UNITED STATES NUCLEAR REGULATORY COMMISSION

BRIEFING ON STATUS OF IMPLEMENTATION

OF ENERGY POLICY ACT OF 2005

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MONDAY, MAY 15, 2006

1:00pm – 3:30pm

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NUCLEAR REGULATORY COMMISSION:

NILS J. DIAZ, CHAIRMAN

EDWARD MCGAFFIGAN, JR., COMMISSIONER

JEFFREY S. MERRIFIELD, COMMISSIONER

GREGORY B. JACZKO, COMMISSIONER

PETER B. LYONS, COMMISSIONER

PANEL 1:

LUIS A. REYES, EDO

STEVE O'CONNOR, SENIOR OPERATIONS

ASSISTANT, EDO

SCOTT MOORE, CHIEF,

RULEMAKING & GUIDANCE BRANCH, IMNS

KATHLEEN SCHNEIDER,

SENIOR HEALTH PHYSICIST, OSTP

GARMON WEST, CHIEF, NSIR

PANEL 2:

PEARCE O'KELLEY, CHAIR, CRCPD

JARED W. THOMPSON, PAST-CHAIR, OAS

PANEL 2 (CONT'D):

SALLY W. SCHWARTZ, NUCLEAR PHARMACIST,
ACMUI MEMBER

ROY W. BROWN, SENIOR DIRECTOR,
FEDERAL AFFAIRS, CORAR

ALSO PRESENT:

JANET SCHLUETER, STP

KAREN CYR, OGC

CHARLIE MILLER, NMSS

TRISH HOLAHAN, NMSS

C-O-N-T-E-N-T-S

P-R-0-C-E-E-D-I-N-G-S

1:00 p.m.

CHAIRMAN DIAZ: Good afternoon. I think we're missing the EDO. This is a unique opportunity.

(Laughter.)

CHAIRMAN DIAZ: We should go ahead with a series of management issues very quickly.

COMMISSIONER MCGAFFIGAN: I would point out, this meeting wasn't supposed to start until 1:00 –- this part.

CHAIRMAN DIAZ: That is true.

MS. VIETTI-COOK: Yes, this is -–

COMMISSIONER MERRIFIELD: Well, just in time doesn't apply to Commission meetings, so -–

(Laughter.)

CHAIRMAN DIAZ: Well, shall we –-

COMMISSIONER MCGAFFIGAN: Who is the next ranking person?

CHAIRMAN DIAZ: That's okay. I can entertain us for the next two or three minutes. There's no problem with that. Normally, I'm at a loss for words, but on this occasion, I can find a few words.

So, anyhow, the Commission going to meet with the staff,

with its representatives of the Organization of Agreement States, the medical industry, and the Advisory Committee on the Medical Use of Isotopes, to discuss the progress on implementing the requirements that were set forth in the Policy Act of 2006.

Now, as you know, the Policy Act of 2006 created many challenges for many, many agencies, and one of those agencies where challenges were very present is the NRC. I think the staff has been working for quite a bit of time, and the Commission has been kept aware of where we're going with those issues.

In some, we seem to be progressing quite well. In others, we're having difficulties of the timing and implementation. I believe that what we are looking for today is a clear understanding of where we stand. We want to hear from the stakeholders that are visiting with us today in what they see on their side of the issue. The Commission, I'm sure, has different and varied opinions on the subject. That will raise some questions. I would like to point out that Commissioner McGaffigan has been keeping track of these issues very closely, and by pure chance, he's going to go first today. So he's going to be using a little bit of his time.

COMMISSIONER MCGAFFIGAN: I will still promise to ask questions the last five seconds of my time in order to extend my time.

CHAIRMAN DIAZ: We can note that.

COMMISSIONER MCGAFFIGAN: Typical Commission practice.

CHAIRMAN DIAZ: Would you please make a note of that, Madam Secretary: that Commissioner McGaffigan is going to take some time to ask questions, besides making some comments.

I think that being that it is 1 o'clock, we can go ahead and proceed. Oh, I'm sorry…

COMMISSIONER MCGAFFIGAN: Mr. Chairman, I think we can filibuster a little longer for Luis. I just wanted to join you in welcoming folks. We're going to focus today on areas where we're having a little bit of difficulty in implementing EPAct, but we have done a heck of a lot in terms of implementing the provisions of the Energy Policy Act of 2005. We're well ahead of the game, compared to, I think, our sister agency at the Department of Energy.

On the other hand, we have perhaps fewer provisions, but a much higher percentage of our provisions have rule language associated with them, and we're well along with the rulemakings. So I commend the staff for that. We only get laws passed about once every 13 years, that affect us – 1992 being the previous case. And I know our staff wants to be the A student when it comes to doing everything necessary to

implement the law.

COMMISSIONER MERRIFIELD: Mr. Chairman, I would only join Commissioner McGaffigan in recognizing a significant amount of work in progress by our staff and want to compliment them for their commitment to that duty of time limits. And certainly, Mr. Chairman, I know we've got some issues we'll be discussing today, but hopefully that will give us an opportunity to focus a bit more and come to resolution so we can meet those timelines.

CHAIRMAN DIAZ: He's growing a mustache.

(Laughter.)

COMMISSIONER MCGAFFIGAN: We gave him time.

(Laughter.)

CHAIRMAN DIAZ: We've got to be careful.

COMMISSIONER MCGAFFIGAN: I – I'm sorry.

COMMISSIONER JACZKO: I don't have anything at this point.

CHAIRMAN DIAZ: With that, the new version of Mr. Reyes.

(Laughter.)

PRESENTATION BY MR. STROSNIDER

MR. STROSNIDER: At the risk of seeming presumptuous, I'll deliver his message. Actually, I'm acting for Marty today. So if this is

wrong protocol, you can talk to Marty, I guess.

Good morning, or good afternoon, Commissioners. Sorry. The staff and stakeholders are here today to update the Commission on activities that are being conducted under the Energy Policy Act of 2005. We have made a number of accomplishments as an agency in a short time since the Energy Policy Act was passed by Congress and signed into law by the President nine months ago.

This afternoon, the staff will brief you on the status of those activities, with a focus on three sections of the Act that require rulemaking. The Energy Policy Act expanded NRC's authority significantly, such as regulation of NARM and fingerprinting for access to materials. And the staff is working diligently to implement those portions of the Act.

Following the staff's presentation and the Commission's questions, a second panel of stakeholders, including representatives from the Organization of Agreement States, the Conference of Radiation Control Program Directors, and the Council on Radionuclides and Radiopharmaceuticals, and the NRC's Advisory Committee on the Medical Uses of Isotopes will bring their perspectives to the table. And I'm going to say, we really appreciate their participation today.

Now, I'm joined in this briefing by Steve O'Connor, currently

serving a rotation in the EDO's office as a Senior Operations Assistant; and Scott Moore, our Chief of the Rulemaking and Guidance Branch in NMSS. Also at the table are Kathleen Schneider, Senior Project Manager in the Office of State and Tribal Programs; and Garmon West, Chief of the Licensing Personnel Security Branch in the Office of Nuclear Security and Incident Response.

With that, I'm going to turn it over to Steve.

PRESENTATION BY MR. O'CONNOR

MR. O'CONNOR: Thanks, Jack. Good afternoon, Chairman, Commissioners. I'm going to provide a brief overview of the staff's activities to date in implementing the Act by starting with our accomplishments.

I'd like to point out, though we've completed many of the NRC's actions mandated in the Act, the status of the significant implementation milestones are shown in the table provided in the background materials.

We've modified the table to be used as a handout for the audience today by eliminating the milestone dates. My overview is not intended to provide a detailed status of the staff's activities. That detail has been provided to you in a Commission paper dated May 4th, and it is also included in the background material. This overview is more of an

overall status of our implementation activities.

The table in your background material summarizes significant agency actions required for implementation of the Act. As you'll see the staff has completed more than a third of the overall actions and is well on the way to completing the majority of the remaining actions. A TBD is shown on three sections where we're awaiting input from another agency, such as the Department of Energy, or the Department of State.

The staff has completed all actions related to certain sections of the Act by issuing final rules amending the regulations related to Sections 601 through 609 of the revised Price-Anderson Act, Section 625 for the elimination of antitrust reviews, Section 630 for revised export licensing criteria, and one portion of Section 651(d)(1) related to additional controls on the import and export of radioactive materials.

We've also cleared all actions related to Section 651(a)(3), for assigning Federal security coordinators to each region, Section 651(b) for requiring backup power for certain emergency notification systems, and Section 651©)(3) for promulgating provisions to cover travel expenses for certain individuals who either are assisting NRC or employed by the NRC.

The Commission paper we provided to you on May 4th contains much more detail on the status of each of the sections of the Act, and in some cases also provides interim staff milestones for completing the more significant actions shown on the table, or internal milestones for incorporating the action of the agency procedures.

However, several of the remaining actions have been a bit more of a challenge for staff to implement within the timeframes mandated by the Act, primarily due to the impact of the proposed actions on our stakeholders. In particular, the Sections that will be discussed next in more detail are Sections 651(e), 656, and 652. The staff has been working to resolve the differences in approaches to addressing these sections with our stakeholders, but several challenging issues still remain to be resolved.

That concludes my overview of the agency's implementation of the Act. I'll turn to Scott Moore to provide you with a more detailed discussion of the staff's implementation plans on these particular sections.

PRESENTATION BY MR. MOORE

MR. MOORE: Thanks, Steve. Could I have slide number 4, please?

Good afternoon, Commissioners. My presentation is going

to focus on three portions of the Energy Policy Act that are in progress: Section 651(e), on amending the definition of byproduct material, otherwise known as the NARM rulemaking; Section 656, on secure transfer of nuclear materials; and Section 652, on fingerprinting and criminal history records check.

The Energy Policy Act amended the definition of byproduct material to include three new groups of radioactive materials highlighted here. The staff has developed a draft proposed rule that is with the Commission in SECY-06-0069. This NARM rulemaking will be the first area that we focus on today.

The Act requires the NRC to define the term “discrete source” which applies to the radium-226 and NORM materials that pose a threat similar to the threat posed by discrete sources of radium-226. The term “discrete source” doesn’t apply to accelerator-produced radioactive materials.

The staff consulted with other agencies in developing the draft proposed rule. And in our view, and the views of other agency representatives, nothing was identified that poses a threat similar to the threat posed by a discrete source of radium-226. So, for the purposes of the draft proposed rule, this is just a placeholder. No such materials known at this time.

Finally, the Act gives NRC authority over material produced for use for a commercial, medical, or research activity. It covers material in these three categories produced before, on, or after the date of the Act.

Could I have the next slide, please?

Because the Energy Policy Act was immediately effective and gave NRC authority in an area previously regulated by the States, Congress created a provision for the Commission to grant waivers. This provision allows current programs to continue regulating and individuals to continue using NARM materials while NRC develops a regulatory framework and infrastructure. NRC issued a waiver on August 25th, last year; less than three weeks after the Energy Policy Act was signed into law. And the waiver was published in the Federal Register on August 31st.

The waiver provides time for an orderly transition to NRC authority in this area, continuing regulatory oversight and protecting public health and safety at the same level as before the Act, while NRC develops its final regulations and licensing and inspection program.

Can I have the next slide, please?

Section 651(e) requires NRC to issue final regulations by February 7, 2007. The Energy Policy Act's language specifically

requires NRC to "consult with states and other stakeholders." The Act also requires the Commission, to the maximum extent practicable, to cooperate with States and use model State standards.

The Conference of Radiation Control Program Directors, CRCPD, publishes suggested State regs for control of radiation, also known as SSR's. The staff reviewed the SSR's and State requirements and found that most Agreement States have adopted the SSR's or requirements similar to the SSR's, although not always verbatim. Non-Agreement States use the SSR's to varying degrees.

In developing the draft proposed rule, the staff used the SSR's to the maximum extent practicable and adopted an approach similar to the States by putting the requirements for NARM radionuclides throughout the existing regulations and 10 CFR, rather than creating a new special section of the regulations for these materials.

Could I have slide number 7 please?

While developing the draft proposed rule, the staff conducted a number of outreach activities with states and stakeholders within the time constraints imposed by the Energy Policy Act for the final rule.

We held a public meeting with a roundtable discussion format on November 9 here at headquarters to solicit input. That

roundtable discussion helped our rule writers because it was held early and included a number of different viewpoints at the table, and it helped shape the proposed rule.

Also, last November, we held an interagency meeting with representatives from other Federal agencies to discuss the definition of discrete source. Included at that meeting were the Department of Transportation, the Department of Energy, including the National Nuclear Security Administration, the Department of Defense, the Department of Commerce, the Department of Homeland Security, and the Environmental Protection Agency.

Could I have the next slide, please?

The NARM rulemaking has involved states to an unprecedented degree, and we have consulted and cooperated with both Agreement and non-Agreement States. Shown here are examples of how states have been involved in the 651(e) rulemaking.

Four States -- Florida, Michigan, Oregon, and Texas -- served on the Rulemaking Working Group in the development and writing of the rule. Two States, Arkansas and California, had representatives on the Steering Committee, representing OAS and CRCPD respectively.

Because of the rapid timing of the rule and other implementation issues, the Steering Committee met frequently, nearly

every week between mid-January and March. Two States, Oregon and North Carolina, participated in the NMSS EPAct Task Force. That was a separate unit that we created within NMSS to address many of the Energy Policy Act requirements.

The Oregon representative's involvement was notable. That was Martha Dibblee – in that NRC, CRCPD, and Oregon arranged for her to come work here out of Two White Flint for six months. The arrangement provided staff with immediate access to a State rep's views and assistance.

Two States, California and Illinois, had representatives who provided assistance as needed to members of our Working Group and/or Steering Committee.

The level of State involvement and coordination on this rule has been unmatched in recent memory, and we're indebted to the States for their insight, their expertise, and dedication to this effort.

