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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)

+ + + + +

AUGUST 22, 2006

+ + + + +

LAS VEGAS, NEVADA

+ + + + +

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.

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

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

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

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

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

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

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

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

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1 public comment period.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 states.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 representatives in the public meeting.

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

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

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

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

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

25 There were also a lot of discussions on

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

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

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

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

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

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

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

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

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

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

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

8 In Part 30, the major changes I have
9 outlined here. Also, the change of the definition of
10 byproduct material, which is consistent with the Part
11 20 definition. We added some definition, including
12 accelerator-produced radioactive material, cyclotron,
13 discrete source, and particle accelerators. Some of
14 the major provisions that we have included, including
15 the implementation approach, I have discussed before.

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

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

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

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

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

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

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

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

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

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

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

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

25 Part 35 will probably be the part that

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

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

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

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

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

25 Part 110 is actually -- it's our

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

7 Part 170 and 171, it's the licensing fee
8 provisions. 170 is the one-time licensing fee and
9 171 is the annual licensing fee. And we tried to
10 take a look at the existing fee category and tried to
11 fit this new byproduct material within the existing
12 framework and tried to make sure the fee is
13 reasonable. What we have included in the proposed
14 rule is based on 2005 fee charge. So when the final
15 rule is published next year it will be slightly
16 adjusted.

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

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

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

23 MS. CHANG: Sure.

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

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

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

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

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

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

21 MR. MOORE: Thanks a lot, Lydia.

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

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

6 In your Federal Register notice, on page
7 42970, there's a summary of issues for public comment
8 that we're specifically looking for comment on. And
9 as Lydia pointed out, a number of those questions we
10 have for public comment have to do with the radium-
11 226 source issue. Again, that's page 42970. Thanks
12 a lot, Lydia.

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

17 DR. DODD: Thanks very much.

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

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

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

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

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1 some details before formulating them into our
2 formal comments.

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

11 The Health Physics Society has a
12 relatively long history of advocating for a more
13 uniform and compatible regulatory framework for the
14 responsible regulation of radiation and radioactive
15 materials. Over 14 years ago, in January 1992, the
16 Society issued a position statement titled
17 "Compatibility in Radiation Protection Regulations."
18 This position statement was driven by the HPS's
19 concern over the differences in radiation regulations
20 that existed between individual states in their
21 regulation of non-Atomic Energy Act radiation sources
22 and materials, and over the differences between these
23 state regulations and NRC regulations for Atomic
24 Energy Act radiation sources and radioactive
25 material.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 written submittal.

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

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

22 Within the USA, the IAEA categories 1 and
23 2 have been associated with high-risk sources and
24 activities of concern to common defense and security.
25 The requirement to evaluate other naturally occurring

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 University to develop specific DACs for those two
2 radionuclides. And much to our surprise, what we
3 found is the DACs that were calculated using ICRP 40
4 methodology along with EPA Federal Guidance Number
5 13, we found that the DACs we calculated in
6 (indiscernible) per mill were virtually identical to
7 what NRC has in the proposed rule and they really
8 weren't 20 to 40 times higher than they should have
9 been. So we were surprised in that.

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

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

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

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

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

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

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1 we're concerned with operators of small PET
2 cyclotrons. And when we say small PET cyclotrons,
3 these are typically 18 MEV or less. We feel that
4 these cyclotrons, really running at maximum beam
5 current and maximum duty load, it's really not
6 possible to generate the kinds of isotopes with the
7 half lives in the quantities that are address in Part
8 30.35 that would trigger the financial assurance
9 requirements.

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

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

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

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

9 MR. MOORE: Thanks very much, Roy.

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

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

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

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

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

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1 detailed comments in writing on September 11th.

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

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

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

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

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

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

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1 period.

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

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

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

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

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

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

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

11 Just to elaborate a little bit on the
12 decommissioning cost, we will be submitting written
13 comments before the September 11th deadline. But
14 just to expand on the core sampling that Roy
15 mentioned, two weeks ago we had to do four core
16 samples for concrete in one of our cyclotron rooms.
17 And this is on a self-shielded cyclotron. Cost for
18 those four core samples including analysis was
19 \$10,000, and they were all just -- they were negative
20 for any induced activity. So a more elaborate
21 facility would require, I think, quite a few more
22 core samples than just four. This was a pretty
23 limited trenching operation.

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

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

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

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

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

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

12 Donna-Beth, do you want to handle that?

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

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

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

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

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

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

15 MR. MOORE: Thanks very much, Roger.

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

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

25 That was the people that preregistered.

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1 Vivian, are there others that asked to speak?

2 (No audible response)

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

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

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

13 MS. PETULO: No. These are some --

14 MR. MOORE: But we'd be --

15 MS. PETULO: -- like definition --

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

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

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

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

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

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

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

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

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

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

7 MS. CHANG: Uh-huh.

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

11 MS. CHANG: Uh-huh.

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

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

16 UNIDENTIFIED SPEAKER: (Indiscernible)
17 please.

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

25 MS. CHANG: Sure.

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

3 MR. MOORE: Okay.

4 MS. CHANG: I guess another possibility
5 is the Atomic Energy Act, when first promulgate in
6 1950's, it does have two components: a DOE component
7 for the defense related operations versus the
8 commercial aspects that NRC regulates. So this
9 regulation's really related to commercial aspect of
10 the use of the radioactive material, while DOE still
11 works on the defense aspect of radioactive material.
12 So that would be another possibility.

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

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

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

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

2 MR. MOORE: Thank you.

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

6 Okay. With that, we will be here till
7 noon. And we'll stay in case anybody else comes.
8 I'd like to thank everybody for your comments. The
9 public comment period will stay open until September
10 11th and we will be taking comments by mail, fax, or
11 email. The information's provided in the Federal
12 Register notice that's in your packet. We do
13 appreciate your attendance and the comments that were
14 provided here today. Thank you very much.

15 (Off the record)

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

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

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