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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

+ + + + +
TUESDAY
NOVEMBER 9, 2010

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The Public Meeting met in The Universities at
Shady Grove Conference Center Auditorium, 9630
Gudelsky Drive, Rockville, Maryland, at 8:45 a.m.,
Kenneth Bailey, Facilitator, presiding.

- PRESENT:
KENNETH BAILEY, Facilitator
BERNIE BOGDEN
JOHN SCHRADER
MARY SHEPHERD
STEPHEN V. MUSOLINO
SUSAN LEITMAN
KEVIN NELSON
MICHAEL TAYLOR
RONALDO MINNITI
BRIAN DERMOTT
ARNOLD EDELMAN

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PRESENT (CONT.)

JOHN ZARLING

ROBERT DANSEREAU

ROBERT J. LEWIS

JOHN P. JANKOVICH

CYNTHIA G. JONES

SARENEE HAWKINS

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

8:31 a.m.

FACILITATOR BAILEY: Good morning again, everyone and welcome back to Day 2 for the public meeting to discuss the draft policy statement on the protection on cesium chloride sources.

Again, my name is Kenneth Bailey and I will be the facilitator for the remainder of today.

Just a few reminding notes from yesterday, please refrain from using any discussion that leads into classified information. If, in fact, we have discussions that seem time consuming, we will put those things on the pocket, the flip chart in front of us indicating the parking lot and discuss things prior to the end of the day.

Additionally, to my left is John Jankovich, subject matter expert for this, along with Cyndi Jones and Sarenee Hawkins.

At this time we will begin with a review from yesterday from Cyndi Jones and we will continue on with the first panel discussion after Cyndi Jones.

DR. JONES: Thanks very much, Ken. Well, good morning, everyone. Can you hear me okay in the back? Very good.

My name is Cynthia Jones. I'm the Senior

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1 Technical Advisor for Nuclear Security in the Office
2 of Nuclear Security and ~~Instant~~ Incident Response at
3 NRC. And let me just first say that as the co-
4 coordinator for this workshop I'm just very pleased
5 with the level of participation and quality of the
6 presentations we've received thus far which will
7 assist us greatly in developing the cesium chloride
8 policy statement for the Commission consideration
9 early next year.

10 As of yesterday, we had about 67 attendees
11 and we're anticipating a few more today for even more
12 discussion.

13 It was exactly this type of stakeholder
14 exchange that we envisioned and that we were hoping to
15 achieve with this meeting in order to document the
16 variety of views to help inform the Commission on the
17 issues that are being presented for a draft policy
18 statement and later a final policy statement on the
19 protection of cesium chloride sources.

20 So to advance our discussions today, and
21 to provide additional input to those of you that were
22 not able to attend yesterday, let me share with you
23 some of the key points on the issues that were
24 presented at yesterday's sessions. Please note that
25 this is only a very brief overview of the many

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1 discussions that took place. A full meeting summary
2 and complete list of participants at this workshop
3 will be posted on NRC's cesium chloride website that
4 is listed in both the Federal Register notices and
5 then I've again listed on the last slide of this
6 summary.

7 NRC began the meeting by providing a brief
8 overview of cesium chloride sources. The draft policy
9 statement, as presented, would provide the
10 Commission's current policy regarding secure use of
11 these sources and expressed the Commission's potential
12 actions in the future if changes in the U.S. threat
13 environment necessitate action.

14 As an independent regulator, NRC has the
15 responsibility to license and regulate the civilian
16 use of radioactive materials for commercial,
17 industrial, academic, and medical purposes in a manner
18 that both protects public health and safety and
19 promotes common defense and security. NRC embraces
20 openness and public participation in its decision-
21 making processes including comments on its proposed
22 regulations, guidance documents, and policy statements
23 such as this one.

24 Next, we were provided with an overview of
25 the 2010 Interagency Task Force on Radiation Source

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1 Protection and Security. Since its inception with the
2 Energy Policy Act of 2005, this Task Force with NRC
3 as chair, was established to evaluate and provide
4 recommendations on the security of radioactive sources
5 in the United States for potential criminal or
6 terrorist threats or including acts of sabotage,
7 theft, or use in a radioactive dispersal device,
8 sometimes called a dirty bomb.

9 The legislation requires that the task
10 force provide its first report in 2006, and every four
11 years thereafter. The 2010 report submitted to the
12 President and Congress on August 11th this year,
13 presented the status of the recommendations and
14 actions from the 2006 report, as well as new
15 recommendations in the following four areas:
16 coordination and communication, improvement amongst
17 Government agencies and the public, advances in
18 security and controls of radioactive material, end-of-
19 life source management, and alternative technologies.

20 As we heard yesterday, a Task Force
21 subgroup also completed a study to assess the
22 feasibility of phasing out the use of cesium chloride
23 sources and concluded that immediate phase out of
24 these sources would not be feasible because the
25 sources are extensively used in a wide range of

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1 applications in medicine, industry, and research, with
2 significant health benefits to patients. However, the
3 task force also reported that a gradual step-wise
4 phaseout could be feasible as alternatives become
5 technologically and economically viable and if
6 disposal pathways are identified.

7 Next, we were presented with an overview
8 of NRC and federal agencies' cesium chloride
9 initiatives. Two years ago, I met many of you at our
10 first workshop on cesium chloride sources which
11 focused on the security and continued use of such
12 sources. In 2008, NRC was in a gathering mode of
13 information from users, licensees, and the public on
14 the uses and needs of cesium chloride as well as a
15 discussion of alternatives that could be used instead
16 of these sources.

17 The presentations yesterday provided an
18 overview of the types and numbers of use of cesium
19 chloride licensees used in the U.S.; 237 licensees for
20 blood irradiation; 265 licensee irradiators used in
21 research; and 61 licensees for use in calibration
22 purposes such as calibration of radiation survey
23 instruments or dosimetry.

24 We also received a brief history of the
25 work that NRC has performed on cesium activities since

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1 2005, which included the funding of a National Academy
2 of Sciences report entitled "Radiation Use in
3 Replacement, a National Academy's Report"; a report in
4 2008, from NRC's Advisory Committee on the Medical Use
5 of Isotopes on the use of cesium irradiators which
6 included a survey of the users' of these devices;
7 completion of the previously-mentioned Task Force
8 report in 2010, and then again in June 2010, issuance
9 of a proposed policy statement on the protection of
10 cesium-137 chloride sources and notice of this public
11 meeting.

12 The next slide presents a summary of the
13 three issues that were discussed at this public
14 meeting. For Issue 1, we heard presentations on NRC's
15 role, licensees' responsibilities, and panel
16 presentations with regard to NRC's current security
17 and control requirements. NRC management discussed
18 the safety -- excuse me, discussed that the safety and
19 security of risk-significant sources is an essential
20 part of our mission. As licensees are well aware, it
21 is their primary responsibility to securely manage and
22 protect sources in their possession for misuse, theft,
23 and radiological sabotage.

24 Three major issues were emphasized.
25 First, NRC and the Agreement States have imposed a

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1 program of enhanced security requirements for the
2 International Atomic Energy Agency, IAEA, Category 1,
3 2, and aggregated quantity Category 3 sources.
4 Second, with respect to these security requirements,
5 there is increased attention for additional security
6 for cesium chloride sources. And third, NRC currently
7 has a proposed rulemaking process underway to take the
8 Orders that were issued by NRC in the 2005 and '06
9 time frame and turn these into regulation which will
10 be incorporated into a new 10 CFR Part 37, whose
11 comment period will end on January 18, 2011.

12 Lastly, NRC discussed its new National
13 Source Tracking System called the NSTS, which provides
14 near-term tracking of Category 1 and 2 sources as they
15 have been purchased, transferred, or disposed of.

16 We also heard a regional NRC perspective
17 regarding the use and status of security inspections
18 that were designed to verify and implement the
19 security requirements for these Category 1, 2, and
20 aggregated quantities of Category 3 sources. These
21 security inspections began in 2007, after the
22 increased requirements, so-called increased controls,
23 were issued. Specifically, we heard that initially
24 licensees experienced some growing pains with regard
25 to the new security regulations as far as how best to

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1 implement the requirements, but overall, increased
2 and steady improvements by licensees in the source
3 security area has now been seen.

4 Initially, there were questions from
5 licensees when implementing the trustworthy and
6 reliability requirements, called T&R, or an
7 understanding by licensees trying to understand how to
8 work within their departments as to how best to
9 complete requirements for the increased controls.

