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NUCLEAR REGULATORY COMMISSION

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INDEPENDENT EXTERNAL REVIEW PANEL MEETING

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TUESDAY, FEBRUARY 19, 2008

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VOLUME I

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ROCKVILLE, MARYLAND

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The Review Panel met at the headquarters of the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 2:00 p.m., Mr. Thomas E. Hill, Chairman, presiding.

PANEL MEMBERS PRESENT:

THOMAS E. HILL, Chair

MICHAEL T. RYAN, Member

BENJAMIN NERUD, Member

NRC STAFF PRESENT:

AARON McCRAW

TERRY REIS

ALSO PRESENT:

JANET SCHLUETER

LYNNE FAIROBENT

A G E N D A

P R O C E E D I N G S

(2:04:23 p.m.)

CHAIR HILL: If the meeting will come to order. This is the first day of the 6th Meeting of the Independent External Review Panel to identify vulnerabilities in the U.S. Nuclear Regulatory Commission's Materials Licensing Program.

This meeting is being conducted in accordance with the provisions of the Federal Advisory Committee Act, and Aaron McCraw is the Designated Federal Official for today's session.

In accordance with the Federal Advisory Committee Act, this meeting is being transcribed to insure an accurate account of today's discussion. Please use one of the microphones when making statements. Please identify yourself when speaking, and speak with sufficient clarity and volume. We ask that you conduct any necessary side conversations outside the room, and if you have a cell phone or pager, we ask that you put them in silent mode, or turn them off at this time. The panel appreciates your cooperation with these requests.

This is a public meeting. If you haven't already, I ask that you sign in on the sheet provided here behind me. And members of the public will be

afforded an opportunity to provide oral statements at a time designated in the agenda. Back on the table next to the door is a list of reference materials, documents that have been, or will be discussed by the review panel. There are also feedback forms for anyone who wishes to provide his or her comments on today's session.

I will, at this time, introduce the panel members. I'm Tom Hill, Chairman of the panel.

MEMBER RYAN: Mike Ryan, panel member.

MEMBER NERUD: Ben Nerud, panel member.

MR. McCRAW: Aaron McCraw, Designated Federal Official.

CHAIR HILL: And, Aaron, at this time, give us an overview of our agenda.

MR. McCRAW: Well, the agenda is pretty open for the next couple of days. It's to accept any public and/or stakeholder comments. As well, it gives you plenty of time to work on converting your draft report into a final report, and working on the slides for your Commission briefing in March.

CHAIR HILL: Okay. Thank you.

We've got listed kind of a synopsis of previous meetings. We have had briefings on licensing, various aspects of the licensing process,

and security. And in previous briefings from NRC staff, Headquarters, Region, and also from the State of Florida. Mike Stephens talked to us about Florida's licensing program.

At the last meeting, we did a summary of our draft report, and released the draft report. And it hit the street about the 11th of February.

MR. McCRAW: Yes.

CHAIR HILL: So it is out for the public to review at this point. Mike, Ben, any other comments that you have at this point?

MEMBER RYAN: Just one. I think in all of our briefings, I'd like to compliment the NRC staff for all of their detailed information, for their forthright thoughts and sharing not only what they had as finished products, but also sharing the work that's underway, and what their insights are. And they've actually shared those as they've developed with us, which has helped us do a better job. And it's that forthright kind of here's where we are at this moment, and what's going on. And we really ought to compliment them for giving us every insight they could possibly give us.

CHAIR HILL: Okay. Ben, any thoughts?

MEMBER NERUD: No, not now.

MEMBER RYAN: I might add that I hope we'll -- you'll maybe cover that comment when you brief the Commission.

CHAIR HILL: I think that that would be most appropriate.

MEMBER RYAN: Thank you.

CHAIR HILL: Because they have been very, very supportive, and trying to work with our schedule, and their schedule.

MEMBER RYAN: Yes.

CHAIR HILL: And I do appreciate the efforts that they have made.

Well, we have an opportunity for discussion of the draft report. This is open also for public participation.

MEMBER RYAN: Should we do that first, if anybody has some comments they want to make?

CHAIR HILL: Do you have any thoughts, Janet?

MS. SCHLUETER: No, sir.

MEMBER RYAN: Aaron, have we had any comments that you'd like to share?

MR. McCRAW: There hasn't been any formal written comments received that were requested through the Federal Register Notice. I did hear some informal

grumblings in the hallway, which I have passed on to you already, such as certain observations, need to provide more justification. And I think you guys have already gotten a start on that.

MEMBER RYAN: Yes, that's helpful, anything we need to explain further to indicate our thinking and intent. We can certainly do that.

I think there's one other item that we probably do recognize. I hope the report reflects it, and I hope that if it doesn't, that we can recognize that and be clear; but that is on this issue of long lead time items. I think the Committee, and the panel, rather, recognizes that. Talking about a web-based licensing and source tracking system, if it's integrated and becomes, basically, the checkbook, if you will, by which both the NRC and Agreement States can track sources in a live fashion is not something that's going to click in overnight. But I think, ultimately, if you share the vision that if we have a system where if a licensee obtains a source, it's on his balance in the electronic system. If he wants to obtain another source, he can, for example, notify the vendor. You can look at my license, or get information about my license with this pass code which is good for two days. And that vendor can be told

yes, you may ship one curie of whatever it is, and that's perfectly okay. And put this number on your shipping paperwork, so that can then be a tracking of that additional purchase, if you will. Just like your credit card, you go into a restaurant, if you buy a $50 meal, that's probably well within your credit limit. If you want to spend $10,000 on a party, somebody probably wants to talk to you before that happens. So I think if we can create that kind of a live system, which, hopefully, can be developed as a national resource, both the NRC and Agreement States, that really addresses, I think, and I'd defer to a security expert, some of the vulnerabilities that GAO identified, or most of them, most of them I can think of.

