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on Cesium-137 Chloride Sources

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING ON THE DRAFT POLICY STATEMENT

ON CESIUM-137 CHLORIDE SOURCES

+ + + + +

MONDAY,

NOVEMBER 8, 2010

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ROCKVILLE, MARYLAND

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The public meeting convened in The
Universities at Shady Grove Conference Center
Auditorium, 9630 Gudelsky Drive, at 8:45 a.m., KENNETH
BAILEY, Facilitator, presiding.

PANEL MEMBERS PRESENT:

EDWARD MAHER

GRANT MILLS

RICHARD RATLIF

TERRENCE REIS

STEVEN REYNOLDS

PRESENT:

KENNETH BAILEY, Facilitator

CHARLES L. MILLER

MICHAEL F. WEBER

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1 PRESENT (Continued):

2 JOHN P. JANKOVICH

3 MERRI HORN

4 JOSEPH P. RING

5 KEVIN NELSON

6 MARK MAIELLO

7 TODD MASSE

8 BLAIR MENNA

9 MARY SHEPHERD

10 IOANNA ILIOPULOS

11 RUTH SYLVESTER

12 CATHERINE RIBAUDO

13 CYNTHIA G. JONES

14 SARENEE HAWKINS

15

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

(8:46 a.m.)

1
2
3 FACILITATOR BAILEY: Good morning. I will
4 be the facilitator for today's public meeting. I will
5 reintroduce myself a little later, but before we get
6 started, we will have the opening from the Director of
7 the Office of Federal, State, and Material and
8 Environmental Programs , Dr. Charlie Miller.

9 NRC WELCOME & INTRODUCTION

10 DR. MILLER: Good morning, everyone. I
11 really appreciate your attendance here today because I
12 know with your busy schedules, it probably is some
13 effort to get here, especially for those of you that
14 had to travel long distances.

15 We're really happy today to have a broad
16 representation that cross-cuts across both the
17 industry and public interest. We have manufacturers.
18 We have users. We have licensees. We have people
19 from the biomedical research area, the calibration
20 community, representative of alternative technologies,
21 such as X-ray manufacturers. And we have government
22 agencies responsible for public health and safety and
23 security, both federal and state.

24 The NRC really values your participation
25 in this. Our policy statement is important to the

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1 Commission. And a draft policy statement was issued
2 with the best thinking in mind, that it is very
3 important for the Commission as we try to finalize
4 this to make sure that your input is received and we
5 really get the stakeholders' perspectives on this so
6 that we make sure that we have a robust policy
7 statement that is realistic and that at the same time
8 gives us a look forward with regard to what we really
9 need to do with cesium chloride.

10 We will give careful consideration to what
11 we hear today. We want this to be interactive. And
12 we hope that you will have an opportunity to
13 participate so that we can get your perspectives.

14 Our meeting today will be transcribed. So
15 we will ask as you ask questions to please go to
16 microphones so that our recorder here can get who you
17 are, your affiliation so that we can make sure that
18 the record is straight.

19 For a few housekeeping things, there is
20 coffee and bagels and doughnuts up at the top if
21 you're so inclined. The restrooms are just down the
22 hall here at the top of the steps to the right. So
23 feel free to take advantage of the facilities as we
24 move through the two days here.

25 First on our agenda today, Mike Weber, our

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1 Deputy Executive Director, who has the materials
2 program as part of his purview, is going to give some
3 opening remarks and a keynote address as we move into
4 the sessions, the workshop.

5 Mike has had a long, illustrious career at
6 the NRC. And he is very familiar with this subject.
7 So, without further ado, I would like to introduce
8 Mike Weber, have him come up, and let's get the
9 session started.

10 (Applause.)

11 OPENING REMARKS BY THE DEPUTY EXECUTIVE DIRECTOR for
12 OPERATIONS

13 MR. WEBER: Well, good morning. Let me
14 add my welcome to all of you. And thank you for
15 taking time out of your busy schedules to participate
16 in our conference here today and tomorrow.

17 The next couple of days are an important
18 event for the NRC because we get to hear your
19 perspectives on the draft policy statement and the
20 associated issues.

21 The NRC staff and the Commission are quite
22 interested in your views, your perspectives, and your
23 informed comments on the draft policy statement. And
24 we will thoroughly and thoughtfully consider the
25 comments that you offer, both here in the meeting as

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1 well as comments that you may submit after the
2 meeting. We will talk about that in a little bit.

3 As an independent regulatory agency, you
4 are no doubt aware that NRC prides itself on openness.
5 And NRC takes an active role in the President's Open
6 Government Initiative with its focus on open,
7 accountable, and accessible government.

8 The NRC has a long history of and
9 commitment to transparency and participation,
10 collaboration in our regulatory process and our
11 regulatory activities. After all, nuclear regulation
12 is the public's business.

13 NRC considers public involvement in our
14 activities to be a cornerstone of a strong, fair
15 regulatory program. And we recognize that the
16 public's interest is in the proper regulation of
17 nuclear activities and, consequently, provide
18 opportunities for stakeholder participation in that
19 process.

20 And, consistent with NRC's approach to
21 open government, the agency is committed to providing
22 meaningful opportunities for the public to participate
23 in NRC's decision-making process. Participation also
24 allows you to contribute ideas and expertise so that
25 your government can make policies and programs with

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1 the benefit of the information, the perspectives that
2 you share with us.

3 So why are we here today and tomorrow? As
4 you are probably aware, the mission of the NRC is to
5 ensure the safe and secure use of radioactive
6 materials. As a regulatory agency, we accomplish our
7 mission by establishing requirements by rules or
8 orders. We accomplish our mission in authorizing uses
9 of radioactive materials through licenses. And we
10 oversee the safe and secure use of those materials
11 through a comprehensive program involving inspection,
12 assessment, enforcement, investigation, and incident
13 response.

14 Now, as part of the regulatory program,
15 the Commission requested the NRC staff to develop a
16 policy statement on the protection of cesium-137
17 chloride sources. The policy statement is a tool that
18 the Commission uses to communicate with licensees and
19 other stakeholders about matters that are important to
20 the Commission. And the policy statements help guide
21 the staff's business but are not regulations or
22 requirements.

23 Besides the draft policy statement, which
24 is the focus of our meeting here today and tomorrow,
25 the Commission has developed other policy statements,

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1 such as the one on safety culture that is currently
2 under development.

3 We conducted a public workshop on safety
4 culture back in Las Vegas in late September. And
5 we're using the comments that we received on that
6 draft policy statement in preparing a final draft for
7 Commission review in early 2011.

8 So why the focus on cesium chloride
9 sources? We have recognized for many years that
10 certain radioactive materials would be more attractive
11 than others for use in a malevolent attack, such as a
12 radiological dispersal device, or an RDD.

13 Our attention increased following the
14 terrorist attacks of 9/11 as we work with our federal
15 and state counterparts to assess the need for
16 additional security measures to ensure source security
17 and to protect against the heightened threat from
18 malevolent use.

19 We have made significant progress during
20 the last decade in strengthening the security of the
21 most risk significant sources, both here in the United
22 States and overseas in working with the International
23 Atomic Energy Agency, foreign counterparts, vendors,
24 licensees, and operators. You will hear more about
25 these enhancements in the presentations that follow.

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1 Now, considering all of the progress that
2 has been made since 9/11, the question remains whether
3 additional measures, up to and including potentially
4 banning the use of cesium chloride sources, are
5 necessary and appropriate.

6 Even if continued use of the sources is
7 justified, beneficial, safe, and secure, should we
8 work collaboratively with our federal and state
9 counterparts to promote the pursuit of alternatives
10 that one day may be suitable for replacing the
11 continued use of cesium chloride sources?

12 These questions are the focus that the
13 Commission has embraced and serve as the foundation
14 for the six issues of discussion in this meeting.
15 These issues are, number one, are NRC's role and
16 licensee responsibilities clear and sufficient to
17 ensure safe and secure use of the radioactive sources?
18 Two, are NRC's regulations sufficient to ensure
19 adequate security of the sources? Three, are there
20 design improvements and alternatives for cesium
21 chloride sources that could enhance security and
22 safety while continuing to ensure the societal
23 benefits are obtained from the use of the sources and
24 these alternatives? Four, are there alternative forms
25 of cesium chloride sources that are feasible and

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1 desirable from a security and safety perspective?
2 Five, what are the current and projected fields of
3 beneficial use of cesium-137 sources? And, six, what
4 is the status of the disposal capacity and access for
5 cesium chloride sources?

6 We are very interested in your comments
7 and your perspectives on these issues as well as any
8 comments that you may share with us on the draft
9 policy statement on the use and protection of cesium
10 chloride sources.

11 NRC staff will consider the information
12 that you share with us in refining and improving the
13 draft policy statement before recommending a final
14 draft to the Commission in early 2011.

15 I want to thank each of you for your
16 participation and for your providing comments to us on
17 the draft policy statement and on related regulatory
18 products, such as the draft or proposed security
19 requirements in Part 37.

20 If you are ready to share your comments
21 with us in this meeting on the draft policy statement,
22 we are eager to hear them and to discuss them with
23 you.

24 The public comment period on the draft
25 policy statement remains open until December 17th,

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1 2010. So if you prefer to listen to the discussion
2 during the next couple of days and then reflect on the
3 information you heard and consider that before
4 submitting your comments, we welcome that approach as
5 well. We are open to the comments both now and in
6 follow-up. What counts is your constructive
7 engagement in improving the draft policy statement.

8 Thanks again for your participation in our
9 regulatory process. We look forward to having a
10 productive meeting with you. And if there is anything
11 that we can do to make your participation more
12 meaningful, please don't hesitate to bring it to our
13 attention.

14 And now I guess I turn it back over to our
15 facilitator, Ken Bailey. Thank you, Ken.

16 (Applause.)

17 FACILITATOR BAILEY: At this time I would
18 like to introduce the primary project manager, who
19 will give you an overview. And that is Dr. John
20 Jankovich. Oh, I'm sorry. Reintroduce Charlie
21 Miller. I'm sorry.

22 DR. MILLER: To kind of set the stage for
23 the workshop, I wanted to take a few minutes to walk
24 everyone through an effort that has been going on for
25 the last four and a half years or five years. And

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1 that relates to the Radiation Source Protection and
2 Security Task Force.

3 SUMMARY SOURCE PROTECTION TASK FORCE REPORT

4 DR. MILLER: This Task Force was
5 legislated in the Energy Policy Act of 2005. And at
6 the time that Congress legislated this activity, as
7 part of the security requirements of that legislative
8 activity, it gave the Task Force a very short period
9 of time, basically one year, to produce its first
10 report.

11 And so what I thought I would do is walk
12 through what the initial efforts were, what the
13 subsequent efforts have been, and some of the
14 accomplishments and challenges, especially as they
15 relate to cesium chloride, which is the topic of this
16 discussion today.

17 The Task Force has been one of the primary
18 vehicles for discussing and addressing issues related
19 to the security and protection of radiation sources.
20 And it is very important that we keep that in
21 perspective because following 9/11, when this Task
22 Force was first set up under Section 651 of the
23 Energy Policy Act, it required that the agencies come
24 together and participate as a group. Federal agencies
25 is primarily what I am talking about here.

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1 This slide shows the membership for the
2 Task Force. Initially membership was limited. We
3 expanded the membership a little bit to include the
4 Office of Science Technology Policy and Health and
5 Human Services as well as inviting the Organization of
6 Agreement States and the Conference of Radiation
7 Control Program Directors (CRCPD) to join the Task
8 Force so that we make sure we had the states'
9 perspectives into our thinking.

10 It designated in the legislation that the
11 chairman of the NRC or his designee would lead the
12 Task Force activities. And Chairman Jaczko does
13 indeed lead the Task Force overall. However, he has
14 delegated to me to lead the meetings of the Task
15 Force. So I'm pretty much the day-to-day senior
16 manager that oversees the Task Force activities and
17 coordinates the activities with the aid and the hard
18 work of my staff.

19 So at the time, to set the stage, at the
20 time in 2006 that this first report was written, it
21 took a monumental effort to get the federal agencies
22 to talk to each other because I think if we're
23 realistic and I think if we're honest with each other,
24 prior to that time, a lot of the work that was being
25 done subsequent to 9/11 was being done in silence.

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1 Every agency was trying to write fast and trying to
2 increase security. And, to some degree, we didn't
3 talk to each other as well as we could.

4 And, as you will see in my remarks as I go
5 on, this Task Force has been a wonderful vehicle for
6 getting the federal agencies together and trying to
7 get some of our activities coordinated so that we work
8 together in trying to make sure that we're at the
9 right security levels for radiation sources.

10 So, as I mentioned, the first report was
11 due to Congress in 2006, which was really only one
12 year after the formation of the Task Force. The
13 legislation itself designated some of the activities
14 that the Task Force should undertake. So it gave us
15 somewhat of a guideline of what Congress wanted us to
16 look at at the time.

17 As I mentioned, one of the primary
18 vehicles that the Task Force was trying to look at is
19 having a collaborative discussion of what needed to be
20 done and to focus on the current programs that are out
21 there that are being conducted by many of you. It was
22 to try to identify if there were any gaps or overlaps
23 or inconsistencies or obvious weaknesses in our
24 security. And it was to evaluate and provide
25 recommendations relating to the security of radiation

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1 sources in the United States so that we would be
2 protected from potential terrorist threats, including
3 acts of sabotage, theft, or the use of a radiation
4 source in an RDD.

5 So what I would like to do is just briefly
6 walk through what we found in 2006, and what we have
7 done since then. Some of the conclusions in the 2006
8 report were that there were no areas that needed
9 improvement that weren't identified or that were not
10 being already addressed or planned to be addressed.
11 The combination of regulations, orders, guidance
12 provided reasonable assurance of this and the need to
13 verify through inspection that the activities were
14 being carried out appropriately.

15 There was a need to continue the
16 activities on background checks and other actions, but
17 the largest gap that I think that was identified at
18 that time related to international transport security,
19 basically taking domestic security requirements and
20 folding them into the IAEA guidance with regard to
21 transportation and to the IAEA code of conduct.

22 Transit and transshipment were
23 particularly the areas that we felt that work needed
24 to be done on. The report, in 2006, primarily dealt
25 with creating recommendations and actions that needed

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1 to be taken. In that one year, we really didn't have
2 a time to accomplish a whole lot but really provided a
3 planning vehicle for things that the federal
4 government needed to work on over the subsequent
5 years.

6 The legislation itself provided for after
7 the first report to supply reports to Congress at
8 least once every four years. And so in 2010, the
9 second report was due. The 2010 report was delivered
10 to the Congress at the end of the summer. We met our
11 date in August to try to do that.

12 And we tried to take a little bit
13 different focus in the 2010 report so that we should
14 show the accomplishments that were made over the four
15 years.

16 And one of the main things that we wanted
17 to illustrate in the report, if you look at the 2006
18 report and you look at the 2010 report, I think you'll
19 see a radical difference in the presentation style.
20 The 2006 report basically had a list of
21 recommendations and actions. It was a very detailed
22 report. And, if I'm quite honest with myself, I would
23 say it was pretty dry reading.

24 And so we really didn't get any reaction
25 from the Congress or the President. And I neglected

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1 to mention that the report has to be delivered not
2 only to the Congress but to the President.

3 And so we wanted to have something in the
4 2010 report that would be more eye-catching, that
5 would really illustrate the work that had been done.
6 So we decided to change the format of the 2010 report
7 and focus on four main topical areas that we have
8 looked at over the last four years.

9 The areas that we looked at were primarily
10 coordinated into these four areas: communication
11 improvements, security and control of radiation
12 sources, end-of-life management, and alternative
13 technologies. And so these topics are also going to
14 be central to this workshop over the next couple of
15 days. So I think it is important that we lay that
16 out.

17 We came up with 11 new recommendations.
18 And some of our key accomplishments in the 2010 report
19 that were identified were that we achieved a lot
20 better interagency coordination over the four years.
21 We really feel that we have got the federal family
22 talking to each other and working together in a much
23 more congruent manner than we had in 2006.

24 We tried to focus also on public
25 education. One of the things that is recognized is

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1 that public education is very important. And it was
2 very important that the federal family try to reach
3 out to the public and to the stakeholders for each of
4 them to deal with and give a consistent message about
5 radiation safety and security so that the public was
6 not getting mixed messages.

7 So a public education campaign was
8 undertaken. And there were a lot of actions that we
9 had put forward that needed to be done to try to make
10 sure that we do have a good public education campaign.

11 A lot of actions taken by the federal
12 agencies over the last four years were identified in
13 the report. Let me just name a few. The increased
14 controls, of course, were put in place. The National
15 Source Tracking System was put in place by the NRC.
16 Voluntary enhancements for things like blood
17 irradiators that were Homeland Security and
18 NNSA-spearheaded at the time. The accomplishments
19 that have been put in place with regard to that were
20 identified.

21 Training for local law enforcement, which
22 was important because what we find in many cases is in
23 the States, the people that are basically in charge of
24 emergency response, especially as it relates to loss
25 of local law enforcement, weren't necessarily versed

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1 in the types of things in radiation security,
2 especially for nuclear materials. So it's important
3 to have them educated. So we felt that that was an
4 important topic. And that was taken on over the four
5 years.

6 Disposal solutions are one of the biggest
7 areas that was identified that still needs attention.
8 Many of the radiation sources that we will talk about,
9 especially many of the cesium chloride sources,
10 include greater than Class C waste when they're going
11 to be disposed of.

12 And currently there is no disposal
13 pathway. So one thing that the Task Force was united
14 on was that a disposal pathway is needed in the future
15 if we're ultimately going to consider alternative
16 technologies or used sources are going to be
17 permanently disposed of. It's very important that we
18 do that given that there is no current pathway.

19 In terms of cesium chloride, specifically
20 the report recommends that while it is prudent to
21 continue to look to viable alternative technologies
22 for the sources, a decision on whether to discontinue
23 NRC or Agreement State licensing or export of cesium
24 chloride sources containing risk-significant
25 quantities -- I'm primarily talking here about IAEA

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1 Category 1 and 2 in the Code of Conduct -- and this
2 radioactive material, you know, any movement towards
3 going to another alternative technology or
4 discontinuing the use of these sources needs to be
5 prudent. And it needs to be taken contingent on
6 existence of viable alternatives technologies and take
7 into consideration the availability of disposal
8 capacity, as I had talked about and the changes in the
9 threat environment. Okay? The threat environment
10 changes continuously. If you read the newspapers,
11 different things are going on every day.

12 So you need to bring all of these things
13 together and not just act without a judicious
14 approach, recognizing the fact that the beneficial use
15 of these sources is extremely important for health,
16 for industrial purposes. And we want to make sure
17 that we don't do anything that is a knee-jerk reaction
18 that might not be prudent. So I think that the Task
19 Force concluded that we have to take a very measured
20 approach for this for the future.

21 Next steps. What do we hope to accomplish
22 in the next four years? Well, first we enclosed
23 letters to the President and to the Congress with the
24 report that was delivered on August of 2011. And, as
25 all of you know, the activities of the last few months

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1 by the Congress were focused on maybe other things
2 than the cesium chloride and the Task Force report.

3 And so I think the Task Force wants to
4 make sure that we try to get Congress engaged with
5 this to see if they have any insights or to see if we
6 can get them engaged, especially for taking a look at
7 some things that we feel possibly would need
8 legislative activity before we could proceed.

9 I think we wanted to make sure that to get
10 their attention, we had to really let the elections
11 get out of the way. So I think the Task Force itself
12 recognized that it would probably be sometime this
13 winter before we could really get Congress engaged.
14 And we do hope to try to get some feedback from
15 Congress on the report. So far, to my knowledge, we
16 still haven't got any, but that is understandable
17 given the recentness of the elections.

18 So we wanted to make sure that there was a
19 new Congress in place and we'll refocus our efforts on
20 trying to reach them at that time.

21 We then like to focus our discussion on
22 what we were going to do to implement the
23 recommendations in the 2010 Task Force report and what
24 we want to focus on in the next four years. We can't
25 focus on everything at once. Everyone has limited

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1 resources. So we want to make sure that we focus on
2 the things that we feel are most important. And, of
3 course, the next report that we will prepare is in
4 four years and would take place in 2014.

5 I have put up here a website. The report
6 is publicly available. And it looks like this. If
7 you are interested in getting a copy and you don't
8 have one or you can't find one, my staff will be here
9 during the whole workshop. Give them your name and
10 address, and we'll make sure you get a copy.

11 It's a publicly available report. And
12 this time I believe it's much easier reading. I think
13 it groups things together in a very good manner.

14 This report itself had the endorsement of
15 every federal agency that is on here before we could
16 send it. And for NRC endorsement of what was in the
17 Task Force report, it took the review and endorsement
18 of the entire NRC Commission.

19 So we are pretty proud of this report. We
20 think there is a lot of good work that has been done
21 over the last four years. Any feedback that you see
22 from this report that you would like to get in we are
23 always happy to hear as the Task Force continues its
24 activities over the next four years.

25 Let me just stop there and take any

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1 questions if anyone has one. I just wanted to use
2 this to kind of set the stage. Anybody have any
3 questions or comments that they would like to make at
4 this time?

5 (No response.)

6 DR. MILLER: Great. Well, seeing none,
7 let's get on with the activities. Thank you.

8 Ken?

9 (Applause.)

10 FACILITATOR BAILEY: Okay. Forgiven past
11 error, we will now go on with John Jankovich, one of
12 the primary project managers for the cesium-137
13 chloride sources.

14 OVERVIEW OF NRC AND FEDERAL AGENCIES

15 CsCl INITIATIVES

16 DR. JANKOVICH: Good morning. Thank you
17 for coming to our meeting. And I appreciate the
18 effort you have put into this to come here Monday
19 morning.

20 I would like to give you an overview of
21 what NRC has done in the last couple of years
22 regarding cesium chloride. We have had a very good
23 introduction this morning to see the big picture of
24 NRC's activities and the Task Force's activities that
25 Mr. Weber and Dr. Miller gave us. Now I want to focus

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1 on cesium chloride.

2 As you know, we had a public workshop two
3 years ago. At that time, the subject was different
4 than today. At that time, NRC was in the information
5 mode, information-gathering mode. And the information
6 we have gathered since that time resulted in this
7 draft policy statement. Now we want to get final
8 input into the draft. And then the NRC will issue the
9 policy statement. That will be the guiding principle
10 for the future regarding cesium chloride.

11 As you know, NRC is responsible for public
12 health and safety but, in addition, also security for
13 the use of radioactive materials. And when it comes
14 to cesium, we thankfully can say that the safety and
15 public health issues didn't cause any problems to us.
16 However, security is an important point of
17 consideration. And all what we talk about from now on
18 is about security.

19 We in this field, radiation protection,
20 grew up emphasizing public health and safety. When we
21 went to college, that was our primary field. Since
22 then the situation changed. And now we talk about
23 security.

24 In addition, as Charlie's Task Force
25 established, and the Energy Act of 2005, it's not only

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1 public health and safety but security and
2 socioeconomic impacts of misuse of radioactive sources
3 that are important. What did we know about those
4 when we went to college? So this is the focus of this
5 meeting.

6 Quickly, I want to sum up a few basic
7 concepts about the use of cesium so those in the
8 audience who are not familiar with the subject could
9 see it and we all would be on a common denominator.
10 Thank you.

11 So for the purpose of this meeting, I came
12 up with this definition of the source. Radioactive
13 material is in a closed capsule to be used for some
14 technological purpose. Of course, there are other
15 definitions in the NRC Code of Federal Regulations,
16 and so on.

17 We talked about cesium sources, in that
18 case cesium-137. And that is a gamma emitter and used
19 in irradiators. And why is it used? Because it has
20 an ideal energy spectrum when it emits radiation, only
21 one peak at 670 kilo-electron volts. And that is good
22 for measurements. It's good for all the research we
23 intend to do with it. In addition, it has a long
24 half-life, 30 years. And it is readily available.

25 Properties of the cesium, what we are

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1 using at the present time. It is used in the chloride
2 composition chemically. And being in the chloride
3 family, it is readily soluble in water, just like
4 table salt, sodium chloride. That is one important
5 thing, what we have to keep in mind.

6 In the physical form, it is made in
7 compressed powder form. It is similar to the Tic Tac
8 candy. And, consequently, if it is pulverized, it is
9 readily dispersible when it is dry.

10 Finally, what are the mechanical designs
11 of these sources? The compressed powder pellets are
12 double-encapsulated in two stainless steel capsules.
13 The inner capsule is welded shut with end caps. And
14 the outer capsule is similarly welded shut.

15 Where do they use cesium chloride sources?
16 I like to distinguish the use into two categories:
17 Low activities in the millicuries up to one curie
18 activity level and then in high activity levels.

19 Low activity levels are used in moisture
20 density gauges at road constructions, building
21 foundation constructions, leveling gauges at
22 petrochemical plants, flow rates in pipes. They use
23 cesium sources in well-logging and in brachytherapy.

24 This is not the subject of our meeting
25 today. We talk about the high activity sources.

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1 These sources are in the hundreds and thousands of
2 curies. And we use them in blood irradiators, in
3 biomedical research, and calibration, very important.
4 And we talk about calibration.

5 Since the beginning of the atomic age, the
6 entire national or international system of
7 measurements is based on the spectrum of cesium
8 because it has one peak. And right in the middle of
9 the energy spectrum, we want to measure. And it is
10 easy to design instruments which have a flat response
11 rate throughout the energy spectrum.

12 All survey meters you ever used in your
13 life, all field measurements are calibrated to the
14 cesium spectrum. So this is very important.

15 And we talk about biomedical research.
16 Fifty, 60 years of pharmaceutical, medical research is
17 based within irradiation containing cesium.

18 Here, just again for those who are not
19 familiar with the machines, here is a typical blood
20 irradiator. It has a big shield in the middle, which
21 is the gray area. A part of the shield is rotating.
22 The rotating part has a chamber in it. That is where
23 we put in whatever we want to irradiate, for example,
24 blood pouches. Then the rotating unit turns toward
25 the source . Irradiation takes place. The rotating

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1 part turns back out. The chamber is opened. We take
2 out the sample through the door.

3 Okay. Here is another machine. It has
4 two sources. In this case, the white part here is a
5 drawer which rotates out. They put petri dishes,
6 animals in it for irradiation, turn back, and close
7 the door. Then the sources move.

8 There are two sources in that one. Around
9 the drawer, one underneath, and then the sources in
10 the shield in that position, the big black container.
11 When irradiation takes place, the sources move to a
12 collimator. Irradiation takes place. Sources move
13 back to safe position. They open the door. The
14 machine, we have seen the column here is shown closed
15 up. That's how they load it.

16 There is another manufacturer's
17 irradiator. I show you an old calibrator. That is
18 manually operated. They put the survey meter on the
19 rack inside, close the door. It manually cranks,
20 they move it up and down, left and right to line up
21 with the collimator. Then the source from the shield
22 moves to the collimator. They calibrate the
23 instrument. The source goes back to the same
24 position.

25 Here is a similar calibrator. It's all

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1 computer operated. And it has a very fancy program.

2 Here is an important slide. I think we
3 all ought to consider this. As you see, the first
4 column lists the three areas of use. But then let's
5 put the use in proper perspective. As you see, we
6 talk about in Column 2, about Category 1 and 2 only
7 and then how many licenses, how many locations there
8 are for blood irradiators, 300, how many units are in
9 use, less than 600. Now it comes to the total curie
10 content of cesium in use in the nation, 33 percent.
11 So one-third of the curie content for cesium is used
12 for blood irradiation.

