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 in General License Regulations

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
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OFFICE OF FEDERAL AND STATE
MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS

+ + + + +
IMPACTS OF COMPATIBILITY CHANGES
IN GENERAL LICENSE REGULATIONS

+ + + + +
THURSDAY,
SEPTEMBER 22, 2011

+ + + + +
HOLIDAY INN MANSFIELD
31 HAMPSHIRE STREET
MANSFIELD, MASSACHUSETTS 02048

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The public meeting was convened at
1:58 p.m., Alison Rivera, Facilitator, presiding.

NRC STAFF PRESENT:

- ALISON RIVERA, Facilitator
- STEPHEN POY
- DENNIS SOLLENBERGER
- DUNCAN WHITE

REPRESENTATION FROM THE COMMONWEALTH OF MASSACHUSETTS:

ROBERT GALLAGHER, Department of Public Health

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

(1:58 p.m.)

FACILITATOR RIVERA: Good afternoon, and welcome to this afternoon's Category 3 public meeting to discuss the impacts of compatibility changes in general license regulations.

My name is Alison Rivera, and I am your facilitator for today's meeting.

As your facilitator, my job is to make sure that today's meeting is informative and productive. I'm going to strive to keep us on schedule and focused on the task at hand.

As a Category 3 meeting, members of the public will have an opportunity to actively participate in today's meeting to maximize the exchange of views and information.

Hopefully, everyone had a chance to sign in in the back of the room and pick up some of the meeting handouts. But if not, please let me know and we'll make sure that you get a copy.

Also, hopefully you got a copy of the feedback form, and at the end of today's meeting we would appreciate it if you could fill it out and either give it to one of the NRC staff members or you can mail it back. It's postage prepaid.

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1 For today's agenda, we are going to start
2 with a few opening remarks and presentations from NRC
3 and the agreement state, and then we are going to
4 follow it up with open discussions with questions that
5 are focused to specific end users and generic
6 questions on this compatibility change.

7 I'm going to move on to a few logistics.
8 If everyone could please turn off or mute anything
9 that buzzes, beeps, otherwise causes disruption, we
10 would appreciate it, because we are having this
11 meeting transcribed and it will help us get a clear
12 transcript.

13 Bathrooms are straight out the doors that
14 you came in to enter this room, and the exits are all
15 marked by the exit signs. But the main one probably
16 is straight out through the back.

17 When speaking, I'm going to bring around a
18 hand-held mic to people. Please introduce yourself
19 and your affiliation the first time you speak, and
20 then after that you can just give your name. And I'll
21 go back over that again when we get to that part.

22 Please try to minimize side conversations
23 and listen respectfully to all the fellow
24 participants.

25 So with that, I'm going to go ahead and

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1 turn it over to Duncan White, who is the Chief of the
2 Agreement State Programs Branch in NRC's Office of
3 Federal and State Materials and Environmental
4 Management Programs. I promise, I'm only going to say
5 that once. You will probably hear it referred to as
6 F-S-M-E or FSME from here on out.

7 Duncan?

8 MR. WHITE: Thank you, Alison. And,
9 again, thank you all for coming to today's public
10 meeting.

11 Today we are here to collect input and
12 information on the impacts from the Commission's
13 decision to change the compatibility designations for
14 10 CFR Parts 31.5 and 31.6 from compatibility
15 Category B to Category C.

16 A little background why we -- how we got
17 here. The Commission, last December, issued their
18 final vote and decision on a proposed rulemaking
19 involving limiting the quantity of byproduct material
20 in a generally licensed device. The Commission, in
21 their staff requirements memorandum, or SRM, decided
22 that they -- voted to deny publication of the rule,
23 effectively terminating the rule process.

24 They also directed staff to change the
25 compatibility of Parts 31.5 and 31.6 from Category B

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1 to C. They directed staff to revise policy statements
2 involving adequacy and compatibility, and they also
3 directed staff to do an analysis of transboundary
4 impacts focusing -- which is the focus of today's
5 meeting.

6 The product from this particular endeavor
7 will be a report to the Commission due next June of
8 2012. The report will, of course, summarize the input
9 that we get from these public -- two public meetings
10 we had, and of course written comments. And we are --
11 the Commission also directed us to do a -- present any
12 corrective actions listings that we may find during
13 the course of our production of data information.

14 Again, since the Commission has already
15 made the decision to change the compatibility
16 designation, we are not here to collect information to
17 start a new rulemaking. So, again, the report that
18 will go to the Commission, the Commission will decide
19 what they will do with that report. Again, it's just
20 a report to the Commission. The Commission may choose
21 to take some other action with that, and they will do
22 that when the time comes.

23 The comment period ends October 30th.
24 Again, thank you for coming here today and providing
25 input, but you still have until October 30th to

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1 provide additional information or if you know someone
2 who would like -- you think it would be -- the impacts
3 that would like to provide information to us. We
4 certainly look forward to that. Again, October 30th
5 is the deadline for that. And if you look in the
6 Federal Register Notice, it provides who to send that
7 information to.

8 We will also -- as Alison said, we are
9 transcribing today's meeting. The transcription will
10 be -- is a public document, and the report and
11 everything else we produce from this, slides and
12 stuff, are public information. And we will be putting
13 that probably on our public website in due course,
14 when we get everything done. And, again, we will --
15 since we have your email address, we will certainly
16 let you know when we do that, so you have that
17 available information.

18 What I'd like to do now is turn it over to
19 Bob Gallagher, who will provide a brief presentation
20 on the agreement state perspective on the Commission's
21 decision. Bob is currently the Acting Director of the
22 Massachusetts Radiation Control Program. Bob?

23 MR. GALLAGHER: Thank you, Duncan. Again,
24 welcome everybody. And full disclosure, I did not
25 write this slide, so I'm going to be reading some of

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1 the notes that I have with it. My apologies. I just
2 got it this morning.

3 I want to start out by saying that the
4 Organization of Agreement States supports the
5 compatibility change from a B to a C for the
6 regulations at 10 CFR 31.5 and 31.6. The agreement
7 state's main concern is the accountability of such
8 devices.

9 But I also want to point out, for those of
10 you who aren't familiar with the regulations, the
11 general license in 31.5 applies to the device users,
12 and the license in 31.6 applies to the GL device
13 manufacturers for installation and service.

14 Again, our main concern is the
15 accountability of GL devices, and we want to describe
16 briefly the life cycle of these devices, for those of
17 you who aren't familiar with it. Distribution
18 includes labeling and testing the information from
19 manufacturer and distributor to the user, responsible
20 individual identified by the user, and the
21 manufacturer and distributor notifies the regulator of
22 the transfer.

23 During the use, there are tests to be
24 performed, records and tracking, notification to the
25 regulator of reportable incidents, continuity of

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1 information. We would like to know when the
2 manufacturer or distributor or service provider is
3 performing maintenance or the source exchange to
4 ensure radiation safety requirements are met, and at
5 the end of the life cycle the requirements are that if
6 you transfer it only to the appropriate party, no
7 disposal is scrap, which, as many of you know, has
8 become a big issue in the country, and the user is
9 supposed to notify the regulator of the final
10 transfer, which is rarely done in Wisconsin, which is
11 where -- my college, Paul Schmidt, from Wisconsin is
12 the one that wrote these slides.

13 We do have many examples nationwide of the
14 loss of control of GL gauging devices. Surfing NMED,
15 since 1984 -- excuse me, since September of 2006,
16 there have been 44 documented incidents involving the
17 loss of control, abandoned, or stolen GL devices
18 containing cesium-137 or americium-241.

19 The most recent of these was reported on
20 September 9, 2011, so this is not just a historic
21 problem, but it is a common one.

22 Many agreement states have adopted
23 stricter control of GL devices than the NRC, either
24 additional registration requirements or specific
25 licensing, to improve accountability and to protect

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1 the public health and safety. Our goal for all of us
2 is that we have no lost, stolen, or improperly
3 disposed GL gauging devices.

4 Thank you.

5 Alison?

6 FACILITATOR RIVERA: Okay. We are going
7 to go ahead and go into the open discussion. This is
8 where you, the participants, get to have the active
9 role in today's meeting. And Dennis is putting up the
10 questions that were in the FRN that are kind of
11 general in nature.

12 There is also specific questions for
13 manufacturers and distributors and end users, but
14 we're going to go ahead and start with the more
15 generic questions, the first being, what are the
16 impacts of changing the compatibility categories of
17 10 CFR 31.5 and 31.6 from B to C?

18 And, again, I will bring around a hand-
19 held mic or maybe Dennis will bring it around for me.

20 If you could say your name and your affiliation
21 before you give your comment the first time or you ask
22 your question. Thank you.

23 Anybody?

24 MR. BLUTE: Again, well, my name is Jim
25 Blute. I'm with Thermo Fisher Scientific, a group

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1 that -- within Thermo Fisher Scientific that
2 distributes portable generally licensed devices, hand-
3 held X-ray fluorescence analyzers.

4 And I guess just to start off, without
5 really knowing what to say specifically, I think what
6 we are concerned about with right now with this is
7 that it is going to give agreement states flexibility
8 to set more specific rules in their own states that
9 are different from other states, and it makes it very
10 difficult for 10 CFR 31.5, general licensees,
11 particularly when they have portable devices and they
12 are moving from state to state, to maintain
13 compliance.

