UNITED STATES OF AMERICA

U.S. NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING

PROPOSED RULE: REQUIREMENTS FOR EXPANDED DEFINITION OF BYPRODUCT MATERIAL (RIN 3150-AH84)

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AUGUST 22, 2006

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LAS VEGAS, NEVADA

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The public meeting convened in the Pacific Enterprise Plaza, Building No. 1, 320 Pepper Lane, Las Vegas, Nevada 89120 at 9:00 a.m.

Present on behalf of the Nuclear Regulatory Commission:

SCOTT W. MOORE

LYDIA CHANG

SUSAN CHIDAKEL

DONNA-BETH HOWE

JOSEPH DEUCHER

VIVIAN L. MEHRHOFF

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

9:00 a.m.

MR. MOORE: Good morning and welcome. On behalf of the NRC, we really appreciate everybody being here today. My name's Scott Moore, and I'm chief of the rulemaking and guidance branch in the office of Nuclear Material Safety and Safeguards.

We're having this meeting in hopes of receiving public comments on the proposed rule and requirements for an expanded definition of byproduct material. It's also known as the NARM rulemaking. We committed last fall during our roundtable meeting to try to hold a meeting out west during the public comment phase when the proposed rule is out, so here we are.

You have agendas in your information packets; and if anybody didn't get an information packet, you can from Vivian in the back. I'll begin this morning with some introductions and some logistical comments, and that's going to be followed by Mr. Deucher, who will cover safety and security announcements. Then we'll have some general remarks and a presentation on the proposed rule. We should begin taking comments around 9:45, and we'll take comments until noon.

I'd like to introduce our folks who are here today, beginning with Lydia Chang. Lydia will be making the technical presentation this morning. She's a senior project manager in my branch and she's the primary author and lead for this rule. She heads up the working group that developed the proposed rule. Lydia, if you could identify yourself.

We're joined by Dr. Donna-Beth Howe. Dr. Howe is a medical physicist in our Materials Safety and Inspection branch. Dr. Howe serves as a key technical expert on the working group, especially in the area of medical regulation.

We're also accompanied by Susan Chidakel, an attorney in our office of the general counsel. Ms. Chidakel is the lead attorney for us on this rulemaking.

In addition, I'd like to recognize Vivian Mehrhoff in the back. Vivian is from NRC's Las Vegas office. Vivian's assisting us with logistical support.

And also Mr. Joseph Deucher, who will be speaking to us in a moment from NRC's Atomic Safety and Licensing Board panel. Mr. Deucher is the facility manager here. We appreciate being able to use these facilities for the meeting.

Now a few important administrative points. This meeting's being transcribed by a court reporter, Mr. Floyd Stephens. So when you give your comments today, you can be assured that they're going to become part of the official record for the rulemaking process. I've been asked to let you know that before you provide any comments please state and spell your name for the record. And I'll remind you of that when we get to that stage.

If you prefer not to give your comments verbally today at the mic here, then you can present them in writing to the court reporter. So you might want to be thinking about that if you don't want to get up in front of the group. If you'd like to have your comments read into the record today, you can write them down and give them to us and tell us you want them read to the entire group today to give people a chance to think about that. It's your choice.

Otherwise you can also just hand them to the court reporter and we'll take them and have them docketed as part of the rulemaking record, if you just want to provide them in writing but don't care if they get read to the whole group. Of course you can always submit them to us via fax or email or mail during the

public comment period.

We're here today until noon. We'll take a break around 10:45 a.m. and continue to take comments after the break. I'd ask that you keep in mind we'd like to give everybody a chance to speak who wants to provide comments today. I don't think that's going to be a problem with the time. So if it looks like there is going to be a long list of speakers, we may ask you to try to keep your comments to a reasonable amount of time.

To gauge the available amount of time and to assist with the transcript, we'd ask that anybody who wants to provide comments today to sign up with Vivian in the back where you came in the door. That'll also help the court reporter as well.

After everyone who's had a chance to speak has signed up and had the opportunity to provide comments, then we'll also take additional comments from anyone else in the audience as long as time permits up until noon.

An important note about our format for today. Following Lydia Chang's presentation we'll move into the public comment period. We're seeking your comments and statements about the proposed rule, so we will generally not be responding to the feedback

right now in this forum. If you have questions for clarification about the rule, I'd encourage you to approach us during the break or afterwards. Our goal while the rule is out for public comment is to take comments of all types on the proposed rule.

And with that, I'd like to say good morning. Thanks for being here. We're glad that you could make it here to the public meeting. And I'd like to turn it over to Mr. Deucher.

MR. DEUCHER: Good morning, ladies and gentlemen. Again, on behalf of the Nuclear Regulatory Commission, I'd like to welcome you all to our facility. Just a few brief comments before we begin.

Should there be an emergency in the facility, as you see, we have two clearly marked emergency exit doors here in this room. Also, immediately upon leaving the hearing room, straight back we have an emergency exit, as well as through the lobby would be areas of exit.

In addition, our public restroom facilities and our drinking fountain facilities are located to your immediate right when you leave this room, should you avail yourself of the facilities. In addition, we also ask that there be no eating or drinking here in the facility, with the exception --

in this room, with the exception of water. Also, if you have any questions or require any assistance, please see me or any of our security staff. Thank you.

MR. MOORE: I want to start off with a few general comments on rulemaking. The writing of regulations is one of the most important things that we do at NRC. Regulations are important because they're our vehicle for implementing national and international policy, and for achieving NRC's goals for maintaining safety and security. They, of course, translate into what is actually happening out in the field. It's an extremely important activity to us.

One of the most important parts of the activity is what's happening here today. It's the opportunity for public stakeholder involvement in the rulemaking process. We take public involvement very seriously and we want your comments. From that perspective, I really appreciate your being here at this meeting. I encourage you to share your comments and perspectives with us. That input will help us to get the best regulations in this and every area that we work on.

With regard to the rulemaking on expanding the definition of byproduct material, I begin by

saying that this endeavor has been probably one of the largest rulemakings that we have undertaken in the past decade or two and we have been moving at an incredible speed. Congress gave us 18 months to promulgate a final rule from the time that the Energy Policy Act of 2005 was enacted last August, just 54 weeks ago.

Two-thirds of that time has passed, and we now have a proposed rule on the street that expands the definition of radio -- of byproduct material to include discrete sources of radium-226, and accelerator-produced radioactive material, and includes the associated requirements to implement the expanded definitions. We're moving rapidly towards the statutory mandate to have the final rule issued by February.