Finally, as shown on the next slide, the staff made a number of presentations to organizations, including OAS, CRCPD, CORAR, and ACMUI, all of whom you're going to hear from on the next panel.

Here is a list of the meetings at which we made presentations or held discussions. The staff balanced requests from stakeholders for additional public meetings with the need to issue the

proposed and final rules on time, considering that the same staff would be working on both outreach efforts and the rulemaking.

In correspondence and in SECY-06-0069, the staff has committed to holding at least one public meeting during the public comment period on the proposed rule.

COMMISSIONER MERRIFIELD: Scott, these all have a tune of familiarity to them, but the High Country Nuclear Medicine Conference: what does that refer to?

MR. MOORE: It is a nuclear medicine conference arranged by CORAR, and we were invited by CORAR to speak at it. We made a presentation at it. Actually, I would like to recognize Lydia Chang. Lydia Chang, the team leader for the group that wrote the SECY paper, went to the nuclear medicine conference and made the presentation there on the proposed rule.

On slide number 10, the current status of the NARM rulemaking under Section 651(e) is that a proposed rule is developed and is with the Commission. As of April 7, the draft proposed rule and SECY paper were made publicly available on the NRC's website.

The Energy Policy Act requires the Commission to issue final regulations, establishing the definition of byproduct material, not later than 18 months after the enactment; that is, February 7, 2007.

This date is aggressive, since normal notice and comment rulemaking takes longer, and this is one of the most significant rules that we've developed. Currently, we're behind our original schedule which forecasts publication of the proposed rule by the end of April. We expect to make that up during the final rule phase, but it's going to be a challenge to make the February date.

Could I have the key issues slide please?

The Commission paper and the draft proposed rule and the SECY paper address a number of key issues on the NARM rulemaking. This slide touches on a few of them.

The definition of "discrete source" is central to the amount and type of radium-226 that NRC regulates. After consulting with other agencies and working with the States, the staff is proposing a definition that includes the concepts of a source with physical boundaries, separate and distinct from the radiation present in nature, which the radionuclide concentration has been increased by human processes, and with the intent that the concentrated radioactive material will be used for its radiological properties. Other radium-226, such as pipe scale that's not regulated by NRC, will continue to be regulated by States.

Another key issue is the degree to which NRC should regulate radioactive material incidentally produced in an accelerator.

Staff quickly learned that accelerators have both intentionally produced radioactive material –- that's the target material -- and incidentally produced radioactive material from activation.

In the draft proposed rule, we propose regulating the radioactive material both intentionally and incidentally produced in accelerators that are operated to produce a radioactive material for use for commercial, medical, or research activity. That is, if the accelerators are operated to intentionally produce radioactive material, such as a PET production facility, then both types of radioactive material would be included. We do not propose to include other types of accelerators, such as medical LINACS used to treat patients.

The staff wrestled with the issue of how to regulate certain discrete sources of radium-226, especially older consumer products, like radium watch hands and antiquities.

While the staff would have preferred to establish an exemption for such products -- and there are apparently a lot of them in circulation still -- we don't have a sufficient technical basis to support an exemption. Without that specific information, we are proposing a graded approach, recommending a general license for certain items containing radium-226.

Finally, the strategy for implementing the final rule and

terminating the waiver is fairly complex. The waiver currently runs through August 7, 2009. We do not want every possessor of accelerator-produced material and discrete sources of radium-226 in each non-Agreement State to submit an application for license on that day because the applicants may be in immediate noncompliance on the very following day.

So we are working with our OAS and CRCPD reps on the Steering Committee to develop a transition plan. We plan to terminate the waivers in groups or in batches, allowing possessors time to file amendments and applications.

Could I have slide number 12, please?

Another key issue during the rule development was compatibility of the definition of byproduct material. To put this into context, there are numerous sections of the draft proposed rule that require compatibility determinations. A table in the draft Federal Register notice shows well more than 50 revised or new sections with compatibility determinations.

We followed the process described in Management Directive 5.9, Adequacy and Compatibility of Agreement State Programs, in determining the correct level for the definition of byproduct material. In particular, Handbook 5.9, Part 3, is a series of questions that the

reviewer is supposed to ask in making a finding.

For the definition of byproduct material, the staff recommended the designation of H&S, health and safety. A designation of H&S is actually an adequacy designation; it's not a compatibility criteria. One goes through the compatibility questions and then asks the final question about whether the absence of the essential objectives could create a situation that could directly result in an exposure in excess of the limits. If the answer to that question is yes, then the program element is not required for compatibility, but it is identified as having a particular health and safety significance. Agreement State programs are required to address H&S designated items, and then NRC staff reviews them.

Could I have slide number 13, please?

Agreement States did not agree with staff's conclusion generally that the definition of byproduct material and the definition of discrete source as well should be designated H&S. In particular, State members of the Steering Committee representing OAS and CRCPD disagreed with the designation of H&S for byproduct material, noting that it would require statutory changes in some States.

OAS and CRCPD wrote to NRC expressing disagreement with the staff's designation of H&S for the definition of byproduct

material. In the spirit of full disclosure, we've attached the letters from OAS and CRCPD to the Commission paper in their own words, rather than paraphrasing them for you, so you could see what OAS and CRCPD said.

The States would strongly prefer a compatibility category D for the definition of byproduct material. However, the staff notes, in the third bullet on this slide, that a compatibility category D program element isn't reviewed by NRC staff, either in house or during IMPEP, because they are not a required part of an agreement program.

The next slide provides a quote from the Commission paper, SECY-06-0069, Enclosure 5, which sums up the staff's conclusion on why the definition of byproduct material should be designated H&S.

If the definition of the term "byproduct material" or some other term, such as "radioactive material" that encompasses all of the byproduct material was not somewhere within the State program, then it's possible that some byproduct material could escape oversight and result in an overexposure to an individual in excess of the Part 20 limits.

We wouldn't have a problem if the State used a term such as "radioactive material" throughout its regulations and that term encompassed the new forms of the byproducts material. However, we

found that there are differences in terminology within individual State regulations. For example, States that use both the terms “radioactive material” and “byproduct material.” A designation of H&S would require States to assess their own programs to see if changes or updates are needed, if at all.

Could I have slide 15, please?

So to summarize where we are on the NARM rulemaking: We have developed a draft proposed rule that included stakeholder outreach and State involvement in a very short time period. The draft proposed rule addresses a key Energy Policy Act issue, namely, the expansion of NRC’s authority to cover NARM and discreet sources of radium-226.

In developing the draft proposed rule, staff tackled a number of tough policy issues.

Next slide, please.

We will continue outreach activities after the proposed rule is published, holding at least one public meeting and continuing to interact with Agreement States, non-Agreement States, the public, and affected industry.

Finally, achieving the February 7, 2007 due date for the final rule will be a challenge. We must continue at a very fast pace to meet

the statutory deadline.

Our second topic on the next slide is Section 656 on secure transfer of nuclear materials. The Energy Policy Act requires that for materials transferred or received pursuant to an import or export license, the Commission shall establish a system such that that materials are accompanied by manifests and that each individual receiving or accompanying the transfer shall be subject to a "security background check conducted by appropriate Federal entities."

Next slide, please.

The statute requires that the Commission issue regulations not later than a year after the date of enactment of the Act; that's August 8 of this year, and from time to time thereafter, as it considers necessary, identifying radioactive materials or classes of individuals that are appropriate exceptions to these requirements.

Although the regulations must be issued within a year, the statute allows the background check requirement to become effective on a date established by the Commission.

Next slide, please.

Currently, we're developing a proposed rule on Section 656. We drafted an initial version of the proposed rule and provided it to the Agreement States and NRC offices for review and comment. We're also

coordinating with the DOT, the Transportation Security Administration, and the U.S. Coast Guard.

The initial version of the proposed rule had been crafted to rely heavily on existing background check requirements and other agency's regulations. As with many of the rulemaking activities in the Energy Policy Act, this action has an aggressive schedule. The draft proposed rule is due to the Commission in June.

The statute requirements for a system of manifests are not a problem. There are already existing DOT and NRC requirements for shipping papers that already require this information. The statute requirements for a system of security background checks have proven to be a lot more difficult.

The particular issue is that Section 652 on fingerprinting and criminal history background checks, which I'll discuss last, is broader than Section 656. Sequentially, it would make more sense for to us complete the requirements for the more comprehensive Section 652 rulemaking first.

Slide number 20 please.

In their review of the draft proposed rule, Agreement States and DOT raised some concerns. Some Agreement States note that Section 656 ties the system of security background checks to an import

or export license. They note that NRC alone has authority to issue import and export licenses, and they suggest that these requirements should be placed by NRC on the importer, not by the Agreement States on the possession licensee.

DOT agreed with our findings that manifest requirements are not a problem, but they raised issues about it's staff's overly broad definition of "accompanying".

We note that establishing exceptions now for Section 656 rulemaking may set a precedent for the more comprehensive Section 652 rulemaking on fingerprinting and criminal history records checks. And, finally, the staff is cautious about opening Part 110 to establish requirements of this nature on importers. We have not used Part 110 in this manner in the past, so it would be a departure from past practice with regard to importers.

Could I have the next slide, please?

In response to stakeholder comments, we're drafting a proposed rule that provides exceptions for material other than the most risk-significant quantities. Rather than establishing a system of background checks now in the Section 656 rule, we would address fingerprinting for the most risk-significant licensees through orders until the broader Section 652 rulemaking can be completed.

The immediate 656 rule would just address the exceptions, as we are crafting it now. The rest of the security background check system would be handled through orders until Section 652 could be put in place through rulemaking. Staff would clearly indicate in the Statement of Considerations for the Section 656 proposed rule that we will revisit the exceptions when the Commission finalizes its broader fingerprinting and criminal history record check rules, such as Section 652.

Next slide, please.

Our next steps are to complete the draft proposed rule, as I just described, and send it to the Commission in June. We are also drafting a letter to inform Congress that we will likely not meet the August 7th due date for a final rule. Although this approach may allow to us come closer to the due date, we still expect the notice and comment rulemaking will take until fall of this year to finalize the rule on Section 656.

We are reaching out to Agreement States, DOT, TSA, and the Coast Guard, and are going to continue to do so. Wherever possible, for persons receiving and accompanying the material, we are trying to reference or point to other agencies' requirements and tier off of those, and that would be done in the orders now.

The staff will send out orders to require fingerprinting and criminal history records checks for unescorted access to material to applicable licensees with higher-risk sources. That addresses for those licensees the statute's requirement that the Commission establish a system to require security background checks for individuals receiving or accompanying the material.

Finally, the staff plans to address the broad issue of fingerprinting and criminal history record checks in the more comprehensive Section 652 rulemaking, which brings us to our last focus area on the next slide.

Section 652, fingerprinting and criminal history records checks. This slide shows the key requirements of Section 652. The statute has two key aspects requiring fingerprinting: unescorted access to radioactive material that the Commission determines to be of such significance, and next, access to safeguards information.

Could I have the next slide?

The law also requires the fingerprints to be submitted to the U.S. Attorney General for identification and criminal history records checks.

Next slide, please.

The statute requirements for access to safeguards

information became effective on the date that the law was enacted last August because the law didn't grant the Commission discretion on who it applied to in the same manner as it did with access to materials. And because it covers any individual, everyone who has access to safeguards information must now be fingerprinted or be exempted by rule.

The staff is rapidly developing orders to those licensees, other than power reactors, who have or will receive safeguards information, including modified safeguards, requiring that they submit fingerprints for access to safeguards information.

To expedite implementation where licensees need to receive safeguards information, some licensees have been called and verbally requested to submit their fingerprints.

In addition, the staff is quickly drafting an immediately effective final rule so that certain groups of individuals could be relieved of the requirement to submit fingerprints for access to safeguards information. That would include individuals such as State officials, members of Congress, and the final rule will also permit the Commission to continue sharing SGI with its international partners.

The statute also requires fingerprinting and criminal history records checks for access to materials that the Commission deems to be of such significance. In response to Commission direction, we're

currently developing orders to require fingerprinting for manufacturers and distributors, as well as pool-type irradiators for unescorted access to radioactive materials.

Could I have slide number 26?

Resolution of many of the issues on access to safeguards information can made through the SGI rule, which is with the Commission now. That package is in the proposed rule stage. It will need to be issued for comment, and final rule is not expected until later this calendar year. Between now and then, as I mentioned, the staff is working on an immediately effective final rule to provide relief for certain groups of individuals from fingerprinting for access to safeguards information.

Fingerprinting and criminal history records checks for access to material will be addressed later in a broad rulemaking that will revisit the exceptions granted under the current Section 656 rule.

The next slide number 27, please.

Here is the schedule. The orders are being developed right now, both for access to safeguards information and for access to materials. The final rule on access to safeguards information is dependent on the timing of the staff requirements memorandum for the proposed rule. The final rule can be delivered by OGC to the

Commission roughly four to five months after an SRM is received.

The final rule on Section 652 for fingerprinting and criminal history records check for unescorted access to radioactive material is scheduled to be delivered to the Commission in September 2008.

Next slide, please.

In summary, we immediately began in August of last year to implement the provisions of the Energy Policy Act, and we have moved rapidly as an agency to make progress. You heard today about some of those accomplishments from Steve O'Connor. In addition, we embarked on one of our most significant rulemakings in the history of our materials program.

Just as important under the Energy Policy Act, but not the subject of today's focused discussion, we are nearing issuance of the final rule on the National Source Tracking System, and we move forward with our Federal counterparts and States on the Radiation Source Protection And Security Task Force. We've made considerable progress in a short time, but we're not content to rest on our accomplishments.

Can I have the last slide, please?

Beyond just meeting the statutory deadlines of the Energy Policy Act, we recognize that communications, outreach, and interaction with our stakeholders are a key part of the process that leads to

improved results. We reached out to States in an unprecedented manner on the NARM rulemaking and created opportunities to solicit stakeholder input.