14 And it makes it very difficult for the
15 manufacturer and distributor of the device to help
16 this customer base maintain compliance and to, you
17 know, advise them on what to expect when they move
18 from one state to another in terms of how these
19 devices are regulated.

20 And it is already difficult, I would say
21 in some ways much more difficult than even specific
22 licensing. This general licensing category is not
23 treated consistently already throughout the country,
24 and this -- we view this as, you know, giving it the
25 potential to be even more difficult to maintain

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1 compliance.

2 FACILITATOR RIVERA: Thank you, Jim.

3 MR. WHITE: This is Duncan White. Just a
4 followup perspective on where the states are with
5 regard to adopting compatible regulations to the NRC
6 with regard to this particular requirement.

7 We have a handout in the back, and that
8 was -- the handout is based on the information we have
9 had -- the states had at the time of adopting
10 regulations at the time. This would be in
11 October/November of last year, just before the
12 Commission's decision. And in that we found that 13
13 states had equivalent regulations to the NRC.
14 Basically, it had the same regulations as 31.5/31.6
15 are today.

16 We found 10 states had more -- some
17 portion of 31.5 or 31.6 was more restrictive than the
18 NRC. We have had five states that had some portion of
19 it which was less restrictive than the NRC, and then
20 there were four states that were both more restrictive
21 and less restrictive.

22 We also made -- I'd point out that earlier
23 this year we polled some of the states about some very
24 similar issues we are talking about here today. And
25 one of the things we asked them is, you know, do you

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1 plan to make any big changes to your regulations, you
2 know, coming here? Again, we didn't want to hold them
3 to this, because obviously they will have to make that
4 decision themselves. But the majority of what we have
5 heard is that there is no plans to make any changes to
6 the states.

7 So one thing I just want to point out is
8 we say 13 states have the same as we have, and I think
9 one of the comments that the gentleman just made with
10 regard to -- implementation becomes I think important
11 at that point, if we have the same regulations and we
12 have a different outcome.

13 Whenever there is a -- there's just
14 something, from a implementation standpoint you want
15 to elaborate on a little bit more with regard to that,
16 because they have the same regulations, you'd have
17 something a little bit different. Is there something
18 there you want to --

19 MR. BLUTE: Well, I guess one mystery to
20 me is: why did they have different approaches to
21 general licensing if it was compatibility B? So this,
22 to me, seems to be just allowing incompatibility
23 between state to state to continue.

24 So it's not just a concern that, oh, there
25 is not going to be, you know -- it doesn't really make

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1 me feel comfortable that states are saying right now
2 "We're not going to make changes in the future because
3 of this, because I would like to -- I think this
4 problem is now that we should be moving in a different
5 -- in the opposite direction. We should be trying to
6 get states to be more compatible."

7 And I kind of see this as an
8 acknowledgement that states already aren't very
9 compatible, so let's just make it okay for them to not
10 be compatible. So it's really about endorsing what I
11 think is already a problem, from our perspective
12 anyways, of difficult -- it's really difficult to
13 maintain compliance with the generally licensed device
14 as you move about.

15 And also, I think, you know, I will state
16 that just because agreement states are saying right
17 now they don't make any plans -- they don't have any
18 plans to change things, once they have this
19 flexibility and then they run into certain problems,
20 as often they do, they can now take their own unique
21 agreement state approach to solving that problem that
22 is different from the state next door. And over time
23 I think it will just get more and more difficult in
24 this licensing category.

25 MR. WHITE: Duncan White again. Again, I

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1 would point out that we are not holding the states to
2 make any changes. A number of them communicated they
3 are not going to make any changes, but, you're right,
4 this doesn't mean that they won't make changes. There
5 is no guarantee of that.

6 Just another comment about the -- there is
7 no -- you said to reaffirm -- the change in
8 compatibility reaffirmed what the states were really
9 doing from a practical standpoint.

10 As you folks may know, the Commission back
11 in 2000 changed the compatibility from C to B for
12 these same regulations. And then, the states normally
13 have three years to bring their programs to be
14 compatible with the NRC.

15 I think it was about 2004 I think the
16 Organization of Agreement States and the State of
17 Florida petitioned the NRC for -- in part for changing
18 compatibility.

19 From a practical standpoint, from what the
20 NRC does, because the petition is out there, we put
21 any final terms of any -- take any additional action
22 in terms of the states not changing the compatibility
23 kind of into abeyance until the petition -- the
24 outcome of the petition, because, if the petition --
25 the outcome of the petition was to not support it or

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1 support it, whatever it can -- the different action
2 requirements to the states.

3 So that's one reason why I would -- again,
4 I'm not saying the entire reason why the states did
5 what they did, but, again, that's one reason, you
6 know, that we took the action that we did -- or
7 actions we did not take is because the petition was
8 out there, and we had to honor that.

9 FACILITATOR RIVERA: Thank you.

10 MR. FORTKAMP: My name is Jonathan
11 Fortkamp with ABB Incorporated, and also representing
12 the Association of Device Distributors and
13 Manufacturers.

14 You know, I want to reiterate, you know,
15 one of the big issues that we have with the changes in
16 compatibility is that there is just -- there is no
17 consistency, and as a manufacturer and distributor and
18 a service provider going into states, we don't know
19 what the regulations are, flat out.

20 We can go and we can look at what is
21 posted online, or, you know, get hard copies of the
22 regulations, but that is only one aspect of it. The
23 other aspect is the interpretation of those rules, you
24 know, some of the issues that we have had significant
25 problems with or that there are significant variances.

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1 What is the definition of a generally
2 licensed device? The State of Louisiana, for example,
3 classifies if you have a device that is registered
4 with a B, so it's either -- it's both generally
5 licensed and specifically licensed, they require that
6 to go under a specific license. It's not coded
7 anywhere within their regulations. That's a policy
8 statement on their part.

9 As a service provider, what are -- what
10 falls in under services that require reciprocity, what
11 services do not require reciprocity? Again, you get
12 significant variances. If you do a leakage test, is
13 that applicable to reciprocity? Is it only if you
14 handle a source? There is significant variation in
15 the interpretations of those across states.

16 So we run into a lot of problems, you
17 know, one trying to identify, you know, what kind of
18 approval do we need to go into a state, and then, you
19 know, once we get -- once we figure out what is
20 written down on the rules as far as what approvals we
21 need, are we actually in compliance with what they
22 really want?

23 And those change. You know, we may go
24 into, you know, one state we may work in 365 days a
25 year. Another state we may work in one day a year.

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1 So depending on what state it is, you know, how much
2 time are we required to put out there to really hunt
3 down and find out what the regulations and the
4 interpretation of those regulations is?

5 It's very cumbersome, as a service
6 provider/manufacturer/distributor, to stay on top of
7 that, and essentially impossible at this point.

8 MR. WHITE: Duncan White again. One thing
9 you mentioned was that the implementation of it -- I
10 mean, could you comment on how much you -- obviously,
11 changing compatibility would change what is actually
12 written in the regulations, would force that change.

13 One thing you mentioned was the
14 implementation of the regulations. How much -- even
15 if all the states did adopt, you know, the exact same
16 regulations, one of the things, you know, I heard from
17 you and from the other gentleman was there is an
18 implementation issue. How do the states actually
19 enforce stuff? Is this part of the problem or part of
20 the concerns that you have maybe -- not only
21 compatibility but how well the rules are written and
22 how they are used by the states?

23 MR. FORTKAMP: This is Jonathan Fortkamp.
24 Certainly, that is a concern. I think with a well
25 written rule you eliminate a lot of possibility for

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1 various interpretations.

2 Also, in many of the statements of
3 consideration that get published with the rule, they
4 clarify a lot of those points that may not be
5 necessarily codified, but they certainly clarify what
6 the intent of the regulation was or, you know, how it
7 was developed and what comments led to that. You
8 know, so they set a precedent for how a certain
9 regulation should be interpreted.

10 FACILITATOR RIVERA: Does anybody else
11 have some input or information they would like to
12 provide?

13 MR. CHAPEL: Hi. This is Sean Chapel
14 representing the Association of Device Distributors
15 and Manufacturers and President of IRSC Inc.

16 The Association of Device Distributors and
17 Manufacturers met with the Commission in the fall of
18 2010. At that meeting, we expressed our desire for
19 more standardization of reciprocity regulations. So
20 we were disappointed when the Commission voted to
21 decrease the compatibility.

22 We are all in favor of increasing
23 compatibility. Some of the issues involved already,
24 like John said, this is one complication on top of
25 another. And one of the issues is that states will

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1 adopt 10 CFR 31.6 and it will be in their regulations.

2 However, as a matter of policy, they do not honor it.

3 So, for example, 10 CFR 31.6 says,
4 "Service providers may service a device in an
5 agreement state without filing for reciprocity." But
6 if you go -- and if you look at agreement state
7 regulations -- for example, Massachusetts -- that same
8 verbiage is in there. But as a matter of policy, if
9 you call the state, reciprocity is required to be
10 filed for that service.

11 So what we find with our members is that
12 there are no regulatory guidance documents for
13 reciprocity as there are for many other licensing
14 issues, and there are also different interpretations
15 by different states and different staff members. So
16 this is just further complicating the position, and we
17 would just love to see greater standardization of
18 reciprocity regulations.