We've not gotten to that point alone. We received considerable support from agreement and nonagreement states on the working group and various other Energy Policy Act functions. We also took substantial input last November at the roundtable discussion public meeting as we were beginning to develop the proposed rule from industry, professional organizations, members of our advisory committee on the medical use of isotopes, federal agencies, and

states.

In the end, the proposed rule represents NRC's best effort to balance input and information from various sources while providing a regulatory framework that protects public health and safety, and provides for the common defense and security.

I want to point out a very key point here. We want to make sure that the rule that we put in place will serve everyone's needs, but we need to know what those needs are. We need to continue to work with the states and we need your input today. Similarly, other stakeholders need to provide input so we can understand your perspectives. So I want to take this opportunity to thank all of the stakeholders involved for their efforts, both for past and future activities. A special word of thanks should go out to the Organization of Agreement States and the Conference of Radiation Control Program Directors for their organization's assistance on this rulemaking. And I appreciate that the OAS is represented here today.

As I said earlier, I encourage you to participate in our rulemaking process by providing comments on the proposed rule. If I may provide a specific suggestion.

In my review of rules as they come through me as the branch chief, I do look very closely at the public comments and how we answered those public comments. I cannot underscore the importance of the public comment process. The comments that we are looking to you to provide to us today and throughout the public comment period are important, and we look to those to shape the rule. We can put out a proposed rule, but we look for public input to mold that into a final rule.

We particularly examine the agreement state comments. The agreement state comments are important to us. We may not always agree on issues, but we absolutely give them thorough review and consideration, and we often do come to the same conclusion with our co-regulators. We do hope that we will get comments from you today, and we will consider them seriously as we put together the final rule.

I encourage you to speak candidly today and to provide input to us. Your comments will help us enhance the NARM rule and provide an important tool for maintaining the safety and security of our nation. We appreciate everybody being here. And with that, I'd like to turn it over to Lydia.

MS. CHANG: Before I start, I just want to bring to your attention of the information packet that we have provided. Your packet, to the left-hand side, we have included today's agenda, of course my presentation, and then we also have a public meeting feedback form. We really appreciate you take the time to give us feedback so we can improve in future meetings, not just in NARM rulemaking, but for all NRC public meetings.

Following that -- following on that, we have one sheet of paper on how to submit your comments. There are many ways you can submit your comments. You can either mail to us, send us a email, go through our NRC rulemaking web site, hand delivery, fax, or present them today.

I also include a map of the agreement state and nonagreement state to at least, let you know which one is -- if you are looking in a state, whether you're NRC regulated or agreement state regulated.

And then after that I've included two Federal Register [notices]. One is the waiver that we have published last year, back in August [2005] and another one's the notice of availability of our web site. We will continue to put information on our

web site. So if you want to know what's going on, just go to the web site and, you'll know, read some of the background information.

Now on the right-hand side of the packet we have the proposed rule. We have the Federal Register of the proposed rule. We also have the regulatory analysis. That's our basis in making some of decisions. And then we have the environmental assessment. So those are all the supporting documents that we have on the rulemaking.

Okay. Again, my name is Lydia Chang, and I'm just going to summarize the NARM rulemaking process. Today, I will (sic) just generally going to sum up the background information and then summarize the proposed rule, and then go over the next steps.

The Energy Policy [Act] was passed into law on August 8, 2005, and it became (sic) effective immediately. The Energy Policy Act gave NRC authority over additional radioactive material by changing the definition of byproduct material to include discrete sources of radium-226, accelerator-produced radioactive material, and discrete sources of other naturally occurring radioactive material that pose a threat similar to discrete sources of radium.

Based on the working group's analysis, we do not believe there is any other naturally occurring radioactive material that fits on the third category. So even though in the byproduct material definition we did include that, but we have not identified any radioisotope that will fit in there.

We also publish a one-time waiver back in August 31st [2005]. And I have the citation over here for your convenience. That was necessary since the Energy Policy Act was effective immediately, and we do not want to impact the individuals and also the agreement states. Therefore, we published a waiver to allow the person that's owning, using, and otherwise engaged in activities involving the NARM material to continue with their activities; and also to allow the states to continue to regulate the NARM material. As you know, most of the agreement states and some of the nonagreement state have already been regulating this material for quite some time.

The NARM rulemaking, the Energy Policy Act requires NRC to issue a final rule within 18 months, which is a very, very aggressive schedule. Normally a rulemaking of this complexity would take at least two or three years. So we are all being challenged by congress.

The Energy Policy Act also requires us to consult with states and other stakeholders. As I mentioned before, states have been regulating them for quite some time and we really want to gain the experience and fold into our regulations, and to cooperate with states and use their state standards to maximum -- to the maximum extent practicable; and also to consider the impact on availability of radiopharmaceuticals to the physicians and the patients. We definitely want to have minimal impact and yet to be protective of the public from safety and public health perspective.

So NRC's approach to meet this aggressive schedule that has mandated by the statute is to involve the states as early as possible. We are very pleased that we have so many agreement states; and also include nonagreement state to participate in our working group, and also in our steering committee and also our task force.

The working group is the primary group that has been developing the rulemaking, the regulations and the rulemaking documents, such as regulatory analysis and such. And the task force, we have NMSS Energy Policy Act task force, who's responsible for the implementation aspect of the

Energy Policy Act. So we also have state representation on that. In addition, we have a steering committee which oversees both the working group and the task force. And we have two state representatives on the steering committee making decisions along with NRC. So it's really a partnering with the states, you know, for this rulemaking process.

We also used suggested state regulations for the control of radiation known as SSR's as our basis for some of our proposed languages. We also have met with many, many federal agencies, such as FDA, DOT, DOC, DHS and DOE, EPA, OSHA. Not just to understand what's their concern, but also make sure that what we develop is consistent what they are doing and there are no overlappings.

As far as the stakeholder is concerned, we had a public meeting last year back in November. And we had a very, very large number of turnout. We have more than 70 people show up for the public meeting. And we also hear a lot of the comments from the medical communities, and hopefully, you know, in this proposal we have addressed most of their comments when they brought up back in November. We also have lot of federal agency and the state

representatives in the public meeting.