13 Let's look at the research. It's very
14 interesting. Well, let's look at the research. It's
15 very interesting that 66 percent, two-thirds, of the
16 curie content in the country is used for research.
17 And then it comes to calibration. It's very
18 important. But the curie content, as you see, is just
19 one-third of one percent which is used in calibration
20 at 104 locations, 104 units. So this is an important
21 slide. It gives you an idea about the scope of the
22 work we are facing.

23 Current status. I would like to let you
24 know that we are all concerned about security as
25 citizens, as scientists, as specialists in this field.

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1 So it is important that we understand that where we
2 use these sources, we have used them in the three
3 areas that I outlined. And the security of the use is
4 sufficient as far as the NRC currently can assess it.
5 And there is an integrated and comprehensive program
6 in place to maintain the secure use.

7 Requirements were not put in place
8 haphazardly. They were considered on the specific
9 areas of use, and what is the risk environment in
10 that use? And then the NRC and the Agreement States
11 placed appropriate security requirements there; for
12 example, for large irradiators, for manufacturers,
13 distributors, transportation, and the staff, who is
14 using the radioactive material, there are in place
15 controls and requirements. The NRC continues to work
16 with domestic and international partners to maintain
17 this security environment.

18 History of the cesium chloride, what we
19 have done so far. This is the most important slide
20 that I have. And I would like to ask you to keep this
21 in mind for the rest of this meeting because this puts
22 things into proper perspective.

23 As Charlie Miller has pointed out, focus
24 on cesium chloride started with the Energy Policy Act
25 of 2005. Why? Because that act established two

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1 important things regarding cesium. One is the Task
2 Force. We know already that the activities of the
3 Task Force are focused on certain aspects of the Task
4 Force's recommendations , which address cesium
5 chloride. Charlie didn't have the opportunity in his
6 overview to focus on this particular subject.

7 And there is another outcome of that Act.
8 That was the act to the NRC was to fund a study with
9 the National Academy of Sciences to study security of
10 radioactive sources.

11 Both the Task Force and the National
12 Academy study are broader, but each has important
13 conclusions about cesium. That's why they listed are
14 here.

15 Then the Task Force in 2006, came up with
16 its first report, and that first report established
17 the subgroup. That is so-called Cesium Chloride
18 Working Group to produce a study for the Task Force so
19 they could proceed about this particular subject:
20 cesium. The subgroup finished its report in 2008.

21 These are activities which involve many
22 agencies and representation is broader than the NRC.
23 We started focusing on NRC's activities that I talked
24 about in 2008.

25 One of our NRC's advisory committees,

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1 which is listed here as ACMUI, Advisory Committee for
2 the Medical Use of Isotopes, produced a report for the
3 Commission. And that was a very important starting
4 point. And it comes to cesium chloride. I will talk
5 about it a little bit separately and sum up the
6 conclusions for you.

7 Then time goes on, and we come to the
8 present time. As you heard, the Task Force produced a
9 second report, which has a number of recommendations
10 directly affecting cesium chloride. I will show you
11 those, too.

12 Then NRC issued the draft policy statement
13 that is for comment to solicit input from the public.
14 We hold this public meeting. Then we will proceed
15 with the final policy statement.

16 So keep this in mind. We had the
17 workshop, the previous workshop, in 2008. At that
18 time the subject was, as you may recall, should the
19 use of cesium chloride be eliminated, banned? NRC
20 gathers information since that time. And now with the
21 final policy statement, NRC wants to establish
22 principles which would govern the use of cesium for
23 the future. So the subject is different.

24 Charlie showed you the summary of the 2006
25 Task Force report. What he didn't tell you is that

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1 the -- that is my last bullet on this slide -- that
2 the Task Force established this working group, cesium
3 chloride working group. And the charter of that
4 working group was very clear: determine the
5 feasibility of phasing out disburseable forms of cesium
6 chloride. So there are three important things here
7 what that working group had to answer. Is it feasible
8 to phase out disburseable forms? And a lot of work
9 went into the report, what we produced. I show you
10 quickly.

11 And first, let's give credit to this
12 Working group because it was the first time that the
13 three distinct areas of use were distinguished from
14 each other. And that conclusion was that blood
15 irradiation, research, and calibration should be
16 treated differently because one blanket consideration
17 doesn't apply to these different fields of use.

18 Here are the conclusions of that Working
19 Group. They said that immediate phase-out would not
20 be feasible. However, they said that step-wise slow
21 phase-out could be possible. And they said it could
22 be possible, but the number of challenges would need
23 to be overcome in order to phase the cesium chloride
24 out.

25 Challenges. You can call those

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1 preconditions. And these preconditions are, of
2 course, time. It should be done in a timely manner.
3 And disposal pathways had to be available. Viable
4 alternatives had to be available. It must be executed
5 in a proper sequence, proper time frame. And in the
6 meantime, interim security measures must be
7 maintained.

8 I would like to say a few words now about
9 the report that the ACMUI, Advisory Committee for the
10 Medical Use of Isotopes, produced for the NRC because
11 that is I think a very important input for all the
12 work that NRC has done since that time.

13 They had a very interesting and succinct
14 set of conclusions. I tell you quickly here. It is
15 very interesting. Of course, they said that
16 irradiators are essential for medical practice and
17 research. They said that the security requirements
18 are sufficient because the sites have requirements for
19 security. The individuals, persons must meet certain
20 criteria and the devices themselves are properly
21 designed. The devices are also sufficiently secure.

22 Then they addressed a number of specific
23 subject areas. And those are important. They did not
24 just draw conclusions based on their own experience.
25 They went and searched all the reference information.

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1 Extensive technical references are provided in this
2 report. They surveyed applicable fields of use.

3 We can proceed when we get back to the
4 slide. For example, they talked about alternative
5 technologies, specifically X-ray devices. And they
6 concluded that the results of previous medical
7 research conducted with the cesium spectrum cannot
8 readily be extrapolated to irradiation conducted with
9 X-ray machines. They listed the specific features of
10 the models that were available at that time.

11 An example of the survey that they
12 conducted is that they surveyed an organization called
13 American Association of Physicists in Medicine, AAPM.
14 The results of the survey showed that physicists use
15 85 percent of the time cesium irradiation. And they
16 use it because it is reliable, low-cost, and they had
17 no plan to replace the present technology.

18 The Advisory Committee has a chapter
19 devoted to some other alternative technologies,
20 specifically linear accelerators. They concluded that
21 linear accelerators are not a suitable replacement for
22 these areas of application. Why? The initial cost is
23 very high, \$2 million per machine, annual operating
24 cost is \$200,000.

25 They looked at alternative nuclides. What

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1 is alternative which is feasible? Of course, the
2 first obvious choice would be cobalt-60. They looked
3 at cobalt-60. And they found that there are no
4 suitable irradiators for the application we consider
5 at the present time.

6 And regarding cobalt, they concluded that
7 the short half-life of cobalt, five years, made these
8 irradiators not suitable because they are not cost-
9 effective as the cesium products are concerned.

10 What they presented to us from the survey
11 of a research institution is that 250 users used
12 cobalt irradiator 30-40 times a day and that 20
13 projects are involved. And it would take years to
14 establish any conversion factor from the cesium
15 spectrum to X-ray irradiation.

16 Regarding security, they concluded that
17 the security measures at that time were sufficient.

18 And regarding alternative forms of
19 cesium, we talk about cesium chloride because we are
20 using it at the moment. It's easy to manufacture and
21 inexpensive. But if the cesium was in other chemical
22 or physical forms, then maybe the disadvantages, such
23 as solubility and dispersibility, could be solved.

24 Interestingly, even at that time, in 2008,
25 ACMUI concluded that there is no evidence that

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1 alternative forms would provide any further security
2 benefit. And this is a very important conclusion way
3 back because further studies conducted since that time
4 came to the same conclusion.

5 Charlie also talked about the results of
6 the Task Force report that was sent to the President
7 and Congress this year in August. And you see some
8 duplication. However, I want to emphasize something,
9 what he didn't have time to explain. He talked about
10 the four main topical areas. And the last one is
11 areas for alternative technologies.

12 When you look at this report, keep this in
13 mind. To understand the findings, we have to look at
14 it as a matrix because it gets complicated. They
15 looked at alternative technologies using other
16 isotopes than the present machines. They looked at
17 other technologies that don't use radioactive sources.
18 So that is already one set of variables.

19 Then they looked at the technology. And
20 for radioactive sources, they classified the
21 alternative technologies as those which are
22 technologically feasible but need some research and
23 refinement. And there are those technologies which
24 need further research even to prove that they are
25 technologically feasible.

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1 The matrix is not done yet because for all
2 of these variations, they looked at seven
3 technologies. I want to read this all so you could
4 see how complex the conclusions are, but also when you
5 read the report, you will orient yourself very easily.

6 So they looked in terms of these variables
7 at blood irradiation, calibration, research
8 irradiators, well-logging , industrial radiography,
9 industrial irradiators, and teletherapy.

10 As Charlie told us, the report has
11 recommendations. He didn't go into the details. Four
12 of those recommendations directly address cesium
13 chloride. Even though the report talked about all
14 uses of radioactive sources in all applications, four
15 recommendations spell out cesium chloride. One is
16 indirectly related.

17 Then for your orientation, I quickly tell
18 you what these details are. Recommendation 3 ,
19 discontinue licensing in the exports of cesium
20 sources. And they used the word "contingent" on
21 disposal capacity alternative technologies and the
22 threat environment.

23 This makes sense because if they ban the
24 use of cesium chloride here in the United States, we
25 don't want the existing machines complete with

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1 existing sources, which have a long half-life, would
2 be exported because we will just move the threat from
3 the U.S. to other countries. So this recommendation
4 is about exports.

5 Recommendation 4 , disposal. The report
6 used very strong wording, actually. Disposal says
7 that the current system for cesium sources doesn't
8 provide any solution. The current compact systems are
9 not suitable for disposal of cesium sources at these
10 activity levels. And Congress should take positive
11 steps to promote the development of a disposal
12 facility.

13 Recommendation 10 , it is very
14 interesting, it talks about the alternative
15 technologies in general but also talks about cesium
16 chloride. And it says about cesium chloride that
17 options for voluntary use should be encouraged. And
18 that should be the -- it depends on the disposal.

19 Recommendation 11, discontinuation of
20 licensing cesium chloride. Again the report uses very
21 strong words. And it says discontinuation is a
22 laudable goal. It should be done only if there are
23 viable alternative technologies and also if the threat
24 environment justifies it.

25 Recommendation 9 is indirectly related to

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1 cesium chloride. It talks about that the government
2 should sponsor and encourage research for the
3 development of alternative technologies in general,
4 again says including cesium chloride application.

5 Now we come close to the objective of this
6 meeting. The draft policy statement, as you are
7 aware, at the moment now -- when we published it in
8 June, had seven major statements. And also,
9 following those major statements, it had specific
10 areas for discussion. Those specific areas constitute
11 the foundation for the seven principles.

12 This is a policy statement, what the NRC
13 wants to publish. And, for that reason, it uses big
14 words in proclamation style. We all know about the
15 Declaration of Independence. It has declarations,
16 right? All people are created equal. Every person
17 has the right to life, liberty, the pursuit of
18 happiness. So, consequently, the policy statement is
19 written in that style.

20 So quickly, I recap for you those seven
21 major statements because that is what we will be
22 talking about today. So the NRC's mission is
23 protection of public health and safety and security.
24 The licensees are responsible for protection of
25 radioactive materials at their site. Third, NRC

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1 declares that if the current security requirements are
2 followed, then we have reasonable assurance that the
3 security is sufficient and well maintained. NRC finds
4 that design improvements will be made and encourages
5 such design improvements. The NRC recognizes the
6 three major areas of use, which have socioeconomic
7 benefits. The NRC recognizes the lack of disposal
8 facilities. And the NRC monitors the threat
9 environment and is ready to take further actions if
10 the threat environment requires further security
11 measures.

12 So based on these principles, the seven
13 principles, we put together this workshop. And all of
14 these declarations are put into the six technical
15 sessions that we have today and tomorrow to discuss
16 each and solicit public comment from all of these
17 principles .

18 We also published the second Federal
19 Register Notice, which listed the six technical issues
20 in question format so it would be easier to conduct
21 this meeting and then also for the public to see what
22 type of answers the NRC needs for each of them. We
23 announced the date and location of this meeting.

24 So what comes next? When this meeting is
25 over and the comment period ends on December 17th, the

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1 NRC staff will summarize all the inputs that we see.
2 NRC is an open agency. We don't make decisions in the
3 dark. The public is involved.

4 This is similar to the rulemaking process.
5 The draft was published so that the NRC could get
6 comments. Those comments will be consolidated. And
7 the final policy statement will be put out. Again we
8 will publish it in the Federal Register.

9 Our schedule is that we will, the NRC
10 staff in this case will, put forward the final policy
11 statement to the Commission in April 2011. Then the
12 Commission will decide okay, publish it, and that
13 comes out in the Federal Register.

14 Thank you.

15 (Applause.)

16 GROUND RULES

17 FACILITATOR BAILEY: Okay. Once again
18 good morning. Again my name is Kenneth Bailey. I'm
19 an affirmative employment and diversity specialist who
20 works in the Office of Small Business and Civil Rights
21 in the Nuclear Regulatory Commission. I will be the
22 facilitator for today's meeting, in addition to
23 tomorrow. I will give every effort to ensure today's
24 meeting is productive and beneficial to all attending.

25 Before I go over the process, I would like

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1 to note that this is a public meeting. So we ask that
2 discussions be limited to information that is publicly
3 available. We request speakers and participants do
4 not discuss specific security-related information
5 about your facilities.

6 There also should be no discussion about
7 specific scenarios, additional specific scenarios, or
8 additional security measures that should be added to
9 certain devices. Discussions such as these could
10 potentially cross safeguard or classified information.
11 So we would greatly appreciate your help in assuring
12 you provide only information that is publicly
13 available.

14 Before I begin, I would like to thank in
15 advance the participants as well as the public, in
16 addition to the Director, Office of Federal, State,
17 Material and Environmental Management Programs,
18 Charlie Miller, and the Deputy Executive Director,
19 Mike Weber.

20 The purpose of today's meeting is to
21 provide you with an opportunity to give us comments to
22 improve the draft policy statement on the protection
23 of cesium chloride sources.

24 When comments exceed the time, to prevent
25 us from keeping on schedule, items or items that may

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1 be covered later in the presentation, we will place
2 those items in the parking lot.

3 In front of you, in front of the stage,
4 you will see a flip chart, on which we will place
5 items for the parking lot to be discussed at the end
6 of each day.

7 Today's meeting is only one of several
8 ways you can participate in the commenting process,
9 others of which will be provided during the
10 presentations.

11 At this time, before I go any further, we
12 will take a 15-minute break from this point. I have
13 five till. We will recommence at ten after, ten after
14 10:00.

15 (Whereupon, the foregoing matter went off
16 the record at 9:54 a.m. and went back on the record at
17 10:14 a.m.)

18 FACILITATOR BAILEY: Just another few
19 notes on the ground rules again. We'll ask that you
20 do not use classified information during your
21 presentations or discussions. Additionally, when you
22 do have questions or comments, please go to one of the
23 two mikes on each side of each aisle and speak clearly
24 in the mike.

25 The meeting is being transcribed. So we

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1 would like to fully capture your comments. Please
2 help us get a clean transcript when you ask a question
3 or desire to make a comment.

4 Also, please try to minimize the side
5 conversations so that it will not lose the focus of
6 the transcriber from the person who is speaking.

7 We ask that you please turn off all
8 electronic devices or, at a minimum, place them on
9 vibrate.

10 We have provided you, additionally, with
11 public meeting feedback forms. Please fill them out
12 here today and give them to the NRC staff prior to
13 departure or mail them in if you'd like. Your opinion
14 on how this meeting went will help us to improve
15 future meetings. So please take a minute to let us
16 know what you think.

17 Emergency exits are marked here. And
18 there is actually one underneath of the stairs.

19 When we break for lunch, the use of the
20 campus cafeteria is permitted. It is located in
21 Building 3.

22 ISSUE NO. 1: NRC'S ROLE, LICENSEE'S RESPONSIBILITIES

23 FACILITATOR BAILEY: I would now again
24 like to reintroduce John Jankovich, in addition to his
25 assistants for this project. Just for your

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1 information, for any additional logistical or
2 administrative questions that you may have, they are
3 John Jankovich, Cyndi Jones, and Sarenee Hawkins.

4 At this time we will begin with the panel.
5 I will allow the panel to introduce themselves,
6 beginning from the left, from my left, your right, to
7 the right.

8 DR. MAHER: Edward Maher, President, the
9 Health Physics Society.

10 MR. RATLIFF: Richard Ratliff with the
11 Texas Department of State Health Services Radiation
12 Program representing the Conference of Radiation
13 Control Program Directors.

14 MR. MILLS: Grant Mills, health physicist
15 with the North Carolina Agreement State Program. I
16 believe I am representing OAS.

17 MR. REYNOLDS: This is Steve Reynolds. I
18 am the Director of Division of Nuclear Material Safety
19 out of the NRC Region III office in Lisle, Illinois.

20 MR. REIS: And I'm Terry Reis. I'm the
21 Deputy Director, Division of Material Safety and State
22 Agreements under Charlie Miller and Rob Lewis here in
23 headquarters.

24 FACILITATOR BAILEY: And at this time we
25 will begin the presentations with Terry Reis for NRC's

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1 current security and control requirements, cesium
2 workshop.

3 Thank you.

4 MR. REIS: Thank you.

5 PANEL PRESENTATIONS:

6 NRC'S CURRENT SECURITY AND CONTROL REQUIREMENTS

7 MR. REIS: Before I begin, I want to let
8 you know that I'm in John's chain of management. And
9 I wanted to repeat a housekeeping item. We got some
10 comments during the hall break about people having to
11 travel on Sunday in order to get here on Monday. We
12 apologize for that.

13 Here at the NRC, scheduling meetings is a
14 very difficult issue. The last time we had this
15 meeting, we had a major faux pas, and we scheduled it
16 on a holiday. And we didn't want to do that again,
17 but we looked very closely at these dates. And this
18 was really the best we could do within our budget.

19 So we thank you for coming, but we
20 apologize. And we always try to look at how we can
21 accommodate everyone's needs, but this is how it ended
22 up. So thank you.

23 With that, I want to talk about that we
24 have a panel here to talk about current security and
25 control requirements. And my role in that is to talk

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1 about, well, what have we done? What are the current
2 security and control requirements?

3 I have about seven pages, but what I
4 really think, I think you could take away from it
5 three things. I always like to tell you, you know,
6 what I am going to tell you and then tell you what I
7 told you.

8 So the first thing is after 9/11, the NRC
9 in conjunction with the Agreement States has imposed a
10 program of enhanced security and control measures of
11 radioactive materials, particularly on what are
12 defined as quantities of concern. And we will define
13 them for you as we go through the presentation.

14 So there are regulatory binding
15 requirements in the form of orders that have enhanced
16 control of radioactive material. The second thing I
17 want you to take away from it is that there is
18 increased attention above and beyond the enhanced
19 controls of all risk-significant radioactive material
20 for cesium chloride.

21 The third thing I want you to take away
22 from it is we are currently in a rulemaking process
23 called Part 37 with the public comment period ending
24 the middle of January, which takes a fresh look at the
25 requirements posed by orders and translates them into

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1 permanent regulatory requirements.

2 So, with that, the next slide, Sarenee?
3 The role of the regulator is it's NRC's mission to
4 license and regulate civilian use of byproduct source
5 of special nuclear materials to ensure adequate
6 protection of public health and safety, promote the
7 common defense and security, and protect the
8 environment. Okay?

9 You are going to learn about the increased
10 controls. They were imposed under the premise of the
11 Atomic Energy Act under public health and safety. And
12 that means that enables us to do this role, as we
13 normally do, with most of our regulatory items through
14 our agreement with the Agreement States.

15 If anybody doesn't know what that means,
16 the Atomic Energy Act allows us to relinquish our
17 authority for the regulation of byproduct materials to
18 the States under certain conditions provided they can
19 demonstrate that they have a program that is adequate
20 and compatible with the NRC's. Currently we have 37
21 Agreement States.

22 So we came up with the increased controls
23 in conjunction with the Agreement States. And in
24 conjunction with the Agreement States, we impose those
25 controls upon our licensees and the Agreement State

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1 licensees.

2 Okay. Well, what are risk-significant?
3 What are categories of concern when it comes to
4 radioactive material? You've got the right slide.
5 This comes from the IAEA Category 1 and 2
6 classifications. A Category 1 source is a source in
7 quantity if not safely managed or securely protected
8 could cause permanent injury or probably death if an
9 individual is close to the source for a few minutes.
10 Okay? These are very high curie content sources.

11 Category 2 source is a source in quantity
12 if not safely managed could cause permanent injury if
13 an individual is close to the source for a short time,
14 minutes to hours, could be fatal to be close to the
15 source for periods of hours to days. Okay? So it's
16 been a Commission policy decision that those are the
17 two categories at this time that we will impose
18 increased controls on, Category 1 and Category 2.
19 Okay?

20 The next slide just shows the 16 nuclides
21 is that correct, Steve? It's 16. It's 16 isotopes
22 that we have imposed the increased controls and the
23 categories, the quantities of concern. And you can
24 see them there. Okay? One of them, of course, is
25 your cesium-137. And you can see the quantity of

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1 concern, of which we are concerned, is 27 curies at
2 the Category 2 limit.

3 Next slide. What are the increased
4 controls? We have a Web page there for you to look
5 at. This is all publicly available. But the
6 increased controls, essentially it's a matter that
7 you can break it down into access controls and the
8 ability to detect, assess, monitor, and respond.
9 Those are the fundamental concepts of the increased
10 controls.

11 So we have background checks. And then
12 that has always been there. And then with the EPA Act
13 of 2005, it gave us the ability to do fingerprinting.

14 We have access controls. We have enhanced
15 monitoring. We have prearranged plans with the LLEA.
16 Those of you who don't know what that means, that is
17 the Local Law Enforcement Agencies. We coordinate
18 with them, make sure they know what is in their
19 jurisdiction and they know how to respond and how
20 important it is for them to respond.

21 Closer monitoring of shipments: making
22 sure we ship something that somebody knows that
23 they're about to receive it and can notify people if
24 it's late and start those notifications, prompt
25 notification of incidents, and document retention and

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1 handling.

2 And then, as I said, this is all being
3 transposed into the Part 37 rulemaking, which is a
4 public process. It has already been out for public
5 comment for 120 days. It was extended by another 120
6 days. And that will end on January the 11th.

7 We could have an entire session on that.
8 That is not the intent right here. I just want to
9 make you aware that is out there and awaiting your
10 comment as we finalize what will be our byproduct
11 materials security requirements.

12 Finally, something that we are very proud
13 of is it has been in the works for a long time, but we
14 are now coming up to our second, finishing our second
15 full year of operation. And that is our National
16 Source Tracking System.

17 We now have the ability to have -- we have
18 near-term tracking. Actually, I never liked the word
19 "tracking" because it implies other things, but we
20 have near-term accountability of who is in possession
21 of all the risk-significant sources that are in
22 civilian use at any given time in the country through
23 this system.

24 The National Source Tracking System is up
25 to date, and it tells us who is in possession of

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1 Category 1 and 2 materials at all times. And it is
2 working, and it is up to date.

3 Next Slide, Sarenee. The increased
4 control on retention of cesium chloride, what we have
5 done is, as you have heard from John, the strategy for
6 the security and the use of these sources, working
7 with other agencies on alternatives, alternative
8 technologies, alternative forms, coordination with
9 stakeholders on alternatives.

10 We have a voluntary program to harden. We
11 work now with NNSA to harden these devices to lock
12 the sources in place to increase the delay time in the
13 event that someone gained unauthorized access and was
14 attempting to malevolently steal the source from the
15 device.

16 We have an effort to harden the new
17 irradiators at the point of manufacture. And we have
18 an effort where we work with the FBI so that we ensure
19 that they know where all these irradiators are
20 located. They, in turn, work with the local law
21 enforcement agencies to understand that they
22 understand the importance of response, the importance
23 of these isotopes, and the importance of coordinating
24 with the licensees in their community.

25 And I think that is the last slide. This

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1 is a summary of the current status. And we say with
2 confidence the security and control of radioactive
3 sources has been significantly enhanced per NRC and
4 Agreement State requirements since 2005.

5 There has been an integrated and
6 comprehensive program in place for the U.S. for the
7 management and control of radioactive sources. And we
8 are continuing to work closely with our domestic and
9 international partners to improve security worldwide
10 on these issues.

11 That was the essence of my talk. I would
12 recommend we hold questions until we get through the
13 panelists. And Steve is going to take what I have
14 presented to you and talk about the regional
15 inspection experience with these requirements.

16 MR. REYNOLDS: Yes. Thanks, Terry. I
17 appreciate that.

18 SECURITY INSPECTION FINDINGS BY THE NRC REGIONAL
19 OFFICES

20 MR. REYNOLDS: The NRC and Agreement
21 States have been doing what we call IC, increased
22 control, order inspections since the IC order came
23 out. So we have several years of experience. The
24 regions, three regions, in the NRC that do inspections
25 have done several hundred inspections at licensees

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1 that have quantities of concern. And many of those
2 licensees have cesium chloride.

3 When I look at the results of our
4 inspections, it is pretty consistent across the board.
5 There are six basic increased control points: IC 1,
6 2, 3, 4, 5, and 6. IC 1 is basically on access
7 authorization, which is trustworthy, reliability, and
8 fingerprinting.

9 We have found problems similar to problems
10 there where the licensee is trying to understand what
11 is required and how many people and what types of
12 people do they do access authorization on.

13 There is a need to know component in there
14 so you don't go in and make everybody trustworthy and
15 reliable (T&R) and fingerprint everybody. There is a
16 need to know component there, some violations, some
17 concerns in that area.

18 IC 2 I will break down in two pieces. One
19 is establishing a program with a local law enforcement
20 agency. And the other part of IC 2 is the actual
21 equipment that your detector assesses, monitors, and
22 responds.

23 Again, we have found some programs that
24 have difficulty hooking up with the local law
25 enforcement agency. That is really more of a

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1 communication issue where the local law enforcement
2 agency may not understand what their role is, they see
3 it as emergency response, and they want to turn it
4 over to an emergency response organization versus a
5 law enforcement agency, so see a few problems there.

6 As far as equipment to detect, assess,
7 monitor, and respond, sometimes that doesn't function
8 all the time. You know, it may break down if it's not
9 being tested like it should be. That needs to be
10 tested. And I think Part 37 is going to address that
11 concern.

12 Also, sometimes the equipment to monitor
13 area isn't functioning properly, it wasn't designed
14 properly. So we see that across the board.

15 The other area that we see problems with
16 is in IC 6. It is really procedures in the
17 documentation and how that program is controlled.

18 When we step back and look at what the
19 regions have found for cesium chloride, the blood
20 irradiators and the research irradiators, same types
21 of problems but much less, not nearly the amount of
22 findings. It seems that the hospitals and the
23 research universities usually have a very good
24 program. They're on top of fingerprinting and doing
25 the trustworthy, reliability determinations. They

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1 have that pretty well down. Their systems are usually
2 very robust. And they already have a good
3 relationship with their local law enforcement
4 agencies. So that works very well. And then the
5 procedures, since they are a hospital or a university,
6 they are used to having robust procedures. And that
7 works pretty well.