Both NRC and the stakeholders would prefer more time and opportunities to exchange information. But within the timeframes created by the Act, we are maximizing the opportunity for stakeholder involvement.

Finally, while we can point to the progress that we have made since the act was signed into law, many challenges remain, and some of those challenges are formidable. You just heard about the rapid pace of these rulemakings. While it may be fair for staff to respond to shorter deadlines, the faster pace also pushes our stakeholders and limits our and their opportunity for input.

Another challenge is the complexity of the Act. Some statutory requirements for fingerprinting are being addressed through multiple rulemakings over different time periods. While these challenges are great, the staff will continue to press hard to address them and implement the Energy Policy Act.

Last August, when Congress passed the Act and the President signed it into law, NRC's authority expanded in a most fundamental manner, from oversight of accelerator-produced material to

fingerprints and firearms at licensed facilities, to a multi-agency task force, the Act expanded NRC's role and authority. The staff understands the importance of these changes, and we are diligently working to put them in place.

This concludes our portion of the presentation today.

CHAIRMAN DIAZ: All right. You want to change places with Mr. Reyes, or his --

MR. MOORE: I guess I'll stay here.

CHAIRMAN DIAZ: Thank you for that presentation. We do realize there are many challenges. However, you realize the Commission is very anxious to make sure that this is done in a timely manner. The schedule is pressing, but we keep asking what else do we need to do and how can we help you. I think that at the end of today's discussions, we really want to hear, what else do we need to do to do that? And with that, Commissioner McGaffigan?

COMMISSIONER MCGAFFIGAN: Thank you, Mr. Chairman. I'll note for the record that Mr. Reyes does have a moustache, too. So it's the glasses that was the difference, I guess I was noting at the outset.

Scott, on the issue of this quick rule for members of Congress, and State officials, and others that I think the current 73.21

allows an exception for them in any case to receive safeguards information, how quickly are you going to get that done? In some sense, we should have had that done earlier. It sounds like a very simple, direct final rule.

MR. MOORE: The Office of General Counsel is drafting on the rule. It is drafted, and it's out for comment by other offices at this time. It exempts a number of groups of individuals, and I think they are working in the timeframe of a few weeks. I'm not sure if OGC wants to provide any further information.

COMMISSIONER MCGAFFIGAN: Karen, do you have a date?

MS. CYR: I mean, I think probably tomorrow. I mean, I saw a version today, which I think includes everybody's comments.

COMMISSIONER MCGAFFIGAN: So it will be sent to the Federal Register tomorrow?

MS. CYR: No, no; it will come to you.

COMMISSIONER MCGAFFIGAN: Why do you we have to --

MS. CYR: Because it's a rule. You have to affirm it.

COMMISSIONER MCGAFFIGAN: Okay. It's a rule, a final rule. So we have to affirm a final rule?

MS. CYR: Right, right, right. But it is immediately effective.

COMMISSIONER MCGAFFIGAN: Mr. Chairman, I might suggest that we add it to the agenda for tomorrow's affirmation session.

COMMISSIONER MERRIFIELD: Can I read it first?

(Laughter.)

COMMISSIONER MERRIFIELD: Being the sole lawyer on the Commission, I feel obligated to meet my fiduciary obligation in that regard, Mr. Chairman.

CHAIRMAN DIAZ: Having learned about the one page worth of the law, I think I want to wait at least until Wednesday.

COMMISSIONER MCGAFFIGAN: Wednesday, it is.

COMMISSIONER MERRIFIELD: I don't know if I will be done reading it by then.

(Laughter.)

COMMISSIONER MCGAFFIGAN: This is a really bite-size rule. I will take my fair share of blame. I'm usually pretty attentive to effective dates, but in this particular instance, I missed it. And this is our provision. We did this to ourselves. So I think it's the problem of being involved in a serious legislative process about once every 13 years, your skills get to atrophy a little bit.

The Section 656 rulemaking. Since we are doing background checks on certain individuals, those who deal with non-

exempt Section 656 materials, import and export, that must be a paperwork collection under OMB Paperwork Reduction Act responsibilities, the Office of Information and Regulatory Affairs has the lead at OMB. How is that clearance being built into your process?

MR. MOORE: The proposed approach that we are taking now would be to do a rulemaking that just gives exceptions at this time. Because we would just be giving exceptions, we would not have to go through –- in the rule itself, we would not have to go through OMB because we would just be accepting people, and there would not be an information collection burden because we would be giving exceptions.

COMMISSIONER MCGAFFIGAN: For those who aren't excepted, there is an information burden that does not exist today.

MR. MOORE: That's correct. And for those who are not excepted, the information collection burden would be imposed through the orders that they received. So there would be an information collection burden in the order.

COMMISSIONER MCGAFFIGAN: And so you would need a number on the order?

MR. MOORE: Yes, sir.

COMMISSIONER MCGAFFIGAN: Are you working on that? As I understand your proposal, it would initially affect the manufacturers

and distributors and large panoramic irradiator employees.

MR. MOORE: Yes.

COMMISSIONER MCGAFFIGAN: So how long does it normally take to get a paperwork collection number from OMB?

MR. MOORE: I'm not sure if admin has authority to go out on orders more quickly than others, and we can get back to you on that. But we could go through and get it fairly quickly, I believe.

COMMISSION MCGAFFIGAN: Well, I –-

MR. MOORE: I don't think we'd have go through on a standard process on an order if we believed there was a health and safety issue on an order.

COMMISSIONER MCGAFFIGAN: Okay. If that's the case, that's better. Do you happen to know, Karen, whether we need to go to a –-

MS. CYR: I don't think it applies to orders, or at least we have a fairly blank –

(Simultaneous discussion.)

COMMISSIONER MCGAFFIGAN: Well, then, that's good. Let me go back to page 21 here, the 652 rulemaking. The long-term vision is that that will affect everybody who possesses material in cat 2 and above in terms of the Code of Conduct, that meets the definition of a

radiation source under section, I think it's 651 also, a different part of 651?

MR. MOORE: I think that's the staff's current thinking right now. We have not mapped out all the details of it, but that is our current thinking. The technical basis would have to be developed for it.

COMMISSIONER MCGAFFIGAN: But it would be very hard -- I have the language, or I had it earlier. But it would be very hard for to us make a determination under 652 that is different from the determination Congress itself made in another subsection of section – or in Section 651 just preceding.

MR. MOORE: That's right.

COMMISSIONER MCGAFFIGAN: I think, theoretically, we could because the two sections are independent sections. But it would strike me that it involves -- it would involve a stretch for the Commission to do that. If we're going to require everyone who has category 2 and above radionuclides of concern, to have some subset of employees who are subject to the fingerprinting, both in Agreement States and non-Agreement States, how many employees do you see per licensee who might be affected by that for a category 2 and above licensee? Is it about 1400, 1500, 1600 of them? I don't know what the total number is of the agreement and non-Agreement States.

MR. MOORE: It sounds about in the ballpark.

COMMISSIONER MCGAFFIGAN: But how many individuals -- if we have 1600 licensees approximately, ballpark, how many individuals per licensee do you all envision having to be subjected to the Section 652 fingerprinting requirement and background check requirement?

I promised you, Mr. Chairman, I would ask a question the last few seconds.

MR. MOORE: I'm not sure we have an exact answer on that number of individuals, but that is certainly something we could take to get an answer on.

COMMISSIONER MCGAFFIGAN: Do you have a ballpark number? Presumably, it is not every individual at the site.

MR. THOMPSON: If we go with what's been the average experience in other areas, like with power reactors, maybe five or six at the site.

COMMISSIONER MCGAFFIGAN: Just to clarify it –- and this will be my last –- If it's, say, Washington Hospital Center or Georgetown or GW, take those hospitals where there are cat 2 materials or above -- maybe some cat 1 blood irradiators – how many folks in the radiation department at those hospitals would be subject to fingerprinting?

MR. THOMPSON: I guess I don't have an exact number for you, sir. We can certainly come up with a number.

COMMISSIONER MCGAFFIGAN: Thank you, Mr. Chairman.

CHAIRMAN DIAZ: Thank you. Commissioner Merrifield?

COMMISSIONER MERRIFIELD: Mr. Chairman, thank you. I think the staff did a good job this afternoon in walking us through the challenges here. I think, at least as it relates to part of this, I look forward to our second panel to help flush out what I think are some of the concerns. But while the staff is here, I just want to get a clarification as it relates to some of the concerns raised by some of the parties we'll have in the second panel relative to 651(e).

In the language of the Energy Policy Act, the Act requires the Commission, to the maximum extent practicable, to cooperate with the States and to use model State standards in existence on the date of the enactment of this Act.

One of the issues that has been focused on is the degree of compatibility with definitions. And I'm wondering if you can explain to me whether there, to your knowledge, was a "model State definition" relative to this material at the time that the Act was passed. Kathy Schneider?

MS. SCHNEIDER: The suggested State regulations did have -- they had a definition for byproduct material that comported with the

one that was previously in the Act to the Energy Policy Act, and they also had a definition for radioactive material. So they had both definitions in the suggested State regs.

COMMISSIONER MERRIFIELD: If you can explain to me what the differences are between what was in the model definition and what the staff is recommending the States find egregious?

MS. SCHNEIDER: Okay. The States -- I hate to paraphrase for them, but they'll be more than – they'll be explaining it on the next panel. But many of the States' regulations use the term "radioactive materials" throughout their regulation, and that term encompasses byproducts or special nuclear material, both NORM and NARM.

For those States that are Agreement States and legislation is an adequacy element, they will enter into agreements with us using the term "byproduct material" that we had in our statute at the time, prior to '78 -- and Karen can correct me, but before the Uranium Mill Tailings Act byproduct material –- you know, after that it was differentiated into 11(e)(1) and 11(e)(2). So we had Agreement States prior to that revision to the Act that entered into agreements with "byproduct material" as the definition that was all-encompassing and didn't have the breakdown.

The definition that was in the suggested State regs now -– because that definition has not been -- they have not done any

corresponding changes yet to the suggested State regs reflect what's been in effect in the old 11(e)(1) and 11(e)(2) provision for byproduct material.

And then, because the States have broader statutory authority under their State law, you'll see in many States they use the term "radioactive material" or "sources of radioactive material." "Sources of radiation," too. And it depends on when we are doing a review of the program what they are encompassing and how that regulation pulls in all these things, because they'll use the same radiation protection standards for their NORM, their scale, previously areas that we didn't regulate, and then their byproduct material, source material, and limited quantities of special nuclear material.

Does that answer the question?

COMMISSIONER MERRIFIELD: To a certain extent, I guess. Basically, what you are saying is that many States have a broader umbrella in their description.

MS. SCHNEIDER: Correct.

COMMISSIONER MERRIFIELD: What we are asking for --- and this is a more specific description of the material that we're intending to focus on here.

MS. SCHNEIDER: Right. Under our definition of byproduct

material, it's very specific. The States historically have had a very broad authority for all sources of material, both those that we regulate and those that we have not regulated. So the suggested State regs have had both the byproduct definition there and have had radioactive material.

I personally am aware of one or two States that I have seen where they define the term "byproduct material" and they don't use it in their sections of their regs because they are using "radioactive material," which is broader.

COMMISSIONER MERRIFIELD: In the comments that we received – and we have that letter from the Organization of Agreement States which listed the specific comments by State, one of those, that of Maine, had an idea that we -- suggesting that the NRC ought to find out what the States have for definitions and an estimate of whether the definitions are all similar or exactly the same.

Did we actually try to do some understanding about where the States were on this, and whether, in fact, as Maine asserts, they're more similar or exactly the same?

MR. MOORE: We did. As part of the rulemaking effort, we went back through and looked at the various State regulations, not just on definition but also on regulations. I'm not sure whether the definitions for byproduct material were exactly the same or not.

What we would have found on that would have been that byproduct material would have been defined in the former definition that we had used. And had we found that, then I think the staff's conclusion on that would have been that byproduct material would need to be changed.

The definition for radioactive material will probably be broad enough that it would be acceptable. I think the question is, how are they used throughout the States' regulations, not just the definition itself.

So, we did go back as a staff in the rulemaking and look at the States' regulations and how they used the model State regulations.

COMMISSION MERRIFIELD: Thank you, Mr. Chairman.

CHAIRMAN DIAZ: Thank you. Commissioner Jaczko.

COMMISSIONER JACZKO: I wanted to just go back and revisit the 656 versus the 652 rulemaking, and I just want to make sure that the staff has thought through this issue. Perhaps you can clarify that for me in answering my question.

The primary issue has to do with, we will accept certain materials under 656 and do a fairly quick rulemaking, if you will, to try to get that done close to the statutory deadline, then come later and do a 652 rulemaking, which will be more encompassing.

Now, if the 652 rulemaking winds up un-exempting people

who have exempted material, if you will, will that be something that will be able to do without any potential problems about the various rulemakings being inconsistent, having accepted, in one case, this material and then later essential un-accepting that material.

MR. MOORE: The 656 rulemaking, as we are envisioning it now, would -- For starters, I guess I should give some background material. The 656 rulemaking only applies to material that is received or accompanied pursuant to an import or export license. So, 656, because of the way the statute is written, does not affect domestic transportation now. 652 could and probably will with respect to background checks and fingerprinting. 656, with regard to material pursuant to an import and export license, the staff is envisioning, in response to the public -- in response to the Agreement State comments that we received, or stakeholder comments -- applying it to only the higher risk categories of sources.

COMMISSIONER JACZKO: 656?

MR. MOORE: 656.

COMMISSIONER JACZKO: Right, that is my question. I mean, we're really only talking about –

MR. MOORE: Manufacturers and distributors in RAMQC at this time.

COMMISSIONER JACZKO: Those are all category 1 sources, or are there some category 2 sources?

MR. MOORE: The manufacturer and distributors could catch some category 2.