(Indiscernible) our strategies to keep the public informed as much as we could, so we actually posted the preliminary draft documents within our web site to keep people informed of what we're doing and make sure the information available within the web site early on. We have included the transcript of the public meeting, meeting notices, and also the waivers, some background information on the act. And right now we have already put the proposed rule there, along with regulatory analysis, environmental assessment. We also include a commission paper in there, which is the (indiscernible) draft proposal and how we presented to the commission on some rationale and our basis in making some of the recommendations.

For the proposal, back in January, we actually send it to agreement states and nonagreement states for a preliminary review to make sure that we have -- to make sure that their comments were addressed, to make sure they don't have any major concerns on the draft. And then later on, we prepare a commission paper outlining all the rationale, along with all the rulemaking supporting documents in there. Last month, we were able to publish the

proposal in the Federal Register, and now the citation is over here.

It is only open for public comment for only 45 days because of the extremely aggressive schedule that's imposed by the Congress. We're not able to give the public any additional time. However, the draft document was available since April, early April, so hopefully you did have an opportunity to review that since April. The comment may be submitted through mail, email, web site, hand delivery, fax, or even today during our public meeting.

For the rulemaking approach, there are some key issues that we needed to resolve, such as the definition of discrete source. There were a lot of concerns on what the discrete source means (indiscernible) source, what it includes (indiscernible) or not. So we actually have a lot of discussions with EPA and also with the agreement states in coming up with the definition of discrete source. The definition is included in the proposed rule, so I strongly suggest that you take a look. If you have any concerns please provide comments regarding that.

There were also a lot of discussions on

authority of accelerator-produced, whether NRC be regulating the accelerator or just the material. And if so, you know, when it'll become NRC authority and when it'll not. There were a lot of discussions. And based on the feedback from the medical community and the agreement states, we did come up with a decision point on that. NRC (indiscernible) will be regulating material that's produced in accelerator and that's used for medical, commercial, and research activities.

So, if you have an accelerator that's only producing X-ray type of thing for either industrial purposes or medical purposes, we are not regulating that accelerator or the activated material that's produced within the accelerator. And we all make that kind of decision very early on by posing the issues and then briefing our management, and up to the commission to have the early buy-in so that we are -- we don't have to revise our rule package often.

And there were also of (indiscernible) on implementation. The timeline to implement even though the energy policy have become effective, a lot of the individuals that's located within nonagreement states were concerned whether they're going to have

enough time to put the application together or whether they're going to have time, enough time to -- whether they can still continue to operate, whether the operation will be impacted.

And even for agreement state, there's a lot of concern: when would they be transitioning from agreement state to NRC back to agreement state, and questions of that sort. So we did consider that comment, and we did come up with a very innovative approach to allow individuals to continue to operate on the activities provided comply -- provided they comply with the health and safety standards. And then we allow additional time for them to submit license amendment and license application.

For radium source we also come up with innovative approach in (indiscernible) that, as you know, even though we are not manufacturing a lot of the new devices that include radium, but back in the early 1900's we do have a lot of commercial products that contains radium-226 and they are still in circulation. And we really hate to have to specifically license these individuals, so we come up with this graded approach to allow some exemptions. And then also allow some general license so that only minimal requirements. And then we will require

specific license for, you know, for large-scale repair or maintenance type of work.

Now, I'm just going to go through part by part on some of the major changes that we have included in the proposed rule. In the Part 20, of course, we have changed the definition of byproduct material to include those three -- to include radium sources, accelerator-produced material, and also the discrete source of NARM as demanded by the Energy Policy Act.

We also have included a couple -- we also modified the definition of waste so that we would allow the 11(e)(3), 11(e)(4), which is the radium and accelerator-produced material, to have broader disposal options, which is also allowed within the Energy Policy Act. We have included couple additional definitions, such as accelerator produced radioactive material, discrete source, and (indiscernible) accelerator. Discrete source definition is required by the Energy Policy Act for us to come up with, and the other two (indiscernible) that we need to include those.

We also included some minor provisions in the disposal section. Primarily for that since there, the 11(e)(3) and 11(e)(4) byproduct material,

which is the waste from radium-226 and also accelerator-produced material, if you want to dispose in the non (indiscernible) low level waste disposal, it is allow under the Energy Policy Act, provided that the facility is regulated under the Solid Waste Act. But if you do decide to use a Part 61 disposal facility, then it will be required to use a manifest.

In Part 30, the major changes I have outlined here. Also, the change of the definition of byproduct material, which is consistent with the Part 20 definition. We added some definition, including accelerator-produced radioactive material, cyclotron, discrete source, and particle accelerators. Some of the major provisions that we have included, including the implementation approach, I have discussed before.

With implementation approach, we are allowing a 60-day effective date to be effective from the day of -- let me see, 60 days from the day of publication of the final rule to be the effective day. We're also allowing an additional six months for any license amendments. So include -- so by the time that the proposal is published you will have a total of eight months, which is two -- 60 days plus six months. So it'll be kind of like eight months for you to submit the license amendment.

For a new license application, we are allowing for an additional one year from the date of the effective day. So it would be a total of 12 [14] months by the time we publish the final rule for you to submit a license amendment.

Within the regulations, we also included exempt quantities for some of the radionuclides included here in lists. And those radionuclides we basically -- are included based on the SSR's that we have from the agreement states. The values from them are between 100 microcuries and 10 microcuries; the one underlined, it's 100 microcurie and the one without underline it's 10 microcurie. So those would be the exempt quantities.

For Schedule C, which is the schedule for consideration for emergency planning purposes, we did add radium. The source is quite high, it's 100 curie. If you have more than 100 curie of radium, then you are required to consider whether you need to have an emergency plan or not.

Part 31 is our general license regulations. And some of the license provision that we have included, including some existing general license provision for detecting, measuring, gauging, controlling devices. In the existing regulation,

it's for americium, and we have added radium into the list. We also have calibration sources that we also have added radium into the list in addition to americium. For the in vitro clinical and laboratory testing we have added cobalt-57, which is accelerator-produced radionuclides within the list.

For the items in self-luminous products containing radium, this is our graded approach. We understand that there're a lot of antiquities and collector's items that includes radium, so we tried to capture a lot of these items in here, as much as possible. So right now we have included luminescent items in certain aircraft, luminescent items no longer in certain aircraft, and we also included some threshold numbers. 100 for items in air -- aircraft type of items and 50 for timepieces items that're no longer in certain timepieces.