8 Overall when you look at cesium chloride
9 in the irradiators, I think the increased controls
10 have enhanced security quite a bit. And we see that
11 the licensees are able to comply with those
12 requirements fairly readily.

13 You heard Terry talk about the voluntary
14 hardening. When we have inspected those licensees
15 that have gone through that initiative, it is clear to
16 our inspectors that it is definitely more robust. And
17 those licensees readily comply with our regulations'
18 increased controls. And there are additional
19 features. They even go beyond that, which makes it
20 even more secure.

21 That is a quick overview. Other details
22 you can't go into in this forum. But, as Terry said,
23 we will take questions at the end. But, just
24 concluding, the increased control orders are working
25 to enhance security at our licensees and especially at

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1 our licensees where they use cesium chloride in blood
2 irradiators and research irradiators.

3 With that, I think, Grant, you are next.

4 AGREEMENT STATE PERSPECTIVES

5 MR. MILLS: Good morning. I oversee and
6 implement the increased controls in North Carolina.
7 And OAS management asked me to give a snapshot of the
8 status there in North Carolina as I guess potentially
9 a representation across the country here.

10 Okay. We have got the slides up there.
11 We can go on to the next slide. Just a snapshot again
12 of the number of licensees in North Carolina in the
13 top. And I guess the take-away here is there are
14 about seven percent that fall into this category of
15 increased security controls. And, again, that is
16 based on the isotope type and quantity.

17 One thing that I noticed, especially here
18 recently, is that there is actually quite a bit of
19 bleed-over of the security culture, especially at the
20 large licensees, had a couple of events this summer,
21 past summer, and this fall, where some minor things
22 happened, you know, like a check source inadvertently
23 being taken out of a nuclear medicine department.

24 And it was obvious that the communication
25 and coordination between the stakeholders, including

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1 law enforcement and on site security, was just
2 fabulous compared to what it would have been just, you
3 know, four or five years ago. And I think that is
4 directly related to the implementation of the ICs and
5 their being effective across the board in how all the
6 stakeholders deal with each other. And I think that
7 is something important we can watch and maybe try to
8 track a little bit if we can.

9 Let's go to the next slide there. Still
10 talking about the numbers of sources out there. And I
11 just wanted to make it clear that because certain
12 licensees have numerous devices, there are actually 27
13 devices in the state that we are monitoring currently.
14 Of course, that is a dynamic number that changes
15 almost weekly.

16 We can go to the next slide. This is just
17 kind of a representation of how we got here. It's the
18 federal threat environment analysis. And, like we
19 have learned, there is enhanced licensing in place.
20 There is the implementation of the security orders.
21 There is voluntary upgrades taking place. And then
22 there is the National Source Tracking System. And we
23 like to think that this all has unquestionably
24 increased the security and accountability of the
25 sources.

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1 There was a paper that Dr. Brian Dodd
2 wrote back in 2004. If you haven't seen that, I
3 recommend you see it. It's great. It's on the
4 integration of security and safety towards control.
5 And that's definitely where we are now, I think.

6 And so my statement would be like these
7 fellows'. In North Carolina, we certainly have
8 reasonable assurance that there is currently adequate
9 security of these increased control sources within the
10 state.

11 Go to the next slide. Operationally we
12 are not regulating cesium chloride any differently
13 than any other isotope that is in the same arena based
14 on specific quantity targets . So an irradiator that
15 triggers the ICs, whether its cesium or cobalt, it's
16 still going to get regulated the same operationally.

17 I will say that when we converse with the
18 different stakeholders, we always share any tools and
19 information we have gathered that indicates the
20 current associated with the cesium chloride.

21 I think the Task Force, the National
22 Academy of Sciences Task Force, some of their
23 definitions and the nomenclature they're coming up
24 with is going to be a good tool when we deal with the
25 different stakeholders, especially at the same time,

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1 so that we can speak one language and everybody
2 understands what we're talking about hopefully.

3 Go to the next slide, please. Just wanted
4 to talk a little bit about the voluntary upgrade, the
5 status in North Carolina. As most of you know
6 probably, the DOE, NNSA, and the GTRI Group -- that's
7 a lot of alphabet stuff there, but I understand they
8 are going to be here hopefully today or tomorrow to
9 talk in detail about what they do, but it's basically
10 a federal group that goes around and does these
11 voluntary hardening and enhancement programs. And in
12 North Carolina, man, we love them. We love them to
13 come into town and take our licensees to the next
14 level, great level of professionalism. And all of our
15 licensees have been thrilled with the outcome. We
16 just can't appreciate it enough what they have done
17 for us coming in.

18 And the things they offer are, again, the
19 hardening kit, the actual physical protection
20 enhancement. And that's kind of the hardware for
21 security systems. They offer some response force
22 training. And this is where they integrate whatever
23 is on site and with the local responders. And then
24 they also play an important role in the potential for
25 disposal of sources. And they have helped out a lot

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1 of our licensees find alternatives for disposing of
2 their sources.

3 I've got their Web site there, but, again,
4 they are going to be here today or later. And they
5 will be able to tell us all about what they do.

6 Next slide, please. And here I just want
7 to give you a snapshot of where we are in North
8 Carolina. Of course, the first one here, my pie is a
9 little bit messed up, but that is okay.

10 The bottom line is about 75 to 80 percent
11 will be hardened if they aren't already hardened.
12 Fifty-five percent are already hardened. And another
13 30 percent are scheduled to be hardened. And we've
14 got about 15 percent we are working on to try to get
15 them to come on board. But if they are already
16 planning on disposal of the source or they are already
17 at a higher level of security because of the type of
18 business they are in, then they really do need
19 hardening.

20 Next slide, please. Then the GTRI's
21 physical protection upgrade, which is kind of
22 something else they offer, again, this is the hardware
23 associated with a security system. We've got about 30
24 percent that are already in place operational. We've
25 got 44 percent that are scheduled to be analyzed. And

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1 then they will take on whatever enhancements that they
2 can come to an agreement on, but they're on board to
3 have it happen. So that is great. And we've got
4 about 25-26 percent that are still on the fence. And
5 we are going to work on them to come on board, but it
6 is a voluntary program. And we always let everybody
7 know that.

8 Next slide there. The force training.
9 This is something that we are very much in agreement
10 with GTRI that where the rubber meets the road, if
11 anything bad does happen, it is when the young men
12 with short haircuts show up. And so we really support
13 this and try to get the licensees to get on board.

14 We have got about 22 to 25 percent who
15 have already gone through the training. We have got
16 about 50 percent that are scheduled to go through the
17 training and 30 percent that have not.

18 And another slide, please. This is
19 actually a licensee in North Carolina that had been
20 keeping some things in the back for 40 years . And,
21 with the leverage that the IC has provided us, we were
22 able to motivate them to go ahead and pay up what it
23 costs to dispose of some of these things.

24 And, again, there are options out there
25 now, largely thanks to GTRI and other federal

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1 programs. We wish there were more options, but at
2 least there are a few. And we're trying to help the
3 licensees out as much as we can.

4 And last slide. From a standpoint of
5 going forward, I've got here negative forecasts for
6 the economy. That should probably be an uncertain
7 forecast for the economy.

8 I think the licensees are concerned about
9 the future. And a lot of people are. And that is
10 making some cascading uncertainties which affect
11 planning. A lot of people are having trouble planning
12 out one, two, five years from here.

13 The expanding threat analysis or threat
14 environment is expanding what mitigation needs are in
15 place. We heard the Part 37 is coming down the
16 tracks, and it is. This is going to represent an
17 increased burden on the licensee. There is no way to
18 avoid that. Licensees recognize it as a burden, but
19 so far I would say they are all on board to accept
20 that burden and go forward.

21 Lack of disposal options is another future
22 challenge. We hope that more disposal options become
23 apparent soon. And the lack of options as far as
24 technologies is something the licensees would like to
25 have as another option. What else can I do?

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1 And that's all I've got for right now.
2 Thanks.

3 MR. RATLIFF: Yes. The Conference of
4 Radiation Control Program Directors asked me to
5 represent what we had seen in Texas in the
6 implementation of the increased controls.

7 In Texas, we have every category that fell
8 under the increased controls. Nearly 300 of our
9 radioactive material licensees that had IC quantities
10 ranging from multiple things -- in Texas, being an oil
11 and gas state, we have a lot of industrial
12 radiographers with 100 and 200 curie iridium sources,
13 a lot of oil and gas producers with radioactive
14 materials, and then a lot of material use in both the
15 blood irradiators and in research irradiators.

16 So when we developed our initial guidance,
17 we knew that this was a new program. We were getting
18 multiple questions. I volunteered and was on one of
19 the Task Forces with NRC developing the increased
20 control questions.

21 So we started out with the outreach
22 programs kind of like this with our licensees. And,
23 as typically happens, the ones who really care showed
24 up. And the other ones didn't realize what was going
25 on.

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1 So we started to prioritize inspections.
2 And in the first year, we conducted over 300
3 inspections. And when we say 300, it was just the
4 radiographers and well-loggers because we look at
5 every field site, even though we have 300, including
6 the blood irradiators and universities and the
7 combined industrial devices. Many of our
8 petrochemical facilities will have cesium-137 and
9 gauging devices. And when you take the aggregate
10 quantity, they came under increased controls.

11 But during those inspections, it was
12 interesting. And we have looked at the trends, what
13 happened. And when you look at all licensees -- and
14 this report, I have been traveling and doing stuff. I
15 didn't get to put this into slide form. But what I
16 have here are trends. It's on our website. And
17 anyone who wants to get this address I can get it to
18 you or you can actually go and look at the PDF file
19 here.

20 When we looked in F.Y. 2007, the IC 1
21 across the board had the highest number of violations.
22 And so our philosophy was we went in after we had the
23 stakeholders' meeting. We did training. We then
24 started the inspections. And if a facility had begun
25 to implement, even if since it was new they didn't

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1 have it all together, we worked with them.

2 Surprisingly, we ran across about 20
3 percent who were waiting for us to come and had done
4 nothing. And so on those we started enforcement
5 immediately. What it helped we thought is the fact
6 that in our state, we have administrative penalty
7 authority up to \$10,000 per day per violation. So we
8 worked with them.

9 We didn't want to penalize so they
10 couldn't do the upgrades needed, but we wanted to get
11 their attention. Industrial radiographers tend to be
12 one of our biggest areas. They just didn't implement.

13 You know, they have mobile sources. And
14 we looked across, especially Increased Control 1,
15 access control. All licensees are failed there. We
16 look in Fiscal Year (FY) 2007. That's the largest
17 violation.

18 As you went across, though, for access
19 control now to fiscal year 2010, all licensees are
20 down to a less than five percent violation.
21 Industrial radiographers have got it. They're down to
22 less than one percent of the violations. Access
23 control, they have done well.

24 A lot of them had challenges because with
25 their mobile devices, they have -- it's almost like a

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1 camper on the back where they have the dark room and
2 the storage and they had to put interlocks on the door
3 so that when they were staying at a hotel, when they
4 were on a field job, they could tell.

5 And they learned quickly that certain
6 types of sensors eroded because they used chemicals to
7 process film. They are vibrated because they are not
8 on the regular highways. They are going up on
9 pipelines. And so they have really evolved and new
10 technology, I think, have stimulated the economy with
11 increased controls in the areas.

12 When we looked at it, the other one that
13 tended to have the large area was IC 2, the detect,
14 assess, and respond that Terry reported on. And it
15 was a little less, but still in 2007, it was high as
16 it struck down. We're at less than five percent.

17 I think it's a good testimony to the
18 States, the NRC, and the licensees working together.
19 As we see these trends, you start out with a new
20 program. You see multiple violations. And you have
21 seen a continuing decrease to the point where now the
22 majority of the licensees are all in compliance.

23 I think one thing that really surprised us
24 was IC 6, the sensitive information, retaining it, was
25 a large percentage of the violations the first go-

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1 around. People just didn't get the importance of
2 keeping this information secured.

3 You know, you have your records that the
4 RSO keeps. And they have them there, but they did not
5 really get into that part about how the security of
6 the records seem to be kept for the sensitive
7 information. That one has almost flattened out. In
8 2010, we have not had any violations on either side.

9 We basically as we did the radiographers
10 found that, you know, they came along begrudgingly.
11 The first question asked is, who is going to pay and
12 who is going to install? And we said, "You and you."
13 And after we got past that, it started getting better.

14 Our second go-around, then, with the
15 cesium blood irradiators -- and we have I think
16 40-some in Texas. The biggest issue we saw there was
17 the fact that we said no one can come in and get this
18 device out of our facility. As we explained to them
19 what the terrorist issues could be, they really
20 cooperated.

21 What we saw that all of them needed to
22 really look at is they set up good security but
23 sometimes failed to remember. The people that control
24 the access badges are usually in IT. And they had not
25 done the T&R on the IT folks that are there. So that

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1 was probably one of the biggest learning areas, that
2 you've got to make sure that anyone who can have
3 access or who can grant themselves access has been
4 T&R.

5 So it was surprising that that sensitive
6 information now has dropped to really nothing. Now
7 that we have looked overall, the fingerprinting
8 basically followed the same track. Once we
9 implemented the fingerprinting in 2009, we have all
10 licensees' violations. Now in FY 10, all licensees
11 are down to less than two percent.

12 Industrial radiographer licensees because
13 of the work they do in petrochemical plants, et
14 cetera, they have required security already. And
15 you've got to understand I don't know if there are any
16 of them here, but this is an industry where their
17 background check may show a lot of failings. They are
18 in bar fights. They have had speeding tickets. They
19 have done all things. But from a terrorist issue,
20 they did good.

21 And they have basically really embraced
22 the fingerprinting to make sure that they can weed
23 out. And it has helped them somewhat because one of
24 the industrial radiography RSOs told me one time in
25 enforcement the problem that they have is if they can

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1 find a person who can pass a drug test and be found
2 acceptable on the fingerprinting, they want to work in
3 an air-conditioned office behind the computer, not in
4 the field, where it is 100 degrees going across
5 country. They seem to find people who can do this
6 job, which is important, because the pipelines, the
7 aircraft, engine frames, everything that we deal with
8 has to have the nondestructive testing.

9 As we have looked more and more at the
10 blood irradiators, we find out that they have really
11 cooperated. We really feel that they have been open,
12 like Grant said, to accepting the hardening of their
13 devices. In fact, they all want to go first and so
14 trying to coordinate with the fighting that had ended
15 until the new fiscal year for Congress.

16 So we really think that at this point
17 because of the proven record of how the licensees had
18 embraced increased controls and the fact that they are
19 taking security serious, the local law enforcement
20 agencies have really come aboard. And when they
21 don't, we have our homeland security people talk to
22 them the money they're getting and how it's to their
23 advantage to help out.

24 And so all of those things together have
25 really increased security. We keep reminding our

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1 people, though, that they have to be diligent because
2 if you let it slack for one little bit, that's the
3 opening that a terrorist might have.

4 And so we think it is a successful
5 program. We really hope that long term if there are
6 alternate technologies, the waste issue is still our
7 biggest issue we see.

8 We have a waste site that may be operating
9 in Texas soon, but it won't take greater than Class C
10 waste. So we are way down the road until we get to
11 that point.

12 I thank you.

13 HEALTH PHYSICS SOCIETY PERSPECTIVES

14 DR. MAHER: I decided to use the podium
15 because my neck was getting sore. Again, my name is
16 Ed Maher. And I am the President of the Health
17 Physics Society.

18 For those of you unfamiliar with the
19 Society, we are a group of 5,500 professionals
20 nationwide whose sole concern is radiation safety of
21 all types of radiation sources.

22 We do not advocate for a particular
23 technology. It is solely we only advocate for the
24 safe use of that technology from a radiological
25 standpoint. So, with that, I would like to -- we

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1 submitted comments to the NRC. And we would like to
2 give our perspective on the NRC's work here.

3 First of all, fundamentally we agree with
4 virtually everything the Commission has done. We
5 agree that they have done a great job in the draft
6 policy statement. And we want to compliment the
7 Commission on that work.

8 We do feel that they probably have not
9 gone far enough. And I want to talk about two areas
10 we would like to see them clarify or amplify on and
11 perhaps move more in a regulatory direction.

12 The first one is the consideration of the
13 Category 3 sources, which were categorically excluded
14 from the policy statement. We believe that there are
15 Category 3 sources that should deserve consideration.

16 And the second area is the integration of
17 alternative technologies in the licensing process. So
18 I would like to go into more detail in both of these
19 areas. The first area is the Category 3 cesium
20 chloride sources. As you know, the IAEA code of
21 conduct was used to justify the Category 1 and 2
22 sources.

23 I would also point out that Category 3 is
24 also classified as a dangerous source by an IAEA and
25 that by "dangerous" means that those three categories

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1 of sources, those size sources, can cause severe
2 deterministic effects in humans. That was the basis
3 for IAEA's classification. Since Category 3 was
4 included by IAEA, we believe that it should also be
5 considered under the policy statement.

6 We realize that Category 3 is a dividing
7 line for enhanced security and controls as a dangerous
8 source by IAEA. However, we do believe that some of
9 the Category 3 sources should deserve further
10 consideration, not all.

11 And emphasis ought to be on increased
12 security, as opposed to increased controls, meaning
13 that we do believe some of these Category 3 sources --
14 and I'll define some of those as well-logging sources,
15 level gauges, should be included the national tracking
16 system, and also have more protective security.

17 We like to see in the draft policy
18 statement or the policy statement going forward that a
19 discussion of well-logging sources and level gauge
20 sources, how they might be protected better. And also
21 on the alternative technologies, what types of
22 technologies are there to substitute for Category 3
23 sources for those uses.

24 Okay. Area number two that we would like
25 to see the Commission go further on is alternative

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1 technologies. We agree that research and development
2 is not in the scope of NRC. We are not exactly sure
3 whose scope it is in because that sort of was left
4 undefined.

5 We sort of think that good candidates
6 might be NNSA or DOE, but it really is undefined whose
7 job is the R&D. And in this specific instance, our
8 use of cesium chloride, it would seem like the
9 security side of the house would take the lead on it,
10 be the champion. And so we're probably looking at
11 NNSA to do something like that. It would be nice. It
12 was a hole in the process. So we're identifying a
13 champion for the R&D.

14 The position to use alternative
15 technologies is provided in the Energy Policy Act of
16 2005. And it says directing it to promote the
17 placement of risk-significant radioactive sources.
18 Although that is discussed in background in the draft
19 position statement, we feel that this needs to be
20 incorporated in the licensing process directly.

21 What we would like to see at some point,
22 that a licensee who is applying for a license for
23 cesium chloride source, that in the application
24 addressed why they did not use a non-radioactive
25 source alternative technology.

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1 And who provides the information of what
2 is acceptable alternative non-radioactive source
3 technology? We believe the interagency radiation
4 source protection in security task group, the Task
5 Force through their annual updates of technologies
6 that are available would be the source of the NRC to
7 review license applications to see if the applicant
8 considered, properly considered, non-radioactive
9 source alternative technologies.

10 Okay. So right now the draft policy does
11 not incorporate any alternative technology in the
12 licensing process. And we do believe that needs to
13 occur. If it does not get put into the licensing
14 process, I don't feel it is going to happen in the
15 long term.

16 Again, because the Health Physics Society
17 is concerned with the health and safety aspect, we
18 believe whenever you can replace a risk-significant
19 source with a non-radioactive source, then that's what
20 you should be doing.

21 Category 3 sources may provide the
22 greatest chance to do that. There are other
23 technologies, alternative technologies, for Category 3
24 sources. We do understand that in Category 1 and 2,
25 there are some limitations in terms of cost,

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1 throughput, and other reasons why, for instance, X-
2 rays would not be a suitable replacement at this
3 point.

4 We also acknowledge that many of the
5 alternative technologies, non-radioactive source that
6 were being considered do not meet many of the
7 performance requirements, costs, and other factors
8 that would go into determining whether or not it was
9 an acceptable alternative on the licensing process.
10 But we do believe that cost and those other factors,
11 throughput, could be a legitimate reason why you would
12 not consider a cesium source alternative.

13 And that's pretty much it. Thank you.

14 (Applause.)

15 FACILITATOR BAILEY: Okay. Thanks again
16 to all of the panelists.

17 Before we proceed, Mr. Ratliff, I think
18 you mentioned a website that would contain some of the
19 information from the oral presentation. If you could
20 please state that for the transcript as well as for
21 the benefit of the audience?

22 MR. RATLIFF: Will do.
23 Www.dshs.state.tx.us/radiation.

24 FACILITATOR BAILEY: Thank you very much.

25 Okay. Now we will proceed to take any

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1 clarifying questions pertaining to the panelists'
2 presentations, in addition to your comments pertaining
3 to those presentations. At this time if you have any,
4 please again approach the mike and speak clearly,
5 loudly and clearly. Once again, please state your
6 name as you begin and the organization which you are
7 representing.

8 STATEMENTS & ROUND TABLE DISCUSSION

9 DR. NELSON: Hello. My name is Kevin
10 Nelson. I am the Radiation Safety Officer at Mayo
11 Clinic. And I will also be one of the panelists over
12 the next couple of days.

13 I was reading with interest the policy
14 statement, draft policy statement. I thought it was
15 very well put together. There are three separate
16 locations that I can find where security is mentioned
17 and that we currently feel, the NRC currently feels,
18 that services are secure.

19 And that led me to ask myself why Part 37
20 was really even necessary. And I think I have heard a
21 little bit now from Terry and Steve about some of the
22 issues. And perhaps it might be useful, then, if Part
23 37 is required. And I do think it's a little bit more
24 prescriptive than the orders that originally came out.
25 You might want to consider addressing that in your

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1 policy statement.

2 FACILITATOR BAILEY: Thank you for your
3 comment.

4 MR. REIS: I hadn't given much thought to
5 it being in the policy statement itself, but, I mean,
6 it's true. It certainly is our way of -- I just gave
7 a presentation on this last week.

8 You know, we don't -- the NRC, we don't
9 normally operate -- we don't regulate normally with
10 orders . You know, it is a quick way to impose
11 requirements or do other things of a regulatory nature
12 that require expediency, but the proper normal way is
13 the rulemaking process.

14 And so we feel that the Part 37
15 incorporates the spirit and intent and takes a fresh
16 look at everything we have done over the past five
17 years and helps fill in any gaps that we perceive is
18 there. Some of those gaps are controversial. And
19 that's why we have the public debate and the public
20 comment period.

21 I think we agree. I need to think more
22 about see where it would fit in the policy statement
23 itself.

24 Steve?

25 MR. REYNOLDS: I basically would agree

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1 with you. I think the real need for Part 37 is just
2 to clear up some confusion we have had over the ICs.
3 We spoke briefly about working on a group to answer
4 questions. I've been on that group for, what, two
5 years or more, at least, answering questions all the
6 time. So I think Part 37 is going to clear up some of
7 that and also fix some gaps that we saw in the
8 increase, especially in the area of periodic testing
9 of the equipment.

10 And, like Terry, I'm going to have to step
11 back and think about whether the switch from the ICs
12 order to Part 37 belongs in the policy statement.
13 That's a good question. I don't know if off the top
14 it does, but I do think Part 37 is going to help
15 licensees understand our regulations better and there
16 are going to be some enhancements to it and to other
17 sources.

18 MR. MILLS: This is Grant Mills, North
19 Carolina. I just wanted to follow up on that, too.
20 It hit me. I saw I think maybe the same thing you did
21 in how they worded that. At one point they worded
22 where it was very clear that it indicated that
23 implementation meant an ongoing day-to-day program and
24 not just the fact that the orders were on the book was
25 the improvement but that the ongoing day-to-day

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1 implementation was the key to it being a success.

2 And I thought that was really good that
3 they made that clear. You know, the fact that the
4 orders were on the book was not a success but that it
5 was a day-to-day implementation that was going to make
6 it a success. And I think Part 37 goes a long way to
7 enhancing that day-to-day operation and making it a
8 continuous improvement program.

9 FACILITATOR BAILEY: Okay. Thank you.

10 We will take the next comment or question.

11 MR. LEWIS: Yes. Thank you.

12 I have a question for the audience. I am
13 Rob Lewis from the NRC.

14 I will add a thought to that thread,
15 though. The increased controls were issued with very
16 little stakeholder involvement. And, of course, Part
17 37 as a formal rulemaking has extensive stakeholder
18 involvement, probably more than any other rule I have
19 been involved with since I have been in NRC. And, of
20 course, Part 37 is a proposed rule and we are getting
21 comments on what is adequate security for these
22 sources.

23 So, along those lines, you know, that is
24 the reason for Part 37. We need the stakeholder
25 involvement in defining what is adequate for security.

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1 We didn't have that when we did the increased control.

2 When we wrote the policy statement that we
3 are talking about today on cesium chloride, we were --
4 in all honesty, prior to the meeting, increased
5 control is what we were talking about when we said,
6 "the existing security infrastructure."

7 But I do have a question. And it involves
8 the role of the regulator for the audience, for the
9 nongovernment people in the audience really.

10 One of the things that is confusing to a
11 lot of people and even was very confusing inside NRC,
12 the people that did work on it every day, was our
13 increased controls are kind of the baseline of
14 security, what is required for security. And Grant
15 and Terry both mentioned the security assist visits
16 and the voluntary hardening that NNSA is doing for
17 these irradiators as kind of an extra-regulatory
18 activity. It goes beyond the baseline of security,
19 but its better security.

20 So I guess the question I have for some of
21 the nongovernment people is, is that causing a lot of
22 confusion? And does everyone appreciate some of the
23 nuances there? For example, the increased controls
24 require detecting unauthorized access.

25 Well, there are many ways to detect

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1 unauthorized access, including some of the ways that
2 the voluntary enhancements that NNSA provides. For
3 example, if they put in some closed circuit TV as part
4 of their security assist upgrades and as a licensee,
5 you now start using that as your means to detect
6 unauthorized access, well, that is no longer
7 voluntary. That is now part of your regulatory
8 program for compliance.

9 So if there is any feedback about how we
10 can better communicate how those programs support each
11 other? We did do a one-pager on this last year. We
12 have been distributing it heavily. I think it has
13 helped. I am not sure. I think within the
14 government, we have our story lined up, but I am not
15 sure that outside of the government, that it is. So
16 any feedback on that would be very welcomed.

17 DR. NELSON: This is Kevin Nelson again
18 from Mayo Clinic.

19 In response to your questions, again, I
20 was very interested in hearing some of the responses
21 given by our panelists. The black hole for us as
22 licensees is we aren't quite sure what actually works,
23 what kinds of things we should be looking at.

24 And some of this information is
25 privileged. The Mayo Clinic that I represent is in

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1 Florida. So we are working with our Bureau of
2 Radiation Control people in Florida in trying to
3 identify what some of the best practices are, as I am
4 sure you are at the NRC. You are trying to figure out
5 what the best practices are. So it is an ongoing
6 thing.

7 But I think it would be useful to know
8 where some of the holes were in this initial set of
9 orders to help us better understand why we need to do
10 some more things that are being prescribed in Part 37.

11 As far as voluntary enhancements, I think
12 they are very useful. We have the NNSA folks coming
13 to our facility the end of the month. We have been
14 waiting for two years, a year and a half or two years
15 to actually have them come to our facility.

16 And I think target hardening for blood
17 bank irradiators is one of the most important things
18 that we can do. But it is just, you know, we have
19 been waiting and waiting and waiting for their visit
20 and to hear about some of their additional security
21 measures that they might recommend.

22 So we are anxiously awaiting further
23 feedback from the NRC, from some of these other groups
24 that are involved in security. We would be happy to
25 look at these things, but we aren't quite sure what

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1 you are finding out.