COMMISSIONER JACZKO: To put my question more specifically, are there category 2 sources that will be accepted under 656 that we might then, when we go back and look at 652, want to recapture some of those types of practices? And that is something that -- Karen, perhaps this is a question for you -- that we will be consistent with being able do that from a standpoint of an arbitrary and capricious definition in the rulemaking process.

MR. MOORE: I think the answer -- and then OGC can give a legal view. I think the answer is there could be, under 652, some that we will pick up later when we revisit the exceptions. But with respect to 656 now, there are some category 2, but very, very few.

COMMISSIONER JACZKO: That will be accepted or that will be captured?

MR. MOORE: That will be accepted at this time, because we are only looking at the higher risk sources that would be captured at this time. We went back and looked at who was importing and exporting. And the staff actually looked at one month -- I think it was February --

and who had applied for licenses to import and export.

And then we compared that against who would be picked up against this group that would receive these orders under higher risk sources, and there was a one-to-one match. Essentially, it was a hundred percent of people that applied to import for the month of February would receive that. So I mean, we are at a hundred percent for there. We can't assume that every month, there would be a one-to-one match, but we believe, looking at general data, that it would be in the high 90 percentiles; roughly around 98, 99 percent or so.

COMMISSIONER JACZKO: Karen, maybe you could just –

MS. CYR: I think, as long as you, in your subsequent rulemaking, where you may cast for a broader category of people who previously weren't captured, I think, as long as you have an adequate basis in your rule for why now you feel that your health and safety justifies you to capture a broader category of individuals, it would through – they'll have an opportunity to raise their concerns of why. And we have to justify why it has not covered before and why we now have a basis.

So as long as I think we have a reasonable basis for why now, looking at it in this broader category of reexamination, we think that

they fall within a group which needs to be covered by this, I think we can justify that from a legal standpoint as a process.

MR. MOORE: I should qualify my answer. I was looking at it in terms of total curie content, not in terms of total numbers of licensees. So if you look at it in terms of higher risk sources in terms of total curie content, we would say the high 90 percentile in terms of total curie content.

COMMISSIONER JACZKO: But not necessarily in terms of total number of licensees?

MR. MOORE: Right.

COMMISSIONER MCGAFFIGAN: Mr. Chairman, for somebody watching this in the public, or listening to or reading this transcript, the proposal that the staff is talking about, the law allows us to exempt classes of material and classes of licensees, classes of individuals. And what the staff is likely to do is to say all byproduct sources less than category 2 are exempt, so category 3, 4, 5 sources are exempt. And within category 1 and 2 sources, you are planning to exempt those classes of licensees for whom the Commission or the States issued orders under public health and safety authority, as opposed to common defense and security authority last year.

MR. MOORE: We are working on the words. I'm not sure

we'll use those exact words.

COMMISSIONER MCGAFFIGAN: Well, I'm not sure of those exact words, but that is the spirit that you're going under.

MR. MOORE: Yes, sir.

COMMISSIONER MCGAFFIGAN: So you are exempting -- In the materials and the source materials, you're exempting all materials category 3 and below, and then, in the individuals, even if they have category 1 and 2 material, you are exempting those who receive public health and safety as opposed to common defense and security orders?

MR. MOORE: Yes, sir.

CHAIRMAN DIAZ: Commissioner Lyons?

COMMISSIONER LYONS: Let me first congratulate the staff, both on the presentation and the progress that you have made in working towards the various deadlines in the Energy Policy Act.

One perhaps very trivial question: Scott, on I think it was slide 4, you mentioned the radium-226 and antiquities. I have no feeling for how large a range of strengths we are talking about represented in antiquities. Do you have any feeling for what that number is?

MR. MOORE: We have some anecdotal evidence, but I don't –- specifically, it's very low. But we just had anecdotal evidence; we

didn't have enough of a basis to make an exemption. So I don't, no, sir.

COMMISSIONER LYONS: I guess my gut feeling is that it would have been a very low source strength, and probably quite easy to treat in a simple way; at least that would have been my hope.

Turning then to the NARM rulemaking, I understand the States' interest in compatibility D, and I understand the staff's argument against the use of compatibility D. And as explained to me, I don't see how compatibility D could possibly be allowed for this particular case.

But the States have made an alternative proposal on one of their slides, and because we're dealing with two different panels here, I wondered if it would be out of place to ask you if you would be willing to comment on the alternative proposal that the OAS or CRCPD made on your slide 6. And since not everybody may have that, let me just say that as an alternative, they are recommending that the Statements of Consideration should acknowledge that certification by the Governor that the State has an adequate NARM program which should preclude definitional changes.

I was curious whether staff had had an opportunity to evaluate that proposal from OAS or CRCPD.

MS. SCHNEIDER: If that's okay, I'll take this one. Really, this is looking at what we consider the implementation of health and

safety and our determinations as to whether this program is adequate and compatible. And I'll say we take a look at this as we do all new rulemakings, and we categorize all of it. And then we take a look as to where they fall out.

This would be one of the things we're expecting whenever this rulemaking is finished and whatever the Commission decides on the various -– on both compatibility and adequacy designations. Then we're going to take a look and see how the States address it.

If it is a health and safety, something like this would be something that I think we could –- you know, if the State goes through and says they've covered sources of radioactive material, actually meets and is all-encompassing, and that we then cover -- I think what they are looking for is some sort of comfort that we are not going to be changing when we do our implementation, that this a health and safety and that there is a lot of flexibility in addressing the essential elements of this program element, which is, have you covered this material such that there's not exposures to the public and public health and safety are being protected.

COMMISSIONER LYONS: That is consistent with my understanding, too. I do support the staff's recommendation of the H&S approach to this. And to the extent that this alternative can be

considered in that process, I think that would be --

MS. SCHNEIDER: I think the staff, as we preliminarily talked about it, believe this is part of our normal implementation, which we look at whether it's through regulation, legally binding requirements. Some States have statutes. The State will have to -- Each Agreement State will have to take a look at each of the elements, but this is certainly something that would be an acceptable approach, I believe -- that they have the certification by the Governor, plus any other additional supporting elements for covering these materials.

COMMISSIONER LYONS: I appreciate that response. And I did want to make it clear that I do not support the compatibility D suggestion from the States, but the suggestions are quite reasonable. Karen, did you want to add to that or is that sufficient?

MS. CYR: And Kathy addressed it. And the question is whether -- in our follow-up reviews, whether, in a sense, it minces a legally binding requirement? This would represent a judgment on their part at the time they certified that, in fact, it complies with the health and safety version of our things. And I think that's certainly something we could accept with the staff looking at it.

But, again, as an ongoing IMPEP process, you might go back and look at that at some point. But I think that the issue is, that would be

a way for them to represent that, in fact, they are meeting this element of the program.

MS. SCHNEIDER: I can tell you from experience that we have had States that have occasionally made changes in regs or in legislation that, under IMPEP, we've identified, and we have had to go back with them and say, this didn't meet this element, compatibility element, or this didn't meet this health and safety element.

We've had both of those calls where we have had to bring that to the State's attention, and they have had to address that to bring them back into performance standards of adequacy and compatibility.

COMMISSIONER LYONS: Thank you very much. That's all, Mr. Chairman.

CHAIRMAN DIAZ: Thank you, Commissioner Lyons. Let me go back to one point that Mr. Moore made. And I'm sure that you really meant what you said, but I wrote it down, and that's dangerous. And it's May of 2006, and we are really getting ready to roll these things out. And if I may quote you, you said we have not mapped out all the details. Now, that's what you said: we have not mapped out all the details. I understand that.

My point is that in some reasonable time in the future, we need to map out all the details. The clock is ticking, and I know

everybody has been working on different things. But this would be consistent with Commissioner -- all the Commissioners in a certain way. It's time to put this in one of my favorite tools, a matrix, and make sure that all the details are there and that there is a consistency, both internally and externally. So, hopefully, next time you come to the Commission, the first statement will be for the Commission, we have mapped out all the details, and we have also implemented them. I'm looking forward to hearing that from someplace.

Let me go back now to the same point that consumed a little bit of us, which is the issue of the stakeholders from the States and the issue of compatibility D, and public health and safety, and all the things we have talked about. I do believe that the law has some words that I think are very, very strong that they use to the maximum extent practicable, to use model State standards.

I think, in a certain way, that is asking us to go beyond where we have always been. I think this Commission and the relationship with the State is mature enough that we can go beyond where we normally are, and compatibility D just does not cut it.

The States by themselves putting something that is out there and does not allow us to make some checks that provide the basis for our assurance of public health and safety won't do it.

But if there are mechanisms that we can incorporate, a kind of formal review of the IMPEP program, for example, as Karen mentioned, there must be ways in which we can actually reframe this, where we can use the best of the State, comply with the intent of the law, and provide for the NRC level off -– and I'm not going to use the word compatibility –- a level of interchangeable standards for radiation protection for public health and safety that will allow this to work. I'm not sure what they are, but I believe they do exist. I think sometimes we get in boxes, compatibility D, compatibility B, compatibility –- you know.

And there is a time in which, you know, we need to come up and say, the law says this; this is where we are. We now know better. We now have what I hope is a better relationship with the States. We know how to do this thing, and we have a longstanding, very proven IMPEP program. I believe that it is a way out.

And Commissioner McGaffigan, I think I'm learning from you: I'm making statements instead of questions of late. It must be contagious. So, is that something that could function?

MS. SCHNEIDER: Chairman, I personally believe we do that now. I believe that's how we have implemented it in the past. And my position is involved in both project managing IMPEP and doing reg reviews now, and that is how we handle it. And the essential elements of

the program itself and health and safety will allow us to work reasonably and to -– I'm blanking on the word; I apologize. I'll ask Janet to stand up a little bit -- allow us to attain the objectives I think that will allow to us implement this, and in a less disruptive way as possible with the States, because we do believe, at least from our standpoint in State and Tribal Programs, that many of the things are already covered within the State's regulations because of the way they have been regulating these materials over the years.

MS. SCHLUETER: True, exactly. I think that we are in a little bit of a unique situation here because the states have been regulating these materials that are now under the Atomic Energy Act and the NRC's purview. So we are looking for ultimate degrees of flexibility under the current adequacy and compatibility policy statement, and I think we do have that under health and safety.

It's not only the IMPEP review that will take place, but before we even get to that point, just like every other rule that we put out there, the States have to then ensure that they have addressed the elements of the rule. And in the NARM paper that you have before you, if you look on page 87 of that paper, that's where we have a chart with regard to the elements that are in the NARM rule.

And with every rulemaking, the Agreement State then sends

in the rule package within the three years that they have to implement the final rule. And they do a crosswalk, and they go down our rule and they look in their own rules, and they determine where is it addressed in their own rules.

So between what they have on the books today and what they have for NARM and what they have on the books under their agreement, we will probably find than in almost all cases, they will have covered and addressed the NARM material that's now under AEA in some form or another, whether it's under the definition of byproduct material or radioactive material. It must be covered because they have been regulating it.

And then there is the issue of the State law and whether or not they have to go back and amend that in some way to change their existing definition of byproduct material. Again, we are looking for ways to implement that in a flexible manner because they have been regulating it for 50 years. And it may be enough for the Governor to send in that certification and determine -- make their own independent determination that their program is adequate. So we're working with OGC and the States to do that.

CHAIRMAN DIAZ: All right, thank you. Now, I believe that was a very long answer by staff, if I may say so. But I got it. I don't

know if my fellow Commissioners have some very brief pointed questions.

COMMISSIONER MCGAFFIGAN: I just have -- With regard to the new radionuclides we are adding, do you have exempt levels and levels requiring specific licenses for these radionuclides similar to what might be in Parts 30, 31, 32? I saw that you had some exempt concentrations. I didn't see an exempt concentration of, say, radium-226. Is there an exempt level for radium-226? No? That goes to your point that didn't know where to draw the exempt line?

MR. MOORE: That's correct, because we don't have the specific information on the number of sources that are out there and how they are used out there.

COMMISSIONER MCGAFFIGAN: How much fluorine-18 do I need –- fluorine18 is in our current rolls because a reactor can produce it, too. But how much fluorine-18 do I need to require specific licensing, as opposed to general licensing? Does that concept stick -- go through these rules?

MR. MOORE: We can get back to you with an answer.

COMMISSIONER MCGAFFIGAN: I saw thresholds. You added some radionuclides for the exempt concentrations.

MR. MOORE: Right.

COMMISSIONER MCGAFFIGAN: You added radium-226 for the general license tracking system at 100 – no, no; one millicurie? What was the number for radium-226? You added it in the general license tracking system. I just missed anything for the general license/specific license line. So I just would be interested in that. And I've got 15 seconds. I had a second question, but I'm getting old. Twice in a week now I have forgotten the second question. So I guess I'll pass.

CHAIRMAN DIAZ: Commissioner Merrifield?

COMMISSIONER MERRIFIELD: Pass.

CHAIRMAN DIAZ: Commissioner Jaczko?

COMMISSIONER JACZKO: I'm going to try to get two questions in, so very brief answers, if you would.

On the radium-226 for some of the consumer products, you said the staff does not have an adequate technical basis to make a determination for exempt -– to determine exempt quantities. Can you just briefly talk about –- Effectively, these are going to be under general license. But what would be the practical difference between exempting them and general licensing?

MR. MOORE: In generally licensing, we can actually put some kind of requirements on them. Exempting them, we have no

requirements at all on them.

COMMISSIONER JACZKO: What's missing? What is this kind of information you don't have in order to make it?

MR. MOORE: We don't have information on the number of sources that are out there, the exposure rates from the sources, as Commissioner Lyons mentioned. The number of -- how they are disposed of. We have anecdotal information.

COMMISSIONER JACZKO: And I appreciate that. From there, if we impose a general license -- ultimately, those are the kinds of things we need for the general license, as well. How are we then going to figure out how many sources there are, who's got them? I mean, if we impose a general license, what would be the practical effect, then, on people who have some of these things?