10 We heard also that licensees are now
11 routinely contacting their local law enforcement
12 agencies to provide them with both an overview of the
13 radiation safety control program and the security
14 requirements for the radioactive sources. The North
15 Carolina representative here yesterday mentioned that
16 in one specific case a few small activity check
17 sources had inadvertently been removed from the
18 licensee's site and resulted in immediate coordination
19 between the licensee administration and local law
20 enforcement. Coordination of this event was termed
21 "fabulous" because of the prearrangements that had
22 been made and knowledge of the security programs in
23 place.

24 Operationally, we learned that cesium
25 chloride is not regulated any differently than any

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1 other isotope that requires increased security and
2 control. Regulators and inspectors stated that
3 licensees appeared to be willing and have planned to
4 accept any increased burden for security involving the
5 future Part 37. However, lack of disposal options was
6 cited as a great concern for them as there is
7 currently no disposal pathway for cesium chloride
8 sources in the U.S.

9 In summary, we heard that from a licensee
10 perspective, the increased controls have enhanced
11 security of these facilities, that there is an
12 awareness amongst their users of radioactive sources
13 for security, and that there is now a more robust
14 program enhancing the safety security interface.

15 We also heard from our partners, the
16 Agreement States, who are partners in regulation.
17 Agreement States are defined as those states that have
18 signed an agreement with NRC authorizing the State to
19 regulate certain uses of radioactive materials within
20 that State. The Agreement States regulate about 80
21 percent of the radioactive sources in the United
22 States. They continue to see a decrease of security
23 violations as the years have passed since
24 implementation of these Orders and increased control
25 indicating that a great deal of increased knowledge

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1 and the implementation of trustworthy and reliability
2 checks and required fingerprinting has been done.

3 It was noted that many of the licensees
4 that work in the petrochemical plants such as
5 radiography and well-logging already had
6 fingerprinting requirements for their staff. The
7 Agreement States also noted that the waste and
8 disposal issues for these sources is still the biggest
9 concern.

10 We heard perspectives from the Health
11 Physics Society president who represents about 5500
12 professionals in the field of radiation safety. The
13 Health Physics Society supports NRC's path forward on
14 a proposed policy statement, but believed that the
15 statement should be expanded in ~~into~~ two areas.
16 First, consideration of certain IAEA Category 3
17 sources and second, possible integration of
18 alternative technologies in the licensing process.
19 The Health Physics Society agrees also it is not
20 within NRC's mission to perform research and
21 development with respect to cesium chloride sources.

22 For Issue 2, we were presented with the
23 issues concerning the U.S. regulatory requirements for
24 security. We heard about the new proposed Part 37
25 rulemaking for physical protection requirements of

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1 Category 1, 2, and aggregated quantities of Category 3
2 sources which included items such as security zones,
3 monitoring and detection, assessment and response,
4 maintenance and testing, and reporting of events.

5 In the proposed rule, licensees will still
6 be required to coordinate with local law enforcement
7 authorities and it is proposed to expand to provide
8 local law enforcement authorities notification of
9 temporary job sites as well.

10 Mobile device measures were also discussed
11 and a requirement for an annual program review would
12 be required to be conducted by licensees.

13 Discussion of the access authorization
14 program was mentioned, including a new proposed
15 requirement for the reviewing official to also go
16 through a full trustworthy and reliability review.
17 NRC staff noted that there is also a very large
18 implementation guidance document posted on the website
19 that the staff is also requesting public comments on.
20 Comments for both Part 37 and this new guidance
21 document are due January 18, 2011.

22 Next we heard several licensees'
23 perspectives of security requirements for cesium
24 chloride sources to offer us an alternative way to
25 look at physical security. One licensee looked at the

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1 risks and needs of the use of cesium chloride and
2 viewed it from the perspective of the protection of a
3 scientific asset. Some universities put together both
4 short-term and long-term programs for security systems
5 of these sources. Faculty at several institutions
6 stated that there is a scientific necessity for cesium
7 chloride with no alternative.

8 Moving forward, these licensees stated
9 that implementing the security requirements such as
10 those proposed in Part 37 are planning by their
11 institutions to be implemented because there appears
12 to be a natural extension of the existing security
13 program that is already in place.

14 Next we heard a discussion of the needs
15 for the use of cesium chloride as it is used to
16 radiate blood. In hospitals, the need to balance
17 patient care activities with the need for security is
18 paramount. Concerns about maintaining adequate
19 throughput, estimated at one facility to be about
20 18,000 units per year is a necessity and a relatively,
21 maintenance-free device such as cesium chloride
22 irradiators are needed.

23 Several licensees noted that currently
24 concerns with x-ray machines do not meet their needs
25 for throughput. They noted that hospitals have taken

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1 additional voluntary security measures to make it even
2 more difficult to tamper with or move these licensed
3 devices. In this respect, several licensees noted the
4 assistance of the Department of Energy, National
5 Nuclear Security Administration, the Global Threat
6 Reduction Initiative, or GTRI, which have assisted in
7 enhancing cesium chloride sources' security even
8 further beyond what is required by regulatory
9 requirements.

10 Several discussions centered on the
11 licensees' ability to perform the necessary T&R
12 reviews. While credit checks are common in some
13 industries, they are not common in all and in the
14 majority of cases credit checks can only be done on
15 current, but not prospective employees. It was noted
16 that credit checks may force a value judgment about
17 who is trustworthy and who is not. Though definitely
18 may be an indicator of a perceived crime, it was
19 stated yesterday that it is not an indicator of a
20 person who is not trustworthy or reliable.

21 Some consideration of what are the
22 ramifications of denying someone access based on a
23 poor credit check is something the human resource
24 departments are having to deal with currently. In
25 addition, it was noted that the increased number of

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1 credit checks done on an individual can be
2 detrimental.

3 Next, NRC's threat assessment process from
4 the perspective of NRC's Intelligence Liaison Threat
5 Assessment Branch, or ILTAB, was discussed. This NRC
6 branch provides strategic and tactical intelligence,
7 warning and analysis of all threats to the U.S.
8 commercial nuclear sector and serves as NRC's liaison
9 and coordination staff to the U.S. intelligence and
10 law enforcement community. In the U.S., 17 federal
11 agencies represent the intelligence community. NRC's
12 threat branch coordinates with many of those agencies
13 outside the NRC, such as the Federal Bureau of
14 Investigation, the Office of Director for National
15 Intelligence, and the Department of Homeland Security,
16 as well as many other agencies and departments.

17 It was noted that while there has been
18 some attempts to develop and use an unconventional
19 weapon such as chemical or biological by terrorist
20 groups worldwide, no terrorist group has ever
21 successfully detonated a radiological dispersal device
22 or RDD. The bottom line is that while there is a
23 general credible terrorist threat to NRC licensed
24 facilities and radioactive materials, there continues
25 at this time to be no specific credible threat to

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1 radioactive material licensees or their materials.

2 The last session yesterday for Issue 3
3 asked the question: could hardware improvements be
4 made that would further mitigate or minimize the
5 radiological consequences of a potential radiological
6 dispersion device or RDD? From the manufacturers'
7 perspectives, we heard about the in-device delay or
8 IDD, retrofit programs that adds passive hardware
9 features to the cesium chloride device that makes it
10 inherently more secure.

11 One of the challenges of the IDD retrofit
12 process is that these enhancements are performed at
13 the licensee facility which requires early
14 coordination and planning for installation. Usually
15 the process takes one to two days and it involves
16 grinding, drilling, and painting the irradiator once
17 completed. And once the process is done, a full test
18 is completed on the device.

19 Factory IDD upgrades are also being
20 designed in coordination with Sandia National
21 Laboratory. And since the first unit has already been
22 completed, the sealed source and device evaluation for
23 this device has been submitted to the NRC for
24 evaluation and eventual approval. About 214 of these
25 upgrades have been performed thus far in the United

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1 States and about 622 installations remain to be
2 completed over the next few years.

3 Next, we received an overview of the
4 Global Threat Reduction Initiative program at DOE.
5 GTRI works with the NRC, the Agreement States and
6 licensees to provide additional security enhancements
7 at their facility after they have completed and
8 implemented the increased security control
9 requirements from NRC or the Agreement State that
10 they're in. It was emphasized by GTRI that these
11 enhancements are complementary to, and do not replace,
12 NRC or state security control requirements.

13 GTRI stated that they also provide
14 training to law enforcement. This program is deemed
15 by NNSA as an example of a good federal/state licensee
16 process to enhance overall security enhancements at
17 facilities. Some of these enhancements include tamper
18 seals, remote monitoring systems, installation of
19 irradiation detector in the room, and passive infrared
20 motion detectors.

21 NSAA also provides both classroom and
22 table top training at a new facility they built in Oak
23 Ridge, Tennessee to facilitate training for both
24 industrial users and in a new hospital setting that
25 they have designed and built.