2 DR. JONES: If I could just interject one
3 second? We will be having a presentation on that. My
4 name is Cyndi Jones. I am co-coordinator with John on
5 this workshop. I am also with NRC in the Office of
6 Nuclear Security and Incident Response.

7 This afternoon we will be having a
8 presentation on Part 37. And I think that your
9 comments are very valid that we have that discussion
10 at least included. So that we don't have to put it in
11 the parking lot perhaps but at least keep it so that
12 we ask Merri Horn, who will be here later this
13 afternoon when that comes up on the differences
14 between the Orders and Part 37, of which there are
15 quite a few, and what were the reasons for the
16 differences.

17 So if we forget to put that on our parking
18 list, we will bring it up this afternoon. Thanks.

19 MS. CARR-GREER: My name is Allene
20 Carr-Greer.

21 FACILITATOR BAILEY: Okay. One more time,
22 Madam. Speak just a little louder into the mike.

23 MS. CARR-GREER: My name is Allene
24 Carr-Greer. And I am with AABB.

25 Perhaps I misunderstood what I think it

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1 was this gentleman just said. I am not sure who you
2 were with, but maybe I misunderstood what you were
3 saying about voluntary, when a voluntary program is
4 put into place. And then if it becomes part of a
5 standard operating procedure, it is no longer a
6 voluntary program.

7 MR. REYNOLDS: I think I can try to help
8 her out.

9 MS. CARR-GREER: Thank you.

10 MR. REYNOLDS: What he's saying, under
11 increased control, IC 2, you have to have ability to
12 detect, assess, and respond. And if you come in and
13 have a voluntary upgrade to whatever system you have
14 and say you switch to like logigram from, say, motion
15 detector to closed circuit TV and you got rid of your
16 motion detector, that voluntary effort that you do not
17 put in is being used to meet IC 2. That is your only
18 method of detecting the necessity of the situation.
19 That now becomes required under IC 2.

20 If you left in your motion detector for IC
21 2 and you added your closed circuit TV, your closed
22 circuit TV would still be voluntary, but if you take
23 out one of your mechanisms to assess and detect. If
24 you only rely on the voluntary one, that's not
25 required.

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1 MS. CARR-GREER: So you can upgrade, you
2 can change?

3 MR. REIS: I think what we're saying -- we
4 get this a lot -- is that you just have to be careful
5 that when you work with GTRI, which we encourage, is
6 that you know what you are getting and you reconcile
7 it with your regulatory basis so that you know if you
8 are taking credit for it within any of your
9 requirements of the ICs because if you are taking
10 credit for it, then it is no longer voluntary.
11 Understand? You still look a little --

12 MS. CARR-GREER: No, no. I think --

13 MR. REIS: Okay.

14 MS. CARR-GREER: What I think I wanted to
15 ask was does that preclude upgrades? It happens then.
16 You have experience form North Carolina.

17 MR. MILLS: I suspect these guys have a
18 lot more experience than I do. It is always your
19 program. If you want to -- the day after GTRI leaves,
20 if you want to tear everything out and put a Doberman
21 Pinscher in there, you can do that. But, like they
22 said, it is always your program and you are going to
23 have to have a current IC 2 that reflects how you are
24 doing business that day.

25 MS. CARR-GREER: Thank you.

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1 FACILITATOR BAILEY: I'm sorry, ma'am.
2 You used an acronym to describe your agency or
3 organization. Would you mind --

4 MS. CARR-GREER: It is called AABB,
5 formerly known as American Association of Blood Banks,
6 which is probably how we are still best known.

7 FACILITATOR BAILEY: Okay.

8 MS. CARR-GREER: Thank you

9 FACILITATOR BAILEY: Thanks.

10 MS. SHEPHERD: I'm Mary Shepherd, JL
11 Shepherd and Associates.

12 Regarding voluntary enhancements, we are
13 participating in the GTRI voluntary enhancements. And
14 we have been inspected to the new voluntary -- to see
15 things that we put in place, which I can't talk about,
16 but, as those steps get finished, we do get inspected
17 to those upgrades that we have done. So, again, it
18 will depend on how you write your increased controls
19 and your compliance with them.

20 It is a very interesting -- you know, we
21 did voluntary. And we had no idea we were going to be
22 inspected as soon as it was finished to the upgrades
23 that we did. So that was comment 1.

24 For comment 2, I had the R&D for
25 alternative technologies. There is a program in

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1 place. Sandia National Labs is funded to provide
2 alternative technologies. And it depends on the
3 funding, congressional funding cycle. And we are
4 working with some people on our alternative
5 technologies.

6 For the increased controls, manufacturing
7 distribution licensee, we check with our licensees
8 that their increased controls are in place before
9 Category 1 or Category 2 is installed, not just the
10 license but that their ICs are there so they're ready
11 to accept the irradiator, no problems once we get
12 there.

13 And for the unescorted access, everyone
14 asks us for the T&R letters when we come into their
15 facilities, sometimes before we even have the crew
16 assembled. We T&Red everybody. So it's no problem.
17 And I say that for the last year, everyone has asked
18 for the T&R letters. And it's working very well.

19 FACILITATOR BAILEY: Thank you.

20 DR. JONES: T&R is trustworthy and
21 reliability.

22 FACILITATOR BAILEY: Anyone else at this
23 time?

24 DR. JONES: I have one comment, one
25 question, Ken. I think it would be helpful for the

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1 audience members and for the people that will be
2 reading this transcript in months and years to come.

3 When we issued the increased controls in
4 around 2005, there was a period of opportunity for the
5 Agreement States to implement them at a later date.
6 Could the panelists speak to when the Agreement States
7 implemented the increased controls and when did the
8 inspection of those facilities start? Thank you.

9 MR. RATLIFF: I know in Texas and I think
10 all of the other Agreement States in 2007, we had to
11 determine our priority, anyone that had Category 1 and
12 2 sources and then with that priority, do priority one
13 inspections within the first year. Then within a
14 three year period, we had to have inspected all of the
15 licensees that came in under increased controls.

16 Unlike NRC, we can't issue emergency
17 orders or orders unless it's an emergency. So the
18 States, I think almost every State did apply license
19 condition. And once those were issued, the
20 inspections commenced on the priority level.

21 MR. MILLS: I'm afraid I transitioned in a
22 year after they implemented them. So I don't know.

23 DR. MAIELLO: Mark Maiello from Pfizer,
24 Pearl River.

25 In answer to that question, New York State

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1 has been very diligent inspecting us every year prior
2 to IC. And then their first inspection after IC, they
3 included the IC inspection as part of the overall
4 program inspection.

5 Just a question, a curious question. How
6 have we been doing with the not-for-profits that have
7 sources of concern? Have we brought them pretty much
8 all up to the level of well-heeled corporations and
9 firms? Have you had any experience with that?

10 MR. RATLIFF: I think in Texas, the ones
11 we have seen who had the hardest time were some of the
12 not-for-profit blood banks. The industry, the
13 universities, the industries that have radiography
14 well-logging, you know, have income, but the
15 not-for-profits we have worked with and maybe worked
16 more one-on-one within the given guidance still
17 insisted that since they have these sources that would
18 be ones that terrorists would look, they had to meet
19 the requirements. And most of them have looked at
20 what their funding is and have been able to, maybe not
21 at the same level as others, but they did meet the
22 requirements.

23 MR. MILLS: I'd say in general the only
24 trend I picked up on is the ones who have more control
25 locally tend to have a little better handle on things.

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1 The ones who have to reach back and wait for
2 resources, they have a little harder time.

3 MR. REYNOLDS: I would say the NRC's
4 experience is the same as Richard's and Grant's. We
5 haven't found any anomalies with not-for-profits.

6 DR. JONES: Can you use the mike?

7 MR. REYNOLDS: Sorry. I thought I was.
8 Again, the NRC's experience is the same as Richard's
9 and Grant's. Not-for-profits, all their facilities
10 turned out okay.

11 We do have some they have to go back to
12 where their corporate is. If it's like local, it's
13 easier for them or -- they all seem to understand the
14 need for that, and they try the best they can.

15 DR. JONES: Any other questions that
16 people have?

17 (No response.)

18 DR. JONES: If we look to the participant
19 deliberations and discussion points that were outlined
20 in the Federal Register notice, we really touched on
21 the first two quite well. We had the status and
22 history of the current requirements, and we heard a
23 little bit about the licensees' experiences in
24 implementing the increased controls.

25 One thing that we heard was that there was

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1 -- and please correct me if I am wrong. We heard that
2 there was an opportunity of increased improvement for
3 licensees between the first time we went out to
4 inspect them and maybe the second time.

5 One thing that you referenced was
6 administrative procedures or administrative
7 corrections that needed to be done, that term I think
8 you mentioned, Steve, "violations" of that nature.

9 Were there any other more serious
10 questions that licensees had about not being able to
11 follow the increased controls or do the security
12 inspections who are having difficulty with law
13 enforcement on their procedures? Can you speak to
14 that?

15 MR. REYNOLDS: Sure. I'll speak a little
16 bit to IC 2 and then maybe Richard or Grant. IC 2 is
17 the area where the local law enforcement is required
18 and the ability to detect, assess, and respond.

19 We have seen with some licensees that make
20 the attempt to contact the local law enforcement
21 agency or they did make an attempt and they didn't
22 explain it to -- in fact, we had some licensees go to
23 the local law enforcement agency and say, "I need to
24 talk to you about emergency response."

25 The local law enforcement ushered them

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1 over to the local fire department or local emergency
2 response group. It's not really emergency response.
3 So they use the wrong choice of words. We try to
4 explain to them, you know, it's really to respond to a
5 theft or a break-in or something. Once the local law
6 enforcement hears that, they understand their role.

7 So I think early on, if we would prepare
8 the licensees, they may be able to develop security
9 plans with the local law enforcement agency.

10 That area, the equipment used for IC 2's
11 ability to assess, detect, and respond, some licensees
12 have contracted out with alarm companies. And between
13 the alarm company and the licensee, they got it
14 backwards, didn't have the right equipment in, wasn't
15 able to really monitor and assess, detect or some
16 licensees reported if you have a closed circuit TV,
17 they do not have somebody monitor it continuously,
18 things like that, or it's some places they have an
19 alarm-type system and they would turn it off. It
20 needs to be done .

21 And then sometimes modifications are done
22 in a building. We have had cases where hospitals had
23 upgrades to the building and it's affected the alarm
24 system and they didn't test it or check that. So it
25 had a lot of equipment problems because it worked

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1 properly the first time and as an item intended and as
2 maintained or protected, ongoing maintenance around,
3 test it, verify it still works.

4 We had another licensee that used an
5 analog system. And then the vendor decided to go to
6 digital and didn't tell the licensee. And they didn't
7 check it. Our staff just went out and checked it.
8 And they corrected it. They now have a digital system
9 that does work, but those are the types of things.

10 I don't know if Richard has any or Grant
11 has any others.

12 MR. RATLIFF: Yes. I think initially
13 local law enforcement agencies in large cities,
14 Houston, Dallas, basically said, you know, "We're
15 dealing with murders, rapes, other crimes. And we
16 don't want alarms going off all the time." But I
17 think as they were trained and they realized the
18 importance and what would really happen, they have all
19 come on board.

20 Smaller communities, the issue has been
21 there may be multiple jurisdictions that overlap and
22 try to figure out which one is the primary responder.
23 And I think they have done a good job. If nothing
24 else, their local law enforcement now knows that they
25 have licensees in their jurisdiction. I think that

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1 has been a net positive.

2 MR. MILLS: Ditto what these folks have
3 said. We have seen that law enforcement is a
4 transitional occupation, kind of like radiography, I
5 guess. And licensees would get a point of contact in
6 a relationship with a police officer and then not
7 maintain that at a frequency. And, sure enough, when
8 we do the inspection and call, he left three months
9 ago or something like that. Nobody at the police
10 station knows what is going on.

11 These are the things that I think you will
12 hear Part 37 will correct a lot of those issues.

13 MR. REYNOLDS: I think what needs to be
14 clarified, we're talking probably all IC licensees,
15 just not licensees with cesium chloride blood banks
16 and research. It's all ICs. I think with the NRC,
17 our experience has been, like I said earlier, blood
18 banks and research actually perform better in general
19 than IC licensees.

20 DR. JONES: Thanks for that clarification.

21 Have you seen, for the panelists that were
22 part of the inspections or part of the inspection
23 program, has there been any decrease or increase in
24 the number of lost, stolen, or missing sources since
25 the increased controls were put in place? Is there

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1 any way to notice any difference or is it too early to
2 tell?

3 MR. REYNOLDS: We haven't seen any
4 increase. If you combine the increased control order
5 with other regulations, like 30.34(i), our Category 3
6 sources, we have actually seen probably a decrease in
7 lost or stolen sources.

8 But Category 1 and 2 sources I'm just
9 thinking off the top of my head. I can't remember any
10 being lost or stolen. So I guess we haven't
11 increased.

12 MR. RATLIFF: No. In fact, the States as
13 well. I think what we see is the Category 4 and maybe
14 the 3 sources generally I think across the States in
15 which the gauges that are left in the back of the
16 pickup and opportunity for theft but nothing that
17 really reaches the thresholds of increased controls
18 that I am aware of.

19 MR. REIS: Cyndi, we'll go back and check,
20 but I had this discussion with someone. Rob?

21 MR. LEWIS: Yes. Just for the record, I
22 think I am very confident to say that since the ICs
23 have been put in place -- and NSTS is a big part of
24 that becoming operational about two years ago -- there
25 have been no lost or stolen Category 1 or 2 sources

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1 that haven't been immediately found. I mean, they
2 might get misplaced during transit or something, but
3 they find it right away. Prior to the ICs, we could
4 not say that.

5 DR. JONES: Thank you.

6 MR. MILLS: I just want to reiterate
7 something I said earlier. There is no question in my
8 mind that there is bleed-over from the ICs to all
9 sources. The cooperation and understanding between
10 all the stakeholders now is a much higher level. And
11 there have been events that I have seen that would
12 have, you know, maybe not ever have been reported or
13 been reported in weeks. And now they handle it, jump
14 right on, and take care of it. There is a heightened
15 awareness for the security of all radioactive
16 material.

17 DR. JONES: Any other questions or
18 comments?

19 DR. MINNITI: Yes. Good morning. My name
20 is Ronaldo Minniti. I am from NIST.

21 I had a question for the President of
22 Health Physics Society. That was a nice presentation,
23 by the way. You mentioned that we should include the
24 Category 3 sources in terms of increasing security.
25 Could you a little bit tell us about what are the

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1 typical activities, the sources you are referring to?

2 DR. MAHER: You mean in terms of
3 activities?

4 DR. MINNITI: Of curies.

5 DR. MAHER: Oh. Well, if you go by the
6 IAEA classification, 3 is severe deterministic effects
7 can occur. I believe from hours to days is the
8 exposure range. So these are sources if they are
9 stolen or taken or improperly used, then we're talking
10 about hours. And severe effects could occur. And
11 that's why we felt IAEA includes them as dangerous
12 sources that perhaps the NRC ought to also.

13 DR. MINNITI: I was asking more like
14 numbers and curies. I know Category 3 is --

15 DR. MAHER: Well, I think it's, you know,
16 probably a couple of curies to millicuries.

17 DR. MINNITI: A couple of curies.

18 MR. REIS: I need to check. I can check
19 that.

20 DR. MAHER: We could check that.

21 DR. MILLER: It's a factor of 100 below
22 Category 2.

23 DR. MAHER: It's a factor of 100?

24 DR. MILLER: That's right. Category 2.

25 DR. MAHER:

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1 MR. REIS: So if you look at the Category
2 table that is in my slide, it's a factor of 100
3 below that.

4 DR. MILLER: It's a factor of ten.

5 MR. REIS: It's a factor of ten?

6 DR. MILLER: This is Charlie Miller again.

7 Yes. If you look at the IAEA Code of
8 Conduct, Category 2 sources, which we are currently
9 requiring to be protected from increased controls, to
10 go to Category 3, it's one-tenth of Category 2. For
11 the various nuclides that are included in the IAEA
12 code of conduct, I think we had a chart up there
13 earlier that kind of showed what they were.

14 DR. MINNITI: Thank you.

15 FACILITATOR BAILEY: Okay. Again, sir,
16 could you please state the name of your agency in full
17 for the transcriber?

18 DR. MINNITI: Yes. It's NIST, National
19 Institute of Standards and Technology.

20 FACILITATOR BAILEY: Thank you.

21 DR. NELSON: This is Kevin Nelson from
22 Mayo Clinic again.

23 And, just as a follow-up to that question,
24 having worn my a few years ago the President of the
25 Health Physics Society hat, as Ed is doing this year,

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1 I am just sort of curious why Category 3 sources were
2 not included initially. I'm asking specifically the
3 NRC representatives.

4 MR. REIS: That actually predates me, but
5 I won't try to -- I think the simple question is that
6 the way this worked, if you go back through the
7 history, which I have had to do -- I have only been
8 with the program three years -- there were things
9 called vulnerability assessments done, where we
10 determined the risk. And, as in most everything we do
11 in the NRC, we take a risk-informed approach to our
12 protection schemes.

13 And so when we did the vulnerability
14 assessments and we presented the information to the
15 Commission, the decision was at that time it was
16 decided that, at least initially, we were going to
17 draw that line at Category 2.

18 Now, there have since been policy papers
19 before the Commission, for instance, to expand an STS
20 to Category 3 or one-tenth of Category 3. And that
21 position didn't carry the day. So we're still in
22 discussions with the Commission, but right now the
23 policy decision is Category 2.

24 DR. MILLER: This is Charlie Miller.

25 To give a little bit more perspective on

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1 what Terry said, he is absolutely correct. If you
2 look at following 9/11, we tried to take a graded
3 approach to this. And we wanted to make sure that the
4 sources that were most risk-significant, as Terry has
5 said, were taken care of first and that we wanted to
6 make sure that we had programs that could adequately
7 do that.

8 I mean, think its walk before you run. If
9 you go from Category 2 to Category 3, if you think of
10 it from a pyramid perspective, you're going to include
11 many, many, many more sources. And if we try to take
12 everything on at once into our programs, the program
13 would probably have fallen in on itself. And it's
14 taken us a lot of effort and a lot of work on your
15 parts for those of you that are regulated industry to
16 be able to get those in place.

17 And so things like the National Source
18 Tracking System and increased control orders, we want
19 to make sure the most risk-significant sources were
20 taken care of and that we had programs that adequately
21 did that.

22 The staff has made proposals to the
23 Commission with regard to further expansion of that.
24 At this point in time, the Commission in its wisdom
25 has chosen not to do that. It doesn't mean that we

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1 will never do that. It just simply means that at this
2 point in time we have limited it to Category 2.

3 We wanted to make sure that the programs
4 for those are operating efficiently. We got the
5 feedback. We got the practical feedback. And we got
6 the implementation feedback from what the hurdles
7 were, heard some of that this morning from the
8 panelists, some of the things that they observed in
9 the inspection activities of implementing these
10 things. And it takes time to shake out the problems
11 to get a practical implementation of them.

12 And so we wanted to make sure that we
13 didn't overburden the industry also with a program
14 that was not practically implementable. So that is
15 some of the thought process that went into it as we
16 went forward to try and implement this program.

17 Thank you.

18 DR. JONES: If I could mention one thing?
19 And then Mary will have another comment. This is
20 Cyndi Jones with NRC.

21 Being with the program for a long time,
22 having done some of those vulnerability assessments,
23 it is important to note that the IAEA as well did not
24 envision Category 3 and national source tracking
25 systems that were envisioned to be established by

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1 countries that signed up to adhere to the Code of
2 Conduct.

3 But I think that they wanted to encompass
4 countries that had effective and very strong
5 regulatory programs. And also those countries that
6 were developing programs were security of the sources.
7 If they didn't have a strong regulator, then there was
8 perhaps a potential need to include Category 3 because
9 the regulatory framework was not there.

10 So IAEA had a very difficult job of
11 writing a framework, if you will, for the safety and
12 security of radioactive sources from Category 1
13 through Category 5, but they did not say directly that
14 Category 3 should be included in the national source
15 tracking systems that countries establish, only
16 Category 1 and 2.

17 Thank you.

18 MS. SHEPHERD: Mary Shepherd, JL Shepherd
19 and Associates.

20 I believe the Category 3 under increased
21 controls, if you have a lot of Category 3 sources,
22 then you are required to implement your increased
23 controls. And I don't think that has changed. So
24 there is a mechanism if there are a lot of Category 3
25 sources that you have to implement fully.

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1 MR. RATLIFF: Yes. In fact, we saw a lot
2 of if they're collocated, a lot of petrochemical
3 plants may have 200 gauges of 200 millicuries or 500
4 millicuries of cesium-137. If they are collocated,
5 that became a real issue of what is collocated. And
6 the working group worked through that as to whether
7 they would have two independent barriers.

8 But I think the ones that were really of
9 concern have been controlled. The others, there are
10 so many sources that are -- and when you look at what
11 is typically used out there, you don't see the others.
12 You almost drop to the floor the ones that are
13 collocated or there are so few that, really, I don't
14 think it was an issue.

15 DR. MUSOLINO: Steve Musolino, Brookhaven
16 National Laboratory.

17 I just wanted to give a vote of support to
18 the Health Physics Society position on the Category 3
19 issue. And the reason why I would say is regulations
20 by their nature are black and white. There is no
21 gray.

22 So if you are a user of, just taking
23 americium and beryllium as an example, and you have 14
24 curies of it, that falls off the map because the magic
25 number is 16.

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1 Keep in mind that the IAEA categories are
2 based on the model. The model is not a deterministic
3 model. And the numbers have a degree of softness to
4 them. So I think there are cases where it would be
5 prudent to include Category 3.

6 I wouldn't propose that categorically to
7 adopt Category 3. There are issues on a case-by-case
8 basis that there could be risk reduction achieved by
9 having a little bit of gray.

10 MR. LEWIS: I just wanted to offer a point
11 of perspective that hasn't come up yet today, but it
12 is very relevant to what we have just been talking
13 about.

14 Again, bringing us back to cesium
15 chloride, I think the blood irradiators and research
16 irradiators for cesium chloride are all very clearly
17 Category 1 and 2, as John's slide showed, hundreds, if
18 not thousands, of curies.

19 The Category 2 threshold is 27 curies for
20 cesium. So below that is Category 3. Below about 20
21 curies of cesium I believe most, if not -- a great
22 majority of sources -- put it that way -- are not
23 chloride. They will be a ceramic form or some other
24 form of cesium. It's just the large irradiators that
25 chloride is the chosen form, for many reasons,

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1 historical, chemical, and otherwise.

2 And so when we talk about cesium chloride,
3 perhaps there is a gap, you know, between the 26.9 and
4 20 that would be some calibration sources. But for
5 the most part, when we talk about cesium chloride, we
6 are really just talking exclusively Category 1 and 2.

7 DR. MAHER: Right. And I think we did not
8 envision all Category 3 sources to be included. We
9 would like a case-by-case because there are some which
10 do use cesium chloride, typically those which were
11 taken to the field, where the protection becomes even
12 more difficult because it is a mobile source.

13 FACILITATOR BAILEY: Are there any other
14 questions or comments at this time?

15 (No response.)

16 DR. JONES: Seeing no other comments,
17 let's give a round of applause for our panel members.

18 (Applause.)

19 DR. JONES: Thank you.

20 I see we are a little bit ahead of
21 schedule. And I wasn't sure if Ken had all of the
22 information about logistics for opportunities for you
23 to have a good snack and a cup of coffee or a soda.
24 If you go out of the auditorium and to the left, past
25 the entrance, and go walk across the circular area,

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1 there is a cafe there that you can get salads,
2 sandwiches, and so forth.

3 And I note it's about a quarter to 12:00.
4 We can come back at -- what did you say? -- a quarter
5 to 1:00 or 1:00 o'clock. Audience, what would you
6 like? 1:00 o'clock? Raise your hand. Okay. 1:00
7 o'clock it is. Thank you very much.

8 Anything else, Ken?

9 FACILITATOR BAILEY: No. That's it.
10 Thanks.

11 DR. JONES: Perfect.

12 FACILITATOR BAILEY: Enjoy your lunch.

13 (Whereupon, a luncheon recess was taken at
14 11:42 a.m.)

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A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:03 p.m.

FACILITATOR BAILEY: Again, for those of you who may not have been here earlier, my name is Kenneth Bailey and I'm the facilitator for today's meeting.

On the schedule, we have to pick up continuation of Issue 1, but we kind of -- it looked like we fell short of asking any additional questions prior to closing. But before we move into Issue 2, we want to make sure that there are no additional questions in regards to Issue 1 earlier today.

Questions or comments?

(No response.)

Okay, so we're moving to Issue 2. Issue 2 for discussion, adequate protection of public health and safety is maintained when cesium chloride sources are managed in accordance with the security requirements of the NRC and the Agreement States. The

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1 NRC monitors the threat environment and maintains
2 awareness of international and domestic security
3 efforts. In the event that changes in the threat
4 environment necessitate regulatory action, the NRC is
5 ready to issue security requirements to apply
6 appropriate limitations for the use of cesium chloride
7 in this current form.

8 Again, we will begin with the panel. I
9 will allow them to introduce themselves, from my left
10 to right. And we will begin opening with Merri Horn's
11 presentation.

12 DR. MAIELLO: Mark Maiello, Radiation
13 Safety Officer for Pfizer, Pearl River, New York
14 facility.

15 DR. NELSON: Kevin Nelson, Radiation
16 Safety Officer, for Mayo Clinic, Jacksonville,
17 Florida.

18 DR. RING: Joe Ring, Radiation Safety
19 Officer for Harvard University.

20 MS. HORN: I'm Merri Horn. I'm a Senior
21 Project Manager in the Division of Inter-Governmental
22 Liaison and Rulemaking.

23 FACILITATOR BAILEY: Okay, as mentioned,
24 we will begin this panel with Merri Horn's
25 presentation on the status of proposed CFR Part 37

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1 rulemaking.

2 MS. HORN: As she queues up my slides,
3 I'll get started.

4 Well, good afternoon. As I said, my name
5 is Merri Horn. I'm a Senior Project Manager in the
6 Office of Federal and State Materials Environmental
7 Management Programs at the NRC. Specifically, I'm in
8 the rulemaking group in that office.

9 I'm currently the Project Manager for both
10 Part 37 rulemaking and for the associated guidance
11 document that will go along with it.

12 This afternoon, I just want to give you --
13 I was asked to give you a brief status of where we are
14 with the Part 37 rulemaking. I'm then to give a quick
15 overview of some of the requirements from that rule,
16 and basically, to cover as many as I could squeeze in
17 the little bit of time that I have allotted here.

18 Slide 2, please.

19 The proposed rule was published in the
20 Federal Register on June 15th of this year. The
21 comment period originally ended October 13, so we did
22 extend. So the comment period now ends on January 18,
23 early next year. The final rule, it would currently
24 be due to the Commission at the end of next year. And
25 as far as implementation, it's probably going to be

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1 2013, before you would actually be required to start
2 implementing these provisions.

3 Slide 3.

4 I'm actually not going to cover -- this is
5 just letting you know there are a lot of different
6 ways in which you can submit public comments on this
7 rule. You can hand deliver them to the NRC. You can
8 fax them in. You can mail them. You can go to the
9 Rulemaking.gov website and download them
10 electronically. And I encourage you, if you haven't
11 already commented, please do. We have received a
12 number of comments, but you've still got a couple of
13 months. We do want your input.