MR. MOORE: I think one of the practical effects is that we can take regulatory action as a regulator and enforce our rules with – we have an enforcement mechanism. With an exemption, we don't have such an enforcement mechanism.

COMMISSIONER JACZKO: I appreciate that. I guess my point is, I have some concern about whether we're ever going to be able to find out who take enforcement action and all these things if we don't know who they are.

The other question I want to ask -- and this is perhaps something to get back to later. But this again goes to this issue of the compatibility and the adequacy of determinations. I was just going through the policy statement on adequacy and compatibility. One of the things it says in there is, we need to make adequacy determinations and compatibility determinations.

And I guess I still have a little bit of confusion on my part about why there is not a need in this particular case to have some level of compatibility, in addition to an adequacy determination that essentially comes through the health and safety determination. Again, we are talking about a definition here for byproduct material, and it seems to me, to some extent, this is now regulated under the Atomic Energy Act. There does need to be a level of compatibility among States about what materials fall under their Atomic Energy Act provisions and what materials don't.

Certainly, I think probably one of the simplest things is just to look at accelerators. I mean the staff is looking at accelerators, that will be used to irradiate targets and produce byproduct material. Activation components, I think, as I recall, from those accelerators will be included in the definition, but if it is an accelerator that is not irradiating the target that's covered, the activation products from that will not be included.

So there are issues about what goes into the definition. And I think from the perspective of the Atomic Energy Act, we would want to have some compatibility. I've probably taken too much time on this, but if there is a brief answer from the staff -– if not, that's something you could get back later -- why we don't need a compatibility A or B determination.

MS. SCHNEIDER: I think we go back to fact that we look at that again although that legislation is an adequacy element, when we did the policy statement back in '97, they have to address what categories they'd enter into an agreement. But you go back to, is it going to create –- is it basic radiation one for the A requirements, the B trans boundary –

COMMISSIONER JACZKO: I guess it is the B. It seems there could be issues about –-

MS. SCHNEIDER: What if they're using the term radioactive sources? And I've used as an exaggerant-– What if they called it Green Glowing Goop, and under their State definition, they have covered all the aspects? And the States do. They do the sources, the electronically produced, NARM, NORM. They have for years.

Now, is that going to create a problem with compatibility in the national programs? Is it going to create problems in other jurisdictions by them not using the term "byproduct material"? It's not.

They put "radionuclide" on their license. They don't use the term "byproduct." They say they're regulating radium-226, and they've been able to do that.

So from that standpoint, we believe they need to have it from an adequacy standpoint, but not from compatibility. They don't all have to use that term because they are covering it in their regulations.

CHAIRMAN DIAZ: Commissioner Lyons?

COMMISSIONER LYONS: I don't think I have any questions, but perhaps a comment on the point that Commissioner Jaczko was just addressing on the need for, perhaps, compatibility in addition to adequacy. At least in my own mind, it would be sufficient to stay only with the adequacy statement because of the very strong statements in the legislation about the Commission, to the maximum extent practicable, cooperating with States and using model State standards.

To me, that is almost arguing against a compatibility designation and also why I was comfortable with an "adequacy" –-

MS. SCHNEIDER: And I believe, if I remember correctly, that the Governor certifies that they have an adequate program, not an adequate and compatible program, according to the language in the legislation.

COMMISSIONER MERRIFIELD: Mr. Chairman, having

yielded some of my time, I'll take some of it back. I was going to wait for the next panel to make their points, but: Focusing on this language the use of "to the maximum extent practicable," it does not say "the Commission shall use," and that is a very important distinction. It requires the Commission to do an independent assessment of this language, not merely to take up the State's path. I think that's an important distinction.

CHAIRMAN DIAZ: Thank you, Commissioner Merrifield. I want to thank the staff. I tend to repeat myself occasionally these days. I do believe it is important that we frame every single aspect of this issue so that when the time comes, we can just say we have done this, and we know that.

There is an issue of information and communication, and assembling that information to make sure that everything is done. I'm sure the staff has worked very hard on it. Now that you have all of the things, it's time to find out what you don't know, what you should know, how you get it, and eventually, how you put it together. With that, I want to thank the staff and call for the next panel.

We'll get a two-minute recess right now. Thank you.

(A short recess was taken.)

CHAIRMAN DIAZ: All right, good afternoon again. The

Commission is pleased to meet with different stakeholders, mostly from the State: Mr. Thompson, the previous chairman of OAS; Mr. O'Kelley, the present Director of CRCPD; and Ms. Schwarz, ACMUI; and Mr. Brown from CORAR. We appreciate the time that you have put into coming here and preparing to meet with us. We look forward to a lively interchange. And with that, I don't know who is designated to go first.

MR. THOMPSON: I'm first up.

CHAIRMAN DIAZ: All right.

PRESENTATION BY JARED W. THOMPSON

MR. THOMPSON: Good afternoon Mr. Chairman, Commissioners. On behalf of Barbara Hamrick, Chair of the Organization of Agreement States, the OAS Executive Board, and Board of Directors of the Conference of Radiation Control Program Directors, we would like to thank you for the opportunity to speak with you about the many important issues facing the Agreement States and the NRC at this time.

I would like to focus this discussion on issues related to the proposed rulemaking, implementing Section 651 of the Energy Policy Act of 2005, especially that subsection related to the incorporation of naturally occurring and accelerator-produced radioactive material, or NARM, into the definition of byproduct material.

I will briefly address issues relating to secure transfer requirements of Section 656 fingerprinting and criminal history records check in Section 652.

As mentioned previously in NRC staff briefing, the Organization of Agreement States and Conference of Radiation Control Program Directors identified several staff individuals to work with the NRC on a variety of activities associated with the proposed rule. We greatly appreciate the opportunity afforded to us to collaborate with the NRC on the efforts related to this rulemaking.

The States have a serious concern relating to the proposed compatibility and/or adequacy designation for the proposed definition of byproduct material.

Other definitions resulting from this rulemaking may pose similar problems, but for the sake of this discussion today, we will focus here on the proposed definition of byproduct material.

Next slide, please.

For over 40 years, the States have regulated NARM, which just now has come under the purview of the NRC. In order to accommodate the broader state authority under those –- to accommodate State authority during those years, the States generally relied upon a generic term, “radioactive material,” to define the regulated

material. Since this term is, by State standards, inclusive of byproduct source materials, special nuclear material, and both discrete and defuse NARM.

NRC Management Directive 5.9 formerly acknowledges this in Handbook Part 6, where it states, and I quote, “Changes to reflect increased scope of State authority, especially the use of the term ‘radioactive material’ in the place of the term ‘byproduct material’ would not be considered significantly different for the purposes of evaluating compatibility, requiring that a regulation be essentially equivalent.”

This kind of gets us away from the compatibility A and B, which was talked about briefly by Kathy Schneider. It was therefore somewhat disconcerting to learn that during the deliberations on the compatibility or adequacy designation for the definition of byproduct material, NRC staff, proposing a C designation, which is not as restrictive as an A or B, were of the opinion that this would still require the States to amend their definition of byproduct material in statute and regulation to conform with the definition of the proposed rule.

The concerns of the States primarily rest with the idea of having to change statute. I know in my State in Arkansas, when we became an Agreement State in 1963, in the Act that made us an Agreement State, there is a definition of byproduct material. There is

also a definition of radioactive material. That's what our regulations hinge on. The currently proposed category health and safety adequacy designation would require that the States adopt the essential objectives of the rule in question. This is essentially the same language used in the description of the compatibility category C designation, which NRC staff had already indicated would require a change in the definition in the State statute and regulation to conform to the NRC definition. That is where the concern of the States lies: going back and having to change statute.

This is a very large and significant departure from the policy laid out in the Management Directive 5.9 and may impose a very significant burden upon the Agreement States.

Next slide, please.

After the discussions with the NRC staff regarding the proposed interpretation of a category C compatibility designation and the alternative proposal to assign a definition of category H, health and safety adequacy designation, the OAS went to the Agreement State program directors for input. Thirty-three of the 34 States indicated that a category D was the appropriate designation. If you look on the slide, you see there that 27 of the 34 Agreement States indicated that it might be necessary to seek legislative change for the amendment to State statute

for the proposed definition of byproduct material.

I understand that the NRC is on a fast track to try to get this rule in place. State legislatures move a little bit slower most of the time than Congress doses. I know in my State, it meets once every two years. So there is going to be a lag period if we have to go in and start changing statutes.

Let me reiterate here that the NARM now, under the jurisdiction of the NRC, discrete radium sources and accelerator-produced materials extracted for commercial use, are currently regulated by the Agreement States under the same programs as the byproduct material and have been for well over 40 years.

I'm going to make another statement here, too: No matter what definition of byproduct material you may define, our radioactive material is going to cover more than what your byproduct definition is going to do.

There's some elements here, particularly when you start talking about defuse NORM, that is not going to be under your authority, but still will remain under States. It's going to fall under our radioactive material definition.

As stated in the supplementary information section of the proposed rule, and I quote, "The regulatory structure used by the

Agreement States does not distinguish between NARM and other radioactive material. This regulatory structure subjects NARM users in the States to the same licensing, inspection, and enforcement policies as those using other byproduct source or special nuclear material."

As one of our former program directors used to say, "Radioactive material is radioactive material, and we regulate it the same way."

In short, the Agreement States already have in place a regulatory structure that includes NARM and is consistent and compatible with the regulation of other byproduct material, as each of the Governors will certify to the Commission upon the publication of the NARM transition plan.

Next slide, please.

This slide, we have seen before, and it relates to -- and it has been quoted many times up here, so I'm not going to go into it. But to the extent practical, I think it has already been discussed, and we're just going to move on.

Next slide, please.

To this end, the States recommend that the compatibility designation for the definition of byproduct material be a D, not required for purposes of compatibility, and that no adequacy designation be

assigned.

I do want to make one clarification here. When I was discussing the compatibility C designation, there was obviously a miscommunication on what a compatibility C designation should be. And that raised some concern with the States, was how that was misspoken. And I know that STP, State and Tribal Programs, has done a good job of trying to let the States understand that that was just a miscommunication. That is probably why we are at some of the impasse that we are at today on the compatibility designation of this definition. Some of us -- and I happen to be one of them -- would not have a problem with the compatibility C. That's just me, so I can't speak for the rest of the States. Next slide, please.

The OAS Executive Board would like to suggest an alternative approach to the adequacy issue. We suggest that the Statements of Consideration clearly state that if a Governor certifies that the State has an adequate NARM program as required by the Energy Policy Act, that no definitional changes would be necessary in statute or regulation to meet the adequacy requirements. For example, if the States' current legislative authority encompasses NARM, it would not be necessary or required to make changes to statutory –- and remember, that's where the real issue is, a statutory change -- and regulatory

definition of byproduct material and to other definitions designated as a health and safety.

I'd like to briefly address Section 656 and 652 of the Energy Policy Act. Section 656 deals with the secure transfer of materials crossing our nation's borders, but in many ways, the requirements parallel those found in Section 652, which requires fingerprinting and criminal history checks for persons who have access to radioactive material within the United States.

Next slide, please.

We support the NRC staff's recommendation to proceed with Section 656 by issuing enhanced security orders to the high risk, high priority licensees already subject the NRC's common defense and security orders, and then further address the requirements in rulemaking in parallel with the rulemaking efforts in Section 652.

The OAS and CRCPD look forward to working cooperatively with the NRC staff on this rulemaking. And I will yield the remainder of my time to Mr. O'Kelley.

PRESENTATION B MR. O'KELLEY

MR. O'KELLEY: You left me too much time. I want to reiterate the compatibility issue and what got the States all up in arms was when we were told that, to some, the category C definition was equal

to a category A or B, and if that was the way it was going to be implemented, then that was going to cause some major concerns.

I think the bottom line is that we don't want -- we prefer that a mechanism be found that we don't have to go and needlessly change statutes and regulations for something we have already been covering for years. Looking at the Energy Policy Act, we could say, well, maybe the intent was that NRC become compatible and adequate with the States, but we won't go that far.

But I do think we're on a path, and we can find a mechanism where we don't have to needlessly go and change rules and regulations to cover it because we want to make this performance-based, and as long as we are covering it and regulating it the way you want to, then I think we have accomplished our purpose. And I do believe that 99.9 percent of the State statutes and regulations definitions do cover what you will be changing to your definition of byproduct material. Enough said.

The second area of concern is the Governor's Letter of Certification. I think Commissioner Lyons heard a lot of the States' concerns on that issue -- and again, I think it's an implementation concern, that we find a way to make this as painless as possible and accomplish the intent of the Act. And I know there's some concerns

about, Congressional intent was not placed in this Act, but I do think we all know what it means and that we find a way to minimize the impact on those States that already have programs in place.

I think we probably need to have a lot of discussions back and forth on what is going to be acceptable to primarily the lawyers involved, I guess, in this. One suggestion I have is that you accept a letter from the Governor that says, on the date that the transition plan is published in the State register, I certify that we are adequate and compatible.

There were a lot of questions that you have to have that very date on the letter, and he can't sign it until that date is published in the State register. And then, does it have to be in NRC's hands on that date, and what happens if it comes in a day later. So these are some of the questions that are out there, but I'm pretty sure that the rational minds here can come up with a solution to that to make it very workable and doable and accomplish the intent of the Act.

I'll ditto Jared's 656, 652. We are in agreement with the proposed way to deal with 656 through orders at the present time. And just to go a little bit further, it was our intent or hope that 652 will also be only implemented against those licensees that are currently under increased controls.

Criminal background checks is going to be an issue. We want to find a way or suggest that we find a way and I know it says through Federal means, but in talking with some of the members on the Chairman's Task Force, the FBI, they said that same information is available to our State FBI counterparts. And I think it would probably do a lot to ease up the burdens that are going to be on everybody when we start requiring all of these people to be fingerprinted. And I think some already have been through the increased controls. But any way to ease that process and accomplish the same goal is what we are asking for.