MEMBER NERUD: I agree completely. The long-term solutions: the web-based licensing and national source tracking, all those things are the ideal solution. But what also needs to be incorporated into this, is there some compensatory measures that they can do, and they can do right now? Pick up the phone and call, go visit, those types of things.

MEMBER RYAN: Yes. And I think the other recommendation --

MEMBER NERUD: It's a little more effort on the part of individuals. It could be inconvenient, but the choices we're faced with now are a little bit of inconvenience, or -

MEMBER RYAN: A big problem.

MEMBER NERUD: - a huge, huge problem. And we don't need that, with telephones, and emails.

MEMBER RYAN: Having said all that, I am very sympathetic to the idea that there is a budget, and there is a budget cycle under which this, and every agency, operates, but I don't think we are constrained by that. I think we were asked by the Commission to evaluate and identify solutions that would solve the problem. And if there's a stepwise process to get into a fully integrated electronic version, and, quite frankly, one that's given to the Agreement States, or given access to the Agreement States without a whole lot of expense, we don't want to spend it 50 times over to do that, that, to me, would be a real asset to the regulating community.

MEMBER NERUD: And, frankly, I don't see anything in that report that's out of bounds. They were working on a web-based licensing system, they're working on a national source tracking system, maybe not to the level of consolidation that we wanted to

see, but these things are already in the works.

MEMBER RYAN: Right.

MEMBER NERUD: There's nothing else that we've really got in there that require huge amounts of resources to be expended to implement, a lot of manpower, a lot of time, those types. What it really involves is risk-informed decision making; do we want to do this? How much risk are we reducing by implementing this measure, and is the cost benefit of that measure worthwhile?

MEMBER RYAN: That's a good point. And the other thing, to me, I think is clear, at least I hope it's clear in the report, is we recognize that the staff is wrestling with, I'm not going to say three point something, I'm going to say ten times lower than three, and ten times bigger than four, in terms of where the risk-significant line is.

I hope our report reflects the fact that we'll be happy wherever that line gets drawn, but we're not going to try and guess it in the few short weeks we're here together, because that's a substantive and detailed evaluation. So wherever it's appropriate for us to say well, what sources should be -- are we recommending something? We've tried to identify that line as wherever the staff draws it is

satisfactory from our perspective. We're not going to try and guess it, but rely on that work to come to fruit, and rely on that insight. I think we've got that right.

CHAIR HILL: I think we have. I hope so.

MEMBER RYAN: Again, I would solicit any additional comments here. And if people are interested in that point, that we can clarify that, that's fine.

CHAIR HILL: Ben was talking about risk-informed decision and things not necessarily taking a world of resources and staff time, but if we -- it may take some time to look at the information that is already out there on the street, that may be providing a vulnerability in the decision made on whether some of that wants to be withdrawn, taken back, and what time and effort to evaluate that.

MEMBER RYAN: Have we recommended anything in that area?

CHAIR HILL: Not -- we haven't -- we've not been that specific with it in our recommendations.

MEMBER RYAN: Are you suggesting we should be?

CHAIR HILL: I don't know. As the level of detail, I think --

MEMBER RYAN: Somehow I think that's wrapped up in that where is the line between three and four.

CHAIR HILL: And it's the risk-making, the risk decision --

MEMBER RYAN: Yes.

CHAIR HILL: Risk-informed decision making, that information being out there, because we talk about earlier, and it's not really in the report, basically, an entry portal to get information; like you could go order something on line, they want to know some basic information about you before they'll accept your order, not only for your name, address, and email address, but then they want to know how are you going to pay for it. But that type thing to release some information. List of licensees has already been pulled back, SS&D is no longer available to members of the public. Are there other things that maybe --

MEMBER RYAN: Okay. Well, that would be something new to add. You may want to figure out where you want to add it, if you do.

CHAIR HILL: If we do.

MEMBER RYAN: That's kind of a fine point of detail.

CHAIR HILL: It's almost -- implementation is the reason that --

MEMBER RYAN: Yes. I'm going to guess --

MEMBER NERUD: There's a lot of ways, I think, to do these things, restricting information, additional access controls to information, those types of things. There's 15, 20 different ways to accomplish what you want to accomplish. Listing them all in the report I think is --

CHAIR HILL: Beyond what we were going to do.

MEMBER NERUD: -- a huge laundry list of pick the one you want to do.

MEMBER RYAN: I guess --

MEMBER NERUD: I don't see the point to that. What I see is, here's the vulnerability we identified, which was the ease of access to information that could be used to exploit your processes. You need to think about controlling that information from a risk-informed perspective. Is the benefit of releasing the information greater than the ability of an adversary to exploit it?

Sometimes convenience and business efficiency outweigh appropriate security. I mean, if you look at airports and baggage screening that they

do underneath, it's -- they get less than cumulative 10 seconds per bag to review that bag and see if there's anything in it, and let it go.

Now a real legitimate search is going to take one to two minutes. Well, you've got a choice. Can you pick up the big stuff in 10 seconds and let it go through, and reduce as much of your risk as you possibly can, and do it; or, are we going to cut the number of flights in half so that we can screen all the bags? It's a business decision, and that's what's important here. And I think that's something we really did stress, is risk-informed.

CHAIR HILL: I hope that comes through in our report.