14 Slide 4, please.

15 The primary objective of this rulemaking
16 is to provide reasonable assurance of preventing the
17 theft or diversion of Category 1 and Category 2
18 quantities of radioactive material. As we develop
19 this rule, we actually considered the various security
20 orders that have been issued, the lessons learned from
21 implementation, lessons learned from the inspection
22 against the orders. We also looked at recommendations
23 from the Independent Review Panel and Materials
24 Working Group. And then last, we also considered a
25 petition for rulemaking that was filed by the State of

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1 Washington concerning transportation.

2 We also considered the stakeholder input.
3 We actually posted preliminary rule language on the
4 Regulations.gov site and I believe it was a 45-day
5 comment period on both the Subpart B, C, and D
6 provisions, so we looked at those comments. We
7 actually made some changes in response to those.

8 Slide 5.

9 The proposed rule basically will create a
10 new Part 37 and this contains security requirements
11 for the Category 1 and Category 2 quantities of
12 radioactive material. Less interest to you all, but
13 it also contains security requirements for the
14 transportation of small quantities of irradiated fuel.
15 We'll also be making a number of conforming changes,
16 what I call tie-down conditions and other parts of the
17 regulations.

18 Slide 6.

19 The major provisions are contained in
20 three subparts. Subpart B contains the requirements
21 for the Access Authorization Program. Subpart C
22 contains requirements for the security program during
23 use or storage. And Subpart D contains the
24 transportation security provisions.

25 Today, I'm actually going to focus on the

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1 provisions of Subpart C, but I'll also cover a few of
2 the other requirements as time permits.

3 Slide 7.

4 A key provision of the proposed
5 requirements is development of a security plan. The
6 security plan contains the licensees' security
7 strategy and a description of the measures to
8 implement the requirements. The licensees are
9 required to have procedures to implement the security
10 program and to conduct training on the implementation
11 of the plan.

12 As far as the training goes, it would
13 depend on -- to the extent that they would be
14 implementing the different security measures, if
15 there's going to be an incident and they're going to
16 be responding to an alarm, they need to be trained on
17 that. They need to know what they need to do in case
18 that alarm sounds. And licensees would also be
19 required to protect the security information.

20 Slide 8.

21 All Category 1 and Category 2 quantities
22 of radioactive material at the facility would have to
23 be used and stored within the security zone. The
24 purpose of a security zone is to isolate and control
25 access of material to protect it more effectively, and

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1 deter theft or diversion while providing more time for
2 licensees and law enforcement to respond.

3 A licensee would be required to establish
4 and maintain the capability to continuously monitor
5 and detect all unauthorized entries into its security
6 zones. Monitoring and detection would be performed by
7 either a monitored intrusion detection system that is
8 linked to an on-site or off-site controlled monitoring
9 facility. It could be electronic devices for
10 intrusion detection alarms that would alert the
11 facility personnel. It could be visual monitoring by
12 video surveillance cameras. It could be visual
13 inspections by approved individuals. So there's a
14 number of different methods that you can choose to
15 use.

16 The licensee would also need the
17 capability to detect unauthorized removal of the
18 radioactive material. For Category 1 quantities of
19 radioactive material which is probably going through
20 what a lot of your irradiators are, you would have --
21 a licensee would need to immediately detect any
22 attempt at unauthorized removal through the use of
23 electronic sensors linked to an alarm or continuous
24 visual surveillance.

25 For Category 2 quantities, they would need

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1 to verify the presence of the radioactive material
2 through weekly physical checks, tampering indicating
3 devices or actual usage of the material or other
4 methods that you may choose.

5 Licensees would be required to respond to
6 any actual or attempted theft, sabotage, or diversion
7 of material and then to assess the situation and take
8 appropriate actions. Those actions might include
9 contacting a local law enforcement. It might include
10 contacting the NRC. That would depend on the
11 particular situation.

12 Included in the requirement to maintain
13 the security-related equipment and test equipment to
14 make sure it is operational, you heard from the panel
15 earlier this morning that while a lot of facilities
16 may have some of the equipment in place, it wasn't
17 necessarily operational. So we are, this is one of
18 the lessons that we learned and we put in the
19 requirement to make sure you do maintenance, you do
20 testing, make sure the equipment is actually
21 operational.

22 And then finally, licensees would be
23 required to report events, including suspicious
24 activities. Not much different from what the orders
25 contain.

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1 Slide 9.

2 Licensees would be required to coordinate
3 to the extent practical with LLEA to discuss the LLEA
4 response to threats to the licensee's facility. The
5 licensee would be required to request that the LLEA
6 enter into a written agreement with the licensee, but
7 describes how the LLEA -- what kind of commitments
8 they would provide to a [resource what should this
9 be?] or to a response. This is a little different
10 from the increased control orders because they
11 actually require you to have that pre-arranged plan.
12 So we've actually relaxed it a little, realizing that
13 we don't -- we can't really enforce. We can't force
14 the LLEA to enter into such agreement, but we can
15 request and encourage them to do so. And you will
16 have to document all of the coordination activities
17 that you have with the LLEA, so that if an inspector
18 would come out and say where's your plans, well, we
19 couldn't get them to enter one. You would have your
20 documentation to support that.

21 And then we also would require licensees
22 basically to touch base back with the LLEA on an
23 annual basis so that you have that continual
24 communication going on.

25 This doesn't really impact most of the

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1 cesium chloride folks, but for licensees that conduct
2 work at temporary job sites, the licensee would need
3 to notify LLEA for work -- any site where you would be
4 working at the site for longer than seven days, for
5 temporary job sites.

6 For mobile devices, licensees are required
7 to have two independent physical controls and to
8 utilize the method to disable the vehicle or trailer.
9 Again, these probably don't really impact you. And
10 then we require an annual program review.

11 The next few slides highlights the access
12 authorization and transportation security provisions
13 of the proposed rule. The Access Authorization
14 Program requires that anyone with unescorted access to
15 Category 1 or Category 2 quantities of radioactive
16 material undergo a background investigation. That
17 includes fingerprinting and a criminal history records
18 check, along with a number of other elements. The
19 background investigation must be complete before an
20 individual may have unescorted access to the material.

21 The person that's going to be doing,
22 making that final decision and granting individuals
23 unescorted access is called the reviewing official.
24 They must make those determinations on whether the
25 individual will be permitted unescorted access to the

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1 material. The decision must be based on the
2 information obtained as part of the background
3 investigation and the determination basis must be
4 documented.

5 Something that's different in the rule is
6 that the reviewing official must undergo
7 fingerprinting and the other elements of the
8 background investigation, too. And they have to be
9 approved by either the NRC or an Agreement State.

10 There are several categories of
11 individuals that will be relieved from the
12 fingerprinting requirement and other aspects of the
13 background investigation. There are also provisions
14 in the proposed rule that allow the transfer of
15 background information between licensees. So if
16 you're a service provider, you've done your background
17 investigations, you've granted them access, you can
18 transfer that information and you can still get in.
19 The client licensee would not have to do any
20 background investigation.

21 The Transportation Security Program would
22 include verification of license authorization when
23 transferring Category 1 or Category 2 quantities of
24 material. This is new for some licensees, but not for
25 all. A licensee is required to conduct pre-planning

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1 and coordination activities with the receiving
2 licensee, so that if you're sending a source to
3 someone, they know it's actually coming and have an
4 idea as to when to expect it. This would also include
5 the establishment of a no later than arrival time.

6 And for Category 1 shipments, you actually
7 have to do -- also provide advanced notifications to
8 the States and NRC through which -- the States through
9 which you'll be traveling.

10 For Category 1 shipments, the actual
11 protective measures really aren't that different.
12 Movement Control Centers with the capability to
13 actively monitor shipments, telemetric position
14 monitoring is required, provide primary backup
15 communication capability. You have to have
16 procedures, and you have to train the workers on those
17 procedures.

18 Slide 13. I've been forgetting to tell
19 you that. I'm sorry.

20 For shipments of Category 2 quantities of
21 radioactive material, licensees would be required to
22 maintain constant control and surveillance during
23 transit, to have communication capabilities to summon
24 assistance for shipments. And if you use a carrier,
25 you have to use a carrier that has a package tracking

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1 system and requires a signature before they'll release
2 the package. So basically, your FedEx still works.

3 Slide 14.

4 I just want to quickly let you know about
5 the guidance. There's a very large implementation
6 guidance document that we have prepared. It's also
7 out there for public comment right now. The comments
8 on the guidance document are also due January 18th.

9 Slide 15.

10 This is just a page from the guidance
11 document. We basically set up the document in the
12 form of questions and answers. There was a lot of Qs
13 and As that were out there for the orders already.
14 People seemed to be familiar with that concept, that
15 format. So we decided to maintain.

16 So basically, if you look at the very top,
17 you've got the title section. The second box actually
18 has the rule provision. That's the text that that
19 particular section is going to be talking about. You
20 have a brief explanation of what the rule text means.
21 And then you have the Qs and As that provide the
22 guidance for that particular rule provision that's in
23 the box.

24 Slide 16 shows again, this is a document
25 that's out for public comment. I think it's like a

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1 250-page document, so it is very large, but has a lot
2 of good information in it. It gets into more of the
3 details of what some of the acceptable methods would
4 be. And again, comments are due on that on January
5 18th.

6 And with that, I conclude my portion and
7 thank you for your time.

8 DR. RING: I'm Joe Ring from Harvard. I
9 want to start off by saying that we've gone through
10 the proposed policy statement and we support the
11 policy statement.

12 In my presentation, I want to outline an
13 alternate way of looking at physical security and this
14 is actually what we did beginning around about 2005.
15 One of the things that we did is went out to the
16 faculty and asked them to verify that cesium chloride
17 irradiators were necessary. We went out to all of the
18 science faculty that used these and claimed to have
19 need for them. And we asked them why do you need it
20 if you think you need it? And basically what came
21 back is this is actually email to me, these series of
22 slides.

23 Here is the scientific drawing of why
24 cesium is different than a chemical. And here's kind
25 of the reaction mechanisms. I'm not going to go

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1 through that, but the scientists, the faculty came
2 back and said we don't have an alternative. We need
3 cesium chloride because it's the basis of our science.

4 With that, it becomes a scientific asset,
5 and I give you an outline up here of some of the
6 general classes of basic science that our faculty says
7 they need cesium chloride irradiators for. That then
8 makes this an issue not of security and not of
9 regulation, but one of protecting an asset. To do
10 that, we wanted to sit back and think about what were
11 our risks? What were our needs?

12 We identified, of course, that there was
13 the potential for malevolent use. That changes the
14 way you look at things. We're thinking protection of
15 a scientific asset. That means that we have to look
16 at physical security, access control, but in access
17 control we have to recognize that users have to be
18 able to get in. If they can't get in easy, it defeats
19 the purpose. And we needed to look at law enforcement
20 response.

21 Fortunate in many ways that I have a
22 police department at the university, I have a little
23 bit of a problem though. We span three cities and we
24 have three different police departments to work with
25 and they all have their own differences of opinion.

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1 So I had to work with four police departments. That
2 really means I want to find a solution. And again,
3 you know, at a university it's all about who
4 participates and how you help.

5 I'll give you a general list of the
6 entities that participated in this. I had to get
7 together something like 40 faculty, 500 users, 4
8 independent schools with a bunch of affiliated
9 institutions that shared our facilities, 5 different
10 owners of irradiators, 2 different security companies,
11 4 different security agencies, 4 different police
12 departments, and the Radiation Safety Office and
13 Radiation Safety Committee.

14 It was not an easy task, but I have to say
15 it worked out very well. We looked at things a little
16 bit differently. We defined what the potential threat
17 scenarios were. We had to include that Harvard is a
18 very risk-adverse institution. That changes the way
19 again that we look at things.

20 We brought in and fortunately had on staff
21 certified professional security planners, certified
22 physical security systems analysts, and a very capable
23 police department with three local municipal police
24 departments. With the help of four different schools
25 and the Office of the General Counsel and the Central

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1 Human Resource Program, all five of which are
2 different, we worked together on a user access control
3 system and approval system. That was all then
4 consolidated and made into a recommendation in late
5 2005, to the Harvard Radiation Safety Committee that
6 approved the policies.

7 Basically, what they did with the help of
8 all of the parties aforementioned, is we put together
9 a short-term and a long-term program. The initial
10 program looked at what a comprehensive security
11 program would be and put forth a tiered approach to
12 implementing a different security system. That went
13 around looking at what the physical security should be
14 and set up the specific recommendations for each
15 particular location that would be immediate as well as
16 the next four or five years.

17 They also looked at the physical response
18 plan and the countermeasure plan and implementation of
19 those plans for all radiation devices. Once that was
20 approved, they set forth a program to make those
21 changes and it included relocating in some very
22 substantive security implementation changes. They
23 were directly overseen by the university's police
24 department.

25 Phase 2, which was set back in 2005, we

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1 were fortunate that we were able to implement that in
2 2009, with the assistance of the Global Threat
3 Reduction Initiative. They were very helpful. We did
4 find almost a perfect match between their
5 recommendations and those of our reviewers.

6 I think as a result, what this does for is
7 it makes Part 37 pretty easy. When I look at Part 37,
8 I don't have to make much of a change. My changes
9 really are to implement recertification which the
10 Human Resource Program has been recommending. And
11 they had set a meeting for December to talk about that
12 anyways.

13 One issue that I do find is annual
14 security training for radiation users. The way we
15 went about our system design is that we don't want our
16 users to know much about what it is and to have to do
17 physical security systems training for them manually,
18 I don't know what I'm going to talk about. The way
19 that we did review our security system was different.
20 We looked at it as protection of a scientific asset.
21 In the beginning that was our goal. That's our goal
22 today. And that makes compliance with regulations a
23 little bit different. We're looking above that
24 because it's an asset that our faculty says that we
25 cannot live without.

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1 Thank you.

2 DR. NELSON: My name is Kevin Nelson and
3 I'm a board-certified health physicist and I've served
4 as the Radiation Safety Officer at Mayo Clinic in
5 Jacksonville, Florida for over 15 years. And I've
6 prepared written comments for this panel discussion
7 because I did not want to run afoul of NRC security
8 plan requirements.

9 NRC staff, particularly, Drs. Cynthia
10 Jones and John Jankovich, fellow participants and
11 guests, thank you for the opportunity to speak to you
12 today on the issue of cesium chloride security related
13 to the medical use of Category 1 and Category 2
14 sources.

15 In the few minutes I have allotted to me
16 today, I wanted to give you my impressions regarding
17 the enhanced security orders for Category 1 and 2
18 sources at Mayo Clinic Florida, as well as my opinion
19 of proposed Part 37.

20 As a disclaimer, I should state that the
21 opinions presented by me today are those of my own and
22 don't necessarily reflect those of Mayo Clinic.

23 Medical use of Category 1 and 2 sources
24 predominantly includes the irradiation of blood
25 products and performing certain types of radiation

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1 therapy treatments. For the purposes of this
2 workshop, I will limit my discussion to the use of
3 cesium chloride irradiators.

4 In an article that was published in The
5 Health Physics Journal, it has been estimated that
6 approximately ten percent of all donated blood or
7 about three million units are irradiated annually to
8 prevent transfusion associated graft versus host
9 disease. Irradiators are particularly useful in
10 reducing or eliminating graft versus host disease in
11 immuno-compromised patients receiving blood
12 transfusions. Examples of critical patient
13 populations include fetus receiving interuterine or
14 exchange transfusion, low birth weight neonates,
15 patients with congenital immune deficiencies,
16 allogenic and autologous bone marrow transplant
17 patients, patients receiving both chemotherapy and
18 radiation therapy for hematologic malignancies other
19 than bone marrow transplant patients, and previously
20 sensitized human leucocyte antigen patient, literally
21 thousands and thousands of patients annual.

22 At Mayo Clinic, we have always focused on
23 security of our radioactive material and sources even
24 prior to the tragic events of 9/11. With devices
25 containing Category 1 or 2 sources in a hospital

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1 setting, the challenge becomes how can we maintain
2 proper security over these sources and yet maintain an
3 open environment for our patients?

4 In future security-related rulemaking, it
5 is important to remember a hospital is not a DOE-type
6 facility where additional security measures can
7 perhaps be more easily accomplished. Hospitals are in
8 the business of caring for people who are sick. As
9 you can imagine, this is already a stressful
10 situation. Adding additional security measures must
11 always be balanced with patient care activities and
12 patient perception.

13 I'm aware either directly or anecdotally
14 of many medical institutions that have switched from
15 cesium chloride gamma irradiators to x-ray irradiators
16 simply because of their perception of the amount of
17 effort and cost that would be required to comply with
18 the enhanced security orders. Our institution and
19 many others, however, have not switched due to
20 concerns about the capacity, adequate dose
21 distribution, and maintenance of x-ray generating
22 irradiators.

23 We irradiate approximately 18,000 units
24 per year with one gamma cell which was purchased in
25 1993. We need high through-put with a relatively

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1 maintenance-free device in order to meet patient
2 demand.

3 Currently, only cesium chloride
4 irradiators can meet these conditions. I'm aware that
5 manufacturers of x-ray irradiators have introduced new
6 devices with additional capacity. However, because of
7 differences between the x-ray and cesium 137 gamma ray
8 spectrum, I am still concerned whether an adequate
9 dose can be delivered to the blood products that are
10 to be transfused into immunocompromised patients using
11 higher capacity x-ray irradiators.

12 Mayo Clinic Florida is a medical broad-
13 scope licensee and under the regulatory authority of
14 the State of Florida Bureau of Radiation Control. We
15 use a Nordion, now Theratronics Gammacell 3000 Elan
16 for the irradiation of our blood products. Our
17 enhanced security experience with the cesium chloride
18 gamma cell can be categorized into four categories:
19 one, physical environment; two, interactions with
20 outside agencies such as Florida Bureau of Radiation
21 Control and local law enforcement; three, background
22 checks of employees with access to the irradiator; and
23 four, fingerprinting requirements.

24 And I'll start with the physical
25 environment. Typically, irradiators used to treat

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1 blood products are contained in a clinical laboratory
2 setting. Usually, these laboratories are very busy
3 and at our facility are occupied 24 hours per day, 7
4 days per week, 365 days per year. These areas are
5 also usually very crowded with equipment.

6 Prior to moving to our new hospital in
7 2008, we had a challenge to properly enclose the
8 irradiator due to space limitations at our old
9 hospital. We had the option of either building walls
10 around the unit, or conducting enhanced security
11 checks on all staff entering the area. Since
12 performing background checks on hundreds of
13 individuals entering the blood bank laboratory was
14 impractical, we initially built a roll-up cage
15 surrounding the device. However, the cage was not
16 found to meet the specific security requirements of
17 the Florida Bureau of Radiation Control.

18 Fortunately, it was in the same time frame
19 that we moved the irradiator to the new hospital. We
20 were easily able to surround the device with a walled
21 enclosure with a solid door. Building an enclosure to
22 surround cesium chloride irradiators in a busy
23 hospital setting may be a challenge for many
24 facilities, however, I believe it is one of the most
25 important steps that can be taken to enhance security.

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1 Since moving to our new hospital, we have
2 taken additional security measures to make it
3 difficult for a non-approved employee to enter the
4 room containing the irradiator. Staff also conduct
5 monthly drills with the hospital security department.

6 Item 2, interaction with outside agencies.
7 We have and continue to work closely with the Florida
8 Department of Health, Bureau of Radiation Control, to
9 determine the best and most prudent measures to
10 enhance security for our device. They have been very
11 cooperative, as both institutions are developing best
12 safety practices in a hospital setting.

13 As required, we interacted with our local
14 law enforcement office, in this case, the Jacksonville
15 Sheriff's Office, Department of Homeland Security.
16 Although they could not offer any additional measures
17 to take to enhance security for the cesium chloride
18 irradiator, they appreciated receiving a tour of our
19 existing facility.

20 Our blood bank laboratory is accredited by
21 the American Association of Blood Banks, College of
22 American Pathologists, the Foundation for the
23 Accreditation for Cellular Therapy, and the Joint
24 Commission. As a recommendation, work should continue
25 with accrediting organizations to ensure the uniform

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1 understanding and interpretation of NRC security-
2 related requirements.

3 At the end of this month, we will be
4 participating in the Global Threat Reduction
5 Initiative, GTRI, Domestic Threat Reduction Program,
6 offered by the National Nuclear Security
7 Administration, NNSA, and supported by the NRC and
8 Agreement State Radiation Control Programs. We hope
9 to learn what additional security measures can be
10 taken to enhance the security of our device.

11 I believe GTRI security upgrades such as
12 target hardening is another important step that should
13 be taken by licensees to make it more difficult to
14 remove an irradiator source for malevolent purposes.

15 Number 3 , background checks of employees
16 with access to the irradiator. Currently, we have
17 approximately 25 individuals that require access to
18 our irradiator. Performing background checks on these
19 individuals using a third-party vendor has not been
20 particularly onerous at our facility. Exclusion of
21 information in background checks may be restricted by
22 current law such as Section 605, the Fair Credit
23 Reporting Act. The types of criminal checks conducted
24 by third-party vendors can also vary and could include
25 state-wide or country-wide criminal checks. However,

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1 as reported to me by our trustworthiness and
2 reliability official, counties may not report arrest
3 or conviction data to the state and therefore the
4 information contained in state-wide background checks
5 may be inaccurate. Because of these potential
6 inaccuracies, it may be best to have the FBI conduct
7 initial and follow-up criminal checks as suggested in
8 Part 37.

9 Fingerprinting requirements. I received
10 the greatest amount of concern from our staff when
11 fingerprinting requirements were implemented. After
12 an initial backlog at the FBI, the process has run
13 smoothly. Our T&R official in Human Resources has
14 reported to me "overall, we have been very pleased
15 with the process and the procedures for
16 fingerprinting. The FBI turnaround time has far
17 exceeded our expectations. It is very easy to comply
18 with the regs."

19 It should be noted that in our initial
20 submittal of fingerprints, the FBI identified one
21 individual of interest while conducting a criminal
22 background check. FBI staff immediately met with our
23 T&R official and me. I cannot provide any further
24 details as this may still be an active investigation.
25 However, I am not of the opinion that if FBI

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1 fingerprinting and criminal background checks can
2 identify even one individual with potential malevolent
3 intent, this practice is worth our time, effort, and
4 cost as licensees to ensure the security of our
5 radioactive material.

6 In conclusion, we have not found the
7 current enhanced security orders to be particularly
8 onerous. We are able to meet the current requirements
9 with little additional cost or effort. In reviewing
10 the proposed 10 CFR Part 37 requirements, I found some
11 of the sections to be overly prescriptive such as
12 access authorization program requirements, 37.23;
13 background investigation, 37.25; and general security
14 program requirements, 37.43. Perhaps these
15 prescriptive elements are needed because of regulatory
16 issues identified after issuance of the orders. We
17 will be providing comments on Part 37 in the near
18 future.

19 In my opinion, clarification to licensees
20 and a guidance document might be in order with
21 regulations reserved to define the over-arching
22 security requirements with broad applicability.

23 Thank you.

24 DR. MAIELLO: Good afternoon. My name is
25 Mark Maiello. I'm the Radiation Safety Officer for

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1 Pfizer in the Pearl River facility in New York.
2 Before I go further I'd like to give credit to my
3 Human Resources Specialist, Luchina Smith Scott, who
4 helped me put together this brief presentation.

5 I'd just like to go over some questions or
6 concerns regarding the credit checking element of the
7 T&R assessment under the proposed rule and in fact, it
8 probably would be more applicable if the Human
9 Resources person was giving this talk, but as Slide 1
10 indicates, the Radiation Safety Officer at most
11 institutions guides the T&R process. And if a problem
12 occurs within the T&R process at any particular point,
13 it becomes the RSO's issue. Therefore, I'd like to
14 bring out some of these points and hope that the
15 Commission will consider them and provide guidance
16 where applicable. And in fact, Merri alluded to some
17 of that guidance may already be out there, but I'll
18 plow ahead anyway.

19 Slide 2.

20 The credit checks for employment are
21 common in some industries, but not in many. And when
22 they are common, for example, in the financial
23 services industry, a credit check is expected by the
24 employees and the rationale is clear. Usually, the
25 employee has direct access to clients' funds, so the

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1 credit is deemed as an indicator of -- credit access
2 is deemed as an indicator for potential mishandling of
3 those funds.

4 Where it's uncommon, as it is in my
5 industry, it is procedurally difficult for an HR
6 department to request credit reports on some new hires
7 and not on others. Currently, where I am employed, no
8 system is in place at all to do that, but I'll speak
9 to the details about that just a bit later.

10 Credit checks can only be done on current
11 employees according to my HR Department, if they agree
12 and authorize the company to do so. In an age of
13 concern for ID theft, it would not be surprising if
14 some employees refuse to authorize credit checks
15 because their personal information falls into a
16 greater amount of hands.

17 Point 2, credit checks may not reveal all
18 debt or habits that can lead to debt. Illegal
19 gambling is not revealed, unless severe debt has
20 depleted personal resources. Constant use of debit
21 cards obscures actual debt because a sense of debit
22 card is not revealed in credit reports, nor are
23 bounced checks. And I'm going to stop here for just a
24 second to say because I'm not a Human Resources
25 specialist I may not be able to answer all your

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1 questions or any of your questions you may have about
2 this issue. However, I do have a cell phone and would
3 be happy to contact my Human Resources Department so
4 that you leave with some answer to any questions you
5 might have.

6 Slide 3.

7 Credit check results may force a value
8 judgment about who is trustworthy and who is not. A
9 debt can occur from many sources: ID theft, as I
10 mentioned, poor economic environment that increases
11 job loss, that increases foreclosure rates, that
12 increases the frequency of poor credit. Medical
13 disasters can also result in loss of homes and
14 concurrent with the illness, loss of employment. And
15 divorce, and my favorite, marriage, the wedding, the
16 honeymoon, the mortgage, they also result in debt, and
17 this leads us to another point. Although debt may be
18 an indicator of potential crime, it also happens to
19 the law abiding. It is not a guarantee of future
20 criminal action. But HR and security departments of
21 institutions and companies not adept at this new
22 challenge may have to judge causes in the T&R effort
23 and thus could be a bit of an issue, at least
24 initially.

25 Slide 4.

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1 How deep into debt results in
2 untrustworthy and unreliable? If causes are not
3 rooted out, the decision must be made on the absolute
4 value of the debt. Where is the monetary dividing
5 line to make that decision?

6 Blindly deciding that any debt is reason
7 to deny unescorted access is not necessarily a
8 solution. It can be seen as interference with a
9 chosen career path which leads us to Point 5. Does
10 the credit check result in discriminatory or unlawful
11 practices, assuming someone is debt stricken or has no
12 credit or credit history and is automatically deemed
13 untrustworthy and excluded from gainful employment or
14 access to the tools to perform their work, will this
15 be perceived as discriminatory and/or unlawful. And
16 if so, what are the legal repercussions of such
17 decisions to employers.

18 Slide 5.

19 Refusal of unescorted access based on
20 credit checks may be more frequent than refusal based
21 on criminal background checks, since the latter is
22 usually screened by hiring practices and the former
23 may be much more common. In many industries where
24 work place fairness on many levels is expected, how
25 will the perception of debt as made manifest by

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1 refusal to unescorted access be handled by the
2 employer especially if one is dealing with an employee
3 that is sensitive to the issue.