And I guess in this area we're really looking for a lot of comments to see whether there are more items that need to be examined, whether there's more items that need to be added to the general license, whether we have included everything, whether more specific license might be needed based on health and safety concerns. So we're really looking for a lot of help from you. If you have any

data on those estimates or even concentration on those radium items, we really appreciate of getting that from you so we can do a better job.

Part 32 is our specific license regulation. And in here we also just made some minor adjustments in radium, cobalt within existing regulations. We also have talked to FDA. So we are trying to incorporate some of the languages that're consistent with FDA within our regulation so that we can recognize their program.

We have also grandfathering -- we are also putting all grandfathering clauses so that we will not be impacting the medical community. So, we have grandfathering language for nuclear pharmacists and authorized nuclear pharmacist. Also, expanding the notification process so they can continue to work as an authorized nuclear pharmacy without too much impact on them.

Part 35[Part 33], it's a specific license for broad scope licensees. And over here we basically add a few radionuclides into Schedule A for Column 1 and Column 2 values. Those are the values in determining the type of broad scope license. The -- so the change in here is very, very minimal.

Part 35 will probably be the part that

has changed most since the majority of the accelerator-produced radionuclides are used in the medical area. In here we have amended the definition of authorized medical nuclear medical pharmacist and authorized user. And within the definition, we also recognize the people, who have already been using the NARM. So in reality, it's really having some grandfather clause within the definition.

We also add a few definitions within this part, including cyclotron, positron emission tomography, radionuclide production facility. We added some additional provisions within this part, including implementation approach consistent with the Part 30 that I have described earlier, expanded the use of notification process, and also grandfathering some of the authorized users, radiation safety office, medical physicist, nuclear pharmacist, physicians, dentist, podiatrists, who has used NARM radionuclides for certain -- from certain Part 35 training. Not only they are grandfathered, but they are also grandfathered for some of the T and E requirements, the training and experience requirement within Part 35.

Within Part 35, we also allow the users to use those determination based on the value that

they obtain from the PET production facility instead of using a direct detection method. We're also requiring the label for PET drugs if they are going to be transferred for noncommercial distribution by the medical use licensees. We also allow the medical use licensees to obtain PET radionuclides and drugs from a noncommercial transfer for medical use licensee from a PET radionuclide production facility. This provision we thought was really necessary to try to improve the efficiency and effectiveness, to, you know, maximize the availability of the PET radionuclides by allowing noncommercial distribution, since a lot of the radionuclides half life is very, very short. We also established concentration limits and recordkeeping limits for strontium rubidium generators.

Here's a laundry list of all the parts that have some minor, minor adjustments because of the NARM rulemaking. As you can see, most of them just changing the existing definition to include this newly added definition. And of course Part 61 and Part 62 are primarily revised to recognize that there's more flexibility in disposal options for these additional byproduct material.

Part 110 is actually -- it's our

import/export regulation. They did publish a final rule early this year to change the definition of byproduct material since they only have one year to do that. So with Part 110, it is like a two-step approach, and we're adding couple definitions on their behalf.

Part 170 and 171, it's the licensing fee provisions. 170 is the one-time licensing fee and 171 is the annual licensing fee. And we tried to take a look at the existing fee category and tried to fit this new byproduct material within the existing framework and tried to make sure the fee is reasonable. What we have included in the proposed rule is based on 2005 fee charge. So when the final rule is published next year it will be slightly adjusted.

But within that we did amend the fee category 3B to include radium. We also included a new category for possession of items, including radium. And the fee, it's very, very low since we anticipate some collectors might be fitting into that category. Of course, we added a new category for the production facilities for radionuclides that's produced by accelerators. And the cyclotron would fit in this 3S category.

The public comment period's only 45 days. So, it'll end in another three or four weeks, on September 11th. We will continue to work closely with the states and all the federal agencies and try to improve the regulations. And we would definitely love to hear your comments so that we can address them and input the package. We are still scheduled to have the final rule published by February 7, 2007. Thank you.

MR. MOORE: Thanks, Lydia. I guess I'd ask, could you also add one thing about -- or could you speak to the waivers? You mentioned the implementation date and the effective date being 60 days after the rule, with a six-month implementation date for amendments and six -- another six months for license applications. But a complicated area, and one that we're working with on the states for the transition plan, is -- or nonagreement states on the transition plan, is cessation of waivers. And so I think it's every -- important for everybody to understand that right now everybody's covered under a waiver. And so could you speak to --

MS. CHANG: Sure.

MR. MOORE: -- the effective date really being applicable to only a small subset?

MS. CHANG: The waiver, it's really a complicated process. We published the waiver back in August of last year. The Congress allows NRC to issue a waiver for up to four years. So the maximum time allowed for the waiver is until August 7, 2009. So right now everybody's operating under the waiver to continue with their activity or continue with agreement states regulatory program.

However, once we publish the final rule then it becomes a little bit tricky, because now we have the effective date and then we also have waivers. So we kind of need to decide when we want to terminate the waiver. So the way we have approached this is to take a batch approach, a staged approach.

We feel that for federal agencies and Indian tribes, since they are not being regulated by the states and currently are also not regulated by NRC, we believe that we need to bring them into compliance as early as possible. So right now our approach is to terminate the waiver for the federal agencies and also the Indian tribe after the effective date. So they actually have 60 days to comply with NRC regulations once we publish the final rule.

And then for the rest of the agreement state and nonagreement state and the individuals within, you know, locating in the states, we are planning to take a batch approach, to terminate waivers in batches. Right now the task force is looking at grouping them into either two or three categories to terminate the waiver. And we will be publishing waiver termination at a future date, so that at least people are aware when their waiver terminate. Once the waiver's terminated, then they will have to come to compliance with the regulation. And all those will be happening after the final rule is published.

We also have received desire from several states that want to become agreement states, so that make the transition even more trickier. So hopefully that will all be factored into our transition plan. And also concerning on how we're going to batch the various agreement states and nonagreement states on how to terminate the waivers.

MR. MOORE: Thanks a lot, Lydia.

I think the thing that Lydia pointed out that's important is that the effective date itself that's in the proposed rule is only immediately effective at the 60-day point for federal and Indian

tribes. And the nonagreement states will continue to be covered under waivers until their waivers are terminated, as Lydia said, in batches. And we're working with the OAS and CRCPD representatives on that transition plan, which is a separate topic.