19 And it is certainly possible. We have
20 standardized dose regulations. We have federal
21 regulations under NQSA and all of that. So it is
22 certainly a possibility.

23 FACILITATOR RIVERA: Thank you, Sean.
24 Anybody else?

25 MR. FORTKAMP: This is Jonathan Fortkamp

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1 again. I would also -- you know, I represent a
2 manufacturer/distributor, but in this meeting I would
3 also like to speak up on behalf of our customers who
4 are the end users of these devices. Certainly, there
5 is a push across, you know, all industries for high
6 levels of health, safety, and security.

7 Many of the larger companies out there who
8 are our customers -- the International Paper, the
9 DuPonts, you know, these large companies, they -- what
10 they try to implement across all of their
11 organizations is a common program, whether it's an
12 occupational health and safety program or a common
13 radiation safety program.

14 The discontinuity of the regulations and
15 the implementation of those regulations across states
16 makes it nearly impossible for companies -- and ABB is
17 one of those companies -- we have multiple sites
18 across multiple states. We cannot implement a single
19 program that will ensure compliance with the
20 regulations.

21 We can implement a program that we have a
22 high level of confidence will provide the necessary
23 safety and security, but that's not always consistent
24 with compliance, unfortunately. Some of the impacts
25 are -- you would expect to see increased costs

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1 associated with oversight at the individual sites.

2 You would also see -- you know, the
3 reality is is you are likely to see a decrease in
4 compliance because of the lack of a clear
5 understanding of what those requirements are,
6 especially at individual sites that may not have the
7 technical skills or the administrative time to put to
8 maintaining compliance in those different situations.

9 FACILITATOR RIVERA: Thank you.

10 MR. TRAEGLDE: Hello. Ken Traegde,
11 Department of Public Health, Radiation Control
12 Program. Duncan, I was just wondering why -- I know
13 that the Commission was presented with the opportunity
14 to go to a -- what do they call it? A threshold, a
15 Category 3.5, for all devices. What was the rationale
16 for turning that down, a Category 3.5?

17 MR. WHITE: I think the best way to answer
18 that question is if you'll read the vote sheets for
19 the individual Commissioners. Again, there was a
20 split vote with regard to this rule. One Commissioner
21 did support it. The other Commissioners did not
22 support it. And if you read their vote sheets, which
23 are all publicly available and online, you can see
24 what their thinking was.

25 Again, just remember the impetus behind

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1 this rule was security. And, again, what's -- you
2 know, is there -- you know, does security need to
3 lower this threshold down to one-tenth Category 3 for
4 the IEA categories? And they decided -- the
5 Commission, you know, felt that that wasn't needed at
6 this time. I assume that's why they voted to do that.

7 But the best answer to that question is to
8 look at the vote sheets. Again, this is where the
9 decision comes from. This is where the SRM is drawn
10 from. We did that.

11 FACILITATOR RIVERA: Other questions or
12 information to share on the first question?

13 (No response.)

14 Okay. We may have already started
15 addressing it, but does anybody want to talk about
16 what are the distribution impediments? Okay. How --

17 MR. BLUTE: It's just understanding, you
18 know, what the rules are in every state as a
19 distributor. You know, there is -- we have to follow
20 a lot of rules as a distributor as well that the
21 states are asking us to follow. And, you know,
22 starting with the primary question is: can we even
23 distribute the generally licensed device into that
24 state?

25 And John here brought up a good point

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1 about 31.6 allowing a certain reciprocity that some
2 states aren't -- that, you know, allowing in policy,
3 even though they are accepting the regulation. And I
4 would say as well that 31.6 allows me to distribute my
5 generally licensed device into any agreement state.

6 I think it says it in pretty clear black
7 and white, but yet there are at least 10, maybe 12,
8 states that by policy will not let me distribute my
9 generally licensed device into that state. Other
10 states say that I can only do it if the end user
11 commits to keeping it at a single address, even though
12 it's a portable device.

13 So somehow I, as a distributor, have to
14 figure out what the intent is of my end user, before I
15 can decide whether or not general licensing is even an
16 option. And I have been -- we have been issued
17 violations from the other agreement states, because we
18 have, you know, broken this what I consider a policy.

19 I don't know if someone in the room can shine any
20 light on how they have any regulatory authority to be
21 able to do this.

22 One proposal that was given to me was that
23 because our device registration ends in a B that tells
24 the agreement state that they can choose the license
25 type. I was not aware of that. I thought B meant

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1 that we could -- that the end user could choose the
2 license type. So, and I don't see 31.6 or any other
3 regulation addressing what B means in terms of the
4 agreement state having the authority to just decide
5 not to accept a certain generally licensed device.

6 So these are the kinds of questions that I
7 think folks like us are raising here in terms of what
8 are the impediments is, you know, there seems to be a
9 lot of flexibility -- even when the NRC tells an
10 agreement state by compatibility B that they are
11 supposed to do things a certain way, they still seem
12 to implement a lot of flexibility in how they
13 practice.

14 And now that we're going to a C where
15 we're basically saying not only, you know, are we
16 saying you have to be compatible, now we're saying you
17 don't even have to be perfectly compatible, and there
18 could be more impediments. And distributing is really
19 tough, very, very difficult for us to try to maintain
20 compliance and figure out what 50 different states
21 want us to do.

22 MR. WHITE: This is Duncan White again. I
23 will take a crack at answering -- at least partly
24 answering your question. I probably won't give a
25 completely satisfactory answer.

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1 From an overall -- how we implement the
2 program, we have -- I mentioned earlier we have policy
3 statements, and the policy statements are approved by
4 the Commission and provide kind of the general road
5 map on how we do business.

6 If you go read the adequacy/compatibility
7 policy statement, interestingly, it picks up some of
8 the things you directly talk about -- flexibility for
9 the states -- but at the same time certain places you
10 want a certain level of compatibility, a certain level
11 of uniformity, so you need to implement a national
12 program, you know, in the best interests of the
13 country.

14 And it kind of describes what those things
15 are. And, again, it's hard to -- again, what's the --
16 there's a balance there. There's a balance of having,
17 you know, complete uniformity develop, and at the same
18 time having flexibility for the states.

19 Again, you know, the genesis of the
20 agreement state program back in the '50s was -- you
21 know, was very state rights' driven. Again, you know,
22 Constitution 101, as we all know is that, you know,
23 the Constitution is very strong, you know, supporting
24 the states and states' rights and what they can do.

25 So, and if you go -- and the policy

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1 statement a little bit reflects that. But, again, it
2 talks about things like flexibility. It also talks
3 about, you know, the things that, you know, which you
4 alluded to was, you know, interstate commerce. You
5 know, one thing you can't -- you know, your
6 constitutional rights allow you to sell your products
7 across state lines without that impediment. What
8 you're implying there, there may be some -- there may
9 be impediments there. They are allowing you to sell
10 the devices, but they are putting conditions on that,
11 which sounds like you were talking about there.

12 So, again, it's -- again, the policy
13 statement, again, are very broad and they provide a
14 road map.

15 Again, and what do we use to kind of, you
16 know, narrow that down? We do have additional
17 guidance documents out there to do that, but, again,
18 it's -- the way the agreement state program is set up
19 is that the -- it's a little different than most
20 federal-state relationships in the sense that the NRC
21 gives up jurisdiction. And when you give up
22 jurisdiction, you know, we -- the state is in charge
23 at that point.

24 And, again, that's the way the system was
25 set up back in the late '50s, and it has been

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1 implemented for almost 50 years now like this. And
2 that's one of the challenges of it.

3 NRC does have an oversight responsibility.

4 We do go and audit the states through a program every
5 four years. We do do that. But, again, once the
6 agreement is signed, we turn it over to the state.
7 Again, they have to have an adequate, compatible
8 program. But, again, it's -- you know, where exactly
9 is that? And, again, this is -- again, this was one
10 reason we're having -- we're going to collect the
11 information, because we want to hear, you know, things
12 like this, too, because, again, it's never perfect.
13 This thing is never perfect.

14 MR. BLUTE: That's right. And, obviously,
15 there is a balance that you guys have to cut, and this
16 is just you having -- you know, these -- you know,
17 this is part of the balance is understanding that
18 these create significant impediments -- what it is for
19 us to try to do this all compliantly.

20 MR. FORTKAMP: Well, you know, and I
21 understand that -- you know, that you've got to give
22 flexibility to the -- this is Jonathan Fortkamp --
23 give flexibility to the states, you know, under the
24 agreement state program.

25 However, you know, there are compatibility

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1 categories and one -- and the Category B compatibility
2 is specifically for programs that have direct
3 transboundary implications. I mean, distribution of
4 devices throughout the United States if inherently
5 transboundary.

6 I think that's what the intent of a
7 Category B classification is for this exact type of
8 application for the distribution of devices under 31.5
9 and the service of such devices under 31.6, because
10 you have companies working doing the exact same type
11 of work in multiple states.

12 The Category B classification is intended
13 so that -- to minimize the impact on those businesses
14 that are doing the services and the end users of those
15 devices that are getting those services, so that it
16 can be done as cost effectively, as efficiently, and
17 as safely as possible.