We have got several issues on the Energy Task Force, but I think I will wait until that comes to bear. We I guess mainly want to say thanks for allowing to us participate on that. We appreciate it, and we appreciate the opportunity to talk to you here. And I see I am out of time, so I'll hush.

CHAIRMAN DIAZ: Thank you, Mr. O'Kelley and Mr. Thompson. Dr. Schwarz?

PRESENTATION BY DR. SCHWARZ

DR. SCHWARZ: Thank you. I'm here as the Nuclear Pharmacy representative from the Advisory Committee on the Medical Use of Isotopes. Today, what I would like do is just present some of the stakeholders' points of view.

Overall, PET, kind of a new entity for the NRC to begin regulating, is an integral part of clinical nuclear medicine. This field is rapidly advancing the diagnosis and the treatment of some of the most prevalent diseases that we have in the United States. Greater than 90 percent of the total PET studies that are performed using F-18 FDG are essentially a diagnostic for cancer. Also PET is used to diagnosis cardiovascular disease, using –- and various disorders, using –13 ammonia, rubidium-82 for profusion studies, looking at cardiac viability with FDG. Also brain disorders are clinically evaluated for dementia and for seizures with FDG.

Just a few PET statistics for you all to consider. The number of cyclotrons licensed currently in the United States in 2005 were 177, and the number for 200 -- for 2006 has increased to 185. The overall number of PET scanners in the United States in 2005 was 1280. So a significant number of PET imaging devices.

As far as the projection of the number of PET studies that we actually perform on an annual basis, in 2000, we were at about 211 thousand PET studies, which in 2005 had increased to over a million studies, and projected for 2010 to increase to over 2 million studies in the United States. So we are talking about large numbers of our population. Probably everyone in this room at some point in their lives

will have a relative, a family member, or friend that will have a PET study performed. And I also want to talk a little bit about the advances in PET in terms of the research entity that we are dealing with. There is a tremendous amount of research ongoing in PET in both academic centers and in industry. This research is much greater than current imaging research. Companies such as GE, Bristol-Myers Squibb, Scherring, and Merck, are all involved in developing these PET tracers.

I believe, as many others do, that the future of nuclear medicine really is in the hands of PET as a science. So as far as the development is ongoing for cancer diagnosis, there's agents out there looking at cell proliferation, looking at hypoxia, which is essentially the oxygenation of tumors, using fluoromisonidazole, copper ATSM, also monitoring anti-therapy angiogenesis therapy, which is essentially the development of the circulation for the tumors, which is something that, therapeutically, we would like to inhibit. And there are agents in PET used to essentially –- being developed to look at that therapy.

Also in terms of the research ongoing in neurological disorders, there Alzheimer's research is at a significant pace. As we reach an aging population Alzheimer's has increased dramatically. Diagnosis is being performed in the research centers for Alzheimer's.

Again, they are developing therapies.

So the hope is that with these agents, PIB and fluoro-amoroid, that we will be able to diagnosis this disease at an early state and then institute therapies to essentially prevent the progression of this debilitating disease. As well, Fluoradopa, another agent that is on the research horizon, has been used for neuro-endocrine tumor imaging, as well as for treating or diagnosing Parkinson's and movement disorders. Also, cardiovascular profusion viability agents are being developed, fluorine-18 labeled preferably, and that allows us to not just use them at an institution that has a cyclotron on site, which is the academic research centers, but these agents are labeled with fluorine-18, 110-minute half life, allows us to deliver them to the community essentially for distribution through PET centralized radionuclear pharmacies.

Also agents are being developed to monitor therapy, regular therapies such as chemotherapy, radiation therapy, anti-angiogenesis therapy. We can do pre/post therapy administrations to observe how that progress is going. Should we continue it or should we stop? It's not being effective. So this, again, non-invasively is able to monitor therapies. Also, the new device, the CT PET device, which essentially fuses CT, looking at the anatomy, with the PET image that shows us the metabolic state of these processes, exact locations in the body -- I don't

know if you've ever seen this CT PET images, but they are pretty phenomenal as far as the information that they allow clinicians.

Overall, ACMUI supports the proposed EPAct categorization of accelerators and endorses not regulating the therapy accelerators. ACMUI also supports high compatibility across state lines for mobile PET licensing, for centralized nuclear pharmacy, again, allowing the flow of radiopharmaceuticals for patient use and not prohibiting their movement across State lines.

Also, we would like to see standardized training and experience requirements. Again, this allows trained personnel to be employed in various States under a single kind of training and experience requirement.

Some of the concerns that ACMUI has voiced – one is just maintaining the availability of PET radiopharmaceuticals for research and clinical practice. Both are essential. We are concerned about the timeframe of these legislations as far as the requirements for particularly the research group.

I have talked with the NRC staff regarding institutions which are involved in human research, specifically the licensing -- the legislation talks about cyclotron facilities licensed as pharmacies with the State or licensed with FDA. We have a cyclotron facility at our institution

that is not licensed as a pharmacy. It is not licensed with the FDA. So essentially, we are still performing research, clinical research studies.

So there is some problem in that -- in talking with the staff, what they pointed out was that all of these academic research centers work under the auspices of the radioactive drug research committees in our institution, the RDRC's. And these, they look at as an arm of the FDA. So they assured me, and I'm relaying this to the community, that this is acceptable, that they don't, in fact, have to be licensed as a State pharmacy or as a -- with the FDA, per se, but that they are acting under the auspices of the FDA through the RDRC Committee at their institution.

Again, another issue of concern was noncommercial distribution of PET radionuclides for research and development. Again, the staff has assured me that this is really not a problem. There are academic institutions that are producing radionuclides for distribution to other non-medical facilities, other academic situations, institutions, as well as into the industrial sector. And they said this is covered under the current Part 32; that we don't need additional legislation to cover these PET radionuclides for distribution from these centers.

Also, another concern was the impact of decommissioning financial assurance. It does create a special hardship for older facilities. For example, in our institution, we have two positive ion machines.

They're old 16 and 15 MEB machines. And in order to decommission these two machines, it will cost our institution a million dollars. And again, to assure the decommissioning of these machines, it will be an increase certainly to our financial assurance.

Also, there are concerns regarding the 16 MEB cyclotrons, which are in -- they are above the threshold for neutron activation, so they will require decommissioning assurance. And again, there are machines in the commercial sector: the GE's, the IDA's, the Echo machines, all are the larger 16 machines, roughly, MEB machines used in centralized PET pharmaceutical production.

So again, it's just, as these licenses come into these regulations –- not that I'm saying they shouldn't face these costs, but the timeline is an issue in terms of for us at our institution, thinking in terms of an existing NRC license, that an amendment should be within six months after February 2007 for submission of the amendment, and then a year following, possibly, to be in compliance, will be a very difficult if not impossible task for us.

I also know that the NRC staff has discussed the waiver dates and this is something that, again, has not been clarified, but they did mention that they will break the non-Agreement States into groups, and that there will be different waiver dates set for these.

Certainly, I ask you to at least consider the non -- the academic sites that, again, are a little bit harder to respond than commercial sites, as well. They kind of need a different kind of consideration.

I'm sorry. The next slide, please.

The aggressive implementation schedule, again, may be difficult for new NARM licenses, as well as NRC in terms of accomplishing it, as well as the older facilities -- mobile PET, freestanding PET facilities as new licenses, and our academic sites as being the older institutions.

Again, license guidance is needed at the publication date of the rule, which I know you're aware of. But we feel that this should be vetted license guidance, as previously made available to ACMUI so that we could at least review that guidance before it is published so that we could refine and clarify this as far as licensees.

Next slide, please.

As NRC is moving all RAM under a single umbrella, essentially similar to State regulation, which they have done for the last 40 years, I just want you to think about the fact that this State organizational structure has required years to put into place. And typically the States, when NRC changes regulation, are allowed three

years after the effective date to be able to come into compliance. So, again, with your own existing NRC licenses, it is something to think about, that these waiver dates could allow us the fullest extension possible. This would at least give us additional time to be able to come into compliance. And again, in terms of -- I mentioned previously allowing a sufficient time interval for all the States to come into compliance, and I can't stress that to a greater extent.

But also, just as an aside, FDA, another Federal agency, has been in the process of regulating -- establishing regulations for FDG for the last 11 years. We still do not have regulations that have been published for the preparation of FDG, though this has been an ongoing, regular discussion for 11 years. They are hoping to publish these regulations this year, and then we will have two years after the effective date to come into compliance.

So, again, this is a science, a clinically used process that really does need -- just the thought that it takes time for us to be able to accomplish these tasks and not to essentially suppress the research that is ongoing as the regulatory framework is being put into place.

COMMISSIONER MERRIFIELD: Clarification. By your third bullet, you're in the process of FDA. You're not suggesting that we take ten years?

DR. SCHWARZ: No, no, not at all.

COMMISSIONER MERRIFIELD: That is not the model that this Commission generally accepts.

DR. SCHWARZ: No, no, definitely not. Just, all that I'm saying is, it has been a significant process to try to resolve even one portion of this regulation. Now we're beginning to discuss regulating our accelerators and regulating our facilities.

Medicare, again, has extended its coverage as of May 8, 2006 to cover all cancers under the new PET registry. And this will, again, significantly increase the numbers of PET studies, the numbers that are able to actually have PET studies performed.

COMMISSIONER JACZKO: Just to clarify that: You showed previously a projected increase to 2 million PET –-

DR. SCHWARZ: Right. This is something that –-

COMMISSIONER JACZKO: Does that in include was –

DR. SCHWARZ: I'm not sure that it was included because that projection was done prior to this being accomplished. It may include that, but it may not. I have a feeling that it doesn't fully include it.

Radium-226 as a discrete source is obsolete for medical clinical application since 1989, and there are no other discrete sources that we are aware of similar to radium-226 expected for medical research

use.

The overall number of radium-226 sources remaining in inventory is unknown, but it is felt that it is much, much less than the IAEA Code of Conduct for category 2 sources. Thank you for this time.

CHAIRMAN DIAZ: Thank you. Mr. Brown?

PRESENTATION BY MR. BROWN

MR. BROWN: Thank you. First over all, let me thank the Commission for the opportunity to come speak with you this morning. We have been working with NRC staff very closely since last August, so it is nice to come and speak directly to the Commissioners on this important issues for the medical community.

CORAR, as you know, represents the manufacturers. It is the North American trade association for the manufacturers of radiopharmaceuticals, medical radionuclides, and radionuclides used in research, biomedical and other research. CORAR has also been working very closely with the American College of Radiology, the American Association of Physicists in Medicine, and the Society of Nuclear Medicine.

We can skip over the acronyms. They're there for your reference. If we can go to slide number 3.

First of all, some general comments on the NARM

rulemaking. We feel the staff has put a tremendous amount of effort into the rulemaking. They have accomplished an incredible amount of work in a very very short period of time. The staff, both the NRC staff and some of the Commission's personal staff, has been very, very helpful in understanding the medical community's needs and working with us to work to a logical conclusion on this rulemaking.

Also, it's fair to say CORAR members are generally pretty pleased with this rulemaking. For a long time, we have been in favor of including NARM in the Atomic Energy Act, and we have been very supportive of this. Frankly, we're pretty pleased with this rulemaking. We do have some technical comments and some minor fixes that need to be done during the rulemaking process, however.

Next slide.

Let me discuss some favorable sections of the draft rulemaking, as we see them. First of all, the delineation of the three different types cyclotrons. This was a very, very difficult topic, since the Atomic Energy Act did not really grant –- or since the EPA Act from last year did not really grant NRC the authority over cyclotrons, obviously every time we turn on a cyclotron, to some degree there is some neutron activation with the higher machines.

So NRC staff had a very difficult time in determining how to

not include the cyclotrons but include the materials. So we feel they have done a very, very good job and a very appropriate job in dividing the cyclotrons up into three different categories and regulating two of the three. We are very pleased with that.

Also, we are very pleased with the grandfathering in Part 35, authorized users and authorized nuclear pharmacists. We feel this will be very, very helpful to licensees. For example, if we have an authorized user or an authorized nuclear pharmacist under an Agreement State now, or even under a non-Agreement State, and they transition to an NRC license, they can be grandfathered if they've already been doing that work. If they've been working at a facility for ten years doing that job, they can grandfather under a new NRC license. So that's something that will be very, very helpful for licensees in the field.

Also, in NRC's waiver they published several months ago, it will really allow for a very seamless operation. It will allow time to transition from the old rulemaking structure into the new rulemaking structure. So the waiver will be very, very helpful.

Also, we understand, talking to NRC staff, that they are planning another workshop once the draft rule is published, and we are very pleased with that. As I said before, we feel there are some technical corrections that need to be worked out, and we feel this

workshop is a great opportunity to do that.

Next slide.

Let me discuss some concerns with the draft rulemaking. There's been a lot of talk about compatibility level. We are looking at -- Most of our comments dealing with compatibility don't fall back to the definition of byproduct material. They are on several other parts of the rule in the compatibility level B.

Our concern with the whole compatibility level B issue is, even though a lot of these regulations are assigned to compatibility level B, which is a very high level, they're really not being implemented uniformly across the States.

Some examples of this are the sealed source registry. If one of the CORAR member companies goes out and gets a sealed source, on the sealed source registry in one State, it is not necessarily recognized by another State. So even though there may by adequate regulations, some of the States don't recognize there are other sealed source registries. Some States don't recognize the NRC's sealed source registry.

So even though some of these have very high levels of compatibility, it's very difficult for manufacturers that are trying to engage in interstate commerce to deal with all 50 States when sometimes there

are disparate regulations.

COMMISSIONER MERRIFIELD: Could you repeat that last comment regarding States not accepting the NRC's registry? Is that what you said?