4 Slide 6.

5 The mechanics and cost of credit checks.
6 On a cost-effective and efficiency basis, the checks
7 are best done for all new hires, rather than a few, on
8 an as-needed basis. That's because they're
9 contracted, the work is contracted out. Contracted
10 work is less expensive, if not perceived as special or
11 as needed. The contractor would have to be hired and
12 internal policies written to handle the sensitive
13 information between a company and the contractor. And
14 the company would have to agree to incur credit check
15 costs as part of pre-employment verification and incur
16 additional head count costs to administer the program.

17 What is an adequate frequency of credit
18 checks? As we all know, debt can occur at any time.
19 Credit checks show on an individual's credit report
20 and may ultimately reduce their credit score. The
21 number of credit checks performed on an individual can
22 be detrimental.

23 And my final consideration, the current
24 physical security programs and the current T&R
25 assessment appear successful. Modifications to the

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1 T&R assessment such as credit checks may not add
2 enough net benefit for the effort they incur for the
3 HR issues they may cause.

4 Thanks for your attention. I hope the
5 Commission will consider these issues.

6 MR. MASSE: Thank you very much. My name
7 is Todd Masse. I'm the Branch Chief of the
8 Intelligence Liaison and Threat Assessment Branch at
9 NRC in the Office of Nuclear Security and Incident
10 Response with the Division of Security Operations.

11 I spent about 15 years in the intelligence
12 community. I've been at the NRC for a grand total of
13 about six months now and even though I've testified
14 numerous times before Congress, when you're testifying
15 before Congress oftentimes you can say can we go into
16 closed session to discuss classified matters? So I
17 know we can't do that here, so you'll forgive me if
18 any of the potential responses to some of your
19 questions may be classified, if I can't respond to
20 those questions as fully as you would appreciate.

21 One of the issues I'm going to talk about
22 with you today is ILTAB, that is the Intelligence
23 Liaison and Threat Assessment Branch. Our mission and
24 responsibilities, a little bit about the design-basis
25 threat, about some of which you folks may be aware of,

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1 that is the physical, the regulatory regime under
2 which we have physical security requirements, a little
3 bit about my group, the Intelligence Liaison and Treat
4 Assessment Branch, the liaison activities we have with
5 the intelligence community and the law enforcement
6 community nationwide. And then I'm going to segue
7 into a little bit about terrorism and radiological
8 threats, some of the terrorist use and attempts to use
9 unconventional, that is chemical, biological,
10 radiological and nuclear weapons which is a field a
11 little bit beyond and more broadly constrained than
12 what we're talking about here today, and then a bottom
13 line threat with respect to radiological dispersion
14 devices.

15 The NRC, as you're all aware, is an
16 independent regulatory agency, but it's also a non-
17 Title 50 agency. And what I mean by that is Title 50
18 agencies are all agencies that are within the
19 intelligence community. Currently, there are 17
20 agencies in the intelligence community and the
21 intelligence community at large spends about \$80
22 billion per year. This is a top line figure that was
23 just recently revealed for the first time this year.

24 The NRC is not a member of the
25 intelligence community. We are outside the

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1 intelligence community, therefore we're a non-Title 50
2 agency. I just wanted to make that clear.

3 The mission in my group, the Intelligence
4 Liaison and Threat Assessment Branch is to provide the
5 strategic and tactical intelligence, warning and
6 analysis of all threats to the commercial nuclear
7 sector and serve as the NRC's liaison and coordination
8 staff to intelligence community and law enforcement
9 agencies.

10 Some of our responsibilities are the
11 design basis threat, that is in 10 CFR Part 73.1.
12 There are two elements of the design basis threat.
13 One of them is the protection of radiological sabotage
14 of nuclear power plants and other facilities. The
15 second one theft and diversion. That is preventing
16 the theft and diversion of any special nuclear
17 material at Category 1 fuel facilities.

18 Then I'll talk to you a little bit about
19 liaison with law enforcement in the intelligence
20 community, which agencies we do and how we accomplish
21 this.

22 Liaison responsibilities. The FBI has
23 been mentioned numerous times here. I spent about a
24 decade with the FBI. We work very closely, my branch,
25 with the FBI in terms of their weapons of mass

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1 destruction directorate, the National Joint Counter-
2 Terrorism Task Forces, Counter-Intelligence Division,
3 Counter-Terrorism Division, Intelligence Directorate,
4 and the Cyber Division. One of the elements that we
5 see in today's world is the threat moving not only
6 from the kinetic, from the very much, very real
7 explosives sense of a threat to a non-kinetic, that is
8 foreign intelligence and cyber threats.

9 Many of you may have read about the Stuxnet
10 malicious worm that's been out there. A lot of press
11 on that. These are two elements. Historically,
12 there's been a focus on the kinetic, but now looking
13 at the non-kinetic.

14 We also work closely with the Office of
15 the Director of National Intelligence. In the wake of
16 9/11, we had the Intelligence Reform and Terrorism
17 Prevention Act of 2004 that was passed that
18 established the Office of the Director of National
19 Intelligence who essentially is a Chief Operating
20 Officer for all the 17 agencies within the
21 intelligence community. Part of that responsibility
22 is they have mission managers. There's a mission
23 manager for counter-terrorism which is the National
24 Counter-Terrorism Center; the National Counter-
25 Proliferation Center, works on counter-proliferation

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1 both in the chemical, biological, nuclear realms as
2 well as missile nonproliferation. And then the Office
3 of the National Counter-Intelligence Executive whose
4 primary responsibility is to ensure that information,
5 whether it's classified or proprietary or economic
6 information is not stolen from the United States to
7 undermine our national security, a component of which
8 is national economic security.

9 We also work very closely with the
10 Department of Homeland Security, both the Office of
11 Intelligence and Analysis that is an element of the
12 intelligence community and the Office of
13 Infrastructure Protection that is looking across all
14 of the critical infrastructure or key resources in the
15 United States and trying to protect it. The task is
16 to translate threat to make sure that these
17 facilities; this critical infrastructure is adequately
18 protected.

19 Some of the continued liaison
20 responsibilities, these are the three letter agencies
21 that we work very closely, the CIA, DIA. Within the
22 Department of Defense NORTHCOM, which has
23 responsibility for homeland defense, looking inward
24 versus looking outward. Certainly, the U.S. Cyber
25 Command a new command which is located up at Fort

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1 Meade, established only six months ago, which is
2 looking at these sets of issues that I talked about
3 earlier, the Stuxnet type of threats, the nonkinetic
4 cyber threats and how does the United States respond
5 to those threats and what is an act of war?

6 If a missile comes in over the horizon, we
7 know that's an act of war. If a terrorist attack
8 comes in, or any type of cyber attack comes in, that
9 may be bounced off 17 different servers before it gets
10 to the United States. So what are the thresholds,
11 what are the legal, regulatory thresholds against
12 which you would judge a cyber attack and then how do
13 you respond? So we're working closely with cyber
14 command, certainly the Department of Energy.

15
16 State and local fusion centers. In the aftermath of
17 the attacks of September 11th, a lot of states and
18 localities set up what's called intelligence fusion
19 centers. It's kind of a misperception that these were
20 DHS-sponsored centers. Initially, they were, but by
21 and large these centers of which there are about 72
22 today around the country, are primarily sponsored by
23 the state and paid for by the state and local
24 governments. They started off as counter-terrorism
25 focus centers, but now they've migrated to all

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1 hazards, all crimes. And so we're working closely
2 with them to coordinate our activities.

3 Looking at some of the terrorism and
4 radiological source threats, I wanted to point out
5 first two limitations of intelligence. Number one is
6 that intelligence is not policy. Intelligence informs
7 policy. The policymaking body at the Nuclear
8 Regulatory Commission is the Commission. My group,
9 the Intelligence Liaison and Threat Assessment Branch
10 does not own the design basis threat. We merely
11 inform the design basis threat, so when the
12 Commissioners are making decisions about what is in
13 and what is not in the design basis threat, they can
14 make them in an informed manner.

15 The second limitation is that intelligence
16 is rarely specific. The recent case that we saw with
17 the PETN in toner cartridges was one of those rare
18 instances in which because we had a specific (Saudi)
19 source with good intelligence liaison work, we had a
20 very specific source who could tell us look for these
21 packages at this time with these code numbers so we
22 could track them very closely. Very, very rarely do
23 you get that type of intelligence. Very rarely will
24 you find that there is a threat to cobalt-60 or cesium
25 chloride and we're going to hit this facility at this

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1 particular time and this is how we're going to do it
2 and these are the weapons we're going to use. You
3 just don't find that. That is the exception rather
4 than the rule in the intelligence world.

5 When you look at the open sources,
6 terrorist groups continue to target special nuclear
7 materials, that is, high enriched uranium and
8 plutonium, as well as radioactive materials. Every
9 year, the DNI, is responsible as required by law, to
10 provide to the House Permanent Select Committee on
11 Intelligence and the Senate Select Committee on
12 Intelligence an Annual Threat Assessment. What are
13 the threats to the United States from a global
14 perspective?

15 As in prior years, this year's threat
16 assessment, covered the WMD terrorism threat.
17 According to the statement, U.S. and allied counter-
18 terrorism actions have dealt a significant blow to al-
19 Qaeda, al-Qaeda near term efforts to develop a
20 sophisticated chemical, biological, radiological, or
21 nuclear tactic capability, although the IC judges the
22 group is still intent on acquisition of WMD.

23 No terrorist group has ever successfully
24 detonated a radiological dispersion device. However,
25 there have been some attempts to develop and use an

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1 unconventional weapon. And I'm going to show you some
2 examples of this. That is terrorist use and attempts
3 to use unconventional weapons. Now an unconventional
4 weapon again, includes chemical, biological,
5 radiological, nuclear, and not necessarily just
6 radiological.

7 The first one is chemical here. Aum
8 Shinrikyo, a Japanese cult, that attempted to build a
9 nuclear weapon, they even went so far as to buy a farm
10 in Australia where they attempted to mine natural
11 uranium. And they were going to try and enrich that
12 so they would have HEU to build a nuclear weapon.
13 They failed miserably. They found out how difficult
14 it was. Instead, they decided to turn to something
15 they felt was infinitely more easy and that was
16 chemical weapons. Manufactured some sarin gas and
17 they attacked a Tokyo subway in March 1995 and killed
18 12 people. Again, CW, a chemical weapons attack.

19 In 1995, Russia, you have the Chechen
20 rebels, Russian law enforcement authorities found some
21 cesium-137. The rebels wrapped some conventional
22 explosions around it and buried it in Izmailovsky Park
23 in Moscow. The device was never detonated for reasons
24 that still remain unclear. Subsequently, a couple
25 weeks later, the rebels called the Moscow police

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1 authorities and told them it was there. Law
2 enforcement authorities went and found it and disarmed
3 the weapon. Chechnya was subsequently invaded and
4 continues to be a blood bath between Chechnya and
5 Russians.

6 When you look at some of the intent, one
7 of the most difficult threats to protect against and
8 you'll find this all in the open sources, the lone
9 wolf terrorist. That is, there is a spectrum of
10 threat activities between someone who is acting on
11 their own and through that self radicalization
12 process, they decide they're going to go out and they
13 start reading all the jihadist literature on the
14 Internet. And they're going out and they may try and
15 find a radiological source that they're going to wrap
16 some explosives around and knock off a dirty weapon.

17 That's one extreme. These next two
18 individuals, Jose Padilla and Dhiren Barot, aren't the
19 lone wolf. They're sort of midstream. That is, these
20 are individuals that traveled over to Pakistan and
21 Afghanistan, received some terrorist training. We'll
22 start off with Jose Padilla here. That's the
23 gentleman in the orange jumpsuit there, second picture
24 down. U.S. citizen, traveled to Pakistan, Afghanistan
25 training camps in 2000. Proposed to al-Qaeda that he

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1 detonate an atomic bomb and that term is used very
2 loosely here, (means lots of different things to
3 different people), but proposed that he detonate one
4 of these bombs in the United States and al-Qaeda
5 rejected this as unfeasible. You don't necessarily
6 have the materials to do this, they said. Do
7 something more simple. See if you can get some
8 depleted uranium or some type of radiological source
9 and explode that in the United States. Due to some
10 good intelligence and law enforcement work, he
11 returned to the United States, was subsequently
12 arrested and convicted and he's now serving a 17-year
13 sentence.

14 The final individual here, Dhiren Barot,
15 relatively sophisticated individual, converted to
16 Islam at age 20, arrested in 2004 in the U.K. Charged
17 with conspiracy to commit public nuisance by the use
18 of radioactive material, toxic gases, chemicals,
19 enough explosives to cause disruption and fear of
20 injury.

21 In 2006, in an open Court, again in the
22 U.K., he stated very plainly that it was his plan to
23 detonate an RDD in the United Kingdom. He was
24 convicted and he's currently serving a 30-year
25 sentence in the United Kingdom.

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1 So what's the bottom line on threat? The
2 bottom line is that there is a credible, general
3 terrorist threat to NRC license facilities and
4 radioactive materials. However, at this time there is
5 no specific credible threat to licensees, to materials
6 or to CsCl.

7 Terrorists will likely continue to favor
8 the use of conventional weapons, that which is easy.
9 You've seen in the recent cases whether it's the
10 desire to do a Mumbai-style attack, whether it's PETN
11 being loaded on to aircraft ..these are traditional
12 terrorist tactics going back to the 1960s. They work.
13 They instill fear and they're effective.

14 However, the terrorist intent (and the
15 intent has been very clear) must be married to
16 capability before it can become an actuality. Given
17 terrorist intent, continued vigilance in the
18 protection of all radiological sources is necessary.

19 Thank you.

20 FACILITATOR BAILEY: Okay. Quickly, if we
21 can give the panel for their presentations. Thank you
22 very much.

23 (Applause.)

24 At this time we will entertain clarifying
25 questions or comments in regards to the panel's

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1 presentation.

2 (Pause for microphone adjustment.)

3 MS. SHEPHERD: I'm Mary Shepherd. J.L.
4 Shepherd & Associates. Regarding Part 37 for
5 manufacturing distribution licensees, is adoption of
6 Part 37 going to do away with our SGI orders or will
7 they remain separate, safeguard information?

8 MS. HORN: The information that was
9 considered safeguards information under the order will
10 remain SGI under Part 37. There's no change to that.
11 I will point out that the provisions for SGI have
12 already been placed into the regulations, so they're
13 actually contained in 73.21, .22, and .23. I'm sorry,
14 73.21, .22, and .23.

15 MS. FAIROBENT: Lynn Fairobent, American
16 Association of Physicists in Medicine.

17 Kevin, I know you talked about your
18 experience at Mayo in Jacksonville. Is that pretty
19 much what's being seen both in Mayo in Minnesota and
20 Mayo in Arizona or are there differences in your
21 lessons learned or experiences? I had heard a
22 briefing with Rich Vetter when he was the RSO at Mayo
23 Rochester and on the ACMUI, Advisory Committee on
24 Medical Use of Isotopes. And I just wondered if you
25 all have compared what your experiences are?

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1 DR. NELSON: I have not done a formal
2 comparison. I think one of the reasons I'm here is
3 that we do more transplants at Mayo Clinic
4 Jacksonville than Mayo Clinic Rochester and Mayo
5 Clinic Arizona combined. So we certainly have a need
6 for cesium chloride irradiators whereas some of those
7 other facilities, Rochester and Arizona who don't do
8 as many transplants, they may not have the specific
9 concerns or needs identified with cesium chloride.

10 MS. FAIROBENT: I think what's also real
11 interesting is since this session is on Part 37 and
12 potentially the overlapping implications of that, I do
13 know that when Dr. Vetter spoke about the experience
14 of the orders at Minnesota, his numbers of individuals
15 under background and security was certainly greater
16 than yours in Jacksonville. So I think it would be
17 interesting to take a look and see how the
18 similarities across all three of Mayo's licenses were,
19 since you're all in three different Agreement States
20 as well.

21 DR. NELSON: Right. I think that's a good
22 comment. Florida has 5,000 employees. Rochester has
23 35,000 employees. That's one of the reasons.

24 MS. FAIROBENT: How many in Arizona?

25 DR. NELSON: About 5,000. A little under

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1 5,000.

2 MR. LEWIS: I had a question. Several of
3 you spoke about the investments you've made, you know,
4 the physical changes to the building and placement of
5 things to comply with the increased controls. And
6 have you looked at the new Part 37? And many of your
7 comments about the new Part 37 were very positive. So
8 thank you for that, by the way, and make sure you
9 submit those.

10 (Laughter.)

11 We need both sides. But having looked at
12 the new Part 37 from the point of view of whether that
13 would incur additional upgrade costs or that the
14 physical upgrades you've already done would carry over
15 into the new rule, because that's an important part of
16 this proposed rule.

17 DR. MAIELLO: A lot of finger pointing.
18 You want to go?

19 DR. RING: Joe Ring, Harvard. We have
20 looked at Part 37 and the word we got back from the
21 police department was they did not see a necessary
22 change in any aspect and the preliminary word from the
23 Human Resource Program is the only thing they see as a
24 change is to add the recertification of users.

25 DR. NELSON: Kevin Nelson from Mayo

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1 Clinic. In looking at proposed Part 37, I don't see a
2 significant amount of additional things that we would
3 have to add in order to comply with that. I am
4 looking forward again to having the NNSA folks visit
5 us at the end of this month and getting some further
6 input from them.

7 DR. MAIELLO: Mark Maiello again.
8 Clearly, I have a human resources problem. My folks
9 would have to be much like Phase 1, Phase 2 of the
10 original process, educated into doing what they need
11 to do. And if we have to pay for a contractor to do
12 credit checks, then that's what we have to do.

13 As far as the law enforcement part goes, I
14 can see a minor problem in that our law enforcement
15 agency has -- I think somebody mentioned earlier in
16 the program, the personnel had changed and that's
17 what's happened to us. So again, another sit down,
18 another meeting, another bring them on to the site and
19 show them what they're facing is going to be
20 necessary. But again, these are not intractable
21 problems. They just need time to be implemented.

22 DR. NELSON: If we're looking at the broad
23 spectrum -- I was just focusing initially on the
24 physical environment. But we do have some concerns,
25 as you do with some of the background investigations.

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1 And again, we'll provide, be providing this in formal
2 comments to the NRC. Credit history verification, we
3 have similar concerns. Because of the way we collect
4 criminal background data, we have some concerns
5 whether we can do an adequate job of that or if that
6 should just be something the FBI should do.

7 Character and reputation determination,
8 boy, that's a tough one. And independent information
9 to collaborate what the applicant has provided, I
10 think I understand what the NRC is intending by that,
11 but tell me how I need to quantify that? How do I
12 actually determine that?

13 And so I think there's some information we
14 would need to get some clarification on. Perhaps it's
15 in the guidance document which I have not looked at.
16 But these are some of the issues we have with some of
17 the background checks.

18 DR. MAIELLO: Yes, I'd agree on a broad
19 perspective. It's clear that in our efforts to meet
20 Phase 1 and Phase 2 of the T&R, we learned a lot and
21 we were able to overcome our initial trepidation. I
22 can remember my supervisor speaking probably and
23 properly about what he thought the researchers'
24 response would be to Phases 1 and 2. And thinking
25 that well, scientists are a very liberal group, are

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1 not going to want any kind of intrusion into their
2 lives, especially in Phase 2 of the FBI fingerprinting
3 and criminal background check. But that never really
4 evolved. It never really happened.

5 So I can see here where there would be an
6 initial resistance and obviously I'm getting it now,
7 but you would have to move forward and I think with
8 our ability to meet the original T&R assessment
9 issues. We'll probably be able to overcome these too,
10 but not without a little problem. It's evident.

11 MR. RATLIFF: Richard Ratliff, Department
12 of Safe Health Services, Texas. As I said to the
13 panel earlier, we've seen the increased control really
14 work, you know the licensees embrace it. They've
15 taken security seriously. I think two major problems
16 though we see is the credit check. The blue collar
17 workers who x-ray the pipe to bring your oil to your
18 heating, your automobiles, and ones that do the x-ray
19 on your aircraft engines when you fly, live from
20 paycheck to paycheck. It's a waste of time, I think,
21 in my opinion to do credit checks. We're not looking
22 for clearance.

23 Then on the notifying local law
24 enforcement for temporary job sites that are greater
25 than seven days, if you ever come to Texas and look at

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1 a pipeline that's going 500 miles, you run across so
2 many local law enforcement agencies, it becomes a
3 burden for no net benefit. So I really would hope
4 that the NRC would not only take the comments from the
5 Agreement States, the CRCPD and the State of Texas,
6 but also implement them.

7 FACILITATOR BAILEY: We'll take the next
8 comment, but just for your information, we do have the
9 other mic back up again. Thanks.

10 MS. FAIROBENT: Lyn Fairobent, AAPM. For
11 those of you who have indicated that your HR official
12 has been serving as your T&R, your Trustworthy and
13 Reliable official, is your individual cleared for
14 unescorted access? If not, there's a difference in
15 the reviewing official under Part 37 than the T&R
16 official under the orders. And I've wondered if
17 you've looked at that impact because that individual
18 will have to be cleared either by the Agreement State
19 or by NRC at least as proposed in Part 37 at this
20 time.

21 DR. MAIELLO: I don't have that situation.

22 DR. RING: Joe Ring from Harvard. We have
23 gone through that process, although they can't open
24 the door. We have gone through all the other pieces,
25 but we don't grant them access to unlock the door.

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1 DR. NELSON: And this is Kevin Nelson from
2 Mayo Clinic and the same would be true for us that
3 they've been reviewed, but they don't have access to
4 the door, to the device.

5 MS. FAIROBENT: Thanks.

6 MR. MILLS: Grant Mills, North Carolina
7 Agreement State Program.

8 Part 37, as I understand it, there's one
9 section now I can't remember the exact title they give
10 the person, but it's kind of like the program czar who
11 is going to have to sign off on all of the procedures
12 and be the point of contact for the entire program.
13 Does that ring any bells?

14 MS. HORN: The security plan and the
15 security implementing procedures do have to be signed
16 by whatever you want to call them, but whoever is
17 going to be in charge of security. Hopefully, someone
18 is already approving and doing that sort of thing now.
19 But yes, you would have to have somebody do that. It
20 could be the RSO. It could be some other position in
21 the facility.

22 MR. MILLS: For the folks who are
23 operationally implementing this, do you all see that
24 being a problem or will that just be business as
25 normal?

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1 DR. MAIELLO: Mark Maiello again from
2 Pfizer. We don't see it as a terrible problem. We've
3 overcome worse.

4 FACILITATOR BAILEY: Merri, for the
5 benefit of the transcriber, RSO?

6 MS. HORN: Radiation Safety Officer.

7 DR. RING: Joe Ring from Harvard. We're
8 already doing all the pieces. Back in 2005, our
9 Radiation Safety Committee mandated that that happen.

10 MS. HORN: I'd just like to point out with
11 the exception, maybe the Access Authorization Program,
12 if you really look at the security provisions that are
13 in Part 37, they're really not that different from the
14 orders that are already out there in licensee. If you
15 have certain enhancements that you've used, they're
16 probably going to meet the requirements for Part 37
17 also. We do have requirements now that you have to
18 have a written security plan, that you have to have
19 written procedures, that you have to have training.
20 But I suspect a lot of folks already had procedures
21 and were doing training.

22 We do require maintenance and testing on
23 the equipment to make sure that it's operable. That
24 is something new. We had discovered some issues with
25 that, so we're requiring it. But the actual

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1 provisions, the alarms, the monitoring and detecting,
2 those requirements really are not that different. And
3 if you move into transportation security area, the
4 primary difference there is that we're requiring a
5 little more upfront coordination with the licensee
6 that you're sending the material to which frankly, I
7 think is a good idea. If you're sending a Category 1
8 or Category 2 source to someone, hopefully, they know
9 they're going to be getting it so that they can ring
10 the bell if it doesn't come in on time.

11 So other than those types of things it
12 really isn't that different and if you look at the
13 access authorization program other than the background
14 investigation elements themselves, again, it's really
15 not that different. You have to have procedures to
16 implement the program. There's an individual that's
17 making that final decision on whether you're being
18 granted access or not. Granted, we're calling it
19 something else. It's now called the reviewing
20 official, but the basic elements are not that
21 different.

22 Now I will point out that we do require
23 the reviewing official to be fingerprinted and to go
24 into the background investigation. And the only way
25 in which we can require that was to require the

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1 individual to have access to the material or to the
2 SGI information. But these gentlemen said, they can
3 do that, they just don't let them through the door.
4 So if you really look at the basic aspects of the
5 program, they really are not that different. I will
6 say the credit history has certainly been the most
7 controversial one and the temporary jobsite obviously
8 with the radiographers. But if you take those two
9 aside, the requirements are really not that different.

10 FACILITATOR BAILEY: One more time, SGI
11 information?

12 MS. HORN: Safeguards Information.

13 FACILITATOR BAILEY: Thanks.

14 DR. MAIELLO: And if I might, Mark Maiello
15 again from Pfizer. Just to reiterate, my question
16 from earlier this morning. We shouldn't forget that
17 there are nonprofits involved. That there are smaller
18 companies involved for provision to Part 37, like the
19 credit checks involves extra money that has to be
20 appropriate, it could present a problem. One would
21 hope the guidance and/or shall I say the word
22 "funding" be out there for that kind of thing.

23 MS. HORN: I will say we've already gotten
24 a lot of comments on the credit history aspect and so
25 we will be looking at that. I don't know if it will be

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1 in the final rule or not. That will be a decision
2 that we'll be making in the future. But there's
3 arguments both ways.

4 I know particularly at the NRC, one of
5 the primary reasons you're denied is sometimes your
6 credit history. But on the other hand, we're not
7 trying to say if you had bad credit you can't have
8 access to the material. It does become a judgment
9 call. It means maybe you want to look at some of
10 those other elements of the background investigation
11 and see how they all measure out and then you document
12 that basis.

13 FACILITATOR BAILEY: Cyndi, do you want to
14 add something?

15 DR. JONES: One quick question, Merri, and
16 we'll let the next speaker ask a question. I'm not
17 sure if there's someone here yet from DOE and NNSA,
18 the Global Threat Reduction Department? Great. Maybe
19 Ioanna can help us with these questions. But for
20 those individuals and organizations that have had the
21 enhancements from NNSA, you mentioned, Merri, that in
22 the new Part 37 they need to document in their
23 security plan what they're using to meet the
24 recommendation.

25 So NNSA comes out, say, in two or three

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1 years after Part 37 is completed, would that licensee
2 be required to change their security plan in writing
3 to note the new changes in their security program for
4 physical security?

5 MS. HORN: Yes, if -- the rule does not
6 specify the exact measures that a particular licensee
7 has to use, so they have the flexibility to change
8 those. They would have to revise their security plan
9 to reflect those things that they're not relying on.
10 But the security plan is not submitted to the NRC. We
11 are not reviewing and approving. We will look at it
12 during an inspection, but there isn't any approval
13 process. So they're free to make those changes
14 whenever they want to.

15 MS. SYLVESTER: Ruth Sylvester with
16 America's Blood Centers. I just wanted to second the
17 comments about not for profits. I represent the
18 independent community-based blood centers which are
19 all not for profits. Many of my members are small
20 entities and do not have the expertise to do the types
21 of credit checks and I think background checks that
22 the NRC is looking for. I'm retired military, so
23 everything I read in there looks like and smells like
24 and walks like a security background check without the
25 security being administered. But I think without very

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1 specific guidelines as to what goes into becoming a
2 designation of trustworthy, then I think you don't
3 have any standardization. One person at one center,
4 one entity, may be deemed to be acceptable and then
5 another center may not be. So I don't know that you
6 would really be achieving what you're looking for and
7 that is to have a level of security. So I would
8 question.