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1 Next, we heard from America's Blood Center
2 which is North America's largest network, 76 of
3 community-based not for profit blood programs serving
4 nearly 180 million people in 45 U.S. states and
5 Quebec. In 2010, America's Blood Center conducted a
6 member survey which indicated that with a total of 84
7 irradiators owned and used, 58 of them irradiate more
8 than 552,000 components of blood annually for 1464
9 facilities. It was noted that only one of these 84
10 irradiators had converted from cesium use to x-ray.
11 Several reasons were provided including greatly
12 reduced operating costs for cesium chloride
13 irradiators, greater stability, longer irradiated life
14 and lack of perception of risk.

15 America's Blood Center also provided their
16 experiences with the increased control and stated that
17 since they are a not-for-profit organization, there is
18 a real concern about the inability to reduce their
19 costs, especially when these costs cannot be passed
20 along to hospitals or anywhere else and thus the
21 impact of increased security for them is very real.

22 America's Blood Center stated that they do
23 concur with the intent and language of the draft
24 policy statement to (1) continue to have access to
25 cesium chloride irradiators, to provide an important

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1 public health benefit; (2) to improve designs to
2 enhance safety and security; (3) to find alternative
3 forms of cesium chloride to reduce the risk; and (4)
4 to develop pathways to safely dispose of cesium
5 chloride.

6 Lastly, we heard from the National
7 Institutes of Health who stated that NIH is the
8 Federal Government's biomedical research agency
9 employing more than 6,000 staff. NIH has 26
10 irradiators most of which are cesium chloride, used by
11 about 500 researchers. Applications vary, but are
12 categorized by four groups. First, studying the
13 immune response of cell types, via proliferation
14 assays, including stem cell and cancer cell protocol;
15 second, the ability of cells to measure DNA repair;
16 third, the ability to use animals that are irradiated
17 to study transplant rejection and the study of genetic
18 basis of diseases; and the fourth, the use of
19 radiation for cesium chloride irradiators to induce
20 DNA damage in animals for relevance in cancer research
21 and development of vaccines. Research for
22 refining and developing malaria vaccines was given as
23 an example of on-going irradiator research.

24 Of the 26 irradiators, 15 have had GTRI
25 enhancements. NIH noted that the increased security

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1 controls have resulted in lots of additional training
2 since 2005, between radiation and security staff. And
3 several licensees stated yesterday, "NIH also noted a
4 noticeable change amongst researchers in the use of
5 security with radiation sources."

6 Of the nearly 700 users that underwent a
7 T&R review, about 40 opted out and decided not to be
8 approved for use of sources involving increased
9 control. NIH noted that the cesium chloride draft
10 policy statement gives credit to these researchers and
11 the types of work that they do. However, NIH
12 recommended that more needs to be added to the policy
13 statement on researchers' activities and use of cesium
14 chloride.

15 In particular, NIH stated that an expanded
16 discussion be included in the policy statement to
17 express why researchers need and use cesium chloride
18 irradiators. For these researchers, 40 years worth of
19 research that use the cesium chloride technology and
20 their results would need to be repeated in order to
21 verify application of an alternative new technology.
22 NIH stated that the cesium chloride irradiators are
23 long -lived scientific instruments and few require
24 maintenance.

25 For the researchers that use both x-ray

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1 and cesium irradiators, they have found that with the
2 x-ray units, replacement of the x-ray tube is
3 necessary every six months, not annually or later as
4 we've heard before.

5 NIH stated that you can also irradiate
6 multiple targets in one cycle with cesium chloride,
7 but not so with x-ray units. It was noted that the
8 cesium chloride irradiators have a much smaller
9 footprint than x-ray machines with no infrastructure
10 support that is needed. Alternatively, you would need
11 to find a physically different location to house an
12 x-ray unit in the space that would be provided.

13 Lastly, in view of the types of research
14 conducted currently at their bio-medical facilities,
15 NIH stated that neither cobalt-60 nor x-rays would be
16 sufficient for the majority of their research.

17 So that was a whirlwind tour of yesterday.
18 Please keep in mind that this was only a very short
19 summary of the discussions that we heard. The full
20 transcript of this meeting, as well as the meeting
21 summary, will be posted on the cesium chloride website
22 in about seven to ten days.

23 As was mentioned yesterday, the comments
24 and issues presented from the stakeholder meeting will
25 serve to provide a range of recommendations to the

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1 Commission for consideration of a path forward with
2 regard to the proposed policy statement for cesium
3 chloride sources. And remember, written comments on
4 the draft policy statement after this public meeting
5 are also accepted and should be submitted to the NRC
6 docket by December 17th this year. Please include the
7 words Docket ID NRC-2010-0209 in the subject line of
8 your comments.

9 I fully enjoyed the presentations and
10 discussions yesterday and I look forward to another
11 day of excellent interactions. Thank you.

12 (Applause.)

13 DR. JONES: I see we're still on time. As
14 I mentioned yesterday and a few times the words FBI
15 came up. We are very proud and very pleased to have a
16 representative of the Federal Bureau of Investigation
17 here, Mr. Bernie Bogden, who will be presenting the
18 issues that are outlined on your handout for the
19 agenda today.

20 Mr. Bernie Bogden is currently assigned to
21 the FBI WMD Directorate as the Nuclear Radiological
22 Program Manager. Mr. Bogden has been with the FBI
23 since 1983, and has served in a number of capacities
24 in the National Security Division, Technical Services
25 Division, Criminal Justice and Service Division, and

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1 Counter-Terrorism Division. He has specifically been
2 assigned to work on nuclear radiological matters since
3 1995, and it's been a pleasure to work with him for
4 many years at the NRC.

5 Mr. Bogden.

6 MR. BOGDEN: Thank you, Dr. Jones. I
7 appreciate the introduction and I welcome the
8 opportunity to provide a little bit of perspective on
9 the FBI involvement in this very, very important
10 issue. I also appreciate your flexibility in being
11 able to accommodate me today. I regret not being able
12 to be here yesterday for the discussions, but due to a
13 scheduling conflict I'm not able to do so, but I'm
14 glad to be here today.

15 I really want to just let you know how
16 much I appreciate the efforts of NRC and our other
17 partners and the states as well, the licensees, of
18 course, to protect these materials. And to be honest
19 with you, that's the reason I'm here today because of
20 the role that we play in not only general terrorism
21 response, protecting America from terrorist
22 activities, reacting to incidents, we're also a very
23 proactive agency in hopefully preventing terrorist
24 attacks before they do occur. We have been
25 doing for some time, of course.

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1 I wanted to first lead off by giving you a
2 little perspective on where I sit at the WMD
3 Directorate. Many of you have probably never heard of
4 the WMD Directorate. In a nutshell, it's basically
5 placing all the capabilities, assets, and key elements
6 of the FBI that work WMD all in one specific body,
7 carving them out of their other divisions where they
8 used to reside, specifically the Counter-Terrorism
9 Division, and basically putting them all in one place.
10 It's been in existence since July of 2006. We've
11 worked these issues before, as I said in other
12 entities, but we basically have become sort of a one-
13 stop shopping in tying all that together to provide a
14 perspective or a liaison coordination on coordinating
15 these efforts to protect America from utilization of
16 WMD.

17 Our role is primarily to tie things
18 together. We reach out to other divisions as well,
19 the Counter-Terrorism Division, the Laboratory
20 Division, our Critical Incident Response Group,
21 whoever else we need to tie in from the Bureau
22 perspective to respond to these type of incidents or
23 prevent them from happening. We also have extensive
24 inter-agency liaison, of course, with NRC, DOE, the
25 intelligence community, and other entities as well, as

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1 I'm sure many of you are well aware.

2 We have a very, very robust field office
3 presence out there. We have 56 field offices and
4 about 400 or so what we call resident agencies, small
5 satellite offices that provide us even more robust
6 coverage. They are basically our boots on the ground,
7 so to speak. Those are the folks that would be
8 liaisoning with the licensees, with the local offices,
9 things like that, with resident sites, whether they be
10 commercial power plants, licensees, or whatever. So
11 we really do provide a lot of coordination for us. We
12 test them quite heavily as I'll describe, but once
13 again, they are our boots on the ground. And they
14 actually live in those communities and they're the
15 ones that we would expect to have a very robust
16 liaison out there with the licensees and other folks,
17 the other law enforcement as well.

18 FBI's role is basically to obviously
19 provide the law enforcement response to these
20 utilization of these type of materials for terrorist
21 use, unauthorized possession, threats to use
22 materials, actual utilization of these materials. So
23 we basically have that jurisdiction. And in concert
24 with the other folks, state and local responders as
25 well, we kind of tie everything together from the law

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1 enforcement perspective.