18 FACILITATOR RIVERA: Thank you. Sean?

19 MR. CHAPEL: Hi. This is Sean Chapel.
20 Talking in 2010, the ADDM went to the CRCPD, and we
21 requested a special task force be created for the
22 standardization of reciprocity regulations. And we
23 were told that that was an issue for the Federal
24 Government and we should bring it to the NRC.

25 So we hear what you're saying about

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1 states' rights, and the ability to set their own
2 regulations. But the states themselves told us that
3 this issue should be resolved through the NRC.

4 MR. WHITE: Yes. With regard to
5 compatibility, compatibility is set by the Federal
6 Government. It's part of the rulemaking process.
7 Again, when the proposed rule goes out, it does
8 include compatibility designations, which, again, are
9 -- people can publicly comment on them and suggest
10 changes to them.

11 Getting back to, again, the -- getting
12 back to the policy statement, the policy statement
13 does talk -- you know, again, you're correct about B.

14 It is direct and significant transboundary impacts.
15 That is compatibility Category B.

16 Also with the policy statement,
17 interestingly, it says -- it says it wants to limit
18 that category as much as possible, and it provides two
19 examples of what to consider compatibility B, and
20 that's transportation regulations.

21 And also -- it also talks about sealed
22 source and advice registry sheets, the importance of
23 having those sheets, you know, look identical from --
24 they state the issues.

25 Let me stop one second.

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1 (Whereupon, there was a brief pause while adjustments
2 were made to the sound system.)

3 MR. WHITE: So quite often we talk -- and,
4 again, in terms -- it does address, you know,
5 commerce. You know, it does talk about commerce, the
6 importance of commerce. Interstate commerce, you
7 know, cannot be impeded.

8 And also, when we look at the
9 transboundary impacts, we really look at -- from our
10 agency's standpoint, from a federal standpoint, we
11 look at the transboundary impacts as, really, from a
12 health and safety perspective. Yes, we cannot put
13 something in place that impedes interstate commerce.
14 Again, that's a constitutional right. We can't stop
15 -- we can't do that.

16 But, really, significant transportation
17 impacts is really from a health and -- we look at it
18 from a health and safety perspective. And, again, the
19 guidance that we have in the policy statement talks
20 about, you know, making that as narrow as possible and
21 not as broad as possible.

22 Again, it's this balancing act, as we
23 talked about earlier, of -- for the agreement states
24 to have flexibility, but at the same time maintain a
25 national cohesive program. And, again, that balance

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1 is hard to get -- hard to -- you know, we are
2 constantly moving. Where do we put that and where do
3 we get that?

4 MR. FORTKAMP: You know, to your
5 discussion there, it seems pretty clear that the
6 generally licensed devices and the work on those
7 devices does fall under what should meet Category B
8 classifications, because they are on devices
9 specifically defined under the sealed source and
10 device registration.

11 FACILITATOR RIVERA: Sorry. We had to
12 turn it down a bit, because someone next door asked us
13 to lower our sound a bit.

14 MR. WHITE: Okay. We're fine. No problem
15 with that.

16 MR. FORTKAMP: So, you know, since these
17 devices are defined under the sealed source and device
18 registration, and they are reviewed under specific --
19 classification-specific criteria for -- as authorized
20 to be distributed to someone under a general license
21 or a specific license, then, again, that reiterates
22 the need that these -- that these fall under the
23 requirements of compatibility Level B.

24 MR. WHITE: Now, I'll just say a couple of
25 things about it. I think one of the challenges we

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1 have is the fact that for this particular part of the
2 regulation it is going back from -- it has flip-
3 flopped back between B and C.

4 I think, you know, in this case it's --
5 you know, even the Commission is unsure where it
6 should fall exactly, and I think it's, you know --
7 again, we had different Commissioners 10 years ago.
8 They decided -- the leaned one way, and now we have a
9 different Commission; they lean a different way. And
10 I guess -- I think this is a good example of, you
11 know, the challenge behind that.

12 One thing I also wanted to mention about
13 the compatibility categories and how we -- how the
14 Federal Government does implement them -- we do have
15 management directives that the NRC does issue. These
16 are very high-level documents and really designed to
17 implement the program that we have.

18 There is a management directive that deals
19 directly with adequacy and compatibility. It's
20 Management Directive 5.9. And these things do
21 periodically come up for revision, and, in fact, we
22 are working -- starting to work right now on revising
23 Management Directive 5.9.

24 Again, these documents are put out for
25 public comment, and, again, you are welcome -- you

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1 will have an opportunity to comment on them also,
2 because, again, it's -- again, how do -- again, how do
3 you -- a lot of regulations are fairly easy to bin.
4 There are some that are not.

5 And, again, always the hardest ones, and
6 they are challenging to the Commission and challenging
7 to staff is, what's a B -- compatibility Category B
8 and what's Category C? It's very hard to determine
9 what the two of those, you know, are sometimes.

10 FACILITATOR RIVERA: Anyone else?

11 (No response.)

12 Okay. I think I have heard some responses
13 on if there are any other impacts brought about by
14 changes in the state regulations, to go ahead and
15 explain them. But does anybody have final thoughts on
16 that before we move to some more specific questions
17 from manufacturers and distributors?

18 MR. FORTKAMP: My comment on changes in
19 state regulations is certainly, obviously, states have
20 rights to make those changes, you know, when and as
21 they see fit. However, you know, being an Ohio
22 licensee and operating out of Ohio, I hear about
23 Ohio's rules, but it's very, very difficult, and in
24 some cases nearly impossible to find out about changes
25 in other state regulations.

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1 Certainly, it is very challenging during
2 the process, unless you're in that loop, which it is
3 difficult to get into and to stay into. And even
4 after they are published, you know, I have heard a lot
5 of stories about people finding out that things have
6 changed by getting a notice of violation. And that's
7 not the right way of doing it, and that's our
8 customers, the end users on these generally licensed
9 devices, as well as the manufacturers/distributors/
10 service providers.

11 There is very poor communication, and so
12 when this gets opened up to the states, you know, we
13 know there is going to be more changes to the states.

14 Now that they have been given official authority to
15 make those changes, it is going to be extremely
16 difficult to find out about those and to stay on top
17 of those, certainly on an ongoing basis.

18 MR. WHITE: I'll just add a comment on
19 what Jonathan just said. The FSME external website
20 does have links to all of the states and all -- where
21 the regulations are. But, again, the states are
22 required to follow their administrative process to
23 promulgate rules.

24 They -- some of them are very different
25 than what we do in NRC space, and some of them are --

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1 some of them are very unique, and some of them are
2 very simple, and some are very complex. And, again,
3 they all require public notification. We know that
4 they all require public notification, but how they do
5 that varies from state to state. And I, again,
6 appreciate Jonathan's comment on that, because it
7 would be particularly difficult, you know, to keep
8 track of those.

9 FACILITATOR RIVERA: I'll bring you the
10 mic.

11 MR. WHITE: Talk into the mic, please.

12 MR. TRAEDE: If I could respond -- hello?

13 MR. WHITE: Just keep talking.

14 MR. TRAEDE: Okay. We are also hearing
15 that -- from the states, when a state issues a
16 violation, based on this distribution of GL devices
17 versus specific, we get to hear it, too. And there
18 was one just recently in Pennsylvania that I am
19 dealing with now.

20 So, you know, the manufacturers and the
21 distributors, you know, we're having the same problem.
22 You know, we hear about violations in different
23 states, and different states have different rules. So
24 I just wanted to comment that we see that, too.

25 FACILITATOR RIVERA: Thanks. Anyone else?

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1 Okay.

2 MR. GALLAGHER: Bob Gallagher. I'm with
3 the Massachusetts program. Just a question for those
4 manufacturers out there having licensees in other
5 states. Would it be worthwhile -- I'm thinking of a
6 mechanism maybe to address that issue -- if, for
7 example, the CRC -- how many are members of CRCPD as
8 affiliates? Mr. --

9 FACILITATOR RIVERA: Three hands raised.

10 MR. GALLAGHER: Well, I'm just wondering
11 if it might be worthwhile to have some sort of a
12 ListServe for the CRCPD when a state promulgates
13 proposed regulations, to list that with the CRCPD,
14 because I know when we went to change our regulations
15 we sent a notice out to all valid email addresses we
16 have for every licensee in the Commonwealth trying to
17 address that. I don't know if you got it or not.

18 But if, for example, we --

19 MR. BLUTE: You can do that in the
20 Commonwealth of Massachusetts, but --

21 MR. GALLAGHER: That's why I'm saying
22 would be ListServe perhaps by the conference, be a
23 mechanism to help address that issue. It's a thought,
24 I don't know. I mean, I don't know how many
25 manufacturers are --

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1 MR. BLUTE: I think it's a good idea. If
2 not that, something I think does need to be done to
3 fill this void where, as a distributor, we have to try
4 to figure out -- you know, there's ways of getting on
5 these lists with a given state. You can -- it differs
6 by state. Not all of them have a mechanism, but most
7 states have a way that I can get in and say, "Okay.
8 I'm interested in any changes to your regulations.
9 Can you put me on your notification list?"

10 But, you know, trying to figure out how to
11 make sure we're getting these notifications from 50
12 states is a nightmare. And for us to try to -- for
13 every individual distributor to be going around to
14 every individual, you know, authority, trying to
15 figure out how to get in on their list, it would be
16 nice if there was a better mechanism where we could
17 just all work on a national basis to -- a rule change
18 in an agreement state -- well, it's going to apply to
19 people outside of that state.

