

Thank you.

MR. CAMERON: Okay. Thanks. And I just would thank all of you for taking the time to be here today and for all the help that you gave me in terms of locating others who should be at the meeting. I appreciate that, and thank you.

John?

MR. HICKEY: Suzanne?

MS. WOODS: I appreciated hearing from you, as a person, one of, as I mentioned, a team of individuals who's been struggling with these issues. It certainly has given us a good deal of insight. You know your customer base, and in that effort, you can greatly affect this process and its successful outcome.

You have the most opportunity to facilitate the understanding of general licensees, and to that outcome, I encourage you to comment on the rule. The date is October 12th, and any ongoing issues, I'm sure the staff and myself are receptive to hearing about.

Thank you.

MR. HICKEY: Okay.

First I want to clarify that we did have a separate meeting with the agreement states. So, that's why they're not here today, and they also have severe budget restrictions on travel.

I'd also say to George that we do appreciate the fact that you and your company supported attendance to the meeting, but I will say in general that lack of attendance in meetings is not a problem for NRC.

Chip and I have been to many meetings with people hanging from the rafters and tv cameras being shoved in our faces. So, we do appreciate your being here, but we generally don't worry about how many people are going to show up at our meetings.

I also appreciate everybody coming, and I think we had a lot of thoughtful comments, and you gave me a lot to think about.

As I said, I've only been recently reassigned back into this area, so I have a lot of corporate knowledge, but I'm still catching up with the specifics of how we're going to implement this particular program, and we really got a lot of good comments, so we really appreciate your being here.

As I said, I'll stay a little while if you want to talk about transuranics or any of the other issues that came up.

The other administrative item I would add is, when you leave, if you don't have a car, come out of the building and turn right, the Metro stop is there, which goes to National Airport, and also there's taxis there all the time.

So, thank you all very much for coming.

[Whereupon, at 5:08 p.m., the meeting was
concluded.]