2 Department of Homeland Security plays a
3 large role as well. They've stood up since 2002.
4 What I always like to tell people is that since DHS
5 stood up, that did not change our role at all. They
6 still have the overall coordination of response, but
7 we basically still have the law enforcement
8 investigative aspect in responding to terrorist
9 utilization of WMD including nuc/rad materials, of
10 course.

11 My perspective is nuc/rad, of course, but
12 we also have similar outreach programs with other WMD
13 materials as well, whether it be biological, chemical,
14 or other even conventional explosives as well. So my
15 remarks today will be unique to nuc/rad, but we also
16 have extensive outreach in these other areas as well.

17 What I'd like to do now is basically talk
18 about our WMD Coordinator. The WMD Coordinator is a
19 Special Agent assigned to one of our 56 field offices.
20 There is at least one WMD Coordinator in each of the
21 FBI's 56 offices. The larger offices, of course, have
22 quite a robust WMD presence, lots of alternates, so to
23 speak, assistants. The New York Office probably has a
24 whole squad that handles these type of matters, just
25 because of the amount of work and territory that New

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1 York has. But there is at least one in every office
2 and they're our one-stop shopping. They are the
3 person that does the local liaison outreach to
4 licensees, commercial power plants, and other folks as
5 well.

6 Unfortunately, we don't have the luxury of
7 having nuc/rad specialists out there, so they have to
8 handle pretty much the WMD spectrum across the board:
9 nuc/rad, chem/bio and other infrastructure issues as
10 well. But we task them very heavily. They're our
11 one-stop shopping. Hopefully, some of you may have
12 come in contact with them. I'm not sure is here
13 today, but hopefully they have reached out to some
14 folks here potentially. That's part of their role.

15 What I'd like to briefly go into now is
16 what we call our Nuclear Site Security Program. It's
17 not rocket science. Basically, our Field Office has
18 an area of responsibility, so to speak. And we want
19 them to know what is out there in their territory,
20 what critical facilities, WMD facilities. Obviously,
21 on the nuc/rad side, commercial nuclear power plants.
22 Like I said, we don't expect them to have immediate
23 recall of every single licensee that's in their
24 territory. However, we like for them to have a
25 general understanding of the higher level sources or

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1 sites such as research and test reactors, and like I
2 said, like high-level irradiators, things like that,
3 cesium chloride sources, and those type of higher-
4 level radiological sources. So that's a primary
5 mission for them to do that outreach. And I'll
6 discuss that briefly in a few minutes.

7 What we task our Field Offices in having
8 is basically a nuclear site security plan, how to
9 respond to these facilities, and of course, the
10 primary emphasis for these is basically the commercial
11 nuclear power plants, the 60 or so some odd sites that
12 are out there: Each Field Office should have a
13 specific plan for that, have established liaison
14 contacts, be able to know who to call if there's an
15 incident and things like that. So those should
16 already be well in place, exercised jointly with not
17 only the site, the facility, but also local responders
18 as well that will be responsible for responding. So
19 that requirement has been out there for many years.

20 Part of our job at headquarters is to
21 assess those plans, see that they're updated,
22 monitoring the Field Office progress to make sure
23 they're up to date and they're compatible. They're
24 very useful.

25 On the other side, basically, we also

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1 require them to like I said update those as possible.
2 Folks change. It's much like the military, our
3 Special Agents out in the field rotate around. We
4 have the luxury of having a few embedded WMD
5 Coordinators that have been there for some time. They
6 have those liaison contacts. But a lot of these
7 response plans, they basically provide a ready, quick
8 access document for the new guy coming in, the new
9 person coming in, so that they have a quick-stop
10 shopping to basically hit the ground running, so to
11 speak.

12 In the last couple of years what we've
13 tried to do is, like I said, we've had this well-
14 established program with the commercial nuclear power
15 reactors, but what we've decided to do is to go beyond
16 that. I mean we intend to be very proactive so we
17 decided to conduct even more outreach in the last
18 couple of years or so and trying to focus on high-
19 level radiological sources which is the source of
20 literally -- no pun intended -- the meeting today.
21 These high-level irradiator type facilities with
22 cesium chloride sources. It's not specifically
23 limited to those sources, but obviously they're a
24 major, major focus because of the inherent nature of
25 the material, high levels of radioactivity and

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1 potential for utilization and radiological dispersal
2 devices. So, of course, there are concerns.

3 We've worked in the last number of years
4 in trying to improve the security and making our Field
5 Offices aware of these sites, where they are, and
6 establishing points of contact.

7 In, I believe it was April of 2009, we
8 actually sent out a tasking to our Field Offices to
9 conduct outreach sites, specifically tasking them.
10 They've always been responsible for knowing where
11 these things were, but at headquarters we try to be a
12 little bit more proactive, actually provide them a
13 listing of these sites and working with NRC as well to
14 try to give our Field Offices a hand, so to speak, in
15 establishing these contacts.

16 I want to make it very clear, these are
17 not security inspections in any way on our part. They
18 are conducted as an independent program of the FBI,
19 basically just to provide situational awareness on the
20 part of our FBI offices with these sites. If not
21 already established, who are the security points of
22 contact, the local law enforcement. They should
23 already know the FBI very well, of course, that they
24 have these relationships established and that the FBI
25 gains an understanding of the security controls in

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1 place there, not to assess them, not to inspect them
2 at all, but just gain an understanding of how they
3 work, notifications, making sure that the FBI is
4 notified as quickly as possible in coordination with
5 local law enforcement, so we can respond to an
6 incident as it's occurring, and hopefully prevent that
7 incident, prevent the material from being lost,
8 stolen, so to speak.

9 That's the basic focus of these exercises,
10 establishing lines of communication. If the licensee
11 believes something is wrong, they should know who to
12 call immediately. The FBI is responsible for these
13 investigations, violations of the Atomic Energy Act,
14 misuse of radiological materials, as I said. So it's
15 as simple as that, opening up lines of communication
16 and gaining that awareness.

17 I can't say that the offices have been to
18 every single site. Like I said, it's just an honest
19 effort. Once again, it's a heavy tasking from us.
20 They're not just responsible for the nuc/rad sites.
21 They're responsible for all the sites as well, but
22 it's an important initiative. We've coordinated with
23 NRC.

24 There was a letter sent out from NRC to
25 the Agreement and Non-Agreement States, I think in

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1 July of 2009, trying to explain the FBI initiative,
2 not to be concerned. The FBI is knocking on your
3 door. I mean we don't look at that as an oh, my gosh,
4 what's the FBI here for? It's a good thing. It's
5 nothing to be intimidated about. They're there to try
6 to find out, establish lines of communication, like I
7 said, and to put a face to a name and vice versa so we
8 know each other. And please call us if you have any
9 suspicious activity going on or even the potential for
10 suspicious activity so to speak. So that's what we
11 want to see.

12 So it's a fairly recent initiative, but I
13 believe it's working well. We've tried to help out at
14 headquarters as much as we can. I know the Field
15 probably doesn't believe so, but we really try to help
16 them out and provide them some more guidance.

17 Even in my own daily work, I've tried to
18 hook them up through the conference of Radiation
19 Control Program Directors, tried to provide certain
20 Field Offices with their points of contact in the
21 field, in the states, who are the Agreement States,
22 bodies, and things like that to help them out with
23 their liaison, so we've tried to do the best we can to
24 improve this process, but I think it's working well.

25 Dr. Jones alluded to the DOE, NNSA Global

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1 Threat Reduction Initiative Program, the voluntary
2 security enhancements. I know DOE and NNSA was here
3 yesterday to explain that process. We've latched on
4 to that basically to help improve the nuc/rad
5 security. At the end of these security enhancements,
6 it selects sites. We do a table top exercise. It's
7 been a very good program. What it is is basically a
8 piggy backing on a legacy program we've had with DOE
9 since 1999, I believe, kind of a spin off, so to
10 speak, to deal with irradiators and research and test
11 reactors where we have the FBI office there, of
12 course, the NRC is there. And we have some folks from
13 the National Capital Area, from DHS as well. They're,
14 of course, involved and play an important role to in
15 the coordination.

16 So it's kind of a three-prong federal
17 agency process where we get the locals there together
18 to work out the notification, the response and
19 hopefully the prevention of an incident before it
20 happens, so they've been going on for quite a while
21 and unfortunately, I can't quote the numbers. It's
22 probably 10 or 12 we've done so far since we've ramped
23 this up. I think this program started in 2008, in its
24 initial stages, but it's going fast and furious and we
25 appreciate the help of the local folks as well.