In your Federal Register notice, on page 42970, there's a summary of issues for public comment that we're specifically looking for comment on. And as Lydia pointed out, a number of those questions we have for public comment have to do with the radium-226 source issue. Again, that's page 42970. Thanks a lot, Lydia.

At this point, we move into the public comment phase. And I'd like to recognize Dr. Brian Dodd, who's the president of the Health Physics Society. Dr. Dodd.

DR. DODD: Thanks very much.

Good morning. My name's Brian Dodd, B-R-I-A-N, D-O-D-D, president of the Health Physics Society. I want to thank the Nuclear Regulatory Commission for holding this public meeting and for providing time for me with the opportunity to make some preliminary comments on behalf of the Health Physics Society. As the former head of the International Atomic Energy's unit responsible for

developing the revised Code of Conduct, the revised Categorization of Radioactive Sources, the IAEA's Security of Radioactive Sources interim guidance of security and documents on regaining control over radioactive orphan sources, it's also personally interesting for me to see the -- perhaps the culmination of work we started over five years ago.

For those familiar with the Health Physics Society, or HPS, it's an independent scientific organization whose members are professional in the field of radiation safety. The Society's mission is excellence in the science and practice of radiation safety. Health Physics Society activities include encouraging research and radiation science, developing standards, and disseminating radiation safety information.

Today I've got three fundamental comments on the NRC's proposed rules and the Requirements for Expanded Definition of Byproduct Material. The Health Physics Society also intends on submitting written comments prior to the public comment deadline, which we expect will include a few additional comments, but which will not be extensive or fundamental to the proposed rule. We feel we need to do some more additional research and discussion on

some details before formulating them into our formal comments.

By way of background on my comments today and on the Health Physics Society's active interest on the subject of the proposed rule, I'd like to quickly review the Society's activities in this area, including naturally occurring and accelerator-produced radioactive materials in the same regulatory framework as Atomic Energy Act, or AEA radioactive materials.

The Health Physics Society has a relatively long history of advocating for a more uniform and compatible regulatory framework for the responsible regulation of radiation and radioactive materials. Over 14 years ago, in January 1992, the Society issued a position statement titled "Compatibility in Radiation Protection Regulations." This position statement was driven by the HPS's concern over the differences in radiation regulations that exited between individuals states in their regulation of non-Atomic Energy Act radiation sources and materials, and over the differences between these state regulations and NRC regulations for Atomic Energy Act radiation sources and radioactive material.

Our concern for the non-uniform regulation of similar radiation risks grew as the basis for radiation protection standards evolved, both nationally and internationally, and as far more -- as more federal regulatory agencies exercised legislative authority over sources of radiation and radioactive materials.

Finally, in August 2000, the Society issued its compatibility position, now titled "Compatibility in Radiation Safety Regulations," to call for a single, independent federal agency to have responsibility and authority to establish all ionizing radiation safety standards for all controllable sources of occupational and public exposures. This revision was driven by the HPS's belief that the current regulatory framework for establishing and enforcing regulatory radiation safety standards results in inconsistent, inefficient, and unnecessarily expensive public health protection policies regarding radiation safety. This position, and all other Society positions, are available on the Society web page, hps.org.

It's important to note for the context of my specific comments on the proposed rules that this

call for a single regulatory agency is for the purpose of providing a uniform and centralized regulation of radiation and radioactive materials for the protection of public health and safety.

Following the events of September 2001, there became a heightened and appropriate concern for increased uniform and centralized regulatory controls on some radioactive materials for the purposes of common defense and security. That concern evolved through a number of legislative proposals, the dirty bomb prevention and nuclear infrastructure society -- security. Eventually the concerns were addressed legislatively in the Energy Policy Act of 2005, including the provision requiring expansion of the definition of byproduct material to include certain discrete sources of radium-226 and other naturally occurring radioactive materials, and certain materials produced by an accelerator.

Throughout the legislative and federal agency work to respond to this need for increased controls on sources of radiation and radioactive materials for the purposes of common defense and security, the Health Physics Society provided this input to congressional and federal agency staff on the issue of safeguarding nuclear materials and

radioactive materials. This input continued to stress that one of the fundamental reasons for invoking some of these increased controls; that is, creating a uniform and centralized control in federal agency; was also applicable to regulation for the purpose of public health and security -- safety.

Specific to the proposed -- current proposed rulemaking for the expansion of the definition of byproduct material, when it became clear that there would be legislation addressing this issue, the Health Physics Society formed a working group with the Organization of Agreement States, or OAS, to study the draft legislation for the purpose of taking a joint position on the draft legislation. In January 2005, the HPS and OAS issued the joint position statement "Congressional Action is Needed to Insure Uniform Safety and Security Regulations for Certain Radioactive Materials," which contained seven specific principles that should be accomplished by this legislation.

The Health Physics Society and OAS also jointly developed proposed draft legislation that would meet the seven principles in the position statement. These principles included the two very important provisions that: 1) the definition of a

discrete source be accomplished by rulemaking and not by legislation, and 2) that the proposed rule be developed in close cooperation with state radiation control agencies. The fundamental position that formed the basis for the seven principles was stated as follows: Our organizations believe that a fragmented radiation regulatory framework allows for inconsistent standards for the possession, use, and disposal of these sources, which can potentially have a negative impact on public health and safety and on common national defense and security.

Section 651(e) of the Energy Policy Act enacted all seven principles of the HPS-OAS position statement. However, it did not support the fundamental position that all radioactive materials subject to the expanded definition needed to be included. Rather, it qualifies materials as being those that "have been produced, extracted, or converted after extraction for use by a commercial, medical, or research activity." That is, it only requires application of the expanded definition to sources created for the purpose of using their radioactive properties, which excluded sources of the same exact radioactive materials that were produced, extracted, or converted for extraction incidentally

to some other process or activity. This leaves the large category of naturally occurring radioactivity known as diffuse NARM as not being controlled under a norm centralized regulatory framework.

With that background, I'd now like to present my three specific comments.

First, the Health Physics Society would like to congratulate the Nuclear Regulatory Commission and its staff and the staffs of the state radiation control agencies for engaging in an outstanding rulemaking process and for developing an outstanding proposed rule. The proposed rule adequately and appropriately implements the seven principles contained in the HPS-OAS position statement to the extent required by the Energy Policy Act. Our review to date has not identified any fundamental radiation safety concerns. We recognize that many details of implementing the proposed rule may be subject to comment, input, and criticism by those responsible for their implementation. Our finding of no fundamental radiation safety concerns does not imply that there are not valid comments, criticisms, or concerns about some details regarding the implementation of the rule. In fact, the HPS may have some comments about specific details in our

written submittal.