MEMBER RYAN: There's a very important element of risk-informed. Ben, you said it the best early on, and that is, as you said, regard to health, safety, the environment, the NRC does a very good job. Those are three elements of culture built into everybody here, happens from the first day you show up. Well, now we've got this fourth leg of the chair, security. So somehow the tools and techniques of how to deal with security issues, and then how to ingrain those into culture, not only of licensing, but of inspection, and all those kind of things, and then get

the Agreement States on board with that is certainly something that's going to take significant effort and time, but is the answer to this challenge.

All of a sudden now the presumption of good faith, and presumption of trust is out, at least for new applicants. And you're always at risk for people doing bad things. The GAO raised that uncertainty, so now to deal with that uncertainty, you've got to, like you said, put speed bumps in their way, and have a system that's live, and current, and takes care of transactions as they happen, and puts red lights on ones that are -- that $10,000 restaurant bill that shows up.

MEMBER NERUD: Exactly.

MEMBER RYAN: I don't know how you answer the mail on the threat, without having that as the goal. And then the interim steps of doing more inspections on the front end for new applicants, and then having follow-up processes that do more than just inspect the facility to make sure the RAD material is there, but also security inspections to make sure the right people with the right credentials, and the right controls are in place, and alive and well. Again, I hope that comes through.

MEMBER NERUD: I don't think there's a

movement from -- a risk-informed approach to security is really going to be -- it's going to take a long time to inculcate that culture into the NRC, I think on an individual level. You're going to see huge leaps forward in that from different perspectives, from the license reviewers. I think they're going to get it, they're going to see the point, and it's going to get ingrained, and they're going to start doing it fairly quickly. I think you'll see that with the inspectors. Where I think you're going to -- where I think it's going to go a little bit slower is from the management, and guidance, and requirement, and regulation aspect, and really ingraining all that in there.

I think from what I saw at Region I, and when I went up there, those license reviewers, the first time you go up and say look, I want you to start -- I want you to suspend the good faith presumption on new applicants. I want you to go out and look, they're all over it.

MEMBER RYAN: Well, again, that's --

MEMBER NERUD: They're great Americans, and that's --

MEMBER RYAN: Yes. That's why I complimented the staff. I think they've done a very

good job of reacting to this in a very open and forthright way, and they want to get it right.

The other part to the report I hope we've done is give some of the stop-gap kinds of things that can be done. Hopefully, the idea that new applicants is where the emphasis ought to be is the highest risk, or potential risk, is that's where you've got to start. We've got to do more oversight, more detailed reviews, more information needs to be checked, all the things we've commented on.

As a record of satisfactory performance builds up over time. You've inspected that licensee some number of times, the principal is the same, the RSO is the same, your financial checks, your business checks all indicate they're a healthy, vibrant company at whatever they are, and that if you've got a record of performance, then you can begin to say well, now there's a basis for trust. It's not just a good-faith basis, it's a performance-basis for trust.

Okay. So now we've got that level of trust. What are going to be the channel markers that tell you something might be wrong? Well, there's three major players that the licensee have changed and left, and there's three new people we don't know. Oops, maybe that ultimately gets in the licensing

guidance. If the authorized users and the RSO are all new, put on the light, not just for health, safety, and environment, but security, if there's a security issue here. Have these people been vetted appropriately for the level of sources that they're allowed to use, and so forth, and so on? So that will come with time, but I hope we've laid out a roadmap that helps explain that.

MEMBER NERUD: I think it's all very achievable. If the NRC was like DOD, they could do this -- nice thing about being able to direct.

MEMBER RYAN: Indeed.

CHAIR HILL: I don't know that I have any additional comment to add to that at this point.

MEMBER RYAN: What do you want to do?

CHAIR HILL: Aaron, do you have --

MR. McCRAW: Well, if I can just add from my perspective, that you're saying is the report -- does it really bring across this risk-informed, does it really bring across that the panel is recommending that you'll go with whatever the NRC decides is the appropriate source categorization. And I personally feel that that comes across in the report; but, however, I'm so ingrained in working with you guys, so it will be interesting to see if we can have some

additional staff come down here and provide some of their insights, and if they have factual comments on the report. We're still working that out, so maybe they could come down tomorrow or Thursday.

MEMBER RYAN: If they can, that's great. Again, although I am very -- I think we're all sympathetic, the budget and schedules for everything. That's not in our wheelhouse.

MR. REIS: Terry Reis. Yes, we've instructed -- there's been a lot, not a lot, but there's been interest among the staff to comment. Sorry, Charles.

Okay. Terry Reis, Deputy Director, DMSSA FSME. There's been a misunderstanding as to what the intention of the draft report was, and comments. And we explained that, it was a FACA requirement, and we were providing for mechanisms for comment, but we weren't, necessarily, soliciting staff comments on it. But there have been some interest, and so Aaron and I have been focusing -- the direction to the staff is we want to hear the comments, if there's factual errors, or something is not clear, or it's a misrepresentation of what the staff has presented to the panel. But we're steering them away from any comments of no, we can't do this because. So we would agree with you,

they're your recommendations, so as long as they're based on fact, and what the staff presented to you, we're going to leave that as it is.

MEMBER RYAN: And, I guess, I believe we all recognize that that is a normal sort of reaction to a recommendation like this.

MR. REIS: Sure.

MEMBER RYAN: But, again, our charter was very specific on what are your recommended solutions to respond to the GAO's report. And that was -- and, again, I hope we've at least attempted to recognize the realities of the work that the staff is doing, and has advised us about. And at least tried to recognize in some ways that we do recognize that they have a lot of work ongoing, and they're addressing this issue in a clear and professional fashion; but if our recommendations transcends the boundaries of budget and schedule, that's a secondary question that I guess the Commissioners will wrestle with, and senior management will have to address, if they want to do it in one bite, or five bites over five years, or do this part now and see how it goes, or however they want to do implement it. But we did not address what's the five-year implementation plan, because that's outside of our charter. And, again, we recognize that people

can have legitimate questions about how would we get this done, if we were to do it? But we're focused on what we felt, and from the evidence we've gathered, and our own deliberations on what might work.