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1 What we've also tried to do is provide our
2 FBI Field Offices training at the Oak Ridge facility
3 with the state and local responders. DOE has got the
4 training, as Dr. Jones said. The facility at Oak
5 Ridge, Tennessee, has had local responders come in to
6 respond and get the layout of basically a generic pipe
7 type facility to practice their incident response. We
8 try to hook up the local FBI office with those
9 responders as with those responders who would be
10 responding with them from whatever specific area
11 they're from. So we think it's been a very good
12 program and we appreciate the DOE and NNSA
13 coordination of that as well.

14 That's really it, a basic snapshot of what
15 we've been trying to do. I really appreciate the work
16 of the folks out there, all your work in trying to
17 protect these nuc/rad sources that they don't get into
18 the wrong hands and are used against us. It's
19 important work. We don't want to disrupt the useful
20 utilization of these materials and many, many very
21 useful processes. We don't want to impede that at
22 all. And like I said, it's a lot of work to do to try
23 to protect these sources. I really appreciate your
24 efforts and thank you for the opportunity to provide a
25 little bit of background on some of our nuc/rad

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1 outreach. Thank you.

2 (Applause.)

3 DR. JONES: If there's any questions for
4 Mr. Bogden, I think we probably should entertain them
5 now. He has another commitment and will need to be
6 leaving probably within the next half hour or so, so
7 if there's any questions from the audience members for
8 the FBI, please.

9 DR. NELSON: Hello, Mr. Bogden, I really
10 appreciated your presentation. My name is Kevin
11 Nelson and I'm the Radiation Safety Officer at Mayo
12 Clinic in Jacksonville, Florida, and once the new
13 Orders went into place and we submitted fingerprints
14 to the FBI, the FBI identified an individual of
15 interest and your local office met with our
16 trustworthiness and reliability official and that went
17 very well.

18 I guess I have a point of information and
19 a question. When an individual of interest is
20 identified by the FBI, how do you interface with the
21 local law enforcement agency? Because in our
22 particular case about six months later, the local law
23 enforcement agency had no clue that this individual
24 had been identified in a casual conversation I was
25 having with that official.

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1 And then secondly, I've learned more than
2 I thought I would ever know about background checks.

3 (Laughter.)

4 And there are holes in the system in at
5 least the system we use for criminal background
6 checks. Is this something that the FBI could take on
7 for these particular sources for initial and follow up
8 on criminal checks?

9 MR. BOGDEN: Thank you, sir. With regard
10 to the coordination and information sharing, I mean
11 the primary conduit for the coordination of local FBI
12 offices and their local law enforcement is the Joint
13 Terrorism Task Force where you actually have someone
14 -- I'm sorry, you're from what area?

15 DR. NELSON: Jacksonville, Florida.

16 MR. BOGDEN: Jacksonville, Florida area.
17 Well, Jacksonville, I can't quote off the top of my
18 head, but there's a Joint Terrorism Task Force in that
19 area and it would be Jacksonville Field Office with
20 those state and local agencies working together. I
21 can't say everyone knows everything else that's going
22 on, but that is the primary conduit where actually
23 state and local law enforcement and other local
24 agencies as well working together sitting side by side
25 dealing with whatever issues need to be handled

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1 including, perhaps, something that you made reference
2 to. I can't say that everything will be discovered by
3 everyone, but that's one of the primary conduits for
4 information sharing.

5 And I think your other question was in
6 relation to?

7 DR. NELSON: Are criminal background
8 checks for individuals that are having access to these
9 Category 1 and 2 devices? Is this something that you
10 think the FBI could take on?

11 MR. BOGDEN: Right now I believe the
12 process is for the fingerprinting requirement. It's
13 basically just the FBI providing the criminal history
14 record back from the fingerprints and I believe it's
15 up to the licensee or I'm not sure what the exact
16 process to make a determination whether suitability
17 based on the results of that check. I really can't
18 comment on that it's something we would take on.
19 Obviously, if there's something of interest, we would
20 help to coordinate that, but I don't have any
21 specifics on whether it's something we would be able
22 to take on or not.

23 DR. JONES: Bernie, one question that
24 comes to mind is in the case that Dr. Nelson just
25 mentioned in Jacksonville, when there is a person

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1 identified as a person of interest, after these checks
2 are done, is that the responsibility of the licensee
3 or of the local law enforcement to get back to each
4 other. If, for example, he didn't hear back from FBI
5 in six months or so, should he make the contact with
6 the individual officer with the local law enforcement
7 to see how this can be closed? I think there's some
8 sense from licensees we heard yesterday that there may
9 be some open ended issues and they're not sure how to
10 go about or if they have a need to go about closing
11 that somehow with local law enforcement.

12 MR. BOGDEN: I would prefer always, if
13 there's some question, ask, ask the question. Please
14 bring it back up again in case -- if you haven't heard
15 anything, please contact again for more follow up if
16 you don't hear anything back. That's not a big deal.

17 FACILITATOR BAILEY: Any other questions?

18 DR. JONES: Thank you.

19 (Applause.)

20 FACILITATOR BAILEY: If we could have the
21 next group of panelists take the stage, please? And
22 while we wait on that, just for your information, the
23 Task Force report that Charles Miller mentioned
24 yesterday, there has been copies made and they're out
25 front on the desk, so please help yourself to a copy

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1 during break or during the lunch time, 90 copies.

2 The next panelists will begin based on the
3 issue for discussion, Number 4, the development and
4 the use of the alternate forms of cesium-137 while not
5 required for adequate protection, it's prudent and the
6 NRC intends to monitor these developments closely.

7 Again, I'll allow them to introduce
8 themselves starting from my left, your right.

9 DR. MUSOLINO: I'm Steve Musolino from
10 Brookhaven National Laboratory.

11 MS. SHEPHERD: Mary Shepherd from J.L.
12 Shepherd & Associates.

13 MR. SCHRADER: John Schrader, REVISS
14 Services.

15 FACILITATOR BAILEY: And we will begin the
16 presentation with John Schrader, feasible alternatives
17 from manufacturers' and users' perspectives.

18 MR. SCHRADER: Good morning. I'm John
19 Schrader, Radiation Safety Officer and Vice President
20 of North American Operations for REVISS Services.
21 It's a pleasure to be able to speak to you this
22 morning to provide an update on the work our staff has
23 been doing to identify possible replacements for
24 cesium chloride in our high activity cesium sources.

25 I'll start with just a little background

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1 of us. REVISS Services has been making sources for a
2 considerable length of time. We started in 1940, as
3 The Radiochemical Center in Amersham, England. In
4 1982, we were privatized by the British Government
5 into a company by the name of Amersham International.
6 In the early 1990s, Amersham management established a
7 trading company to work with the Russians to supply
8 radioactive isotopes into the manufacturing
9 operations. The Joint Venture, or REVISS, included
10 the Russian companies of P.A. Mayak and
11 Techsnabexport.

12 Today, REVISS is no longer affiliated with
13 Amersham and Amersham is also now part of General
14 Electric. We are still connected with P.A. Mayak and
15 Techsnabexport. Our primary operating company is
16 located in Chesham, England. We have a wholly-owned
17 subsidiary, REVISS Services, Incorporated which is
18 located just north of Chicago.

19 And some of you may be familiar with our
20 branded name, PURIDEC Technologies. This is primarily
21 our cobalt business of cobalt irradiators.

22 In our Joint Venture, REVISS provides the
23 design, development, quality and regulatory systems,
24 logistics, sales, finance and administration for the
25 operation of our business. Mayak is the primary

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1 contractor for our sources, including cesium chloride
2 and cobalt sources. And Tenex provides us with other
3 radioisotopes for our creative products.

4 Now what's happening with the replacement.
5 Over the course of the last two years since our
6 previous meeting in September of 2008, my colleagues
7 at Mayak have continued to investigate optional
8 materials to mix with cesium and will provide a source
9 with improved performance characteristics to address
10 the concerns raised by the National Academy versus the
11 current cesium salts used in the high activity sources
12 today.

13 As a result of Mayak's work so far, we
14 still believe there's suitable technology that's at
15 least 80 percent likely to be achieved. We are
16 narrowing the field of candidates to three or four
17 possible alternatives that show a high degree of
18 promise.

19 At this point we have identified as lead
20 products a ceramic and a glass material. Both provide
21 reasonable performance characteristics. The cesium
22 contents of these matrices range from about 50 to 70
23 percent. That compares with cesium chloride which is
24 a little greater than 75 percent.

25 Mayak has been working on several options

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1 in parallel with the glass and ceramic looking at the
2 most viable options to demonstrate that these products
3 will deliver improved performance. The development
4 work includes the maximization of cesium content, the
5 dose output without the need for radically designed
6 equipment in which cesium chloride is currently used.