Number two, while we find that the NRC has adequately met the requirements of the Energy Policy Act in regards to the extent of what materials must be included in the expanded definition of byproduct materials, we point out that the act does require considerations of both public health and safety and common defense and security. The act restricts the extent to which the subject materials need to be included in the expanded definition by restricting its intended use, but not by restricting the activity or quantity of the material.

However, the background discussion in the section "Other Naturally Occurring Radioactive Material With Similar Risk as Radium-226" offers three reasons not to include polonium-210 in the expanded definition. One of these reasons is "polonium-210 is very unlikely to be commercially used in individual radioactive sources with activity levels that would place them within the IAEA Code of Conduct category 1 or 2.

Within the USA, the IAEA categories 1 and 2 have been associated with high-risk sources and activities of concern to common defense and security. The requirement to evaluate other naturally occurring

radioactive materials for including in -- inclusion in the expanded definition is to evaluate those that pose a similar risk as radium-226 to the public health and safety, as well as the common defense and security. Using IAEA category 1 and 2 as a benchmark for the risk of radium-226 does not meet the requirement to include risk to public health and safety. In fact, since the IAEA regards uncontrolled category 1, 2 and 3 sources as potentially dangerous to human health, the HPS would argue that the IAEA category 3 is also a threat and the analysis is deficient by at least not including category 3.

However, having made this comment, the HPS does not disagree with the conclusion of the NRC that polonium-210 does not need to be included in the expanded definition under the category of naturally occurring radioactive materials posing a similar risk as radium because of the more persuasive argument that the production of polonium-210 discrete sources for commercial, medical or research use is by activation in a reactor, and so is already regulated as a byproduct material.

Comment number three. In Section 3 of the proposed rulemaking the NRC requested comments on a number of specific issues, including item number

four, the adequacy of the applicable default ALIs and DACs in Appendix B to 10 CFR 20 for oxygen-15 and nitrogen-13, and whether staff should develop larger specific values for these radionuclides. It has been brought to the Society's notice by its members that the default values could be two or three orders of magnitude less than specifically calculated values and use of the default values would require air monitoring and ventilation systems be significantly greater than necessary. Because of this possibility, it would seem appropriate for the NRC to develop specific values for these radionuclides.

Finally, on the subject of the extent of materials included under NRC jurisdiction, the HPS does believe this regulatory action will provide a step forward in forming an excellent foundation for having uniform regulation for all materials that need control for radiation health -- public health and safety. The HPS will continue to hold the position that sometime in the future, when resources and priorities are appropriate, all radioactive materials that need to be controlled for public health and safety, regardless of their reason for production, should be controlled under a single regulatory framework.

That concludes my comments today. Thank you very much for the opportunity to provide them in this forum. Thank you.

MR. MOORE: Thank you, Dr. Dodd. I guess I'd add in your written -- in HPS's written comments, if it makes comments with regard to the alleys and decks on oxygen-15 and nitrogen-13, one thing that would be very helpful to the NRC is if the HPS advocates that we should develop specific values for those nuclides, how we might go about doing that would be extremely helpful to the staff. Thank you.

Unless anybody has specific time constraints, what I'll do is go down the list of speakers by the date that they signed up. And that would begin with Roy Brown, senior director of Federal Affairs of the Council on Radionuclides and Radiopharmaceuticals. Mr. Brown.

MR. BROWN: Good morning. My name is Roy Brown. I'm senior director of Federal Affairs for the Council on Radionuclides and Radiopharmaceuticals.

First of all, CORAR wants to thank the NRC for the opportunity to be here this morning and present these comments on the draft rulemaking. We had suggested previously that NRC hold another

workshop, or at least a public hearing. So we're glad NRC is doing this and providing the public additional opportunity to get involved in the rulemaking.

First of all, CORAR would like to comment that NRC has done a very, very good job following the congressional intent and what Congress wanted the NRC to do in terms of developing this rulemaking. We feel that the NRC has done a very good job following that congressional intent and have developed a very good proposed rule.

Also, CORAR feels NRC has done a very good job taking the comments from the public and the regulated community, the comments that were made during the first workshop and interaction with the regulated community since this rulemaking process has begun, taking those suggestions and working with the regulated community, including OAS and CRCPD, in the proposed rule. So we want to compliment the NRC with that as well.

The first substantive comment I have is on the DACs (indiscernible). CORAR was also concerned as with the -- as was the HPS with DACs, the default DACs for oxygen-15 and nitrogen-13. CORAR contracted with Dr. Mike Stabin from Vanderbilt

University to develop specific DACs for those two radionuclides. And much to our surprise, what we found is the DACs that were calculated using ICRP 40 methodology along with EPA Federal Guidance Number 13, we found that the DACs we calculated in (indiscernible) per mill were virtually identical to what NRC has in the proposed rule and they really weren't 20 to 40 times higher than they should have been. So we were surprised in that.

Originally CORAR was debating filing a petition for rulemaking specifically requesting DACs for those two radionuclides. In view of what we found with Dr. Stabin's calculations, we are not going to back away and not file a petition for rulemaking.

During these calculations it was also determined that there were some issues in conversion from beckrels (phonetic) per mill to microcuries per million in the proposed rule. We've been talking to NRC staff with that. So we will address that in specific comments to the rulemaking before September 11th.

A second substantive issue deals with grandfathering of cyclotron operators and cyclotron engineers. We had raised -- CORAR before had raised

concerns about the cyclotron engineers and cyclotron operators. There are quite a few of those out there operating at PET facilities, some in agreement states, some in nonagreement states. We're very concerned and want to make sure these folks are grandfathers, as well as authorized users and authorized nuclear pharmacists.

In the preamble in the proposed rule there is discussion that these people will be grandfathered. However, when we look at Part 30 and Part 35 in the proposed rule we really don't see anything that codifies that. So we'd like to see that codified in the rulemaking somehow if that's possible. We will also address this in the specific comments. The point is we want to make sure if these guys were operating cyclotrons before, or were cyclotron engineers before August 2005, that they continue to be grandfathered, continue to be qualified to do that.