MR. REIS: Okay. Aaron, we're clear on that, and that's the message we're communicating.

MEMBER RYAN: That's great. And if people have their thoughts they want to share with us, we welcome it, particularly on, did we hear you correctly?

MR. REIS: Right.

MEMBER RYAN: Because if we didn't get something right, we really want to correct that, any misunderstanding.

CHAIR HILL: One of the things in the charter along that line of making sure the facts are correct, and we didn't misrepresent what was said, was we were to look at import and export licensing, and vulnerabilities there. And I think we've got that captured correctly, and it's reflective of what we heard, but I'm really interested to know if we misrepresented anything, got a fact wrong in that area, too. Lynne?

MS. FAIROBENT: Lynne Fairobent with AAPM. Tom, on page 3 --

MEMBER RYAN: Can I ask you to do us a favor? Rather than us turning around to look at you, why don't you just sit down, because it's easier to use the microphone.

MS. FAIROBENT: Tom, on page 3 of the report -- wait a minute, sorry, page 9 of the report, Observation 4. The last two sentences state: "The panel learned that radioactive materials used by medical licensees that are a security concern are those larger sealed sources used in blood irradiators, radio stereotactic therapy units, and to a lesser extent, the high dose-rate afterloaders." This is a significant part of the inventory of license Category 1 and Category 2 sources.

I'd like the panel to consider clarifying that. HDR is not Category 1 or Category 2 sources. They are Category 3 for high dose-rate afterloaders. HDRs are typically 10 curies of Iridium, and Category 2 limits are 22 curies.

Most HDR licenses, to my knowledge, have been amended so that the maximum possession limit is less than 22 curies today to avoid them being Category 2, or to give the impression that they could have multiple that would exceed. Right now, they're not an aggregated source amount.

What happens, typically, is in source change-out, some of the concern had raised that the source that is being exchanged when they're doing the change-out, perhaps you're -- originally, that's why the possession limits were higher, but that has all been modified since the increased controls. So I would like you to go back and verify that HDR is not a Category 1 or 2 source, and perhaps consider changing some of the language here, rather than the implication that HDR currently is under increased controls. If I might ask that of you?

MEMBER RYAN: Sure. These are mostly license and Agreement States, I'm guessing. Right?

MS. FAIROBENT: Well, no. They're across the board, both NRC and Agreement State licenses.

MEMBER RYAN: Most of them. Most of them are Agreement States.

MS. FAIROBENT: Well, most of your medical licenses are Agreement States, so by definition then most of them would be an Agreement State.

MEMBER RYAN: Is that an easy thing to track in the current database?

MS. FAIROBENT: HDRs currently would not be in the database, because they're not Category 1 or 2. For 2008, for -- I believe there has been a

request to include Category 3 material in the National Source Tracking System. I'm not so sure that's been done across the board yet, or if all of the data has had to be reported yet, Mike.

MEMBER RYAN: Gotcha.

MS. FAIROBENT: Okay? But whether HDR is used in an Agreement State, or a non-Agreement State, the possession limits for HDR are the same, and the use of it would be the same. Okay?

You might hear a little more from this. I understand that there's been phone lines established for industry reps on Thursday, I believe, so you may hear a little bit more about this from the vendors, the HDR vendors if they're on board.

MEMBER RYAN: Right. If you could maybe pull your strings with your constituency, Lynne, and see if they could give us any feedback, you know, if there's a particular state agency with one of the states that does a lot of this, if you could help us get some further information on how they maybe used to be Category 1 and 2, and now they're 3, or they've always been --

MS. FAIROBENT: They never were. By the IAEA limit, they were always -- Iridium-192, definitional limit for Category 2 is 22 curies. Okay?

Some of the licensees' possession, and it depended on the licensee and the way it was, not necessarily the approach taken either by a Region and NRC, or a particular Agreement State, may have asked for 22 curies, was a typical default limit to allow for source change-out.

When increased controls came out, pretty much across the board the limits are -- you may still have a few stragglers that possession limits might authorize up to 22, but those who have sources, no individual source would be at the 22 curie limit.

MEMBER RYAN: So source change-outs just gives you the temporary authorization to have up to 22, but --

MS. FAIROBENT: Well, even with source change-out, my understanding today is they don't come close to that limit.

MEMBER RYAN: Really?

MS. FAIROBENT: Which was why, typically, the vendors produce the sources, and they may ship at like 11 curies. So even if you had two, you could -- two new sources, you may get to 22. But with any decay, once it arrived, you'd be under the 22. So that's why HDRs was -- as long as you only have one HDR source in a room, a physical room, you will not

hit the Category 2 limit, because right now it's not aggregated by site. Okay? If you have two HDR rooms, and you have a source in each of the two rooms, you're below the Category 2 limits.

MEMBER RYAN: Do you think the increased controls would ever change to address having -- aggregating different rooms?

MS. FAIROBENT: My concern, or our concern is that increased controls are going to be applied across the board to Category 2.5-or-less sources, and then the impact on the medical community is much greater than the impact today, which is blood irradiators and gamma knifes, basically being at Category 1 and 2 levels. If we start into Category 2.5 and less, for increased controls, not necessarily --

MEMBER RYAN: 2.5 is what, halfway between 2 and 3?

MS. FAIROBENT: Right. Roughly, or a tenth of the way.

MEMBER RYAN: Tenth of the way.