7 Typical air kerma comparisons between the
8 cesium chloride and our new product is approximately
9 60 to 80 percent. We recognize the efficiency
10 throughputs may be reduced a little as the percentage
11 of cesium first source is slightly reduced when mixed
12 with the glass and ceramic materials, but trust that
13 the user community will find this acceptable.

14 We have been in contact with some of the
15 major users of the source to discuss the potential
16 implications for output and performance criteria as
17 well as a source design.

18 Mayak had been working toward several
19 targets today in their development of these new
20 sources. We have established targets to improve the
21 three major parameters so that we achieve greater than
22 95 percent improvement over our current cesium
23 chloride sources with respect to solubility,
24 leachability, and dispersibility.

25 We are measuring these results by testing

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1 based on, where available, ISO standards, primarily
2 ISO-9978 and ISO-2919. And we have developed testing
3 protocols that are as close as possible to other
4 recognized standards.

5 We are also conducting age-related
6 degradation testing to verify these options will hold
7 up over time so that the sources can achieve an
8 acceptable service lifetime. This testing will
9 continue on into the future.

10 The research is progressing carefully at
11 the present time to ensure potential products will fit
12 the ultimate intended purpose that being a marked
13 improvement in stability over cesium chloride. It
14 has also been slow due to the considerable number of
15 other priorities Mayak have on their plate as well.

16 To give you an update of our primary --
17 our preliminary results, we have been able to show a
18 reduction in dispersibility of materials to
19 essentially 100 percent for cesium chloride to
20 approximately 5 percent for both glass and ceramic.
21 For solubility, we've also achieved results of
22 approximately five percent for both the glass and
23 ceramic versus the cesium chloride 100 percent.

24 For leachability, using the test
25 methodology and the ISO standards, we have achieved

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1 less than 1 percent, however, when accumulated over a
2 30-day period, we're seeing approximately a 3 percent
3 leachability for the ceramic materials and a 5 to 7
4 percent leachability for the glass material.

5 The selected candidates for undergoing
6 preliminary manufacturing trials, where several
7 sources of different geometries are used using these
8 candidates alongside using cesium chloride and the
9 same geometries are being produced, the output
10 activity comparisons can be made between the various
11 materials in the cesium chloride. This trial is being
12 funded by REVISS and Mayak at the present time.

13 From this testing, we will be able to
14 select the most optimal choice and will be ready to
15 develop the product in the commercially viable
16 manufacturing process. This process, we anticipate,
17 will take two to three years to develop to a point
18 where we will be able to supply the new sources to
19 industry. The big pieces of this stage will be the
20 cost and to develop the process whether it can be done
21 cost effectively. And at that point, financial
22 assistance, if available, would be appreciated.

23 As part of this on-going process, we are
24 also investigating the potential for returning and
25 recycling cesium chloride as part of this program. In

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1 order to be able to offer a cradle to grave service
2 for the replacement of cesium chloride, or the new
3 form of cesium source in the future, but, after
4 listening to Blair and Mary yesterday on the hardening
5 of things, I'm not sure that's going to be a real
6 viable alternative.

7 There are many regulatory constraints for
8 doing this return, but it is technically possible,
9 although potentially expensive. We would like
10 feedback as to whether this is of interest to the user
11 community.

12 In conclusion, our partners and Mayak are
13 making progress of producing alternatives to cesium
14 chloride. The issues they run into is the technology
15 is quite novel to the large sources. We've been using
16 the technologies considerably for the very small
17 sources. And the processes are subject to several
18 confidentiality issues. We would also like help with
19 feedback on the acceptability of standards expected
20 for solubility, leachability and dispersibility.
21 That's been one of our issues is we're not sure what
22 the target is going to be for the industry, so we
23 would have that kind of defined. That would make it a
24 bit easier to go after.

25 That's all I have to say. Thank you very

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1 much for allowing me an opportunity to speak this
2 morning.

3 (Applause.)

4 MS. SHEPHERD: Mary Shepherd, Vice
5 President of J.L. Shepherd and Associates. As John
6 says, there's some confidentiality issues, so we're
7 not fully aware of what the new sources are going to
8 be like. So this a supposition based on past
9 experience. Years ago, Oak Ridge was
10 looking at other forms of sources. J.L., when he was
11 at U.S. Nuclear which was back in early '60s which was
12 the predecessor of ICN, also looked at the possibility
13 of other forms of chloride not as expensively as Oak
14 Ridge did. So we have a little bit of experience and
15 this is what the presentation is about.

16 If you have prospective alternate forms
17 like pollucite, glass, ceramic, it may result in a
18 larger replacement capsule depending on the specific
19 activity. It is not something Mayak and REVISS have
20 been able to share with us yet.

21 If this surmise is correct, then the
22 direct source capsule exchange into existing
23 irradiators may not be possible. There's one reason
24 for that. The old Oak Ridge sources that we used to
25 use are a completely different size than what's

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1 commercially available from REVISS now, so there's no
2 direct source replacement from an Oak Ridge source to
3 a current REVISS source if somebody wants to upgrade.
4 You have to buy a new irradiator body.

5 If a current irradiator user could not
6 accept a smaller source with less curies and less
7 output, if the new sources become available, a new
8 body would have to be manufactured for an irradiator
9 and those costs go \$252,000 to \$325,000, today's
10 costs, plus the cost of the source. We have no idea
11 what that's going to be.

12 Additional cost for replacing sources is a
13 freight company that's complying with the RAMQC
14 security requirements. It gets quite expensive in
15 today's costs depending on where you are from
16 California runs -- and that would be a round trip
17 replacement and that's not counting end-of-life cycle.
18 That's bringing the sources back to our plant because
19 we have no idea where they'd be done: \$12,000 plus
20 \$50,000 for transportation. It all depends on the
21 logistics and where you are.

22 And if you go the highway route control
23 quantity which cesium doesn't do, the costs go higher
24 than that.

25 Additional costs. If you're going to do a

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1 source removal and installation, you'll need a new IDD
2 kit installed. And you need rigging. Most of these
3 cannot be done in the room they're situated in, so
4 you've got to find a location where you can do a lot
5 of heavy, move a lot of heavy equipment and that's not
6 easy sometimes too. Rigging can be an interesting
7 challenge. Elevators that are underweight always pose
8 a very interesting rigging logistical problem and some
9 of those, just the crane and non-elevator use can run
10 over \$30,000, \$40,000 just for that little section of
11 the rigging part of the source exchange.

12 Now that also depends on the location and
13 the rigging requirements that are involved. And
14 irradiators are not light. They're not something you
15 just pick up and move easily. Likewise, who's going
16 to pay for this if REVISS develops a new source
17 capsule and it's mandated that all cesium chloride
18 sources are replaced, who is footing the bill? Is it
19 the manufacturers? Is it the client? Is it going to
20 be some sort of regulatory GTRI support with this
21 project? These are all questions and although we're
22 doing the new irradiators with the IDD kits, again,
23 would NNSA pay for a new IDD kit when the source needs
24 to be reloaded. That's possible. The current REVISS
25 sources could be reloadable. Who is going to pay for

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1 the new IDD kit or is that going to be just put into
2 the cost to the consumer?

3 And on alternate forms of technology, I
4 can't say very much because I've signed
5 confidentiality agreements. We have a promising
6 alternate technology. It's in its very infancy, but
7 if anybody knows J.L., we've looked at it pretty good
8 and it does look like it has some promise.

9 This is through the Sandia Small Business
10 Initiative Program where they fund people to look for
11 alternate technologies. So the progress on that is
12 slow, as funding comes around and there are some very
13 interesting technical issues involved. And I think
14 it's probably -- I think it's going to be about five
15 years before we see if it's going to be a real go or
16 not because of some of the issues involved. That's
17 it. Thank you.

18 (Applause.)

19 DR. MUSOLINO: So I'm going to discuss
20 some issues with respect to the dispersibility issue,
21 but in my mind the real question is dispersibility for
22 security.

23 The last two speakers have covered most of
24 this, and also earlier speakers, but cesium chloride
25 is important to medicine and medical research. And

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1 currently there is no alternative. Accelerators and
2 x-ray machines are expensive. They're much less
3 reliable and more costly to maintain. Many operators
4 are not looking forward to a switchover to something
5 like this. Machines also take up a lot more space for
6 things like chillers and associated equipment and
7 space is a premium in hospitals. So many of the
8 hospitals are finding this technology undesirable from
9 a space aspect alone. There will be a financial
10 impact on the medical community no matter what
11 alternative is chosen, and if one is chosen to replace
12 cesium chloride, if it were to be replaced.