20 And we ought to know who -- have a pretty
21 good idea who those people are, or at least have a
22 place where -- like you say, where we can put that
23 information, like the CRCPD, where everyone knows
24 where to get it in one place instead of 50 different
25 places, or what have you. So I think it's --

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1 something like that, it would be nice if it could get
2 done.

3 FACILITATOR RIVERA: Anybody else want to
4 respond to Bob's question?

5 (No response.)

6 Okay. Go ahead. Little bit smaller font,
7 but hopefully you have copies of the questions from
8 the back. What are the current practices used by
9 companies to address multiple jurisdictions and the
10 registration requirements of generally licensed
11 devices in 10 CFR 31.5 and 10 CFR 31.6 or the state
12 equivalent?

13 MR. FORTKAMP: I can only speak for us.
14 You know, our -- you know, when I started with the
15 company, we used to have hard copies of all the state
16 regulations, and, you know, we'd have to pay for the
17 regulations year after year. I think every state now
18 has them -- at least some version of them -- posted
19 online, and I do not keep current copies, hard copies,
20 of those regulations anymore, because they are
21 probably going to be out of date before I get back to
22 printing them anyways.

23 But they are not always easy to find, and
24 it's -- usually you can find current ones, if you --
25 you know, it usually takes quite a bit of digging to

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1 go through the state website, because they are all
2 over the place. But they are out there, so that's --
3 you know, when I get into a situation where there is a
4 question, or if we're doing a distribution in a new
5 state, you go and you look up the regulations.

6 And that's -- you know, that's relatively
7 effective, except, you know, we do a lot of
8 distributions, and then it starts taking a lot of
9 time. We generally go by -- if we've done something
10 within the last year and haven't heard of any changes
11 otherwise that, you know, we don't do another
12 comprehensive review.

13 But that also runs us into the problem of
14 not understanding the policy interpretations that the
15 states implement. And we found out about those in a
16 variety of different ways, and they are not always
17 good ways. It's usually from, at best, a nasty call
18 from the state telling us that we shouldn't have done
19 that, and, at worst, it could be a notice of
20 violation.

21 MR. WHITE: I've got a question for
22 Jonathan. How much -- you said you have to keep
23 track. How much of your time or your staff time is
24 spent doing this?

25 MR. FORTKAMP: It's hard to put a firm

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1 number on it. You know, we probably put, for every
2 distribution we do, anywhere from 30 minutes to an
3 hour of review on regulations, verifying we have
4 current forms, verifying -- because it's not just our
5 requirements. We also work as, you know, kind of
6 de facto consultants to our customers to help ensure
7 their compliance.

8 So, you know, we support them. We make
9 sure we have current forms, current notice to
10 employees, emergency contact information within the
11 states, current copies of the regulations to provide
12 to the states. And some of those -- certainly, some
13 of that information we are required to provide to the
14 states or to our end users under the regulations.

15 MR. BLUTE: Jim Blute from Thermo Fisher
16 again. I'll comment that just within our group at
17 Thermo Fisher -- and I know we have a number of
18 different groups just within Thermo Fisher represented
19 here. Just in my group, it would take me all day to
20 answer that first question, really, if I was to answer
21 it in any kind of detail whatsoever. What do we do to
22 -- you know, to address multiple jurisdictions? I can
23 give you some flavor, though, that I'd like to see on
24 record.

25 We probably are -- out of just our local

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1 business unit alone, we are probably shipping
2 somewhere around three to five generally licensed
3 devices every business day between servicing them and
4 selling them and renting them and loaning them,
5 probably, I think it's safe to say, 20 to 30 a week.

6 We have sales staff all over the country,
7 so there is probably about 30 of those that need to be
8 informed on different agreement state and NRC
9 regulations as they change over time. And they don't
10 come to the office every day, so we have to figure out
11 means of communication to them.

12 We have our service department, who is
13 taking them in and out every day. We have sales staff
14 that are selling -- internal sales staff that are
15 processing orders. The number of people that we have
16 to keep informed, just within our business unit,
17 without -- before we even talk about helping out our
18 customers, just within our own people to sell them and
19 service them, is incredible.

20 And we have -- what works for one group,
21 like a field service person doesn't work for an
22 internal person. So we have used databases, we have
23 used emails, we have used newsletters, we have used
24 spreadsheets, we have used routine training, we have
25 used non-routine training, we have had meetings. We

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1 have done it all, and some things work and some things
2 don't.

3 And it's -- when I talk about it being
4 difficult to comply with a bunch of states that are
5 each doing their own thing and changing over time is
6 -- it's really difficult, and we probably have -- I
7 would say that because of -- just because of the issue
8 of changes from state to state, we probably have to
9 keep an additional staff member.

10 If it was a federal program instead of
11 variable state programs, we would easily be able to
12 save a staff member just in our compliance group
13 alone. And it would save a lot of other people in our
14 organization a lot of time, too.

15 MR. WHITE: Thank you. That was very
16 helpful. And, again, you have -- the comment period
17 is open until October 30th. So if you want to
18 elaborate more on that, you know, you are certainly
19 welcome to provide written comments on that.

20 Thank you.

21 FACILITATOR RIVERA: Does anybody else
22 want to share their current practices?

23 (No response.)

24 Okay. What are the costs incurred by
25 companies by doing business in multiple jurisdictions

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1 with regard to the registration requirements of
2 generally licensed devices in 10 CFR 31.5 and
3 10 CFR 31.6 or the state equivalent?

4 MR. FORTKAMP: Well, you've got your
5 direct costs and your indirect costs. Your direct
6 costs here are going to be mostly associated with
7 licensing, registration fees. They can vary. There
8 are some states under 31.6 or the state equivalent
9 there is no fees, no notification requirements.

10 There are states that do not have the
11 equivalent of 31.6, general license, so you have to go
12 and get specific reciprocity, with fees up to -- I
13 think the biggest one is -- it's Texas or Illinois. I
14 think they are both about \$3,000, \$3,500 per year.

15 In Illinois, we -- you know, we do very
16 limited work in both those states. That's expensive
17 when you look at it, you know, per service. You know,
18 the other states, for any kind of registration there
19 is always a fee associated with it ranging from, you
20 know, a couple hundred dollars up to that \$3,500.

21 In addition to that, you have your
22 indirect costs, which are basically administrative
23 oversight of, you know, maintaining the information,
24 maintaining the -- you know, links to the websites, or
25 whether it's downloading current copies of forms for

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1 customers, reviewing the regulations.

2 And, again, you know, we do that on
3 usually a per distribution or at least an annual
4 basis. Depending on the state and how readily
5 available that is, whether we have to contact the
6 state directly and talk to them or if we can find all
7 of the information online, that can vary anywhere from
8 a half an hour for the easiest states up to a full day
9 on an annual basis, plus what we do for each
10 individual distribution.

11 FACILITATOR RIVERA: Anyone else? Oh, go
12 ahead, Sean.

13 MR. CHAPEL: Hi. This is Sean Chapel.
14 According to the research of the Association of Device
15 Distributors and Manufacturers for 2010, it would cost
16 approximately \$60,000 to have reciprocity agreements
17 with the NRC and all agreement states. And that's
18 under the -- you know, you can typically receive
19 reciprocity up to 180 days. Some states it's as few
20 as 30 days. Then, you'd have to get a specific
21 license. So if you had -- went over the limits, then
22 those fee amounts would be even greater.

23 MR. WHITE: Just, Sean, for clarification
24 that's if someone went to all 37 agreement states and
25 the NRC.

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1 MR. CHAPEL: Exactly.

2 MR. WHITE: Thank you.

3 MR. BLUTE: Okay. Jim Blute with Thermo
4 Fisher. I sort of feel like this question -- it seems
5 to me this question is really about, you know, the
6 costs related to general license registration. And,
7 really, that is just a cost incurred by our customers,
8 and usually just in one state.

9 I don't think personally that -- there are
10 indirect costs, certainly, with tracking and informing
11 customers and everything else. But my perspective is
12 that general license registration is not a big deal in
13 terms of cost. And it seems to me that this
14 compatibility B to C has some basis of root in states
15 wanting the ability to register all devices.

16 And I'd kind of question why we don't just
17 do that across the Board instead of making it -- to
18 me, the cost is going to be more having just some
19 states register some devices and other states
20 registering all devices, and them picking and choosing
21 which ones they want to register and trying to figure
22 that out than just having everybody register.

23 I think the GL registration program is one
24 of the most successful things that they have done to
25 general licensing in a long time, quite frankly. And

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1 it helps my license -- my customers.

2 The ones that are registered, that fall
3 into the GL registration requirement -- and some of
4 our customers do -- I have to spend a lot loss time
5 with them, because they understand they're a general
6 licensee, they -- you know, they are touching base
7 with their -- there's an interaction at least once a
8 year between them and their authority, and it really
9 -- it really, from our perspective, neatens things up.

10 It's the ones that are outside our
11 registration that we spend more time with, I think,
12 and I think it's almost cheaper from our perspective
13 to deal with -- to deal with registered -- annual
14 registrants rather than people that maybe go to eight
15 -- five, six, seven, eight years without ever hearing
16 from a licensing authority and have no idea that they
17 even have a license. They think they are working
18 under our license or whatever.