The last comment we have is on financial assurance and decommissioning. CORAR has long been supportive of Part 30.35, 34.35 in the decommissioning funding and the financial assurance provisions. We feel those provisions and that part of the regulations are very appropriate. However,

we're concerned with operators of small PET cyclotrons. And when we say small PET cyclotrons, these are typically 18 MEV or less. We feel that these cyclotrons, really running at maximum beam current and maximum duty load, it's really not possible to generate the kinds of isotopes with the half lifes in the quantities that are address in Part 30.35 that would trigger the financial assurance requirements.

The trouble with it is to go out there and determine that your cyclotron and your cyclotron bunker do really not -- don't really trigger those parts in 30.35 is very, very expensive. It involves taking concrete core samples, analyzing those core samples, which is a very expensive process. What we would like to see is we would like to see a categorical exemption for financial assurance for PET cyclotrons based on the fact that these cyclotrons really are not capable of producing activation products that will trigger the financial requirements in Part 30.35.

We have done -- gone out and done some calculations looking at activation products from these PET cyclotrons and have determined that at maximum beam current and maximum duty load these

cyclotrons are really not capable of producing that. We will share that information with NRC staff along the way, and we'll also address this further in our written comments prior to the close of the comment period.

That concludes my comments. Once again, we'd like to thank NRC for the opportunity and thank NRC for having this public hearing.

MR. MOORE: Thanks very much, Roy.

Our next speaker is Lynne Fairobent, manager of legislative and regulatory affairs for the American Association of Physicists in Medicine. Lynne.

MS. FAIROBENT: Good morning. As Scott said, my name is Lynne Fairobent and I'm the current manager of legislative and regulatory affairs for the American Association of Physicists in Medicine, or AAPM.

For those that don't know, AAPM's mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients.

Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques, for example, in mammography, computer tomography, magnetic resonance imaging, and ultrasound. They contribute to the development of therapeutic techniques, for example, prostate implants and stereotactic radiosurgery. They collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. They are responsible for insuring that the imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission and various state agencies. AAPM currently represents over 6,000 medical physicists.

Today I'd like to first offer again thanks to the NRC for holding this public hearing opportunity. As Roy Brown indicated from CORAR, this was requested during the November stakeholders meeting and we do appreciate the opportunity for that. AAPM today, as with the Health Physics' statement, has five brief points we would like to include today, but we will be following these up with

detailed comments in writing on September 11th.

First off, AAPM agrees with the NRC's position that accelerators used to, "only produce particle beams and not radioactive materials," i.e., those used through radiation therapy, should not be included in this regulation. AAPM agrees that the intent of Congress was that only the products produced from operating an accelerator be regulated by the NRC in accordance with the expanded definition in the Energy Policy Act of 2005.

AAPM -- and I'll just shorten this, because Brian already talked, as did Roy, on the derived air concentrations. AAPM is also concerned that there is not inclusion of specific values for the DACs in Part 20. Again, we urge that these be calculated and provided in the final rule, and stand ready to assist the NRC in calculating these values. And, Brian, at this time I'll also suggest that we work together to provide a uniform set of recommendations to the NRC that we can all live with.

On the need for a distribution license for PET facilities, AAPM agrees that a distribution license should not be necessary for the PET facilities to distribute isotopes to medical facilities perhaps under contract to them. However,

we feel that clarification is needed on the definition of "medical facilities and its consortium," which is a phrase used in the preamble discussion to the rule.

Decommissioning issues. NRC should define what is meant by "sufficient quantities" in the context of "only radionuclides with half-lifes of more than 120 days that are present in sufficient quantities to cause a public health and safety concern need to be addressed for the purposes of establishing assurances for decommissioning leading to license termination." This, as currently written, is widely open to interpretation and implementation. So any clarification along these lines would be beneficial.

And third, AAPM is receiving calls from members at institutions that are impacted under the August 31, 2005 waiver. And we request that NRC clarify whether there is any additional action on the part of the licensees that are covered by these waivers that needs to be taken. There appears to be confusion, in particular among some of the federal institutions that are regulated by NRC, whether or not there's any action on the part of the licensee themselves that needs to be taken during this waiver

period.

Again, thank you for the opportunity for being here today and for having held this meeting.

MR. MOORE: Thank you very much, Lynne. We appreciate your comments.

Our next speaker is Roger Moroney, a manager of radiological compliance from PETNET Radiopharmaceuticals. Roger.

MR. MORONEY: Good morning. Roger Moroney, M-O-R-O-N-E-Y. I am also a manager of radiological compliance for Siemens Molecular Imaging, PETNET Pharmaceuticals is a wholly owned subsidiary of that group.

As part of this, we manufacture and distribute not only PET scanners, PET CT scanners, but also the compact cyclotrons that are used throughout the industry to manufacture the PET radionuclides. Through the PETNET subsidiary we operate 44 PETNET radiopharmacies in 28 different states, and are well aware of the inconsistencies going from state to state in the current regime.

We've been pleased overall with the rulemaking and with the process that's associated with this, and we do appreciate the opportunities to comment on the proposed rules.

The one area I wanted to discuss first was with the issue of compatibility. And I believe early on in the preamble to the rules you mentioned the inconsistent existing regulatory framework out there through the states. And I would like to urge as much an elevated compatibility level with the different states as we can see. Again, as a company that operates in many different states, licenses in many different arenas, we would like to be able to see a little more consistency there.

Just to elaborate a little bit on the decommissioning cost, we will be submitting written comments before the September 11th deadline. But just to expand on the core sampling that Roy mentioned, two weeks ago we had to do four core samples for concrete in one of our cyclotron rooms. And this is on a self-shielded cyclotron. Cost for those four core samples including analysis was $10,000, and they were all just -- they were negative for any induced activity. So a more elaborate facility would require, I think, quite a few more core samples than just four. This was a pretty limited trenching operation.

I would also like to reinforce, I think, Roy's comments on the inclusion of cyclotron

operators and engineers as authorized users in the PET nuclear pharmacies. Due to the usual hours of operation at these facilities, these individuals are normally there in the evenings or early in the morning hours, prior to production beginning, in order to get the maximum amount of decay on the cyclotron prior to them doing any necessary work on the machine. Therefore, they are normally there by themselves. As many of you may know, authorized nuclear pharmacists are a scarce breed, and staffing at these facilities is normally just a few people. So we would like to see, based on training and experience, that we would include cyclotron operators and engineers as authorized users a little more explicitly, if we could, in the final rules.