13 I want to remind everyone there's been
14 really over 25 years -- I should have updated this
15 slide. This goes back a while -- by Dr. Fred Harper
16 at the Sandia National Laboratory who has been testing
17 how many -- all the materials you can imagine that
18 could be used in an RDD would turn into aerosol if a
19 terrorist used it for that purpose. So we have a
20 scientific answer to how the various physical and
21 chemical forms would behave in the event that
22 terrorists were to use it in a malevolent fashion. So
23 we know that answer.

24 Just to show you this, Fred Harper
25 himself, this is the facility he's been using for many

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1 years at the Sandia National Laboratory. I would
2 bring your attention to the aerosolization chamber in
3 the upper portion of the slide where Fred can use up
4 to a half a pound of explosive material. So what he
5 can do is he can essentially stress whatever material
6 he has under test in the actual conditions in terms of
7 how the shock wave would interact with the material in
8 real life. So we have a very good scientific answer.

9 So if radiological terrorism did happen,
10 eventually the dispersal functions will be a function
11 of the device design, the quantity and physical form
12 of the material, whether it's a powder, ceramic,
13 metal, or whatever, and then whatever the resulting
14 aerosol fraction and particle size distribution is.
15 Now this statement is true for the cesium chloride and
16 it's true for all other radioactive material as well.

17 I personally think we have a very strong
18 focus on cesium, but there's a whole universe of bad
19 things that terrorists can do, cesium just being one
20 of them. And this is what we're concerned about,
21 whether the device is going to be small particles or
22 it's going to make large particles. If it makes small
23 particles, then we're going to have the big cleanup
24 problem that we're all concerned about. But some
25 devices may not make small particles. They may make

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1 large particles that have more of a local problem.

2 So not only is there an issue of
3 dispersibility and solubility for cesium, there really
4 is an issue of device design in something that has
5 never happened and they've never seen one yet. So
6 what if the powder form is changed to a soluble, from
7 soluble to insoluble -- we just heard some information
8 from the past two speakers. It will be costly. There
9 will be a cost to make this -- to do the research to
10 make this changeover. There could be a large and
11 unknown cost to implement it.

12 And as I said, a less dispersible form
13 does not negate the risk of a potentially large clean
14 up and economic cost. It all depends on if a
15 terrorist event happens. It depends on the device
16 design as well. And radioactive materials other than
17 cesium chloride can cause large scale environmental
18 impacts under the right conditions.

19 So I think our main focus should be
20 security because the increased controls have vastly
21 reduced the risk of a terrorist incident of
22 radioactive materials and we can take credit for that.
23 Before the increased controls the risk was enormous,
24 but now that the licensees around the country have
25 addressed this problem, we've made a huge risk

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1 reduction in this area.

2 So my question is does the residual risk
3 still justify eliminating cesium chloride and I think
4 this is a valid question that should be addressed.
5 And are there cost effective ways to further improve
6 the security of licensed materials, if your answer to
7 that question is no, and thus reduce the risk to
8 residual risk of something that is acceptable.

9 So let me tell you about the experience
10 that I personally have had in the New York City area
11 with respect to the security of radioactive materials.
12 We've conducted 94 security reviews within a 60-mile
13 radius of New York City and this is the only place in
14 the country where there's been a systematic review of
15 radiological source security. Fourteen of those
16 licensees were outside New York City and this was a
17 project funded by the Department of Homeland Security
18 under the Securing the Cities Initiative.

19 And New York City came to Brookhaven Lab
20 directly. If you're not aware, New York City is the
21 only city in the country that licenses radioactive
22 material. They're an Agreement City. After the
23 Republican National Convention where there were a
24 number of security reviews done prior to that event,
25 the city realized that it was worthwhile to go review

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1 the security for all their licensees, not all their
2 licensees, but some of their licensees for them to get
3 an idea of the status of security.

4 Now our objective in both of these sets of
5 reviews was to share best practices and provide
6 opportunities for improvement. We were there to
7 complement, but not conflict with regulatory
8 requirements. We were not there to critique the
9 implementation of the increased controls to measure
10 whether they were or not. These were from a
11 compliance facility's perspective. And were just
12 there to give them advice and possibly give them some
13 advice that the regulatory process, by its nature
14 doesn't normally provide. So we made recommendations
15 to mitigate risk. We made in many cases
16 recommendations to enhance the physical security
17 hardware.

18 One of the things we found was with the
19 increased controls, there's many different solutions
20 to this problem. One licensee may have solved it one
21 way and another licensee may have solved it another
22 way and we could give them advice on you did it this
23 way, if you tweak it just a little bit, and you make a
24 little bit of change, you can improve your security
25 further.

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1 We also gave them advice on administrative
2 policy and procedures. You know, we would see how
3 people would handle things procedurally. And in
4 addition, we also looked at Category 3 sources as
5 well. We looked at the whole range of radioactive
6 material use to look at these licensees' facilities in
7 a more holistic fashion. Changes to policy and
8 procedures don't cost any money and we're able to
9 offer improvements there as well.

10 New York City also asked us to write a
11 best practices document for security and in that
12 document we give the licensees some consistent advice
13 on how to design physical security hardware.

14 Our recommendations demonstrated how to
15 make meaningful improvements and invariably at little
16 cost to the licensee. As I said, we took a holistic
17 approach. We looked at the security throughout the
18 hospital, not just the one room with the regulated
19 source.

20 To conclude, changing the physical form of
21 cesium does not eliminate the potential impact from a
22 dispersal. Re-engineering the physical form will be
23 costly. Significant economic impacts and effects to
24 the medical industry will result to replace cesium
25 with any alternative such as an accelerator x-ray

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1 technology. The residual risk of cesium chloride
2 following the implementation of the ICs is at least in
3 my personal line acceptable or close to it. And
4 opportunities exist for cost effective improvements to
5 security.

6 (Applause.)

7 FACILITATOR BAILEY: Thank you all.
8 Again, at this time we will begin taking clarifying
9 questions pertaining to the presentation or your
10 comments.

11 MS. FAIROBENT: Yes, Lynn Fairobent with
12 AAPM.

13 I'd like to take issue with your statement
14 that changing procedures doesn't cost anything. In
15 our experience, at least for some of our members, to
16 change procedures for development cost is anywhere
17 between \$100 to \$200 an hour, plus then the cost of
18 training on it. So there is cost incurred with
19 procedures that have changed.

20 FACILITATOR BAILEY: Thank you. Any other
21 comments?

22 DR. MAIELLO: Mark Maiello, Pfizer, in New
23 York.

24 John, far be it for me to put you on the
25 spot. You may not be able to answer this question.

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1 It may go to security business decisions. But Fred
2 Harper's work does carry a lot of improvements as far
3 as I can tell for the health physics community and
4 scientific community in general.

5 Do you think it's feasible or worth it to
6 submit the final form for testing despite your
7 willingness and the obvious attempt to do it by ISO
8 standards?

9 MR. SCHRADER: I really can't address
10 that. Mayak is working on this. They have been
11 working with the folks at the Cooperative Institute
12 over there. So whether it would be useful to have him
13 take a look at it, it's worth probably a discussion.

14 DR. MUSOLINO: I guess I would add to that
15 that I mean general categories of physical form are
16 predictable at this point. Ceramic versus glass
17 versus powder, cesium chloride form as we know. So we
18 do have an answer for that in a general sense.

19 MR. LEW: Regarding the policy and
20 procedures of best practice recommendations by BNL to
21 New York City, perhaps the specifics are need to know.
22 Some facilities may benefit from your tweaking of
23 procedures used by New York City facilities. If
24 there's something you can say today, maybe one or two
25 things and perhaps we can get back with you and

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1 provide the need to know justification we can benefit
2 from your experience. Thank you.

3 FACILITATOR BAILEY: If you can give your
4 name and organization before he answers?

5 MR. LEW: Bill Lew, University of
6 California, San Francisco, RSO.

7 FACILITATOR BAILEY: Thank you.

8 DR. MUSOLINO: I agree with you and I'd
9 have to say our recommendations to change procedures
10 were made when it was clearly a valuable increase in
11 security. And I would say that -- well actually that
12 occurred with the Category 3 sources, not the ICs.
13 The ICs were in place. We never came across a
14 situation where we needed to question them. So I
15 would suggest that you contact the New York City
16 Department of Health and Mental Hygiene, obtain their
17 authorization. I'd be glad to participate in
18 conjunction with the regulatory authority. I think as
19 a licensee there's some information there that you
20 would benefit from.

21 The good practice document for security
22 hardware design is a public document. That's a BNL
23 report that I can share with you.

24 MR. PURDY: Gary Purdy, NRC. Just to
25 follow up on that last statement, for our guidance for

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1 Part 37, some of the more generic physical upgrades
2 are included.