19 So I would be in support of, you know,
20 everything being registered, and I'm definitely not in
21 support of people picking and choosing what gets to be
22 registered from one agreement state to another.

23 MR. WHITE: Just a comment on fees and
24 registration. Again, NRC, from a compatibility
25 standpoint, agreement state program, we don't really

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1 look at -- it's up to the state to charge whatever
2 fees they feel is appropriate. The only requirement
3 that we require is that the state adequately funds
4 their program and staffs the program, and how they go
5 about doing that is their business.

6 So, again, the state can charge, you know,
7 \$10 or \$2,000 for reciprocity or registration. That's
8 their call completely. We say nothing about that.

9 FACILITATOR RIVERA: Does anyone else want
10 to speak to the costs?

11 (No response.)

12 We'll follow up with another cost question
13 with a different slant. What are the costs to health
14 and safety in doing business in multiple jurisdictions
15 with regard to the registration requirements of
16 generally licensed devices in 10 CFR 31.5 and 31.6 or
17 the state equivalent? Jonathan?

18 MR. FORTKAMP: This is Jonathan Fortkamp.
19 The health and safety of these devices, generally
20 licensed devices, the specifications for it, the
21 criteria, the review, all of that is defined within
22 the source and device registration.

23 If there is a question as to the adequacy
24 of that program for viewing these devices as safe
25 devices, then that's a completely separate question.

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1 One of our frustrations is that with all of the
2 variations, all of the changes proposed by states or
3 that states are implementing, there is no increase in
4 health, safety, or security related to generally
5 licensed devices. There is just no change there.

6 The devices are proven to be safe and
7 effective and secure for normal operations. You know,
8 there was some reference to devices that lost control
9 that fall under the general license, and I forget the
10 exact numbers off the top of my head. But that has
11 little to do with the licensing program that is
12 currently in place right now, because -- nor does the
13 proposed changes or the changes that states are
14 implementing do they -- are they going to
15 significantly reduce those number of losses.

16 Many of these devices are in place for
17 extended periods of time. We have devices that have
18 been in place for 50 years. Changing how, you know --
19 the paperwork that we give at the time of distribution
20 or changing, you know, the fees or something like
21 that, are not going to make those devices be secure
22 for 50 years. There is fundamental changes that need
23 to happen to the general license program to address
24 those issues.

25 MR. WHITE: Let me rephrase this question

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1 just slightly differently. You know, working in
2 multiple jurisdictions, you commented before -- you
3 know, a couple of you commented before about dealing
4 with different regulations and different
5 interpretations of regulations. Did you ever have a
6 problem with, you know, from a health and safety
7 standpoint, you know, trying to deal with these
8 different jurisdictions and different agencies and how
9 they implement their regulations? Did you actually
10 have any problems with those types of issues?

11 MR. FORTKAMP: You know, speaking
12 personally to ABB, we haven't had any direct impact on
13 health and safety. The three-day notification
14 requirement for some states, that can become an issue,
15 depending on what is defined as an emergency within
16 that state. You know, is the shutter sticking, is
17 that an emergency? Maybe, maybe not. There is no
18 clear definition.

19 You know, so if a shutter is stuck open on
20 a device, and there is nobody getting an immediate
21 radiation dose from that, it doesn't -- it is not
22 considered a safety hazard according to the state,
23 then you -- are we still required to provide a three-
24 day advance notice, and then do the service on there
25 for three days? I mean, it's a potential health and

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1 safety effect.

2 Again, you know, ABB, we have not had any
3 direct issues associated with that.

4 MR. WHITE: Just a followup question to
5 that. You mentioned that three-day -- is it -- are
6 most states and the NRC accommodating with, you know,
7 waiving the three days? You say something is an
8 emergency, you have to go in, are most states
9 accommodating to that? Or do you run into a lot of
10 roadblocks?

11 MR. FORTKAMP: Every state says that they
12 will -- or at least every state that I have been
13 involved in, that we have reciprocity with, will
14 provide some sort of emergency, you know, exceptions.
15 Again, the whole question is: what is the definition
16 of an emergency?

17 One example for us is -- one of our
18 devices measures certain properties of paper. So the
19 paper machine is dependent on our device being
20 operational for them to make quality paper. If our
21 device isn't working, they're not making paper.

22 If our device goes down and there is --
23 you know, it's a non-radio -- non-safety issue
24 associated with a device, but it's something where we
25 have to gain access to the sensor -- and that falls

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1 under reciprocity -- many states will not consider
2 that as an emergency situation.

3 I can guarantee our customers get -- see
4 that as an emergency situation with a direct impact on
5 their business. Again, there is just no clarification
6 of what that emergency situation is.

7 FACILITATOR RIVERA: Thank you. Does
8 anybody else want to speak to the health and safety
9 costs?

10 MR. BLUTE: When you look at our products
11 -- hand-held X-ray florescence analyzers -- I could
12 hold two of them up side by side and not too many
13 people here would know the difference except one has a
14 radioactive sealed source inside and one has an X-ray
15 tube.

16 They can be made to do the same job, and a
17 lot of our customers get to choose which they want.
18 Do they want one with a sealed source, or do they want
19 one with an X-ray tube? However, sealed sources give
20 off monoenergetic radiations that can be targeted for
21 a specific application, whereas an X-ray tube we are
22 stuck with getting a wide spectrum of energies, which
23 a lot of them get wasted in XRF. You don't get to use
24 them much. So analytically they don't give you much
25 benefit, but they come along with the other energies

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1 that you do need.

2 So an X-ray tube -- an equivalent X-ray
3 tube device, the in-beam dose rates can be hundreds of
4 thousands of rem per hour up near the exit window of
5 the device, whereas the highest we see is about one r
6 per hour from one of our isotope-based analyzers.

7 So I think that if you want to talk about
8 health and safety of the regulatory community, at
9 least looking at our device -- this isn't going to be
10 applicable to other products -- but just a comment
11 that this is going to -- more variation with general
12 licensing is going to drive potentially people to make
13 the decision to go with an X-ray tube.

14 And although you have accomplished maybe
15 some -- you have bought some benefit and security
16 because there is a lot less security concerns with the
17 tubes, certainly, and long-term tracking concerns.
18 You have created, you know, something that has a
19 higher potential hazard to the actual operator of the
20 device. You have made that more of an attractive
21 option than the isotope version for our products.

22 FACILITATOR RIVERA: Thank you. Anyone
23 else?

24 (No response.)

25 All right. Are there any final thoughts

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1 from a manufacturer and distributor perspective on the
2 regulation of generally licensed devices associated to
3 10 CFR 31.5 and 31.6 or the state equivalent that
4 affect you with regards to where your company is
5 located or where your customers are located?

6 MR. CHAPEL: Hi. One issue we discuss
7 with our clients is that 10 CFR 31.6 only allows
8 servicing on generally licensed devices, and we would
9 like to see that broadened to include exempt devices.

10 The interpretation from the NRC when we asked them
11 was that it definitely did not include exempt devices,
12 but we don't see any reason why that couldn't be
13 broadened.

14 FACILITATOR RIVERA: Okay. Thank you,
15 Sean. Anyone else?

16 MR. WHITE: Duncan again. I think it was,
17 Jim, you mentioned something about shipping stuff to
18 certain locations and single locations of use. Could
19 you -- I think it was, Jim, you mentioned that. Can
20 you elaborate a little bit more on that? As part of
21 your distributing, some states limit you to sending it
22 to certain locations or certain addresses or use at
23 one place or something like that?

24 MR. BLUTE: Okay. So this was earlier I
25 mentioned that, yes. So we have -- like I said, it's

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1 somewhere around 10 or 12 states that prohibit,
2 usually by their policy, portable devices from being
3 generally licensed. They say, "We are not going to
4 take any portable device under general licensing."
5 And our device is portable, so we can't distribute
6 there.

7 Now, that's actually in some ways easier
8 than them saying this -- we see three categories --
9 states that we can distribute the generally licensed
10 device into in pretty much the way the NRC intended
11 them to work, states that prohibit the generally
12 licensed device, and then a third category which is
13 about maybe six, eight states that have -- and
14 Massachusetts here being one of them, which has said,
15 "We will only -- if it's a portable" -- well, really
16 what they have said is, "We don't allow portable
17 generally licensed devices in our state."

18 But we will make an exception to that
19 prohibition under the condition that the licensee can
20 commit to keeping the device only at a single address.

21 They are not going to drive it down the road to go
22 work at another -- so, for instance, for our customer
23 base that means a lead paint company -- a lead paint
24 inspection company in Massachusetts can't use the
25 device under general licensing.

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1 But let's say a manufacturing company that
2 wants to do quality control of incoming parts, you
3 know, and they don't have any need or plans to go work
4 in other places, they can. The challenge can be --
5 there's lots of challenges that these different
6 categories of states can bring about, but not least of
7 which is us -- you know, who is responsible for that?

8 Who is responsible for that commitment
9 that it is going to stay at a single address? Can we
10 get a violation from Ken Traegde here for distributing
11 the device to a company who told us that they were
12 going to be able to keep it at a single address and
13 then they go and not do it? Those are some of the
14 questions that we are faced with daily.