9 We have already submitted our comments to
10 the proposed rule and included those in them, but I
11 just wanted to make sure it got on the record today.
12 Thank you.

13 FACILITATOR BAILEY: Thanks. Next
14 question or comment.

15 MR. LEW: Hi, Todd. I'm Bill Lew, L-E-W,
16 with University of California San Francisco. So this
17 is on things like threat fatigue, perhaps from your
18 perspective, if you learned that there are potential
19 threats and it gets out to say the FBI that fusion
20 community, would the plan include communicating with
21 the local facilities and help the facility learn that
22 there might have been near miss and that would help
23 planning.

24 I don't think anybody here would want to
25 be the first facility. Of course, if there is a first

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1 facility, I'm sure that everything we're talking about
2 would go full board. Any comments on that, Todd?

3 MR. MASSE: Thank you very much. It's a
4 great question. And it goes to the issue of threat
5 fatigue and the extent to which you can share
6 information with individuals that really need to have
7 that information.

8 One of the things that the intelligence
9 community and the state and local law enforcement
10 communities faced in the wake of 9/11 when they were
11 setting up the state and local fusion centers was you
12 needed to get information down to the level that which
13 the threat was directed against and you needed to get
14 it out to site security plan managers. You needed to
15 get it out to the regional security officers and not
16 all these individuals have the clearance for the
17 information. And very frankly, when you get into very
18 highly classified information it can be difficult to
19 strip it of intelligence sources and methods, but it
20 is possible. And it is possible, particularly in a
21 situation where you need, where there is a threat
22 where you have relatively rare information where there
23 is a specific threat directed against a specific
24 facility. That information has to get out
25 immediately. And there are groups now that are set

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1 up.

2 It used to be the burden of proof to share
3 information was on the organization. There was a lot
4 of information hoarding, prior to 9/11. We've gone in
5 the other direction where information sharing now is
6 the norm. The burden of proof is on the information
7 not to share that information.

8 One of the primary tenets of the
9 Intelligence Reform and Terrorism Prevention Act was
10 the establishment of a program manager for the
11 intelligence sharing environment, an individual who
12 does nothing but think about -- morning to night --
13 about how to share information with critical
14 infrastructure with the private sector, with getting
15 that information down to a level where it can be
16 shared with individuals who can take action to prevent
17 the attack or whatever the instance is.

18 So your point is very well taken and there
19 are measures being taken to ensure that information is
20 getting shared down to that level. Thank you for the
21 question.

22 FACILITATOR BAILEY: Additional questions
23 or comments?

24 DR. JONES: I have one. In relationship
25 to that comment, again for Todd. Our second question

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1 on participant deliberations above you is a question
2 whether or not cesium chloride sources should receive
3 special consideration. And Todd, you gave an
4 excellent presentation on how the NRC coordinates with
5 the other law enforcement agencies and intelligence
6 services and you also talked about what the specific
7 or non-specific credible threat was.

8 I guess I would look to the panelists and
9 the audience for an answer or to at least discuss that
10 for a few minutes. Should cesium chloride sources
11 receive special consideration in light of the existing
12 potential threat or non-threat?

13 MR. MASSE: I can just sort of reiterate
14 the statements that I made earlier. It's difficult
15 from an intel perspective, given the nature and
16 inherent limitations of intelligence to look at a
17 particular source and say that there is a threat to
18 that source. There is a threat to the larger and
19 broader categorization or category of those sources.

20 Should there be any very specific
21 information that that source is being targeted by any
22 group, whether that is an international terrorism
23 group that's of the sophistication of al-Qaeda or core
24 al-Qaeda, that is the group that planned World Trade
25 Center 1993, World Trade Center, Pentagon, and

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1 Pennsylvania 2001, other groups, the splinter groups,
2 all the groups that we're seeing right now, the lone
3 wolf groups.

4 Should there be any specific intelligence
5 gathered internationally or domestically that there
6 was a specific threat to CsCl, that information would
7 be shared I think relatively quickly with the
8 appropriate parties.

9 DR. JONES: Thank you. Any other comments
10 on that? Any other questions for the panelists?

11 I will mention that our speaker from the
12 FBI, Bernie Bogden, was unable to make it this
13 afternoon and if you look on your schedule, he is the
14 first speaker after my summary tomorrow morning. So
15 we will hear from FBI, just not in conjunction with
16 this panel discussion. But he'll let us in on what
17 FBI is doing and may reach out and touch some of you
18 as licensees.

19 Again, so Merri, the date when licensees
20 can provide comments on Part 37 is?

21 MS. HORN: The comments on both the -- the
22 comment period for both the guidance document and the
23 proposed rule ends on January 18, 2011. So you still
24 have a good almost two and a half months in which to
25 get those comments together. And I do encourage you

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1 to. We will take a look at every single comment and
2 consider. I won't guarantee we'll make changes, but
3 we will consider that.

4 (Laughter.)

5 FACILITATOR BAILEY: Okay, if there are no
6 additional comments at this time I guess we'll take an
7 extended break.

8 DR. JONES: How about until 3:00 o'clock.

9 FACILITATOR BAILEY: Okay, 3:00 o'clock,
10 everybody. Thank you for your attention.

11 (Whereupon, the above-entitled matter went
12 off the record at 2:25 p.m. and resumed at 3:03 p.m.)

13 FACILITATOR BAILEY: On the record. Okay,
14 once again, everybody, welcome back. We'll now begin
15 discussion for Issue 3, could hardware improvements be
16 made that would further mitigate or minimize the
17 radiological consequences. As before I will allow the
18 panel to introduce themselves beginning from left to
19 right, my left.

20 MS. RIBAUDO: That would be me. Cathy
21 Ribaud from the National Institutes of Health.

22 MS. SYLVESTER: Ruth Sylvester, America's
23 Blood Centers.

24 MS. ILIOPULOS: Ioanna Iliopoulos, NNSA,
25 Office of Global Threat Reduction.

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1 MS. SHEPHERD: Mary Shepherd, J.L.
2 Shepherd and Associates.

3 MR. MENNA: Blair Menna from Best
4 Theratronics.

5 FACILITATOR BAILEY: Okay. And we will
6 begin this discussion with Blair Menna on Irradiator
7 Manufacturers' Safety Features.

8 MR. MENNA: Thank you. So this issue is
9 talking about could we make hardware improvements and
10 indeed we have been. So I'm going to speak this
11 afternoon about the Irradiator Security Enhancements
12 Program that Best Theratronics is working on.

13 The program, they're voluntary security
14 enhancements and we've talked today about a variety of
15 the problems of security. There's the detection.
16 There's the assessment and response. The program I'm
17 talking about this afternoon is specifically delay.
18 So once you've had detection and an assessment while
19 you're waiting for the response it's imperative that
20 you have some delay.

21 So the in-device delay program or IDD
22 program is a retrofit program that adds passive
23 hardware features to the device and these features
24 make the device inherently more secure. The design
25 for the retrofit IDD was developed by Sandia National

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1 Laboratories in cooperation with the device
2 manufacturers. And the modifications compliment other
3 security enhancements at the facility.

4 So the retrofit process, one of the
5 challenges with this process is being done at the
6 licensee's facility. So the process was developed
7 with tools that obviously we could use onsite and that
8 limited significantly what we could do. You can't use
9 large welders, for example.

10 So the process starts with a visit from
11 the NNSA. They come out and they do the site
12 assessment. And at that time they will start
13 collecting information for IDD upgrade process. And
14 once that's been done, they will pass the information
15 onto the manufacturers.

16 At that point, we coordinate with the
17 irradiator owner, schedule the visit, make sure that
18 we have all of our ducks in a row. There is a lot of
19 questions we want to go over with respect to work
20 permits and any issues like that obviously, security
21 issues, getting the T&R paperwork exchanged.

22 Then we show up with our specialized
23 toolkit and do the installation. The duration varies
24 depending on the equipment that we're working on and
25 the facility itself. There is often complications.

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1 Usually the process takes one or two days for the
2 device. And like I said, we've got specialized tools.

3 It includes, the process includes,
4 grinding, welding, drilling, painting. And there's
5 ancillary equipment associated with that like fume
6 extractors and welding blankets. We carry fire
7 extinguishers as a precaution, that type of thing.
8 And once the process is done, we run a full functional
9 test on the device including dosimetry.

10 This slide, the purpose of this slide, is
11 to show that there is no difference from the
12 licensee's point of view. Once we're done, the
13 machine looks exactly the same when the covers are put
14 back on. And it operates exactly the same.

15 The program, the retrofit program, we
16 started the pilot installations in late 2008. These
17 finished in the winter of 2009. Best Theratronics,
18 our pilot program included a total of 16 devices.
19 Seven of these were blood irradiators and nine of
20 those were the Gammacell 40 research irradiator.

21 Halfway through 2009, we moved into the
22 National Implementation Program or the NIP. Because
23 it was a short year, we only managed to get another 16
24 units done. In 2009, six of these were blood
25 irradiators and ten of these were research

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1 irradiators.

2 And then the National Implementation
3 Program for 2010 we hardened a total of 49 devices, 22
4 blood irradiators and 27 research irradiators. And if
5 my math doesn't fail me, that's a total of 81 devices
6 that we've done in the field so far.

7 My last slide, I want to talk just very
8 quickly about factory hardening. So we -- as I
9 mentioned on the retrofit process, the tools that
10 we're using are somewhat limited. There's nine that
11 we wanted to incorporate in the factory. We wanted to
12 be able to take advantage of our machine shop, the
13 large boring holes and welding equipment, to produce
14 what we think is at least as good if not a better
15 design.

16 So we worked with Sandia National
17 Laboratories again to modify that design. We've
18 agreed with them on that design. We're currently
19 manufacturing our first units. We have submitted to
20 the U.S. NRC to amend our device registration
21 accordingly. And we will be ready to ship our first
22 units early in 2011.

23 Thank you.

24 MS. SHEPHERD: Mary Shepherd, J.L.
25 Shepherd and Associates. Blair's done an excellent

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1 job. We've experienced the same design efforts with
2 Sandia. We've worked with Sandia. We've worked with
3 NNSA.

4 We had a little different experience. We
5 had a bit of delay on the rollout because we had to
6 change our prime contractors. Our prime contractor
7 changed and that was about a six month delay. So
8 we're behind on the national rollouts. So probably we
9 performed over 40 installations as of today into in-
10 device delay kits with the IDD. And we'll continue to
11 install these kits as long as the program lasts. We
12 anticipate getting all existing Mark Is in the field
13 done within a five year period and that will just
14 depend on how the funding comes.

15 The funding today is the pace, scope and
16 priority sent by National Nuclear Safety
17 Administration Global Threat Reduction Initiative
18 Schedule. So if you are late or you think we're not
19 responding to your question of when are we getting our
20 IDD kit done, you need to talk to GTRI and bother them
21 a little bit more because it's not my schedule at all.

22 All new Mark Is and for the last year have
23 the IDD kit installed and I should preface that. It
24 may be, depending on which model you have because of
25 transportation restrictions, partially installed and

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1 completed once it's on site. I get into that I think
2 on the next slide.

3 For those, the larger Mark Is, the Model
4 68 and Model 68As, the transportation requirements
5 require that the source be removed for highway
6 transport. So if you have a Mark I 68 and 68A that's
7 on the IDD kit schedule, if you need to move that we
8 need to know that before it's moved. Otherwise, we'll
9 be putting on the IDD kit and taking it off again to
10 relocate it.

11 This is a temporary situation. It's based
12 upon the shipping containers we have available now.
13 Once the new shipping containers have passed the
14 initial modeling we have a fluid design so that the
15 68As and 68 will not be affected by source removal
16 once the package is approved for highway transport.
17 And that situation we will within the next month or so
18 will have all the application modeling finished. We
19 have an application into the NRC. So it could be a
20 year or two year process. And then that whole problem
21 goes away.

22 The Model 143 which is our blood
23 irradiator, that design is in development. We think
24 we have a final design and we're going to pilot
25 installs within the next few months with GTRI. Once

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1 those are implemented and the pilots work, all new
2 blood irradiators will have the IDD kits installed
3 prior to delivery.

4 Finally, I'd like to thank everybody, all
5 the Mark I IDD kit participants, for your gracious
6 cooperation. This is not an easy process and all of
7 your hard work for making this project a success.

8 MS. ILIOPULOS: That helps. You start
9 with the last slide of my presentation and I can work
10 backwards.

11 I'm Ioanna Iliopoulos and I'm with the
12 National Nuclear Security Administration's Office of
13 Global Threat Reduction. I recognize a lot of people
14 out there in the audience that have graciously
15 volunteered to work with our program. And I look
16 forward to your questions and feedback.

17 A little bit about GTRI before I start
18 discussing what we're doing on domestic security work.
19 We are a first line of defense program within NNSA and
20 we focus on both nuclear and radiological materials,
21 both domestically and internationally.

22 Like many federal agencies, we're waiting
23 for Congress to pass our budget. But we're very
24 hopeful that when we do receive our budget this fiscal
25 year will be a little bit more than a half of billion

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1 dollars. And we focus on conversion of reactors that
2 utilize HEU to LEU and isotope production activities.
3 We're also working internationally on a lot of
4 repatriation campaigns to repatriate U.S. origin
5 materials overseas back to the United States and
6 Russian origin materials that are eligible for return
7 back to the Russian Federation.

8 And domestically we run the Offsite
9 Recovery Program. One of my colleagues, John Zarling,
10 will discuss a little bit about that in some of the
11 challenges with source removals and recoveries. And
12 we're providing protection activities, both
13 domestically and internationally, to other than high
14 income economy countries on securing both radiological
15 and nuclear materials.

16 I think this has been covered. Just
17 materials of concern, the NRC led an interagency
18 working group comprising of multiple U.S. federal
19 agencies relooking at the IAEA's categorization of
20 Code of Conduct materials and what we determined is
21 there are about 14 isotopes plus spent fuel that we're
22 concerned about. So we can bound the problem in terms
23 of what materials are out there commercially available
24 and have the power to contaminate if dispersed in a
25 malicious manner of which there are four isotopes of

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1 particular concern because of they're widespread use
2 and activity levels. And they're up there on the
3 screen.

4 I think Todd provided a very good threat
5 briefing. I don't have anything additional here to
6 add. These are just clips from newspapers on the
7 threats.

8 I do want to reiterate and validate what
9 was said that we lack specificity on timing and
10 details of any threats against radiological materials
11 and licensees. But there have been calls by al-Qaeda
12 and non al-Qaeda groups expressing interest in the use
13 of WMD to include radiological materials. And we're
14 also very concerned about the facility insider or
15 insider threats to these facilities.

16 So what do we do? We offer the Domestic
17 Source Recovery Program which is available to
18 licensees that register disused and unwanted sources.
19 And again this will be covered in detail in one of
20 tomorrow's sessions. And on a voluntary basis we work
21 with licensees that would like to subscribe to GTRI
22 assistance to provide additional security upgrades at
23 their facilities, both nuclear and radiological once
24 they've met their increased control requirements.

25 We also provide specialized training for

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1 local law enforcement because we found that has been a
2 gap depending on where a licensee is located. And we
3 work with our Office of Counterterrorism to provide no
4 fault exercises that exercise local, state and federal
5 response to a terrorist incident.

6 There's been a -- Working in close
7 collaboration with the NRC, there was a regulatory
8 issue summary release last January that describes our
9 relationship to NRC increased control requirements.
10 And in a nutshell I just want to say that they're
11 complimentary to and do not replace what a licensee is
12 required to do under NRC increased control
13 requirements. So if there is a citation or a
14 violation you cannot call on GTRI to come in and fix
15 the problem.

16 We're working very closely with Agreement
17 States. And at other federal facilities whereby
18 you're in full compliance with your increase control
19 requirements. But there's another federal program
20 that can provide you with kind of an independent
21 assessment of what additional security initiatives
22 you could benefit from. So it's more of a tailored
23 approach to security utilizing another federal program
24 that can help with federal dollars if that money was
25 not available to you in going through the first round

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1 and meeting your ICs.

2 I think Blair and Mary covered a lot about
3 what we're doing in the area of delay. And I just
4 want to stress: this has been a wonderful federal
5 industry partnership. We've been working very closely
6 with the NRC and DHS, device manufacturers and
7 licensees to make this a big success. But delay is
8 only one aspect of the physical protection.

9 We're also working with facilities to
10 conduct a site assessment and look at ways that we can
11 have better access control and response. So up here
12 this is just a basic sampling of some of the equipment
13 we provide.

14 I do want to mention we don't ask
15 facilities to remove any physical protection they
16 already have at their facilities. In many cases the
17 upgrades that we offer may be redundant systems or an
18 overlay or we try to upgrade some systems they already
19 have in place. But we've seen in the United States
20 that a lot of facilities have done a great job meeting
21 their increase control requirements and having a lot
22 of these elements in place.

23 We may just upgrade a card swipe or access
24 key to using more biometrics if that works at the
25 facility. We'll provide some passive infrared motion

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1 detectors and one of the features we have utilizes a
2 CCTV camera that captures prioritized alarms. And
3 what I mean by prioritized alarms is we typically work
4 with facility operators to wrap our IDC all around the
5 device itself that would trigger an alarm if a
6 perpetrator was trying to take apart the device and
7 remove materials whether it's cesium or cobalt from
8 that device itself.

9 We also install an area radiation
10 detection sensor in the room. And that again is
11 triggered by an alarm if you have elevated levels. So
12 if you would have those two or three prioritized
13 alarms going off it would capture a camera image of
14 what's taking place in the room. And that would
15 provide local law enforcement situational awareness of
16 what's occurring in the room itself and how to respond
17 accordingly.

18 So this just graphically displays the
19 benefits of getting the signals out to local law
20 enforcement. It varies from state to state, county,
21 across the country. But I think one of the challenges
22 that we all face is that because these materials are
23 found in open environments meaning medical and
24 research facilities. They're at universities. They're
25 in major cities.

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1 And typically there's the unarmed site
2 guards do not carry guns. They rely on a 911 dispatch
3 for armed guard response to a facility. I think there
4 have been some unique facilities that do have their
5 sworn local law enforcement at the facility. But
6 typically it would have to go into a 911 dispatch
7 center. So depending on where you are that response
8 could vary. And so we find it very important to get
9 those signals out so if something occurred in the
10 middle of the night somebody could look at a screen
11 and determine how to respond. And how many people to
12 send to a response is very beneficial.

13 This just gives a very good overview of
14 what we've done with both Mary and Blair, working with
15 device manufacturers and also CIS who is not
16 represented here, Pharmeducence. This program is
17 quite new. And while all interagency have been
18 involved in our work, particularly DHS and NRC, and
19 working in close cooperation with Sandia and the
20 device manufacturers, the entire mission got
21 transferred to NNSA a year and a half ago. So we've
22 been making measurable progress over the past year and
23 a half chipping away at this problem.

24 As you can see there are 836 cesium
25 irradiators in the U.S. that we'd like to address over

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1 the five year period. And to date we've completed 214
2 IDD installs which represents 26 percent of our total
3 completion.

4 I talked a little bit about enhancing
5 response force capability. As we identified the need,
6 we felt that local law enforcement officials in some
7 cities and counties that didn't know what an
8 irradiator looks like, what type of material is in it,
9 what's actually -- what critical infrastructure is in
10 their backyard.

11 So to help out with bridging the gap
12 between response and the physical protection we're
13 doing at those sites, we created a mock-up facility
14 down at our Y-12 nuclear complex and we have a mock
15 medical facility down there that has a lot of
16 irradiator shells and a lot of the GTRI security
17 upgrades. So we provide both classroom and tabletop
18 training and then allow law enforcement officials to
19 exercise their response procedures, running through a
20 medical facility. So it's a very unique opportunity
21 to provide situational awareness to those that are
22 very hard to reach in the law enforcement community.

23 If you have any questions, you can contact
24 me after this meeting and we've left our emails and
25 phone numbers. Thank you.

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1 MS. SYLVESTER: Good afternoon again. I'm
2 Ruth Sylvester with America's Blood Centers.

3 Just a little information. America's
4 Blood Centers is actually a trade organization
5 representing the not-for-profit independent community
6 blood centers. We have a total of 76 member centers
7 that collect over nine million donations, 600 blood
8 center locations and transfusions for 2.5 million
9 blood recipients. So we represent half of the U.S.
10 blood supply and the 25 percent of the Canadian blood
11 supply.

12 We did a survey before the 2008 workshop
13 that the NRC hosted and we went back and we've updated
14 that survey just recently, in fact, last week. And
15 what you see here, we have of our members a total of
16 84 blood irradiators. Ten of our members don't
17 irradiate at all. And we got a very good response
18 rate.

19 Fifty-eight of the members that responded
20 irradiate over half a million components every year.
21 And as I said they own 84 irradiators. And they also
22 irradiate for another 1400 facilities which primarily
23 would be hospitals that do not have their own
24 irradiators.

25 One of the -- Only one member surprisingly

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1 after the -- to quote the CEO -- "The hassles of the
2 NRC's increased control orders has decided to switch
3 from cesium to x-ray. But what I wanted to stress to
4 you is why only one out of all of those are looking to
5 switch. And that's because of the remaining life
6 expectancy they have in the current units that are on
7 their floors. For cesium irradiators they still have
8 an on-average ten years life expectancy left in their
9 irradiators. And for not-for-profit entities that's a
10 chunk of change particularly in a depressed economy
11 where what we're finding is that hospital transfusions
12 are down. Therefore, our collections are down. So
13 it's an interesting dilemma they find themselves in.

14 We also asked about implementing the
15 increased control orders. We wanted to know -- We
16 asked how much did this cost you. Did you have any
17 troubles and stuff? We got a response from 24
18 different individuals. It cost them a total of
19 \$182,000 to do facility modifications to implement the
20 increased control orders which averaged about \$10,000
21 per facility.

22 Background checks, they told it was
23 \$42,000 to do the background checks. That could be
24 for in some cases only a few employees. At other
25 places if the irradiator is out in the product area,

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1 it could be a number of employees. So it varied
2 significantly, but on average \$2,000 per facility.

3 And then estimated on-going costs a total
4 of \$34,000 and with an average of \$2200-\$2300.

5 Experiences. This is where we get more of
6 the comments. Some of the challenges, I can honestly
7 say I did get one that said "This wasn't a problem for
8 us. We implemented it." That was the minority of the
9 comments that I got.

10 There were delays in receiving the
11 background checks from the FBI. Some staff just don't
12 like having their privacy invaded. They consider it -
13 - They just are not impressed with it. There were
14 delays with issues with the LLEA as we heard from
15 previous speakers today. As the one preceding me just
16 said, some of them don't even know what it is in their
17 own backyard. And it has been very difficult for some
18 of our institutions to get connected with them.

19 And then there have been some
20 administrative challenges with administrative program.
21 And I think for not-for-profits a big one is an
22 inability to recoup these costs. You know, when you
23 look at our products are sold to hospitals, the
24 hospitals like I said in an economic downturn --
25 they're primarily paid by either Medicare or

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1 insurances -- this is not a cost that is able to be
2 passed onto the hospitals, to our customers. So it
3 just has to be eaten. And that is significant when
4 you're a small, not-for-profit institution.

5 And then the other one was just lack of
6 specificity. We work in a highly regulated industry
7 and some of our members really like to be specifically
8 told how to do it step one, two, three and four. And
9 when they don't get that they're afraid that their
10 interpretation won't be acceptable.

11 So then why go through this with the
12 cesium irradiators? I think these two slides really
13 drives that point home. The original cost of a cesium
14 irradiator against an x-ray irradiator is significant
15 in the difference as well as the life expectancy. The
16 x-ray irradiators is a fairly new technology. It only
17 has around a ten-year expectancy. They are getting
18 better. How long they are going to last in the long
19 run is another story. But for now they're get more
20 bang for the buck for longer when they go with cesium.
21 And that's why they want to continue to use the cesium
22 irradiators.

23 And this just kind of sums up those
24 slides. Cost difference between the technologies, the
25 investment in their current technology that still

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1 remains, and they really believe that the burden needs
2 to be on the manufacturers.

3 Hearing the previous two and three
4 speakers, I believe that manufacturers have stepped up
5 to the plate. Now it's going to be and I'm glad to
6 see GTRI is actually helping the centers and paying to
7 put in those additional hardening aspects.

8 And then there is also really a lack of
9 perception of risk. You talk to the members now and
10 they'll say, "We've done everything they've asked us
11 to do. Now what more do they want?" And so there is
12 I think -- They just don't appreciate the risk that's
13 out there.

14 The draft policy statement which is what
15 this workshop is about ABC and its members concur with
16 the statements. We believe that to continue to have
17 access to cesium chloride is very important for the
18 public health. We agree that improvement designs are
19 prudent. Alternative forms for cesium chloride would
20 be great as long as we can have it at the same price
21 and that it will last the same amount of time. And
22 then pathways to safely dispose of cesium is a must
23 because right now it just doesn't exist.

24 And then I mentioned this in my comments
25 earlier during the last session and I just want to

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1 drive that point home. Concerns over the proposed
2 rule and some changes to the background checks, the
3 lack of uniformity in the application of the
4 individual aspects, the credit history, the local
5 criminal history. Define local when you are near a
6 border and there are multiple locals. Again not-for-
7 profit organizations are not in the business of doing
8 background checks. And then the cost of conducting
9 and repeating these can be onerous because it can't be
10 recouped.

11 That's all I have. Thank you.

12 MS. RIBAUDO: Good afternoon. I'm Cathy
13 Ribauda with the National Institutes of Health in
14 Bethesda, Maryland. The NIH is the Federal
15 Government's biomedical research agency and we support
16 medical discoveries that improve the public health
17 through basic, translational and clinical discoveries.
18 NIH employs 6,000 scientists and hosts several
19 thousand fellows who are actively conducting research
20 in nearly every aspect of biomedical science.

21 And so as perhaps a representative sample
22 of biomedical researchers in academia everything, the
23 NIH is a long-term user of cesium irradiators and
24 other irradiators as well. Radiation exposure is used
25 as a tool in numerous research experiments. Our

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1 license with the Nuclear Regulatory Commission being a
2 Federal agency -- NRC is our regulator -- we are
3 authorized for possession of 26 sealed source
4 irradiators, most of which are cesium, including our
5 satellite campuses. But Bethesda is main campus.

6 NIH irradiators are actively used by
7 approximately 500 researchers and their applications
8 vary widely but can generally be categorized into four
9 groups. And I'll step through each one briefly.

10 So, first of all, high dose radiation
11 versus low dose radiation, in vitro versus in vivo, in
12 vitro meaning irradiation of cells. The majority of
13 studies using high dose irradiation in vitro are to
14 study to immune responses of specific cell types using
15 proliferation assays. And so researchers will
16 incubate immune cells under very controlled conditions
17 to which they've added a stimulus being studied
18 whether that be a virus, a bacteria or other foreign
19 antigens.

20 And stimulated immune cells respond by
21 proliferating or growing which is typically measured
22 then using tritium thymidine incorporation. However,
23 the immune cells that are being grown in culture
24 require the presence of feeder cells in the incubation
25 mixture and that provides critical nutrients and

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1 signals to keep the immune cells alive and functional.

2 And the feeder cells need to function but
3 must not themselves proliferate so that the only
4 incorporation being measured is that of the immune
5 cells. So the feeder cells need to be irradiated
6 typically using a cesium irradiator before they can
7 support the immune cells being studied.

8 And then there are also other studies
9 requiring the presence of feeder cells to such as many
10 stem cell protocols and targeted cancer protocols in
11 which tumor cells need to be heavily irradiated. They
12 are fairly more radioresistant and cultured then with
13 tumor attacking lymphocytes.