MS. FAIROBENT: I'd have to go back and look, but it's, basically, the same thing you're advocating, or the staff has been discussing between 3 and 4.

MEMBER RYAN: Okay.

MS. FAIROBENT: Okay? But the concern is, if -- not so much, necessarily, that Category 3 may be included in the National Source Tracking System, but if increased controls are applied to that, then we are in the process of looking at what that data impact would be, if a decision in the future was made to include those down at the lower category levels.

MEMBER RYAN: We tried to address two specific kinds of sources that were regulated under 10 CFR Part something 100 and something, 200.

MR. McCRAW: 35.100.

MEMBER RYAN: Part 35.

MS. FAIROBENT: 100 and 200.

MEMBER RYAN: Yes. For the specific reason that those are usually fairly well established licensees.

MS. FAIROBENT: HDR and gamma knife under 35.600.

MEMBER RYAN: No, this is something else. Where is that? There it is right there.

CHAIR HILL: Here's 35.100, and 35.200.

MS. FAIROBENT: Nuclear medicine, basically.

MEMBER RYAN: Yes. It was a nuclear

medicine thing.

MS. FAIROBENT: Right.

MEMBER RYAN: We felt --

MS. FAIROBENT: Short half life.

MEMBER RYAN: Let me find it here.

CHAIR HILL: While you're looking for that, is there very many medical licensees that have more than one or two HDR units? Larger university hospitals, possibly, or rule of thumb?

MS. FAIROBENT: I don't know how many have ---- I know that there are a number that have more than one HDR unit. I can't tell you how many.

MEMBER RYAN: Okay.

MS. FAIROBENT: Okay? I could probably --

CHAIR HILL: More than two?

MS. FAIROBENT: Well, I was going to say I can think of perhaps M.D. Anderson has more than two.

CHAIR HILL: Okay.

MS. FAIROBENT: I suspect Mayo Clinic Rochester has more than two. I'm trying to think how many Hopkins had when I was up there.

CHAIR HILL: And each of these, their last possession unit would be maximum of 22, or up to 22?

MS. FAIROBENT: Again, it would depend on

--

CHAIR HILL: They're probably not going to be doing two or three sources changes at the same time.

MS. FAIROBENT: Right. Right. Yes. But I don't know how many HDRs -- I certainly could get you that data within a percent comfort point from the vendors as to how many HDR users there are.

MEMBER RYAN: Yes, that would be great. That would be real helpful.

MS. FAIROBENT: If you want, I can try to get that for you.

MEMBER RYAN: If we get that wrong, we need to fix it.

CHAIR HILL: Yes.

MS. FAIROBENT: Well, it's definitely wrong. They are not Category 1 or 2 sources.

MEMBER RYAN: Okay.

CHAIR HILL: And you were saying the chances of them being aggregated to a Category 1 or 2 quantity is slim to none.

MEMBER RYAN: The exception that we recognized was under this idea of license limits. This is in the panel records as Recommendation 8. "Panel recommends that NRC and Agreement States

continue to encourage licensees to carry only as-needed possession limits, as this helps to determine appropriate financial assurance and applicability of increased control orders. The panel recognizes that this recommendation may not be appropriate to apply to medical use licensees under 10 CFR Part 35.100 and 35.200 that require unsealed short-lived radioactive material. This recommendation provides awareness to licensees that disposition of unwanted or unused materials, as opposed to accumulation, is preferred." I think that was one that we became aware of as an exception that probably --

MS. FAIROBENT: I guess I would also have to go in, Mike, and look at the usage limits for 35.300, which is also nuclear med, for which a written directive is required, to see that 300 should not also be included in that.

MEMBER RYAN: If you can, again, look at that and give us your insights on what you think there, that would be helpful.

MS. FAIROBENT: Okay. And that was Recommendation 8?

CHAIR HILL: Yes.

MEMBER NERUD: A point that I want to make here real quick before we start getting too far away.

The point of that sentence was that these were the types of materials we were concerned with from a security perspective, regardless if it was Category 1, Category 2, Category 3. What we were specifically trying to identify here is that we weren't looking at the radiation therapy seeds and things like that, and the short-lived, short half-life material in there. We were concerned with those things that had a quantity of material suitable for use as a weapon. And that's really where these examples come into play here, blood irradiators, therapy units, and the high dose rate afterloaders. The material that's in them could be used by an adversary to create a weapon, regardless of where it was. And those were the things that we wanted security of, not --

MEMBER RYAN: As Lynne was talking, I think the idea is that these are fairly accessible, not necessarily easy to move, but certain compact in their unit. If you take the last sentence out of that recommendation, does anything else in it not make sense?

MS. FAIROBENT: No, it's factual without the last sentence.

MEMBER RYAN: So let's take the last sentence out, just for the sake of argument.

Although, I still would welcome all the information we talked about. I think we all --

MEMBER NERUD: Yes. I would definitely like to hear that, because that definitely impacts in our National Source Tracking recommendation, and how many of these things are going to be there. It would be nice to have a little bit of info in the hip pocket before we brief the Commission.

MEMBER RYAN: Yes. And I think the idea is that, exactly what Ben said, if we take that out, maybe we were just reaching for an example, and it was a lousy one because it was wrong. I try to make the point, where's the risks? Now, again, remember what I said earlier, that we're kind of in recognition that the staff is wrestling with this question.

MS. FAIROBENT: Right.