MR. BROWN: We have specific examples of States not accepting each other's sealed source registry. I may have misspoken. If I said that States won't accept NRC, I shouldn't have said that. It's one State not accepting another State's sealed registry.

Also, we feel reciprocity needs to be done between the States, especially in the case of sealed sources, authorized nuclear pharmacists, authorized users, and RSO's. We have several examples where, in one State, someone may have been a practicing RSO in one State under an Agreement State license, and when the company wants to move them to a nuclear pharmacy into a different State, all of a sudden, they are not qualified to be an RSO in that new State.

Even though they may have been doing that job five years, ten years, 15 years, 20 years in another State, that new State may have requirement to have a bachelor's degree in health physics that the old State didn't have. So even though that RSO may have been serving in that capacity in another State, in an identical facility, all of a sudden, he is not qualified to be an RSO in the new State.

Also, we have a need for some specific PET-derived air concentrations DACs in Part 20. NRC was faced with a difficult challenge because some of the derived air concentrations for some of the PET nuclides, in particular, oxygen-15 and nitrogen-13, the States had different DACs, depending on which State you looked at. So rather than try to resolve that difference, the NRC chose to go with the default value for O-15 and nitrogen-13 for the DACs. However, that default value is 15 to 20 times higher than it would be if you calculated a specific DAC.

So this is something we have been talking to NRC Staff with. CORAR plans on filing a petition for rulemaking, asking NRC to adopt a specific derived-air concentration for those two radionuclides. It is our hope that NRC staff and NRC will be able to work that into this rulemaking so that our petition for rulemaking and this rule can be finalized at the same time.

Next slide.

There is also some concern about financial assurance for decommissioning. As Sally mentioned, there's several cyclotrons out there, especially the lower energy cyclotrons, specifically less than 11 MeV that are self-shielded. And because they are self-shielded and because of the low energy of the accelerated particles, they have a

tendency not to do neutron activation.

So consequently, our interpretation is, if you look at Part 30 and you look at the pending C values and look at the 120-day half life, those facilities will not have to post a decommissioning bond in order to get their license. So this is something we are going to look for clarification from NRC staff on. That's our understanding, and that's the way it's being explained to us. But we will put that in the form of a formal comment during the rulemaking process.

Also, many States recognize some PET cyclotron operators and some PET engineers as authorized users in their individual States, which is a good thing. However, there is no provision to grandfather these into new licenses and into new NRC licenses. So this is something we would like to see, the grandfathering of cyclotron engineers and cyclotron operators, grandfathering just like authorized users and authorized nuclear pharmacists. So, once again, that is a common word we continue to work with NRC staff on.

Next slide, page 7.

The last concern we have with the draft rulemaking is on the new fee structure. We understand NRC's fee recovery process. However, we feel in some cases, this will be a financial burden for some licensees.

In some particular cases, if a facility, a cyclotron facility in particular, is in a non-Agreement State, right now they may have no license fee, they may have no registration fee, they may have nothing. When they transition to a new NRC license, they will have –- they'll go from paying very low fees or no fees to paying fairly high fees. We recognize that NRC is kind of backed into a corner on this because of your fee recovery processes, and maybe there's not a lot you can do about it. But this will be a financial burden for quite a few small licensees. Next slide.

I have a couple of quick comments about the secure transfer portion of the EPAct. CORAR really feels that radiopharmaceuticals and medical radionuclide shipments really do not warrant an inclusion under the secure transfer rulemaking. Looking at Congress' intent, going back to 2003 when this was being discussed, I'm going to read a small portion of congressional -- from the report of Congress on this.

It says, "The NRC should focus particular attention on identifying radiopharmaceuticals and other medical materials for appropriate exemption from the new regulations to assure the uninterrupted availability of these materials to patients that need them."

Talking to NRC staff, we believe it is their intent not to include radiopharmaceuticals and medical radionuclides in secure

transfer, although we have not seen the draft rulemaking yet, we really can't make that determination. So we hope that these materials, these smaller sources, can be exempt from secure transfer. If it involves IEAA Code of Conduct cat 1 and cat 2 sources, we feel that is appropriate. Anything less than that, we feel may be overkill.

Slide 10.

In summary, thank you once gain for the opportunity to come present directly to you. CORAR will continue to work closely with NRC staff on this rulemaking, and we hope we have the opportunity to come and speak with you again.

CHAIRMAN DIAZ: Thank you, Mr. Brown. Commissioner McGaffigan?

COMMISSIONER MCGAFFIGAN: Thank you, Mr. Chairman. I'll start with you, Pearce. During your discussion of Section 652, you talked about only limiting 652 to those who have currently increased controls. Does that include everybody who has cat 1 and 2 materials, or do you mean by that only those who have common defense and security controls under NRC order?

MR. O'KELLEY: Cat 1 and cat 2; both orders and the increased controls.

COMMISSIONER MCGAFFIGAN: Both?

MR. O'KELLEY: Yes.

COMMISSIONER MCGAFFIGAN: So you are in alignment with me then. That is a good clarification, because I was worried there for a second.

On Section 652, one of the things that concerns me is the pace at which we are getting to it. Arguably, if Congress was thinking rationally about security, it would have placed far less emphasis on 651 and NARM, because there is no security there -- we issued the export and import rule for radium-226 by direct final rule last month, and that took care of the security issue. The rest of it is just very complex.

But in 652, if, God forbid, somebody gets a radionuclide of concern, cat 1 and 2, a quantity of radium of concern between now and, say, 2011, and an Agreement State, assuming that we get the rule finalized in late 2008, and then you guys take three years to implement it if it is done under public health and safety -- maybe we can do it faster if it's common defense and security. But you would be -- it would be 2012. And if somebody steals some cat 2 radionuclides in 2010 and that person would have been caught, you know, Osama Bin Laden's nephew, if he had been subjected to a background check, we'll be up testifying before Congress, at least those of us who may still be here in 2010.

CHAIRMAN DIAZ: Thank you.

COMMISSIONER MCGAFFIGAN: The Chairman will be in the audience smirking, perhaps. But it just frustrates me that we are doing this sort of backwards. We should be focused on the stuff that really has security nexus first and NARM second. Instead, we're focusing on NARM first and Section 652 second.

Is there anything the States could do to do the fingerprinting faster, rather than take the normal three years?

MR. O'KELLEY: I can speak for my State, and Jared might. But this question hasn't been posed to the other States, so I don't want my response to be held against them.

As I use my country boy logic and figure out how we can do this, it would be just a modification to increase controls, and we could do it just, say, as fast as we did that.

COMMISSIONER MCGAFFIGAN: So you could do it just in a few months?

MR. O'KELLEY: Yes. It's a subset. We've already asked that these folks ensure the trustworthiness and reliableness of these people they're using now. It's just an additional step in ensuring that trustworthy and reliableness. I don't see where implementing it would be any -- take any longer than we already have. And I'm thinking, probably, in some cases this has probably already been done.

As far as fingerprints, they may not have gone through the Federal blessing, but from a State perspective, I'm sure that's what some people did to ensure that, hey, when they come in here, they would say, how do you ensure this guy's reliability and trustworthiness, and I think, well, we had his criminal history done, we did the fingerprints, we ran it through our State police.

COMMISSIONER MCGAFFIGAN: That raises the question in my mind. I wasn't intending to go there. This is always surprising. But it raises the question in my mind as to whether we could not do Section 652, the spirit of 652, faster. We have the authority now. Is it only rule and not by order that we can fingerprint under 652? I haven't memorized the section.

But if we could do it by -- if 652 is immediately effective and we can do it, I don't know -- We are talking about 1400, 1500, 1600 entities nationwide, X percentage NRC, X percentage the States, the States having a larger percentage. And we are thinking of only doing the panoramic, the radiators, and the manufacturers and distributors under 656.

But if we could do the whole ball of wax under Section 652 faster, I would feel a lot better because, as I say, 652, we asked for that. We wanted to have this authority to fingerprint key individuals. It isn't

everybody. And if you have any thoughts as to what key individuals would be at Washington Hospital Center, or Georgetown Medical Center, or George Washington Hospital, I would by interested. But we might be able to get it done faster, rather than the schedule we're on, which is a -- 652 has been postponed because it does not have a deadline, the last of the rules.

MR. O'KELLEY: The only comment is that, A, again, I didn't want to speak for all the States, but I do believe -- and somebody correct me; I'm sure they will -- that when we did the increased controls, we did get some stakeholder input from the licensees. And I don't know that we have got that information.

I heard the question earlier about how many people are we talking about. I can see in a large academic research institution, you're talking about a heck of a lot of people.

COMMISSIONER MCGAFFIGAN: Who touch category 2 and above?

MR. O'KELLEY: Well, through -- the potential is there. So I'd like to say if we are going to go this route, we might want to get some stakeholder input.

COMMISSIONER MCGAFFIGAN: Sure. In a hospital, in a category 2 at Washington Hospital Center, or GW, or Georgetown tends

to be the cesium blood irradiator. And that's the focus. That would be the focus. How many people touch the cesium blood irradiator in a way that would require background checks, in your opinion, based on the -- either folks at this end of the table.

DR. SCHWARZ: I'm not sure how many people. I know that they are in the process of putting security in place for blood irradiators at Washington University. But I don't know how people many people are at the finger –

COMMISSIONER MCGAFFIGAN: How many would you -- It isn't every janitor, presumably, who gets fingerprinted. It's the RSO and a few other folks.

MR. BROWN: And I think you'd say that the number is higher at your teaching hospitals and research centers.

COMMISSIONER MCGAFFIGAN: Okay. George Pangburn has come to the–

MR. PANGBURN: Just anecdotally, I think we can offer that under most circumstances, the number is probably between five and fifteen, but a lot of it depends on how many researches are using those blood irradiators and whether they are being used. As you know, in the briefing package we provided to you, the scope of use of that one particular irradiator has scaled down dramatically. So I think that the

numbers are going to be all over the map.

COMMISSIONER MCGAFFIGAN: I'm trying to think of the total numbers. If it's 1500 times five to fifteen, we are talking a couple hundred thousand, max, and maybe 100,000 individuals who today don't have fingerprints and background checks done that we would be fingerprinting and background checking by some date in the future under Section 652. Is that doable in a finite period of time? And I will shut up.

MR. BROWN: I think it's doable from a regulatory control program. Whether it's doable for the licensees, whether it's doable for the law enforcement agencies, and how fast they can get those done, that's one reason I urge to let's –- you know, I think the law says Federal background check, to run these through our State police, which would have the same access, or our State FBI counterparts.

COMMISSIONER MCGAFFIGAN: I think that the Federal background check is in 656. I think, in 652, it shows –-

MR. BROWN: Criminal history check?

COMMISSIONER MCGAFFIGAN: Criminal history check. And I think that can be done.

MR. BROWN: Thank you. Jared might want to --

MR. THOMPSON: Just to follow up a little bit, real quickly: Commissioner McGaffigan, the numbers will change. Whatever set you

do today, a month from now it will be different because of just the way the turnover is, the research aspects of it.

And Pearce is right: Increased controls has opened the door for us to -- we can do a little bit better, get that in place a little bit faster.

CHAIRMAN DIAZ: Commissioner Merrifield.

COMMISSIONER MERRIFIELD: Thank you, Mr. Chairman. I want to turn back to the accelerator-produced material, 651(e). I was listening to Pearce, your comments about the definitions. Remembering back to my legal training, where there is a tendency in statutory construction where folks will sort of pass over the definitions and get right to the implementing language. And the lawyers will always tell you, really you're going to spend most of the time on the definitions because that's really where it all stems from.

I guess I'm trying to understand -- I read all the comments from the States, and I see the number of the folks who think that D is the right way to go. And the heart of the concern, as you've articulated it today, is a concern that you have to go back and make a statutory change in order to effectuate that.

You're further saying that under the way in which you've implemented over years, you are using the more encompassing term of

radioactive material, and we're asking you to do a subset of that, which is byproduct material.

And I guess what I'm trying to understand is, if the State statutory authority is based on the notion of radioactive material, and that's where you are getting your authority to regulate, I guess I don't understand why that is -- because it is a broad umbrella provision, why the regulatory bodies in the State don't have the authority to construct regulatory changes under that more broad umbrella and why you feel you have to go back and get a more specific legislative change?

MR. O'KELLEY: We do have the authority under our umbrella. To get into change was being required by the NRC and the way they were initially defining category C. Please, if you take one thing out of here, take – The reason everybody said D was because of the way somebody mischaracterized C. And if that was the way that compatibility C was going to be implemented, then we couldn't say yes, we will go with category C.

We can do it. We can do it. If NRC tells us we have to have a verbatim definition from the beginning of the sentence to the period exactly like NRC's -- and that was what is coming out initially – and that's why you saw the States get up in arms, because we do have the authority under our State statute to regulate this now. We have been

doing it for years. The issue is whether NRC is going to require us to have the same words written down in our statute and our regulations just because somebody says it's got to be exactly the same. But we are going to regulate it the same. We regulate every radioactive material the same now as we do with the rest of the byproduct material. That's not going to change. Actually, that's just what we call it.

MR. THOMPSON: Perhaps, also, you used the word "have to." We do not know how many States will -– may be necessary. We know that 27 have it in statute, but we do not know how many of them will have to make changes.

COMMISSIONER MERRIFIELD: Well, we've got Mr. Brown on this side of the table who would like to go from C to B or B plus, or whatever.

MR. O'KELLEY: I think he was talking about a different issue, I hope.

COMMISSIONER MERRIFIELD: I may be confused here. I'm sorry.

MR. BROWN: But the definition of byproduct, we are not as hung up on that as we are all the other things. We would love to see everything across the board at compatibility level A, but that's a different issue. But I guess where we have a problem is, we are trying to do

business in all 50 States, and in many cases each State is different, and all the States change, and customers call us and say, well, what does the State of Kentucky require this week? We say, we're not sure; we'll have to double-check. And this is very hard when the States handle different parts of the regulations differently.