14 So sub-lethal irradiation, you're probably
15 aware of this, but the ability of cells to repair DNA
16 damage is a critical function in the ability of an
17 organism to survive. DNA damage can and does occur
18 from a variety of insults including radiation, but
19 also viral infection, environmental causes, chemical
20 causes. And so accurate low dose irradiation of cells
21 in vitro using an irradiator can create specific types
22 of DNA damage in a controlled setting which can then
23 be used to study the cell's repair mechanism to that
24 damage. And some of these DNA damage studies
25 specifically require cesium irradiation and are being

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1 supported by Homeland Security grants to study the
2 effects of repair mechanisms of cells against cesium
3 exposure.

4 Moving to in vivo applications, so
5 irradiation of animals, typically rodents but it could
6 also be larger species, the ability to use animals as
7 living incubators to study disease has really been an
8 important advancement in biomedical science. So, for
9 example, the study of transplant rejection and the
10 genetic basis of disease by injecting genetically
11 different bone marrow cells into a population of
12 typically mice has tremendous potential in biomedical
13 research.

14 And normally this would not be possible,
15 if you remember from basic biology, because the immune
16 cells of the animal receiving the bone marrow would
17 recognize those bone marrow cells as foreign and would
18 attack and kill them. However, if you can first
19 lethally irradiate the animal using an irradiator so
20 it's radio-sensitive bone marrow and immune cells will
21 die, the radioresistant non-immune cells which are
22 still needed in the host for critical nutrients to
23 grow the new bone marrow cells, those will survive.
24 And then you can inject the foreign bone marrow cells
25 which will now rescue the animal with bone marrow from

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1 a different host and repopulate its immune system.
2 And this technique provides the ability to generate
3 chimeras to carefully study the genetic basis of
4 various diseases which might then lead to ways to
5 treat or even cure those diseases. So this is a very
6 widespread use of an irradiator.

7 And then finally sub-lethal irradiation in
8 vivo, this is often used because of the ability to
9 induce DNA damage. So many studies of the responses
10 to and repair of DNA damage take advantage of this
11 technique which has relevance in cancer research
12 especially as well as many other diseases as well.

13 But there's yet another application which
14 at least one researcher that I had interviewed across
15 our population had expressed that cesium was relevant
16 for his research. Controlled DNA damage via sub-
17 lethal irradiation in vivo is used in his case in the
18 development of vaccines against microorganisms that
19 cause diseases. In his example specifically, he
20 studies the development of malaria vaccines and this
21 is aided by the ability to sub-lethally irradiate
22 mosquitoes that harbor the malaria-causing parasite.

23 Sub-lethal irradiation causes DNA damage
24 that is not severe enough to kill the host but impairs
25 the ability of the parasite to cause the disease. And

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1 this is especially important since the basis of
2 vaccination as you know is to immunize the patient to
3 a form of the disease-causing organism that can
4 stimulate an immune response but not actually have the
5 ability to cause the disease in a human. So
6 radiation-induced DNA damage via sub-lethal
7 irradiation is one method of creating these vaccine
8 candidates.

9 So having said all that, the NRC's draft
10 policy statement as far as we at NIH are concerned,
11 this does represent the evolution of the scrutiny and
12 increased security over cesium irradiators. And we're
13 not different. NIH like other licensees has responded
14 to the Increased Controls Mandates of 2005 and 2007,
15 and also we have cooperated with the NNSA for our
16 security assessment and implementation of recommended
17 additional security upgrades. Of our 26 irradiators,
18 15 have been hardened through the GTRI program.

19 And was it hardship? It did require about
20 two days of down time per irradiator for each
21 hardening process. And that was a huge logistics
22 effort for me in particular and an occasional hardship
23 I'll admit to some NIH researchers who had to
24 temporarily find a different irradiator to use
25 meanwhile.

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1 But other than that, the hardened
2 irradiators have not really been a problem to the
3 users. The hardening as we learned is invisible to
4 them. It rarely has anything to do with altering the
5 operation of the irradiators. The institutes got a
6 free preventive maintenance visit out of it. So
7 there's some advantages there.

8 Now the security upgrades have been a
9 large impact to the security and police forces, that
10 side of the house, and also to myself, Radiation
11 Safety. And I won't deny that that has been a
12 hardship at times to get there, has been a real road
13 to travel, but we're there. We've established
14 countless SOPs and policies and gone through numerous
15 training. And so for the most part this is again
16 invisible to the researchers.

17 On the other hand, the NRC orders
18 themselves have had a much more tangible impact to the
19 researchers, to the end-users, particularly with these
20 two factors, the higher security physical access
21 control upgrades and the T&R approval process. If
22 that wasn't an actual hardship, the words "annoyance"
23 and "frustration" come to mind as feedback from the
24 researchers.

25 So we have over 700 approved accessors in

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1 addition to the researchers. There are also
2 populations of users who require access to the rooms.
3 And as we know from the orders, this requires the same
4 level of T&R clearance for those folks. So it's over
5 700 approved irradiator room accessors at NIH.

6 Those have been affected by the upgrades
7 and they've had to undergo a shift in their security
8 mentality. And I'll admit this transition has not
9 been easy. It started from 2005 to the present.

10 Most scientists and many of them have been
11 at NIH for decades, they've long viewed sealed source
12 irradiators as just any other piece of equipment which
13 is to say it's a necessary tool in the research
14 laboratory for use and research experiments. It's
15 just a device to them.

16 But from 2005, with the first increased
17 control going into effect to the present, these
18 scientists have had to ensure a sea change in the
19 regulation and protection of irradiators at the NIH.
20 It impacted them. In fact, for some 40 accessors,
21 they opted out of the entire process and decided it
22 wasn't worth their time, invasion of privacy, whatever
23 rationale they had that they decided to either be
24 escorted or let someone else do the irradiations for
25 them.

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1 But for those who still did need access
2 though, they weathered the changes. They
3 transitioned with us to this new security mindset
4 because they had no choice, because it was a mandate
5 and because this was the deal.

6 So radiation safety through strong support
7 of the Radiation Safety Officer at the NIH, the
8 Radiation Safety Committee, senior NIH management, we
9 took a proactive role and we provided a constant focus
10 to the population of researchers using irradiators on
11 the upgrades to the access control, frequent
12 communications, additional training, specific training
13 on the upgrades, standardized approval process was
14 put in place, follow-ups to all alarm incidents and
15 sometimes this may be a researcher's first dealing
16 with us face-to-face as a follow-up to some irradiator
17 alarm, more training as a result of the follow-ups.

18 All of this has resulted in a successful
19 shift in security compliance and a more or less
20 consistent cooperation from the researchers in their
21 attitude towards irradiator security. They recognize
22 that this is a non-negotiable price to pay for
23 retaining these cesium irradiators at the NIH.

24 So the NRC's draft policy statement on the
25 protection of cesium chloride sources gives credit to

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1 the biomedical research needed for these irradiators.
2 There's a paragraph in there. One paragraph is
3 devoted to this topic. Here it is right here. One
4 sentence speaks to that absolute need for cesium
5 chloride in biomedical research and it's quoted from
6 the draft policy statement here.

7 However, we believe much more needs to be
8 said. More text in the NRC policy statement regarding
9 the absolute need for cesium chloride would better
10 address the needs of the biomedical research
11 community. In addition to other reasons you'll hear
12 later, for example, waste disposal concerns, it's
13 important I believe to go on record with more reasons
14 why alternative technologies cannot readily meet all
15 of the needs of NIH scientists. And it's not just the
16 single reason here of uniform linear energy transfer.

17 And let me just say before I go any
18 further this is not meant to be an x-ray bashing. We
19 actually have quite of a number of cabinet x-ray
20 irradiators at NIH as well. And the folks who use
21 those are very pleased with their performance. But
22 there is a cross section of researchers for whom the
23 cesium irradiators cannot be replaced by alternate
24 technologies.

25 And so for those researchers the points

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1 that they fed back to me when I queried "Why cesium?
2 Why do you need this device so badly," existing
3 research using cesium as the source, it's over 40
4 years old and you know science is rigorous. So
5 there's a real reluctance to go back. Some research
6 would have to be repeated. There's a real reluctance
7 to just simply accept X-ray equals cesium photopeak as
8 far as energy transport. The radiobiological effect
9 unless you can demonstrate that that equal one source
10 to the other it will introduce a new variable to the
11 procedure.

12 Another reason and this was echoed
13 earlier, cesium irradiators are long-lived with few
14 mechanical problems and little required maintenance.
15 And NIH managers appreciate that.

16 One researcher I have uses both cabinet x-
17 ray, cobalt irradiators and cesium irradiators. This
18 group's program has a real wealth of knowledge with
19 the advantages and disadvantages of each. And in
20 their case with their x-ray unit they admit that their
21 reliance on the x-ray means that they will do an every
22 sixth month tube replacement because the risk is too
23 great that a tube could burn out if they didn't stay
24 on top on the PM. It was so critical for that need.

25 In a cesium irradiator you can irradiate

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1 multiple targets in one cycle. The typical feedback
2 from this has to do with the in vivo research where
3 you're generally irradiating mice. And sure you can
4 irradiate mice with an x-ray irradiator. But you
5 might only be able to fit four or five in the holder.
6 Whereas with the cesium irradiator I've got groups
7 that need to irradiate between 10 and 20 at a time for
8 their research needs to stay consistent.

9 So especially for the in vivo the ability
10 to irradiate multiple targets to their way of thinking
11 that's a deal breaker there. That's crucial.

12 Cesium irradiators take up relatively a
13 small footprint. We have irradiators that can fit
14 inside an emergency shower closet, a teeny tiny closet
15 off the hallway. And for these researchers it's a
16 relatively small footprint. It doesn't require any
17 infrastructure support other than the power supply and
18 the weighted floor to support the weight. And then,
19 of course, I would be remiss if I didn't say it would
20 also require the security upgrades for the cesium
21 protection.

22 There is no x-ray unit that would fit in
23 an equivalent small space. You can't equally trade
24 one unit for the other. You would have to find a way
25 physically to fit and find the infrastructure to

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1 support the cabinet x-ray unit. However you would rid
2 yourself of the security upgrade requirements.

3 And, so above all, the common theme was
4 that cesium provides an accurate, reliable and rapid
5 system for irradiating tumor cells, feeder cells and
6 lymphocytes. Because when you have a time sensitive
7 incubation mixture of a cancer patient's lymphocytes
8 and you need to irradiate 8.4 billion feeder cells in
9 one go and that's required to support the lymphocytes'
10 growth in the hopes that this can cure a patient's
11 cancer, mediate the tumor regression, you need cesium.
12 X-ray won't do it. Cobalt won't do it. Cesium is the
13 only machine that can provide this service.

14 So NIH has devoted a lot of time and money
15 to comply with the NRC orders and NNSA has devoted a
16 lot of time and money to provide the hardening of over
17 half our irradiators and the additional voluntary
18 security upgrades to all 26 of them. The NIH agrees
19 with the NRC policy statement in that the extensive
20 safeguards already in place to protect cesium
21 irradiators from malevolent use combined with the
22 successful shift in researchers' security mindset
23 negates national security need to remove cesium
24 irradiators completely from their useful and necessary
25 contribution to biomedical research.

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1 FACILITATOR BAILEY: Okay. Once if we
2 can give this panel a round of applause for the
3 information.

4 (Applause.)

5 At this time, we will now begin to take
6 questions or comments pertaining to their
7 presentation.

8 DR. NELSON: Kevin Nelson, Mayo Clinic.
9 This question is directed at Ioanna and it may not be
10 a question that is listed for this particular issue.
11 But you had mentioned an assay was retrieving orphan
12 sources as part of the program. Is it just orphan
13 sources or if a licensee decided they no longer wanted
14 to use cesium chloride greater than class C type waste
15 what would be the process? Thank you.

16 MS. ILIOPULOS: Right. Orphaned and
17 disused sources, and John Zarling here is sitting in
18 the audience, we'll tell you a little bit more about
19 it. Our program is run from Washington, D.C. here at
20 Headquarters but implemented through Los Alamos
21 National Laboratories. We have a database where you
22 would have to register those materials and then we
23 rack and stack and prioritize materials. So high
24 activity materials are prioritized for more expedient
25 recoveries than smaller materials.

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1 And there are all kind of challenges
2 involved in the removal of these sources. A lot of it
3 has to do with expiring transport containers. I'm
4 looking over here at Mary and others. And disposition
5 pathways where we can take the materials for permanent
6 disposition.

7 But we do recover. We've recovered over
8 27,000 sources to date. We get 3,500 new registrants
9 every year and we have articulated through our NNSA
10 management the need to keep this program fully funded
11 and expanded to meet the needs of licensees that have
12 materials that they no longer need that they would
13 like to receive Federal Government assistance in
14 removing.

15 FACILITATOR BAILEY: Any additional
16 questions? Comments?

17 MS. SHEPHERD: On the GTRI's table topics
18 for sizes, local law enforcement are totally excited
19 about this. We've been invited to one and the
20 response have been we've had to ask for more seats at
21 the table because everybody, local San Fernando, LAPD,
22 L.A. Unified Police, local FBI wants to be involved.
23 Everybody is so excited about this and it's one of the
24 best responses that we've had. They get to do an
25 actual tabletop training rather than just saying "We

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1 need to have your kind of response here" and "This is
2 what we have." They are just thrilled to pieces.

3 I think it's an excellent program and if
4 you get the opportunity take advantage of it because I
5 think there's nothing better for local law
6 enforcement.

7 MS. ILIOPULOS: Thank you, Mary, for that
8 comment. Again, we're working in close collaboration
9 with one of our DOE's offices, the Office of
10 Counterterrorism, and the FBI who jointly pay to put
11 these exercises together because they take 60 to 90
12 days to plan the actual event because we try to
13 exercise a realistic event at that particular site
14 that we're playing the exercise. There's a lot of
15 planning involved working with a trusted agent at the
16 facility to make the scenarios realistic.

17 We've tried to increase the number that we
18 do, but we're limited in terms of how many we can do.
19 We consider it a capstone of our program if a facility
20 has volunteered for the in-device delay and the
21 voluntary security upgrades. But we've done six to
22 eight to date . I think MIT represented the 85th
23 exercise we've completed of which the last eight have
24 involved radiological sites.

25 FACILITATOR BAILEY: Any additional

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1 comments or questions from the audience?

2 (No response.)

3 Okay. Cyndi, now for your notes.

4 DR. JONES: Good opportunity for exercise.

5 This is Cyndi Jones again from the NRC.

6 If we look at the questions for a
7 participant we heard about the status of security
8 designs regarding security enhancements. And I
9 appreciate especially the manufacturers' viewpoints on
10 that.

11 I guess I'm wondering. Have you heard as
12 a manufacturer if you have any requests
13 internationally for changes in design or use of
14 alternative sources? Or are others that are outside
15 the United States using cesium and using the design
16 that you have? Thank you.

17 MR. MENNA: Blair Menna from Best
18 Theratronics.

19 The short answer is yes. Australia I know
20 is interested. Their regulator there has recently --
21 I don't want to call it increased controls, but
22 they've introduced additional security requirements
23 that are starting to force licensees to improve their
24 security. And so some licensees in Australia are
25 expressing interest in the IDD program.

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1 I'll defer to perhaps Ioanna though. Is
2 it premature to talk about some European countries?

3 MS. ILIOPULOS: Well, I think there would
4 be interest if we did more technical exchange and
5 outreach and we've only started that process recently
6 through some of our work with the World Institute of
7 Nuclear Security based in Vienna.

8 And our goal with that is to share lessons
9 learned and how the U.S. has approached security at
10 licensees in the U.S. above and beyond regulations to
11 include discussions about IDD. And what we stumbled
12 across is that a lot of these manufacturers did indeed
13 sell their devices internationally. So where those
14 governments have a lot of the same makes and models,
15 they have expressed interest in learning more about
16 what we're doing to harden them. So I would
17 anticipate more questions in the coming months.

18 MR. MENNA: I suppose I would be remiss,
19 too, if I didn't comment on Canada given that our
20 manufacturing facility is located in Canada. I guess
21 first though I need to preface it by comment on the
22 American program. Countries around the world, anybody
23 I've spoken to, for example, at the IAEA are just
24 amazed at what's happening here. It is a fabulous
25 program. And countries like Canada and Australia just

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1 sort of say, "Wow" and "Wish we could do that, too."
2 So the Americans certainly are much further ahead.

3 I know there is interest in Canada.
4 Unfortunately, there doesn't appear to be any appetite
5 from the government, none that I'm aware of. The
6 licensees are certainly interested. And that's about
7 all I can say to that. Nothing concrete has happened
8 yet.

9 I know there are many European countries
10 that are interested. Ioanna mentioned the World
11 Nuclear Security Institute?

12 MS. ILIOPULOS: World Institute of Nuclear
13 Security.

14 MR. MENNA: Nuclear Security, they held a
15 workshop in Vienna. I think it was in March. And
16 that got a lot of people very, very interested. So in
17 I think a lot of these countries it's their level of
18 awareness is coming up. It's increasing. So they're
19 slowly coming on board but like I said not nearly as
20 far along as the U.S. is.

21 MS. SHEPHERD: We've had some more
22 preliminary -- it's very preliminary -- interest from
23 a lot of the EU countries on it. But it's as they're
24 becoming more aware of it.

25 DR. JONES: If I could follow up. If you

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1 can speak to are there other manufacturers of these
2 devices elsewhere and are they interested in doing the
3 same kind of IDD work as you two are doing? If you
4 can't speak to that, that's okay. I think we're just
5 trying to get a perspective on are there other
6 countries that are involved with this or if they have
7 manufacturers are they also involved?

8 MR. MENNA: There are certainly other
9 manufacturers out there. China and India, for example,
10 come to mind. I can't comment on any activity there.

11 MS. ILIOPULOS: We've had dialogue with
12 Gamma Services in Germany. And we have meetings with
13 Elektra in Sweden who makes a lot of the gamma-cell
14 devices that are sold in U.S. markets.

15 FACILITATOR BAILEY: Any additional
16 comments from the audience?

17 (No response.)

18 Okay. Cyndi, got another note?

19 DR. JONES: No comments. I think you need
20 some more coffee or cookies.

21 DR. MAIELLO: Mark Maiello from Pfizer.
22 Just in an effort to keep the conversation going
23 perhaps, what about the American program other than
24 the manufacturers' enhancements? So intrigued are our
25 European colleagues. Is it across the board? Is the

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1 recovery, for example, of disused sources also
2 something that they aspire to?

3 MS. ILIOPULOS: I was in London with an
4 NRC colleague last week and what we heard from the
5 British regulator is they do have a program that is
6 similar to our Offsite Recovery Program. They call it
7 the Surplus Source Recovery Programme. It hasn't been
8 ongoing, but the British government did provide a
9 certain dollar amount in the federal program and told
10 licensees that if they have disused or unwanted
11 sources it's a good time now to contact them to get
12 subsidies for their permanent removal and
13 repatriation.

14 But what they did tell me I think which
15 differs from the U.S. experience is that they're
16 requiring licensees to put money aside when they
17 purchase or procure new sources so they can deal with
18 end-of-life-cycle issues. So they would have to have
19 money set aside to show that when that source reached
20 the end of its life they could afford to pay for
21 either its recycling and I believe the U.K. sends a
22 lot of its disused sources to Germany for recycling if
23 not for disposition.

24 DR. MAIELLO: Thank you. Just to clarify
25 a very minor point. You mentioned 27,000 sources I

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1 think you covered. Is that worldwide or just
2 domestic?

3 MS. ILIOPULOS: That's been in the U.S.,
4 but we have recovered some international sources as
5 part of that calculation. But it's a smaller subset.
6 Thank you.

7 MR. MENNA: And the IAEA also does do
8 recoveries globally.

9 DR. JONES: And just for clarification,
10 Ioanna, the 27,000 sources are of varying size.

11 MS. ILIOPULOS: Yes.

12 DR. JONES: They're not all Category 1 and
13 2 sources, right?

14 MS. ILIOPULOS: They're not all Category 1
15 and 2 sources.

16 DR. JONES: Okay. Thanks. Any other
17 questions?

18 (No response.)

19 I think this afternoon provided us an
20 excellent opportunity to hear what has been done
21 regarding the status of the current cesium chloride
22 designs, regarding the security enhancements that we
23 have ongoing in the U.S. and what's been done.

24 Probably just one last question for the
25 manufacturers, certainly there is some cost associated

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1 with the IDD's and for your designs that you'll sell in
2 years to come. Will those types of irradiators have
3 those designs in them and then will that cost be
4 included in the price of the new design source?

5 MR. MENNA: Are you asking me if the
6 customer is going to pay for the cost to put it
7 bluntly?

8 (Laughter.)

9 DR. JONES: Yes.

10 MR. MENNA: Yes, they will.

11 DR. JONES: Yes.

12 MR. MENNA: But it's great value.

13 DR. JONES: But it's much less expensive
14 to do a factory hardening than to do an onsite with
15 all the problems that there are onsite. So the actual
16 cost to the customer is greatly reduced than an actual
17 field.

18 MS. SHEPHERD: Okay. So retrofit for
19 clarification. A customer couldn't come to you and
20 say, "I want the old 2001 version instead of the 2010
21 version." You're only going to have the newer version
22 that has the enhancements.

23 MR. MENNA: That is correct. Yes.

24 MS. SHEPHERD: Correct.

25 MR. MENNA: And if you look at it from a

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1 licensee's point of view, there are a lot of different
2 ways you can incorporate delay. We're talking about
3 in-device delay. You could put a cage around it. We
4 heard talk of that earlier.

5 I think that as Mary pointed out doing
6 this enhancement at the factory is a very cost
7 effective way of implementing the delay. So I think
8 it's very good value for your security dollar.

9 DR. JONES: Thank you.

10 DR. NELSON: Kevin Nelson from Mayo
11 Clinic.

12 As a follow-up to that and this is more of
13 an NRC question, have you considered requiring target
14 hardening for all new wet bank irradiators or
15 irradiators period after such and such a date? I know
16 I saw some timelines up there regarding J.L. Shepherd
17 and Best. Are you considering that and are you
18 looking at doing similar things for irradiators that
19 might be manufactured overseas coming over here?

20 DR. JONES: I could speak to the NRC
21 perspective a bit. I think as you heard this morning
22 from Todd Masse and you'll hear again tomorrow from
23 our FBI person that's coming, Mr. Bernie Bogden, there
24 continues to remain to be no specific credible threat
25 toward these devices or sources.

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1 However, just as we did after 9/11, the
2 NRC along with the other intelligence agencies looked
3 to see if there was any change in the threat in the
4 United States that would warrant additional security
5 for these sources or for other sources for that
6 matter. And Todd alluded to that earlier in his
7 presentation about if there is a specific credible
8 threat against a type of source or a type of facility
9 that we have information on we get that information
10 out very quickly.

11 But as of this time there is not a move at
12 the NRC to require these. As Ioanna said, these are
13 complimentary and supplementary enhancements that NNSA
14 has provided. They have a vast experience of
15 knowledge overseas with countries doing these types of
16 in-device delays and additional enhanced security in
17 many cases because those regulatory programs either
18 they do not exist or they don't exist to the level
19 that they do in this country for security of
20 radioactive sources.

21 We looked across the world to see what
22 types of countries have inspection and enforcement and
23 licensing of these sources for security. And we are
24 one of the very few countries that does all three, if
25 not the only one at this point.

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1 Our partners in many other countries, I'll
2 mention ARPANSA and Canada since you've mentioned
3 those. ARPANSA is the Australian regulator, also have
4 good practices for security of sources. Good
5 practices sometimes could mean requirements. However,
6 sometimes they also mean just good practice. They'd
7 like you to do but they can't force you to do it.

8 And I think that regulators across the
9 world are looking at that. They look to us for
10 bilateral assistance as to the Department of Energy
11 Global Threat Reduction Initiative Program on how that
12 can be done.

13 But at this time, back to the original
14 question, we're not looking to provide requirements or
15 require those types of in-device delays at the time.
16 And John can speak a little bit more because in his
17 group he does the sealed source and device registry
18 sheets which Blair mentioned and I think Mary
19 mentioned. When they make a change to the devices
20 they have to be sent in to NRC for approval of those
21 changes.

22 DR. JANKOVICH: I'd like to supplement
23 Cyndi's comment here to answer your question
24 specifically. The question is what will NRC require.
25 NRC has performance based security requirements. And

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1 those requirements don't specify that they're ready --
2 need to be modified. The overall situation for
3 security must be maintained.

4 However, the draft policy statement has
5 one of those proclamations about design changes. And
6 the NRC encourages it. So far what the draft policy
7 statement says is that we encourage it. We don't
8 require it. That's how we see it at the present time.

9 FACILITATOR BAILEY: Additional questions
10 or comments?

11 MS. HAWKINS: I'm Sarenee Hawkins from the
12 NRC. And I actually have a question for the
13 manufacturers since we have you both sitting here.
14 Have either of you encountered instances where the
15 hardened irradiators have -- I guess when you need to
16 repair have you encountered instances where an
17 irradiator has been deemed irreparable or something
18 because it's been hardened. Does the hardening
19 interfere with I guess being able to repair machines?
20 Have they ever needed to be replaced rather than
21 repaired because of the hardening kit?

22 MS. SHEPHERD: We have a false alarm once,
23 but it was not due to the IDD kit. It was part of the
24 other operating systems. The IDDs are really designed
25 not to interfere with the actual operations. So it is

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1 transparent. So we did have one false alarm in that.
2 That was it.

3 MR. MENNA: From our point of view --
4 Well, from all the manufacturers' points of view, the
5 IDD kits were designed so that they would not
6 interfere with the operation of the machine or they
7 would interfere as little as possible. Obviously,
8 when we're talking about retrofits, once the job is
9 done, the machine has to run again. And so the
10 design, working with the folks at Sandia, they were
11 very, very conscious of this.

12 To answer your question, no. We have
13 never encountered a problem and I actually can't
14 foresee how you could have a failure that wouldn't
15 allow for repair.

16 However, there is one thing that's
17 probably important that maybe nobody else other than
18 the manufacturers is really concerned about, you have
19 to remember these are cesium devices we're talking
20 about. And we generally do not replace the sources.
21 With a 30 year halflife the source is good for the
22 life of the machine.

23 At the end of the useful life, when the
24 device is recovered and is destined for disposal or if
25 the source is going to be reused, getting that source

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1 out is not going to be easy. That's the purpose of
2 the in-device delay. So that's a headache that we
3 will have to or whoever recovers the source and
4 whatever plans they have for it, whether it's reuse or
5 disposal, they've got a job on their hands. But that
6 doesn't concern the licensees generally.

7 DR. JONES: Any other comments or
8 questions?

9 (No response.)

10 Seeing none, I would like to give one more
11 round of applause for our participants.

12 (Applause.)

13 And I'll note that tomorrow morning you
14 will be hearing a summary from me. I will be working
15 on it tonight, on issues one, two and three which are
16 the first three issues we discussed today and some
17 general comments and conclusions that we heard from
18 both the audience members and the panel members. And
19 that session tomorrow will start at 8:30 a.m. And
20 I'll have a half hour to summarize that and take any
21 questions and comments.

22 And then at 9:00 a.m. we'll have our first
23 speaker who is Mr. Bernie Bogden from the FBI. So
24 have a good evening and we'll see you tomorrow. Thank
25 you.

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(Whereupon, at 4:15 p.m., the above-entitled matter was closed.)

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