MEMBER RYAN: 1, 2, 3, somewhere in between, and we don't know where that line is going to be drawn. So kind of leaving that as okay, wherever that line is drawn, you should consider, not shall do, but should consider what we've recommended as applying somewhere through that scheme. That's a fair assessment when the times comes, and I think it tries to recognize what the staff is actively working on concurrent with this report going in. So maybe we

just need to be careful not to try and use those groupings, or try to get into 1, 2, and 3s, except to say we're recommending these things for risk-significant sources, wherever that line is drawn. I think that language is in there somewhere, so this was an example where we didn't capture that same thought, and maybe we ought to --

MS. FAIROBENT: Yes. It was just -- the transition to that last sentence really implies that all three of those are part of Category 1 and 2.

MEMBER RYAN: Yes. And that was not our intent. These are kind of the risk-significant sources, because they can be, perhaps, vulnerable, if not properly secured, and all that sort of stuff, with the right folks overseeing it.

MS. FAIROBENT: Right.

MEMBER RYAN: So I think without that sentence it still makes the point.

MS. FAIROBENT: Okay. Thank you.

MEMBER RYAN: Are there any other areas where there are medical licensees that you think need specific attention?

MS. FAIROBENT: I'm not sure they need specific attention, but --

MEMBER RYAN: We tried to capture, Lynne,

and I hope it shows up, the short-lived isotopes are not necessarily on the radar screen, even though the curie quantities can be large.

MS. FAIROBENT: Right.

MEMBER RYAN: If they're short half-life, they don't do anybody much good, except in the hours or days they might be radioactive.

MS. FAIROBENT: I think the only other thing I would just raise a question back to you, because it was clear to me in just reading this, as someone who's sat through several of your meetings, but not lived it like you all have, on page 6 under Recommendation 2, Points one and two I'm not sure exactly what you're trying to state, that you would want taken out of guidance, or the type of material that you would want not identified. And I come at it from the point of view, I work for an association where I provide the advice to many licensees across the board. And more of the information that perhaps is restricted to simply a licensee minimizes the advice an expert like myself can provide to our membership base. So if the guidance document is not there, if the information isn't out in public domain on process, we can't necessarily help our members comply or understand what is being asked of them to

comply, so it's a balance point. I think I know what you're trying to say, but it's a balance point that, for example, I don't think exists in the nuclear power industry because you primarily have one association, and there are some different boundaries that have operated with NEI and the reactor community, versus the fact that we have multiple associations representing materials users.

MEMBER RYAN: And state organizations, and feds.

MS. FAIROBENT: Right.

MEMBER RYAN: And FDA, and everybody else. I fully appreciate your comment.

MS. FAIROBENT: But it wasn't clear to me just reading here what you were going to.

MEMBER NERUD: I can talk to that real quickly. We'll take a look at it again, but what we're saying there is not restricting guidance, not restricting those other things. What we're talking about is information that is not needed for guidance. Okay? And what we'd be talking about there, as I read through a lot of the NUREGs, it talked about the license reviewer is going to perform this step, and these are the checks they're going to do to accomplish that step. Well, that's not something that anybody

outside that reviewer needs to know about. You will be given the guidance out there to submit a complete application in its entirety with all the attachments, and all the necessary data that comes in there is fine. How the license reviewer is going to validate that information that's provided is what we're talking about in that regard.

MS. FAIROBENT: Okay.

MEMBER NERUD: And what that does is when you go back to the GAO report, well, the GAO had all that guidance. They knew exactly what the license reviewer was going to do at every single step, and could anticipate the action. And as Mike had said earlier about having some speed bumps in the process, if a bad guy attempts to do what GAO did, submits the license, and now he's getting a phone call from a reviewer saying I need to review this, and this, and this; well, wait a minute, I'm not prepared for that type of activity, I withdraw my application. I disappear. I go back to my safe house, and I'm done. That's the kind of thing that we're doing here, not limiting information that's needed to accomplish business.

MS. FAIROBENT: I think a different example, perhaps, that you all didn't consider, but

when we were providing comments on Part 35 during the rule making, one of the things that's required to be submitted is manufacturer and model number of a particular source; say, for brachytherapy seeds. We argued that providing the manufacturer should not have to be on the license and codified, because when you go to order those seeds, you may be dealing with a different vendor; and, yet, the vendors are identified on the license as a license condition. That's not to say that there shouldn't be controls so that when you order from Vendor A, he verifies you can possess that material in that form, up to that limit.

MEMBER RYAN: And, again, I think a lot of that back and forth, particularly between the high-volume users, like medical, if you have a checkbook and your credit limit is 1,000 something, and I'm a vendor.

MS. FAIROBENT: Right.

MEMBER RYAN: You call me up and say Mike, I need 300 units of my stuff, and here's your authorization code, just like your credit card. So okay, I dial -- I'm authorized because I'm a licensed vendor. I've got a pass code, there's a vendor, and I'm going to look at 1234 license. I know who that belongs to. I don't see your license. I get an okay

or a no, and it gives me a number. Okay, here's your authorization code. That goes on my shipping paperwork to you. You get it on your shipping paperwork. You say 1234 received, that licensee's location. Your inventory is now up-to-date, just like a checkbook.

MS. FAIROBENT: But right now I can go to the public document room downstairs from where we're at in the other building. I can pull out License A, and I can see every source by manufacturer, by model number up to certain quantities that that facility can possess.

MEMBER RYAN: Right. And, again --

MS. FAIROBENT: And if I did not know ahead of time who the vendors were, just having the isotope, the form and the quantity would make it, I think personally, not AAPM, my personal view as a health physicist, makes it more difficult for someone to try and find where to go buy that material. I may be naive because you can Google it and find it all over the place, but --

MEMBER NERUD: It's one step further, which is why our recommendation for increased controls and prescriptive standards become so important, is that if that information is going to be available,

it's going to be out there for the public, I, as an adversary, know exactly what building to go to to break in to steal all that stuff.