I had a question on the early termination for federal licensees, such as the VA Hospital, I assume, would be the primary target of this. And I didn't have a chance to look this up, but I believe the -- there's a requirement that they get their radiopharmaceuticals from a licensed nuclear pharmacy or et cetera. And I was concerned that if we have the -- how that would work.

If you have early termination of a VA Hospital, for example, and a PET pharmacy -- one of

our PETNET pharmacies, for example, in Missouri was supplying the VA Hospital in Missouri, will there be a conflict there with supplying, once they already have their license amendments to properly absorb the new byproduct rules, would there be a conflict with them accepting material from us on a commercial distribution?

MR. MOORE: We can tell you how the proposed rule is constructed now, and you can tell us what you think about that. But we can tell you how it -- the proposed rule is constructed.

Donna-Beth, do you want to handle that?

MS. HOWE: Yes. The proposed rule is set up so that the federal facilities and the Indian tribes that are recognized would -- the waiver would terminate 60 days after the publication of the final rule. So that's the effective date of the rule. And they have to comply with all the requirements in, for example, Part 20, 19, 30, 35, 34, 36, all of the regulations.

Because the manufacturer would still be covered under a waiver, then I think the requirement to receive material for somebody that's authorized would permit them to receive material from somebody covered by the waiver. If the manufacturer is

covered by the rule but the user's covered by the waiver, then the user could still receive material from the manufacturer, because we will have some period of time in which both entities won't necessarily be covered by the regulation.

But they -- the concept is that the waiver essentially gives the authorization that you would have seen in regulatory space. Does that help?

MR. MORONEY: Thank you, Dr. Howe. That's perfect.

This concludes my verbal comments. As I mentioned, we'll be submitting written comments later on. And again, thanks for holding the meeting for us.

MR. MOORE: Thanks very much, Roger.

Jared, I'd like to ask -- Jared Thompson's here from OAS. Jared, did you want to make any comments? No? Okay.

We'd like to thank OAS for attending the meeting, and I appreciate your attendance. OAS was a key contributor, as was CRCPD, throughout the process to the working group, and also our Energy Policy Act task force. And so we appreciate OAS attending the meeting. Thanks, Jared.

That was the people that preregistered.

Vivian, are there others that asked to speak?

(No audible response)

MR. MOORE: Okay. Is there anybody else in the audience that would like to speak or make prepared -- make remarks?

MS. PETULO: Can we ask questions? (Indiscernible).

MR. MOORE: Sure. Why don't you come to the microphone and state your name. And then yeah, if they're clarification type questions, we'd be glad to try to answer them. You know, we don't want to give justification for why we did here --

MS. PETULO: No. These are some --

MR. MOORE: But we'd be --

MS. PETULO: -- like definition --

MR. MOORE: Yeah. We'd be glad to try to answer clarification questions on how the rule is con -- the proposed rule is constructed and what is in it. Yeah, we'd be glad to try to do that.

MS. PETULO: My name is Colleen Petulo and I just happen to work here at EPA in Las Vegas. And I found out about this public hearing so I decided to come.

The question I have is what defines weaponization, something that can be weaponized? My

point is is it just because something is radioactive that it is perceived that it can be weaponized? Which okay, that's all right. But that wasn't brought out clear to me in any discussions that I -- or anything I've read.

MR. MOORE: Lydia, do you want to answer that? I'm not sure we mentioned weaponization at all in the rule.

MS. PETULO: Well, it's in the purpose of the rulemaking was, based on what I've read, was something about that these radioactive materials, something to do with weaponization. When I saw that -- hang on. Maybe not in your comments, might be in mine.

MR. MOORE: There's a component of the -- there's an important component of the Atomic Energy Act that gets into common defense and security, which is a key aspect under which we promulgate rules within the agency, as well as public health and safety.

MS. CHANG: And I guess one of the aspect that the energy policy was enacted is, from what we understand, that certain aspects related to dirty bomb. And some -- I guess, you know, for radium, it is possible to have sufficient quantity to making the

dirty bomb. And that's one of the reason it's listed in IAEA Category 1 and Category 2 material. But in general, this rulemaking really has nothing to do with weaponization.

MS. PETULO: Thank you. (Indiscernible) within EPA --

MS. CHANG: Uh-huh.

MS. PETULO: And maybe there's a misunderstanding or something that was conveyed to me.

MS. CHANG: Uh-huh.

MS. PETULO: I wasn't hearing that today and that's why --

UNIDENTIFIED SPEAKER: Could you speak into the microphone for the --

UNIDENTIFIED SPEAKER: (Indiscernible) please.

MS. PETULO: I'm sorry. I was extracting this information from an internal email from in EPA, and that individual may have misunderstood, which conveyed that misunderstanding to me. And when I was sitting here today I wasn't listening to anything that sounded like what this email had conveyed. So thank you for the --

MS. CHANG: Sure.

MS. PETULO: -- for clarifying. That's all I wanted, was that clarification.

MR. MOORE: Okay.

MS. CHANG: I guess another possibility is the Atomic Energy Act, when first promulgate in 1950's, it does have two components: a DOE component for the defense related operations versus the commercial aspects that NRC regulates. So this regulation's really related to commercial aspect of the use of the radioactive material, while DOE still works on the defense aspect of radioactive material. So that would be another possibility.

MR. MOORE: But we don't know what was written about it, so we can't address that. Thanks.

MS. CHIDAKEL: I think also that there are various sections in the Energy Policy Act with various implications for the NRC. And perhaps there was something that you might have seen that was outside the scope of this particular rulemaking.

MS. PETULO: Thank you. I'm just -- I'm reading in this email now. It just basically said that the origins of this proposal were for controlling access to such material that had potential to be weaponized. However, the statute as signed into law did not make that distinction.

That's making reference to the NEPA. Thank you.

MR. MOORE: Thank you.

Are there any other comments? Does anybody else have anything we can clarify that's in the rule?

Okay. With that, we will be here till noon. And we'll stay in case anybody else comes. I'd like to thank everybody for your comments. The public comment period will stay open until September 11th and we will be taking comments by mail, fax, or email. The information's provided in the Federal Register notice that's in your packet. We do appreciate your attendance and the comments that were provided here today. Thank you very much.

(Off the record)

MR. MOORE: It's noon, so we're going to officially close the meeting at this time. Thank you.

(Whereupon, the above-entitled matter was concluded at 12:00 p.m.)