15 MR. WHITE: Well, since you brought up,
16 you know, Massachusetts, you know, what does
17 Massachusetts do with regard to these portable general
18 license devices? And do they have a problem with
19 stuff coming in and out of your state? Again,
20 generally -- portable devices that are generally
21 licensed.

22 MR. GALLAGHER: Let me start by saying
23 that this policy -- this policy that Jim has mentioned
24 -- is a few years old. I was not party to that
25 decision. Hearing what I have heard today, I think we

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1 are going to revisit that policy to clarify exactly
2 what the requirements are in the Commonwealth of
3 Massachusetts.

4 In terms of, you know, Duncan, your
5 question how often -- if I understand your question
6 correctly, how often do we face issues with stuff
7 coming in? I don't have a direct answer for that just
8 yet.

9 MR. WHITE: Okay.

10 MR. GALLAGHER: I know that some of our
11 neighboring states do allow these devices to be
12 general licensed, and, as I mentioned a few years ago,
13 our previous director decided that we don't, but I
14 think we need to revisit that to address the
15 difficulty in implementing that.

16 MR. BLUTE: I've had the experience of
17 being told by one agreement state, who normally does
18 not allow our device to go in under general license,
19 if -- so, in other words, if I have a customer in a
20 particular state, in this particular state, that wants
21 to buy our device under general licensing, the state
22 doesn't allow it, because they exist -- their entity
23 is in that state.

24 However, this particular agreement state
25 that prohibits general licensing for their own

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1 companies will allow somebody from a neighboring state
2 to come in under general licensing, for our temporary
3 use. Okay? So it's a state that prohibits general
4 licensing for their own people but will allow
5 temporarily out-of-state general licensees to come in.

6 There is another state -- and I don't know
7 if the states are important, but there's another state
8 that will allow general -- us to distribute generally
9 licensed devices to companies within that state, but
10 they will not allow an out-of-state general licensee
11 to come in and do temporary job site work -- the exact
12 opposite.

13 And so these are two states that exist
14 amongst all the other ones that have -- you know, that
15 don't have rules like this. And so we get a call on
16 any given day from a customer that says, "Hey, I just
17 bought this generally licensed device from you, and I
18 got -- you know, we're going to be working in these 10
19 different states. And I'm kind of going over it to
20 make sure we are going to be compliant. Can you tell
21 us what we're going to need to do to go work in these
22 10 different states?

23 And the best answer I can give them is to
24 start calling every state and having a discussion with
25 them and a dialogue, because we really don't have any

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1 confidence in telling them what -- you know, what to
2 expect. I can tell you what I think they are going to
3 tell you, but it's really difficult.

4 FACILITATOR RIVERA: Thank you. Other
5 thoughts?

6 MR. CHAPEL: Hi, Bob. When you make your
7 policy decision about portable generally licensed
8 devices, can you publish that in perhaps a regulatory
9 guide? It could be on the website, so that
10 manufacturers could refer to that. And other related
11 policy decisions about reciprocity, so everything is
12 clear.

13 MR. GALLAGHER: We can make an
14 announcement to that effect and post it on our
15 website, yes. But the nature of the workload right
16 now, it's not going to happen in the immediate future.

17 FACILITATOR RIVERA: Yes.

18 MR. TRAEGDE: Hi. Ken Traegde. Since you
19 commented, Jim, that, would Ken Traegde give me a
20 violation if this happened --

21 (Laughter.)

22 -- I felt the need to respond to it.

23 MR. BLUTE: And, you know, I'm satisfied.

24 MR. TRAEGDE: Actually, we would work with
25 you on it. We'd look at the conditions and how it

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1 happened and, you know, we'd try to work with you to
2 make sure that that is --

3 MR. BLUTE: And that is --

4 MR. TRAEGDE: Right.

5 MR. BLUTE: -- State of Massachusetts, not
6 every agreement state has --

7 MR. TRAEGDE: Yes.

8 MR. BLUTE: Some agreement states think
9 that a good means of communication is a signoff on --
10 violation of the --

11 MR. TRAEGDE: Right.

12 MR. BLUTE: -- and, you know, we have
13 experienced that. We have also experienced that --
14 that, you know, there are some states that are much
15 more cooperative with us and view us distributors and
16 manufacturers as, you know, view it worthwhile to work
17 with us, you know, but other states really just start
18 off with a violation.

19 And they don't look at it as a big deal,
20 because they say, "Well we're not giving you a fine
21 with the violation." Really, I've talked to them
22 about it and they say, "We're not mad at you. We just
23 wanted to formally let you know that, you know, this
24 is something that's going on."

25 And I say, "Well, you may not think this

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1 is a big deal, but I get paid by an employer who does
2 think it's a big deal when we get violations." And
3 they asked me to send these things up the chain of
4 command, and they think I'm not doing my job when I'm
5 getting a violation when, in fact, I didn't know that
6 you -- all I did was not know that you changed the
7 rule. That's all I did.

8 So I appreciate that you would -- that's
9 your comment. And since this is public record, I
10 guess I'll say to all the other agreement states, it
11 can be frustrating to start off with a violation
12 instead of just a dialogue, especially when rules
13 change.

14 FACILITATOR RIVERA: Thank you. Anyone
15 else?

16 MR. WHITE: I'll have -- I guess I'll get
17 the final word on this. I know that the issue of
18 portable generally licensed devices is a good way to
19 start a healthy debate among agreement states, because
20 of their very difference of opinions in how to
21 implement it.

22 So it's one of those sore subjects, and I
23 appreciate your bringing it up and talking about it a
24 little bit, because I know this is one thing that
25 states are very interested in and, really, they are

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1 trying to figure out how they are going to proceed
2 forward with it. Again, because it's -- as you -- as
3 people pointed out, there is a difference of opinion
4 how to do it.

5 MR. BLUTE: It is those differences of
6 opinion on how to do it that concern us about going
7 from B to C, because there are differences of opinion,
8 and they are going to -- they are going to exercise
9 this flexibility. Even though they may be saying now
10 to the Commission, no, we don't have any plans to make
11 any changes, I expect that they will exercise their
12 flexibility, and their differences of opinion will
13 become apparent.

14 FACILITATOR RIVERA: Okay. Thank you,
15 everyone, for the active participation on that section
16 of our meeting today.

17 Before we move on to the next slide that
18 Dennis has already put up, we have been going a little
19 over an hour, so I think it's about time for about a
20 15-minute break. It's 3:15, if we could come back at
21 3:30. Thank you.

22 (Whereupon, the proceedings in the foregoing matter
23 went off the record at 3:15 p.m. and went
24 back on the record at 3:30 p.m.)

25 FACILITATOR RIVERA: Okay. Welcome back,

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1 everyone. Thanks for returning on time.

2 We are going to go ahead and move on to
3 the perspective of the end users, and the first
4 question being: what is the difference in costs of
5 generally licensed devices purchased by you in
6 comparison to devices without radioactive material
7 with regard to the registration requirements of
8 generally licensed devices in 10 CFR 31.5 and 31.6 or
9 the state equivalent?

10 MR. BLUTE: I don't know if --

11 FACILITATOR RIVERA: Okay. I know that we
12 may not have end users here, but it if M and Ds have
13 any perspectives.

14 MR. BLUTE: Hi. Jim Blute from Thermo
15 Fisher Scientific. That's why I'm speaking up. I'm
16 not an end user, of course, but I -- I don't think
17 there are any here. I can say that for our customers,
18 a lot of them that want to move around to multiple
19 states, it is much cheaper to be a general licensee if
20 states let you in.

21 You know, some of our customers are forced
22 to get a specific licensing. Even though their states
23 allows them to have a general license, if they want to
24 work in a state that doesn't allow general licensing,
25 they can't get in. But if all states would allow

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1 general licensing, it would be a lot cheaper, because
2 reciprocity, as somebody pointed out, if you were to
3 get reciprocity in every state, you know, it can be
4 \$60,000 or something a year.

5 I mean, even if a company wants to work in
6 four or five states, reciprocity can get really
7 expensive, whereas general licensing right now doesn't
8 have any -- in most cases, doesn't have any, you know,
9 reciprocity type of fee. So they only have to get
10 their registration done. The only fee associated with
11 general licensing usually is just if it's a
12 registerable quantity, you've got to pay the
13 registration fee in your one state.

14 And most of you are done with fees, and
15 it's a lot cheaper, so that's why certainly we are
16 supportive of the general licensing as a licensing
17 option. I think my customers are supportive of
18 general licensing as a licensing option, and, again,
19 reiterates why we are concerned about the compliance
20 being more difficult, because, you know, it may be
21 cheaper, but if I can't maintain compliance, and it's
22 costing me money in staff and tracking and everything
23 else to maintain compliance, soft costs that aren't
24 easily added up, but at some point we -- they decide
25 to just go with specific licensing and stop paying all

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1 these reciprocity fees, which are real expensive.

2 FACILITATOR RIVERA: Thank you.

3 MR. FORTKAMP: You know, looking at the
4 question, it looks like, you know, compared to devices
5 without radioactive material, I mean, part of the
6 issue with at least the devices that we distribute is
7 there aren't any viable options that don't contain
8 radioactive material. They can't make the
9 measurements that our beta gauges make on the
10 processes that we are involved in.