MS. FAIROBENT: Right. Well, in fact, one of the things that happened after the new rule was issued, they did have floor diagrams for materials licenses, Part 35 licenses in the public document room. And as they were putting back the information, that information was put back into public domain, and the Advisory Committee on Medical Use of Isotopes was successful in getting that redacted so that that is not in to show the floor diagrams of where all the material is.

MEMBER NERUD: But with what you've just described, you understand exactly what we're getting at here.

MS. FAIROBENT: I understand, but I don't think your words are clear.

MEMBER RYAN: Okay.

MS. FAIROBENT: And that's what I'm saying. When I read the words, it wasn't clear to me what you were trying to get at.

MEMBER RYAN: So, if I'm understanding you right, Lynne, you're saying maybe some examples that sort of spell out a little bit in one and two.

MS. FAIROBENT: Yes.

MEMBER RYAN: Okay.

MS. FAIROBENT: Or maybe a little bit back.

MEMBER RYAN: Back up in the paragraph ahead.

MS. FAIROBENT: Right.

MEMBER RYAN: Okay.

MS. FAIROBENT: But it just wasn't clear to me when I read it, and I've sat through your meetings, and read the transcripts for the meetings I wasn't at.

MEMBER RYAN: I'm sure it's in our heads, but we need to make sure it's on the paper. Thank you.

MS. FAIROBENT: Okay.

MEMBER RYAN: Anything else jump at you?

MS. FAIROBENT: Let me just check. I think those were the main points, Mike, so far. I guess the only other thing was on page 4, and it's your presumption of good faith. I don't disagree that it, perhaps, showed a vulnerability, but it was a targeted attempt to show a vulnerability. It was not a licensee who is trying to circumvent the system, and this was exposed through. It was a specific attempt

by another federal agency to show a weakness in the NRC process.

MEMBER RYAN: And I guess the spirit with which we took the report is that's their job. They did their job. There is a vulnerability.

MS. FAIROBENT: Right.

MEMBER RYAN: So what we tried to do to address that is to split off a new applicant, and we define new applicant for the purpose of our thinking. That may or may not be one that's ultimately accepted, but a new applicant is one where the vulnerability is perhaps the highest, because there's no experience with a new licensee, or a new applicant. And we've defined a new applicant as somebody that's never had a license in an Agreement State or the NRC, or somebody that has not had one in five years, an entity. We went out of the RAD business, now we're back in it. Well, you're brand new if you're five years out.

I think the idea is, we're trying to recognize that once there is a record of performance that allows you to have a presumption of good faith, or a presumption of trust, you can rely on that. I mean, if you've got an Agreement State licensee that is now going to start in a new state, I guarantee you

that Tom Hill called Virgil Autrey in South Carolina and vice versa many, many times. And that's, I'm sure, done all the time, because that's the way -- I mean, they're sharing information, I hope. But if there's experience with a licensee, so be it. You can rely on that. I think we're clear about that, but I don't think you can get around the fact if you've got a new applicant, you're simply going to have to do more to develop that record of performance, at least the starting point of that performance when you have a new applicant.

MS. FAIROBENT: I guess what I was taking issue with, Mike, is the second sentence on the top of page 4, and just the words that are on the paper.

MEMBER RYAN: Okay.

MS. FAIROBENT: "That the practice of relying on the good faith presumption that applicants will be honest in providing information on an application has been demonstrated as a vulnerability."

My knowledge of what's behind there, it was GAO who did it, and not an applicant in good faith.

MEMBER RYAN: But it doesn't say an applicant in good faith. They were an applicant -- I

think the point, though, is, leave GAO aside, instead of GAO, they were a bad guy, they could have gotten the same result. That's where we started. I mean, it's -- I appreciate the fact that some people reacted negatively to that kind of an action by GAO, but they recognized the vulnerability. I don't think we -- that's where we started, is that there is a vulnerability. Two bad guys could have just done the same thing. And it's interesting in the two cases, a speed bump in Maryland was, we're going to come visit you. Oh, well, we're not -- we don't have the paint dry yet, or whatever they said. They ended that avenue, so that's where we are.

MS. FAIROBENT: But --

MEMBER RYAN: Apart from that, to me, what I hope people can see down the road a bit for, and I think we all agree with this, that this kind of a web-based licensing and source tracking system that's live, and has these features where vendors can deal with licensees in a real automatic kind of up-to-date way, well, transactions can be tracked as they occur. That's a benefit to everybody.

MS. FAIROBENT: I think I would agree 100 percent with you, if the tracking system was cradle-to-grave. But my understanding, having sat through

the public meetings on the National Source Tracking System, it's not a cradle-to-grave system.

MEMBER RYAN: We had a lot of discussions with staff on the system, and what we're recommending is a step passed that.

MS. FAIROBENT: Okay. So towards cradle-to-grave.

MEMBER RYAN: Yes.

MS. FAIROBENT: Okay. It's on your license. When it comes off your license, it's either sent back to a vendor, or it's disposed. And why can't it work that way in a checkbook? My money stays in the checkbook until I spend it, and it goes in somebody else's checkbook. So when I transfer something to disposal, guess what? That goes on the manifest, and I take it off my license, and I get authorized, and here's the shipping number, and it's done. And the receivers notify me, here's your code back, we received it, it's disposed, or we sent it back to be reloaded, or reworked in the new source, or whatever it is.

MS. FAIROBENT: Right.

MEMBER RYAN: One of the other recommendations we had is, don't have sources without limits, I mean, have licenses without limits, except

for the cases we identify, because that's another vulnerability. If there's no limit on a license, you can get as much as you want. You have an unlimited checkbook, a platinum card. That just doesn't work.