And they are very -- Within the State, it's fine, but when you try to do business interstate, it's very difficult sometimes.

COMMISSIONER MERRIFIELD: Relating back to your comment there about attempting to get more involved -- Well, no, I'm going to back away f rom that one -- Well, I may have to go back and take look at that. I'm still struggling with --Apparently, there were some comments made by our staff that got you all worked up about this; perhaps more than we had intended, and I'm going to have to go back and take a look at how that all comes together.

MR. O'KELLEY: From a State perspective, the issue is, just don't make us jump through hoops we don't need to jump through when we've already got it covered.

Just a comment: I think you will you find with this that the States will be regulating this the same way we are doing the other medical byproduct materials currently. So I think a lot of your concerns -- I understand the SS&D issue, and I that's kind of happened in one case

when people were trying to kind of push CRCPD's licensing state for NARM. But I don't think it's going to be –

CHAIRMAN DIAZ: I think I'm doing to have to interrupt you because this is a subject for a leisure afternoon someplace doing something else. Dr. Miller?

COMMISSIONER MERRIFIELD: Charlie, you want to -–

PRESENTATION BY DR. MILLER

DR. MILLER: Thank you. I'm Charlie Miller from NMSS. Thank you, Mr. Chairman.

One of the things that I wanted to make clear so that the Commission is clear is, I think the States -- as you can see, this issue on compatibility has caused a lot of emotion, and not all stakeholders agree on where we ought to be. What you see experienced and lived out was the fact that in this rulemaking effort, the staff has probably engaged the States and other stakeholders more than we ever have in my experience in other rulemakings. And what you saw were, the compatibility C was brought out as staff thinking at time.

We had a short timeframe to try to frame something. As we framed something, we shared it through our Working Groups and Steering Committees, and the compatibility C issue brought a lot of interest and a lot of emotion to the table. And all the discussions that we

had subsequent to that allowed us to do further thinking. And you heard Kathleen Schneider eloquently outline how we came out to health and safety.

So in the end, we didn't go with compatibility C; we went with health and safety because we recognized that we felt that that was where we could go to give the States the maximum flexibility, but yet compatibility D, we felt, just didn't do what we needed to have done.

So in the end – and I hate to use the term "it was sausage in the making," but that's kind of what rulemaking is. We debate it back and forth, we exchange ideas, and then we try to come up with the best proposal we can for the Commission.

CHAIRMAN DIAZ: Thank you, Charlie.

COMMISSIONER MERRIFIELD: Mr. Chairman, just a last comment on here. I understand – and, Charlie, thank you for the clarification. I understand the back and forth, and I know that the States are coming from, here we've been regulating this for four years.

I would say, as a personal view -- and I appreciate the fact that the States have been doing this. I think what Congress decided to fill was a gap in the Atomic Energy Act. If we could turn time back, we should have been involved in this thing a long time ago. But it is what it is. Congress has given us the marching orders to get involved in this

area, and we are just going to have to take it from there.

CHAIRMAN DIAZ: Thank you. Commissioner Jaczko?

COMMISSIONER JACZKO: I want to focus a little bit on some of the points that you raised, Dr. Schwarz, particularly if you could talk a little more about the mobile PET licenses. And you mentioned that that was an area where there was some particular concern with compatibility across State lines. If you could perhaps just describe what those machines are and what kind of communities they serve, what kinds of functions they fill, and what some of the issues are that you're concerned about.

DR. SCHWARZ: Again, the mobile PET is actually a camera on a truck. And it essentially moves between institutions. So it provides the ability to have these PET scans performed at different places, and some of them, across State lines. So this is just a concern that we're able to deal with having these devices not have problems working in two different States, providing radiopharmaceuticals for these types of situations.

COMMISSIONER JACZKO: Are there any specific areas where you have some concern that there may be a problem moving from State to State with these kind of –- or is it just right now, on a –-

DR. SCHWARZ: It is just a general statement; no, not a

specific.

COMMISSIONER JACZKO: Okay. Thank you. This is something I asked the staff, and perhaps this is a question for Mr. O'Kelley, or Mr. Thompson, I think you wanted to answer this. I asked about radium-226 and our approach to dealing with radium-226.

Perhaps you may have some more experience or greater access to some information on what the status is of some of the consumer products that are out there and what approaches should be taken to deal with these -- either generally licensing them or exemptions.

MR. THOMPSON: I can speak for my State. We know about where some of the antiquity stuff might be, but to say we have a handle on all of it would be near about impossible to say. You see this stuff popping up on eBay, whether it be watch dials, aircraft dials. It comes up any time. We find them in scrap yards all the time.

I don't know that you could put a number on them. And there's lots of dealers out there. These guys -- And I will give you for instance. Back about are eight or nine years ago, in Arkansas, we had a scrap dealer who had a 30-gallon drum full of dials, radium dials. And I'm not going to tell you -– Then we went back to a non-Agreement State. We don't know what happened to it after that. So they float out there.

They just float around. It's hard to get a handle on just how many of them are out there, where they're at, and who might have them.

COMMISSIONER JACZKO: How do you handle them?

MR. THOMPSON: When we find them, we get them properly disposed of. That's the only method we have to deal with anything that's below a level of an exempt source that's in the SSR's.

COMMISSIONER JACZKO: Are they considered an exempt source, then, in your State?

MR. THOMPSON: We just try to route them to be disposed of.

MR. O'KELLEY: They are not exempt sources. They're not necessarily licensed since nobody, as Jared said, knows where they are. We found some the other day. Somebody called and told us. A gentleman upstate was selling radium paint on eBay. Every time somebody goes and buys an old farmhouse, in the barn, and there is no telling what they find in the backs of those things. You know, watch dials and so forth.

I that it's probably a good direction to maybe look at it more from a risk-based standpoint, if we can put some numbers on them, whether these are risks that need to be regulated or are these risks that do not. I think it is going to ask somebody to do some additional

research.

I think, generally, licensing these is an exercise in futility almost because you don't know where they. You can't get in touch with them. And they're not going –

COMMISSIONER JACZKO: Apparently, they are on eBay.

MR. O'KELLEY: They do show up from time the time on eBay, as well as Night Vision goggles and other things that are out there.

COMMISSIONER JACZKO: I appreciate that. As I said I do appreciate what the staff is doing to try and handle this, but to some extent, there may not be a lot of practical difference between handling it as a general license or going the route of exemption. But I'm interested in hearing more from the staff on that. Those were the – I did have one other question.

This is the issue, Mr. Thompson, you brought up about -- dealing in particular with Section 656 and the Federal background check requirement. You talked about working through the State database, or through the State law enforcement agencies. Do they then process that through the FBI, or do they perform their own background check?

MR. THOMPSON: Mr. O'Kelley.

COMMISSIONER JACZKO: Oh, I'm sorry.

MR. O'KELLEY: Trish always corrects me on this, but I think one of the ladies that was with the FBI on the Energy Task Force did say that that information was available to the States, and the States use that database? Correct me again.

COMMISSIONER JACZKO: Perhaps, Trish, you can clarify this then so that -- I guess the point I'm trying to get at is, a background check that is done that way is effectively going through the Federal database or the Federal system?

MS. HOLAHAN: Yes, that's correct. This is Trish Holahan. I'm with NMSS.

The FBI person on the Energy Policy – the Chairman's Task Force said that if they got it to -- the State police had access to the FBI watch list. So it is a Federal check, but you can get it through the State police.

COMMISSIONER JACZKO: The State police. I don't know if the staff has looked at that. Maybe, Karen, you can answer this one. Is that consistent with the language that says Federal security check, or would it actually have to go through the Federal –

MS. CYR: I think we looked it. I think that meets the -- at least our preliminary look at that meets the understanding or the intent of the statute on doing a background check.

COMMISSIONER JACZKO: Thank you.

CHAIRMAN DIAZ: Thank you. Commissioner Lyons?

COMMISSIONER LYONS: Pearce O'Kelley mentioned that last week in Detroit -- I happened to be here to hear some of the discussions from a number of the State representatives with their concerns on obtaining the Governor certifications. Certainly, as you said, I did hear some very –- at least, stated to be very substantial concerns.

I have to admit, though, that I went away thinking that perhaps some people were trying to make mountains out of molehills and that it just didn't strike me as nearly as hard as what was being portrayed by some of the speakers. So I actually went away quite optimistic from that discussion.

I guess the only question I have -- and I don't know if it for Mr. Brown, or Ms. Schwarz, or maybe a combination of both of you.

But, Ms. Schwarz, you mentioned complications with mobile PET facilities that cross State lines. Mr. Brown, among other things, you mentioned concerns with distribution of radiopharmaceuticals to different States that have somewhat different interpretations of the rules.

I guess what I'm wondering: Are there cases now where, for example, States are not able to bring PET facilities across the State line

so that there are areas of the country that are not receiving the benefits of the PET scans? Or, from Mr. Brown's standpoint, are there States where the differences between State regulations are sufficiently onerous that R&D is being precluded in some States?

I'm just trying to get a better handle on how much of a concern, perhaps, we should have on these State-to-State differences, or whether the community has found ways to work around, effectively, whatever differences currently exist?

MR. BROWN: I can give you a good example of a distribution problem. And this is a real-life situation that happened a few years ago, and it was one of the last NARM radiopharmaceuticals to be approved. This NARM radiopharmaceutical was approved by the FDA in an NRC State. The State where it was approved, the State where it was being manufactured, was not an Agreement State; it was an NRC State. So, consequently, it did not have a NARM license for this product. So that the manufacturer in this non-Agreement State tried to distribute it to all 50 States and went State by State and said, okay, what do you need in your State, what do you need in your State? Some States said, as long as it is FDA approved, bring it in, we don't have a problem it. A couple of States said, well, you have to have some State approve it, from a radiological standpoint.

So the company went to their local State and said, will you review it and approve it, and the State said no, we won't do that. The company went back to the States that would not accept it, and they said, well, what you need, then, is a State that is touching the State from where it's being manufactured to review it and approve it.

So the company went to the four States that were touching the States where it was being manufactured, and now the States said, no, we won't do it, but one of the States said, if you get another State to review it first, we will review their review, and then we'll review it, and then you can get your approval in the State where you want to manufacture it. Then you can distribute it to all 50 states.

That whole process took about ten or 11 months. So it was a case where this new diagnostic radiopharmaceutical, which was a very good and effective radiopharmaceutical, was used immediately in probable 30 States, and in maybe another ten States, it was used within three months, and then the last two or three States, it took close to a year to get it into those States.

So that is the sort of problem we have with the current system that is supposed to be compatible. NRC staff has pointed out that 32.72 now is a compatibility level B. What that means now is that a new NARM radiopharmaceutical, if one were to come out, it would be

clearly a compatibility level B situation. So I'm hoping from that, what would happen with a new non-radiopharmaceutical, it would be compatibility level B. So once the FDA approved it and the NRC approved it, in the same example, then all 50 States would accept it. But that is not clear to me that would happen.

DR. SCHWARZ: I just wanted to mention, in terms of FTG, it is not an approved drug, so again the indications are approved. So that makes the licensing of this particular entity a little different in terms of previous radiopharmaceuticals, as well.

So coming from misery, we are a non-Agreement State and really non-robust regulation within our State generally. So it's curious to me as to how things will proceed. We are not quite sure. We really have not had State regulation, and we have had NRC oversight for our byproduct materials. But this is a new world that we step into. And in the case of many of the non-Agreement States, not many, but certainly there are others similar to Missouri. So we are just concerned about, what does this mean as we step forward?

COMMISSIONER LYONS: But in the case of the non-Agreement States, I would have thought, if anything, moving into the new regime would simplify.

DR. SCHWARZ: Well, additional regulation does not ever

necessarily simplify things.

(Laughter.)

COMMISSIONER MERRIFIELD: We try.

(Laughter.)

DR. SCHWARZ: Thank you.

COMMISSIONER MERRIFIELD: That was understated.

CHAIRMAN DIAZ: I think I need a drink.

(Laughter.)

CHAIRMAN DIAZ: Let me start with a little comment. This is the second time today that I used this phrase: be careful what you ask for, you might get it. And that's why we are going through these pains right now. I do believe that the intent of the Commission, when we ask for something, is clear, and now I guess we will have to come to the realization that we have to exercise what the Congress has given us as an obligation.

Let me just come to another point. It is highly probable, if not most probable, that it will be the last time that I address the Agreement States and CRCPD in my present position, so I want to make the best of it. And I don't have time to ask a question. I have to ask my fellow Commissioners to meet me in seven minutes upstairs, if they can do that, or by 15 to 4:00.

So I'm going to finish my engagement with you with something that I think has been alluded to and is in everybody's mind. But I think we need to come to grips for. In all of my ten years in the Commission, we're always dealing with the State issues, as we should. I am very pro-federalism. I think I have shown time after time that that is the right way to go.

The Commission has been working with issues back and forth. We take different positions. Sometimes we go forward, and sometimes we go back. But eventually there is an issue that remains is that, for this great country of ours, is very important: that certain things be treated with a consistent national approach. And you have one of those issues in your hands.

I think it will benefit this country, instead of arguing about the legislation to eventually receive recommendations from the Organization of Agreement States, and CRCPD, and ACMUI, and CORAR on how we can better ensure a realistic -- because it's not going be perfect -- realistic consistency of dealing with radiopharmaceuticals and other substances that have to cross borders in this country.

We keep going from viewpoint to viewpoint. But you guys have to handle it. So I'm going to ask you personally to send a letter to the Commission with your views on, how can you get a better consistent

national approach on the handling of radiopharmaceuticals, radioactive substances and byproduct materials, because I think it is important that we hear unabashed and totally free from everything, so that you would do that better, and to better serve the people of this country.

And with that, we are adjourned.

(Whereupon, at 3:45 p.m., the meeting was adjourned.)