11 You know, I know in some other
12 applications there are some different technologies.
13 It's generally an X-ray type of technology. X-ray
14 tubes compared to radioactive material source are
15 magnitudes of order more expensive typically. At
16 least that is my experience with the types of -- the
17 sizes of tubes that we get involved in. At least, you
18 know, 10 times more expensive for initial device
19 versus radioactive material. And, again, now that's
20 just some applications. That could be variable all
21 over the place.

22 The real cost, though, difference -- if
23 it's an X-ray device or it's a radioactive material
24 device, there is going to be similar registration
25 requirements. Or, excuse me, there are registration

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1 requirements in nearly all states for X-ray devices.
2 With the generally licensed devices, again, it's just
3 sort of all over the place, so it is hard to do an
4 adequate comparison.

5 FACILITATOR RIVERA: Does anyone else have
6 comments?

7 (No response.)

8 Okay. What regulatory costs influence the
9 end users' decisions in the generally licensed devices
10 that are purchased? Okay.

11 MR. FORTKAMP: Yes. Again, I'm not sure
12 exactly what's getting here. Again, you know, a lot
13 of our customers, they have to have something. So
14 it's not a matter of whether they are going to buy
15 something or not. It's -- you know, they have to have
16 something in their operations.

17 You know, I mean, I can talk a little bit
18 to the costs of a general license versus specific
19 license, and with the general license, you know, there
20 is limited administrative costs that are involved for
21 an end user. Even with a registration, there is a
22 responsible person that is required to fill out some
23 basic information on the device on an annual basis.

24 It's a minimal administrative oversight,
25 which is commensurate with the minimal health and

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1 safety risks from a GL device. When you get into a
2 specific license, there is a lot more cost, because
3 there is a lot more time and a lot more involvement
4 associated with the maintenance of a specific license
5 with the application for a specific license, the
6 process, to go through with the individual states or
7 the NRC getting approval for the initial license.

8 There is costs with amendments every time
9 you add a source, remove a source, change a source,
10 change authorized users, change radiation safety
11 officer. Nearly every jurisdiction will hit you with
12 fees for those changes.

13 So, you know, the costs, again, jump up,
14 as well as the time to maintain the documentation, the
15 training programs, the authorizations, everything that
16 is required under a specific license. And, you know,
17 again, back to my point previous -- I don't see a
18 value to health and safety from just that
19 administrative burden.

20 FACILITATOR RIVERA: Thank you, Jonathan.

21 Sounds like we have moved into the third question a
22 little bit. What choices are made by end users
23 regarding health and safety and security with regard
24 to which generally licensed devices are purchased by
25 end users? Is there further comment on that?

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1 (No response.)

2 Okay. Any additional comments regarding
3 the regulation of generally licensed devices
4 associated to 10 CFR 31.5 and 31.6, or the state
5 equivalent, that affect end users with regard to where
6 the generally licensed devices are being used?

7 MR. FORTKAMP: Well, the other big impact
8 as -- to end users comes under the 31.6 and the
9 ability of manufacturers, distributors, or other
10 service providers to come in and do work on the
11 devices. Obviously, all general licensees and many
12 even specific licensees don't do maintenance on these
13 devices themselves. They don't have the technical
14 expertise, the skills, or they just don't want to deal
15 with it.

16 So they have, you know, the service
17 providers, the manufacturers/distributors, come in and
18 do those services, whether it's routine -- the six-
19 month source inspections or it's a major repair on a
20 device.

21 The costs that we incur as
22 manufacturers/distributors/service providers, they do
23 get transferred down to our customers. We are not in
24 a position to absorb those costs just because we are
25 nice guys. We are obviously in a business for a

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1 profit with, you know, pretty tight requirements on
2 ourselves. You know, everybody is in a tight position
3 now, so, you know, we are not going to absorb those
4 costs, so they will ultimately hit the end users.

5 The administrative burden, the additional
6 time, the additional costs that hit the service
7 providers are going to trickle down to our customers
8 in the price of our products, in the price of our
9 services. So those are a little bit more difficult to
10 capture, because they will vary. You know, they will
11 be spread out a little bit over time and over multiple
12 customers in a given jurisdiction, but they ultimately
13 hit them.

14 FACILITATOR RIVERA: Other comments on the
15 impact with regard to where the device is used?

16 (No response.)

17 All right. There is still plenty of time
18 left on our agenda, so at this point I'm going to go
19 ahead and open the floor to any further information
20 that our audience wants to share with the NRC while
21 we're here.

22 MR. FORTKAMP: This is Jonathan Fortkamp.
23 I spoke at the Organization of Agreement States
24 meeting a couple weeks back now, and there was a
25 presentation there just talking about adequacy versus

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1 compatibility. And, you know, I think what is pretty
2 clear from our discussion here, but also from the
3 states' discussion, the CRCPD meetings, the OAS
4 meetings, is that the general license rules are not
5 adequate at this point.

6 Compatibility is a side issue until we can
7 address the adequacy of the regulations. I think it's
8 time, really, that the Commission goes back and
9 reevaluates what the purpose of the general license
10 rule is and how to apply that in today's environment.

11 With the increased security concerns, with different
12 types of devices than these rules were written for,
13 you know, 60 years ago.

14 The fact that every states wants to go off
15 and vary their regulations says that the individual
16 states don't feel that the rule is adequate. So I
17 think it is important that we pull all of the
18 stakeholders together, reevaluate the regulations, and
19 identify what is adequate.

20 And I think -- you know, I really think a
21 lot of the compatibility issues will go away if we can
22 find out client's regulations that are truly adequate
23 to meet the end users' requirements or the
24 manufacturer's/distributors' requirements, and the
25 regulatory bodies' requirements. And if we do that,

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1 then, you know, compatibility becomes much less of an
2 issue.

3 FACILITATOR RIVERA: Thank you. Does
4 anyone else have additional input they would like to
5 provide?

6 MR. MOLINARIO: My name is Mike Molinario.
7 I'm from Thermo Fisher Scientific, Air Quality
8 Division. And one of the things that is going to --
9 I've been taking in all of this information, and it's
10 a lot of good information. What I'm seeing is what
11 this is going to do for me, it's going to drive me to
12 take my low-level radiation and actually convert it to
13 exempt status, because this is going to make it much
14 more difficult to keep the business going on an even
15 keel.

16 And it is going to -- and I'm not going to
17 be able to take my costs and justify them with my
18 management. So what they are going to do is they are
19 going to now drive me to turn around and take anything
20 that I have left that is not -- that is general
21 material and move forward with federal exemption
22 status.

23 So in a way, this is kind of hurting the
24 state, because anyone that is in my position is going
25 to probably come to the same conclusion and do the

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1 same thing. And the state will lose money rather than
2 get it from further profits.

3 FACILITATOR RIVERA: Thank you, Mike.
4 Other comments, questions? Going once, twice.

5 (No response.)

6 All right. I'm going to turn it back over
7 to Duncan to go ahead and close the meeting.

8 MR. WHITE: Again, thank you all for
9 coming today. Again, your time is always very
10 valuable and appreciate your coming out and spending
11 the afternoon with us and sharing your thoughts on
12 this -- in this area. And I'm sure there will be more
13 dialogue on this very topic.

14 As I said earlier, we are tasked with
15 writing a report that goes to the Commission by June
16 of next year. That report will include -- you know,
17 summarize what we have heard today in the other public
18 meeting, and any written comments that we get. We
19 will also provide corrective actions, whatever that
20 means.

21 And from what I'm hearing today, there are
22 going to be some things we are going to have to
23 suggest in terms of a path forward. But the
24 Commission -- again, what the Commission does with
25 that report is up to the Commission. Again, I don't

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1 know what the path -- I can't say what the path is
2 after June of this -- of next year.

3 I would like to thank everybody. I would
4 like to thank Alison for keeping us on task and on
5 time. Appreciate that -- Massachusetts for all their
6 help with getting this meeting together and bringing
7 some equipment down. Again, thank you. And, again,
8 thank you for all the manufacturers and everyone who
9 came out to talk to us today.

10 Again, comment period is open until
11 October 30th. So that's -- you know, that's almost 40
12 days. Well, maybe not quite 40 days, but, again, lots
13 of time to write -- you know, write to us and let --
14 you know, people said a lot today. If you know
15 someone else who has a particularly strong opinion of
16 that, then we'd appreciate that.

17 But, again, what we heard today, you know,
18 is that, you know, at least from the manufacturers and
19 distributors, that you are, you know, very interested
20 in some more national consistency on this. Again, you
21 see the importance of maybe even revising the
22 regulations. Again, the regulations may not be
23 serving everyone's needs. We need maybe to tweak them
24 and revise them, and just, you know, change them.

25 And you also heard the importance of a

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1 registration program that's broader than what we have
2 now, because, again, from -- this puts a little more
3 evidence to the end users, the importance of what they
4 have and how to deal with it.

5 So with that, again, thank you, and have a
6 safe trip home.

7 FACILITATOR RIVERA: Just one last thing.

8 I forgot to mention, if you would like to fill out a
9 feedback form, there are available in the back of the
10 room, or you may have picked it up as you came in.
11 You can either hand it to an NRC staff member here or
12 mail it back to us.

13 And thank you again for your active
14 participation.

15 (Whereupon, at 3:43 p.m., the proceedings in the
16 foregoing matter were concluded.)

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