MS. FAIROBENT: You might want to go back then and look at your words under 3B, and the observation of 3. It wasn't coming out to me that you were moving towards a cradle-to-grave, versus what I've heard the staff describe as the NSTS, which I know is not cradle-to-grave.

MEMBER RYAN: You are correct, and what we're describing is not what they're describing.

MS. FAIROBENT: Right. And the difference did not come out when I read the words.

MEMBER RYAN: Fair enough. We need to make it clear that we're really thinking --

MS. FAIROBENT: I understand your thought process now, because you just explained it. I didn't follow it --

MEMBER RYAN: Tune it up. Thank you.

MS. FAIROBENT: -- totally from the text.

MEMBER RYAN: Gotcha.

MS. FAIROBENT: But that was my observations going through it, and the questions I had.

MEMBER RYAN: Thank you very much.

MS. FAIROBENT: And I'll be happy in the next -- tomorrow and tonight to see if I can get you some more of the data.

MEMBER RYAN: Yes. I think the one technical or data point that would be helpful is to just inform us that if the afterloaders and those kind of devices are all 3, or it's just a few left in 2, or whatever it is, that would be good information for us to have.

MS. FAIROBENT: Okay. And I'll also check 35.300 to see if you should be including that in the same -- because that's also nuc meds, short-lived isotopes.

MEMBER RYAN: And I guess the real question for 100 and 200 was the amount of material that transfers routinely, like it's a lot of curies that go back and forth. And if that's the same for 300, we'd have to go back and read it, and see if that should be included, as well, but let us know.

MS. FAIROBENT: Okay. Thank you.

MEMBER NERUD: I don't think it needs to be included as an example, and that was really what we were --

MEMBER RYAN: Well, if it's unlike

material, others may have the same question. Why didn't you include 300, because it's the same stuff, moving the same way? If all three are in, we ought to make that conscious decision if it's in or not.

MEMBER NERUD: I think it was just there for an example, and --

MEMBER RYAN: Oh, yes.

MEMBER NERUD: -- the understanding is that you've got to protect this stuff. The increased controls are going to go. However, in a medical environment there are certain radioactive materials that just are not suitable for a weapon; and, therefore, you don't need the increased controls on those, but these types of things you do.

MEMBER RYAN: Yes.

MEMBER NERUD: And if that extends down to Category 3, Category 3.5, Category 4, all the way down to whatever, it doesn't matter. Whatever the Commission decides this is going to be our cut-off for increased controls, well, everything above that --

MEMBER RYAN: Yes.

MEMBER NERUD: -- has increased controls, but do it from a risk-informed basis, which says that if this material isn't suitable for a weapon, then you know what, just keep it in your desk drawer.

MEMBER RYAN: I guess I'd have to say we need to do one of two things. If we're using this as an example, we never say, for example. But if it really is 100, 200, and 300, they're all in the same basic scheme, then we ought to just say all three of those and be clear, if that ends the list. So we'll take a look at that.

MS. FAIROBENT: Okay.

CHAIR HILL: And 300 is primarily, as I remember it --

MS. FAIROBENT: Unsealed material with a written directive is required, and that includes your Iodines above and below 33 millicurie for therapy. It includes parental administration, now it includes FTG for PET, all fairly short-lived material, Tech-99, your generators are under Part 300.

MEMBER RYAN: We ought to take a look. And, again, I mean, I just -- I'm going to guess there aren't very many new entrants in that field per year. And there probably is a fairly good record of performance for folks that are in that business.

MS. FAIROBENT: Right.

MEMBER RYAN: So I guess that's kind of the area where we would view well, if there's an experienced licensee and the regulator is experienced

with them, and so forth. And this material is of low risk because of its short half-life, then --

MS. FAIROBENT: Right. It includes your monoclonal antibodies, it includes Theraspheres and Seraspheres are under Part 300.

MEMBER RYAN: Basically, anything that's in trials, too. I mean, that's where the directive comes in.

MS. FAIROBENT: Yes. All right. Thank you.

MEMBER RYAN: Thank you very much, Lynne. Those are very thoughtful comments. We appreciate you taking the time.

CHAIR HILL: Any other comments? Well, at this point, I think we're about 30 minutes ahead of a break time, but how about let's just pause for a break right now.

MEMBER RYAN: Okay. Terrific.

CHAIR HILL: Come back then 20 after.

MEMBER RYAN: Sounds good.

(Whereupon, the proceedings went off the record at 3:03:51 p.m., and went back on the record at 3:30:03 p.m.)

CHAIR HILL: We will resume from the break at this time. Since the meetings this week are

primarily for opportunities for public input and discussion, I want to ask our members of the public one more time if there are -- give an opportunity for input, any more comments? And there are none for today, so at this time, we will adjourn the meeting, and we'll continue to draft work presentation for our report to the Commission. Anyone else have any comments or thoughts?

MR. McCRAW: Well, with the adjournment, we will resume here tomorrow at 9 a.m. in this room.

CHAIR HILL: Yes.

MR. McCRAW: And any comments from the public will be welcome at that time, as well.

CHAIR HILL: And there may be some comments from staff, also. Is that what I understand?

MR. McCRAW: Yes.

CHAIR HILL: May occur to tomorrow. Okay.

MEMBER RYAN: And just so everybody has got their calendar, on Wednesday, as well, is a time for comments. Yes or no?

MR. McCRAW: Wednesday and Thursday.

MEMBER RYAN: Yes, Wednesday and Thursday. Yes. Okay. Sorry. Yes.

CHAIR HILL: Okay. Then at this point, we will adjourn from the record.

(Whereupon, the proceedings went off the record at 3:31:37 p.m.)