3 DR. MUSOLINO: Yes, and I should add it's
4 in the BNL report, has been used by NNSA without the
5 formality because the security specialist that helped
6 do the reviews has done security reviews for NMSA in
7 their program all over the world and he's been to many
8 other domestic sites with the NNSA team, so in that
9 sense there wasn't anything really unique. We were
10 certainly well coordinated with the work NNSA has been
11 doing for many years, both domestically and overseas
12 which is coordinated with NRC.

13 MR. LEWIS: Rob Lewis from the NRC staff.
14 Very interesting presentations by all of you. Thank
15 you very much. And I think that the policy statement,
16 the draft policy statement makes it pretty clear that
17 the NRC's view is that alternative forms are
18 desirable. It's like the third or fourth bullet. And
19 the source producers seem to think that alternative
20 forms are desirable. And the devise manufacturers
21 seem to think, and users, seem to think that.
22 Although there's costs in all those.

23 What's absent is a driver. An incentive.
24 That goes to the cost issue, but also what's absent is
25 a kind of an integrated path forward. And what I'm

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1 worried about despite what the policy statement says,
2 we could reconvene in ten years and have this same
3 discussion which if you looked ten years ago, even
4 before security was an issue, people were looking for
5 alternatives for cesium chloride. How can we go
6 forward?

7 MR. SCHRADER: I'm thinking if we can
8 develop a good alternative to the cesium chloride in
9 either a glass, ceramic, pollucite type suspension it
10 would probably be a smart idea to go that direction
11 with going forward and then maintain the current
12 cesium sources that we have, cesium chlorides and
13 establish security on the systems. And then as they
14 approach the end of their life and they're removed,
15 they'll be replaced with new machines that have this
16 new type material in them. That would also give us
17 the benefit of being able to maybe redesign the device
18 to hold a larger source so that we could have the same
19 characteristics.

20 They say that we're at 50 to 70 percent of
21 the cesium volume in any particular source so that the
22 source would have to be 10 to 30 percent larger to be
23 able to get the same characteristics. That would give
24 us the opportunity to design the devices to be able to
25 withhold these new sources to get the same

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1 characteristics that we're getting out of cesium
2 chloride today, but implement those over time.

3 MS. SHEPHERD: I think that using an
4 integrated approach if the new technology becomes
5 available, the manufacturers phase it in to the new
6 devices is probably the most logical and cost
7 effective way to go because of all the security that
8 people have invested in their chloride irradiators.
9 And I think that is better for the users also.

10 Say you've got somebody that's bought a
11 low-end source, a 1,000-curies source that's reaching
12 the end of their life, a 1,000-curies source with the
13 reduced output may be about equivalent to what their
14 old source that they're getting rid of. It all
15 depends on what the person has bought and what their
16 applications are, the client. It's hard to put costs
17 on things. It's very, very hard to put costs on
18 things. But I think we don't need to reach a point if
19 there's less dispersibility and for the Brookhaven, it
20 depends on what the approach is even if we go to the
21 expense, there will be still the dispersibility if
22 it's in an RDD. We need to take a sane approach to
23 doing this and not just jump on it, we have a hardened
24 cesium, let's replace all of it within the next ten-
25 year approach. I don't think that would be beneficial

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1 for anybody.

2 FACILITATOR BAILEY: Next question,
3 comment.

4 MS. GOLDBERG: I'm Margaret Goldberg from
5 Argonne National Lab. I just wanted to add a comment
6 regarding the chemical form of the cesium. The
7 dispersibility is certainly one issue regarding cesium
8 chloride, but one other concern that we consider is
9 the solubility. So when you go to a different form of
10 cesium and it decreases solubility that is important.
11 Cesium chloride is obviously very soluble. It's also
12 very deliquescent. So even if it doesn't rain after
13 an NRDB, it was just in a humid environment, we would
14 have mobility of cesium as a chloride whereas you
15 wouldn't get in some of the other forms.

16 I just wanted to add I think it is
17 important to still consider the chemical form.

18 FACILITATOR BAILEY: Thank you.

19 DR. MUSOLINO: I agree with that, but the
20 issue that remains in my mind is that cesium chloride
21 right now is a very hard target and while there's a
22 long-term desire to replace the form which certainly I
23 would not disagree with either, we still have to keep
24 in mind it's sitting in a hard target now and the NRC
25 has achieved their objectives of security with the

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1 cesium. Even if you find that cesium may be extremely
2 expensive to replace ten years down the line, I still
3 think there's a viability to it with proper security.

4 FACILITATOR BAILEY: Any other questions
5 or comments at this time?

6 (No response.)

7 Any additional notes? Okay, at this time
8 we'll take a break. Come back at 10:30. I would ask
9 that the panel members come back to the stage so that
10 we can start on time. Thank you.

11 ISSUE NO. 5: FIELDS OF USE FOR CS-137 SOURCES:

12 BLOOD IRRADIATION, BIOMEDICAL RESEARCH, CALIBRATION

13 FACILITATOR BAILEY: We will pick up
14 beginning with issue 5 for discussion, cesium chloride
15 enables three specific classes of applications that
16 benefit society, blood irradiation, biomedical and
17 industrial research, and calibration of instruments
18 and dosimetry.

19 As before, I will again allow the panel to
20 introduce themselves, from my left to right.

21 MR. DERMOTT: Brian Dermott, Precision
22 X-Ray.

23 MR. TAYLOR: Mike Taylor representing
24 American Association of Physicists in Medicine.

25 DR. LEITMAN: Susan Leitman from the

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1 Transfusion Medicine Department at the National
2 Institutes of Health.

3 DR. NELSON: Kevin Nelson from Mayo
4 Clinic, Jacksonville.

5 DR. MINNITI: Ronaldo Minniti from
6 National Institute of Standards and Technology.

7 FACILITATOR BAILEY: I would like to thank
8 you all for speaking very clearly into the mike for
9 the purpose of the transcriber. Thank you.

10 We will begin the presentations with Susan
11 Leitman, role of cesium irradiators in transfusion
12 medicine.

13 DR. LEITMAN: Thank you. And let's begin.

14 PANEL PRESENTATIONS:

15 ROLE OF CESIUM IRRADIATORS IN TRANSFUSION

16 DR. LEITMAN: Blood components are
17 irradiated for one reason: to prevent
18 transfusion-associated graft versus host disease.
19 TAGvHD is a rare but devastating complication of
20 transfusion. It is mediated by immunocompetent
21 transfused T lymphocytes, which can engraft,
22 proliferate, and mount a severe immune reaction
23 targeted against the HLA or human lymphocyte antigen
24 of the host. The host can be severely
25 immunocompromised and, thus, not reject the transfused

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1 passenger lymphocytes or, by very unfortunate chance,
2 the transfusion recipient may share an HLA haplotype
3 with an HLA homozygous donor and not be able to
4 recognize the donor lymphocytes as foreign, even
5 though the recipient is not immunosuppressed.

6 Patients at risk of transfusion-associated
7 TAGvHD, starting from youngest to oldest, include
8 recipients of intrauterine transfusions -- the immune
9 mechanisms of the fetus are not fully developed --
10 recipients of postnatal exchange transfusions; fetus
11 receiving exchange transfusion for hemolytic disease
12 of the newborn, infants, and children with several
13 congenital immunodeficiency states; allogeneic and
14 autologous hematopoietic transplant recipients, who
15 can get chemotherapy and radiation conditioning, some
16 combination of the two, to allow grafts to take hold;
17 patients with hematologic malignancies, Hodgkin's
18 disease, non-Hodgkin's lymphoma, and acute leukemia;
19 and patients with unusual solid tumors, not the more
20 common kinds but neuroblastoma, glioblastoma,
21 rhabdomyosarcoma -- these are reports of patients who
22 have developed this process -- and patients receiving
23 the newer highly immunosuppressive period analogues,
24 fludarabine, cladribine, pentostatin. That is
25 important because they are given for non-malignant

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1 indications, such as lupus and severe autoimmune
2 disease, indications for which physicians don't
3 recognize the patient might be at risk of TAGvHD.
4 And, lastly and perhaps most frighteningly,
5 non-immunocompromised recipients of HLA homozygous
6 haploidentical blood products, either because they're
7 derived from a related donor or an HLA match donor or
8 by unfortunate accident from an unrelated or random
9 donor.

10 So how often does that happen? This is
11 the frequency of an HLA homozygous donor transfusion
12 to recipient heterozygous. The homozygous haplotypes
13 are not recognized in diaspora by the recipient, but
14 the donor recognizes the other haplotype in the
15 recipient diaspora and that is an immune response.

16 Japanese HLA haplotypes are less highly
17 conserved. And so what you can see if I can get the
18 pointer is that the risk of a parent-to-child
19 transfusion causing a lethal TAGvHD is 1 in 100 in
20 Japan. And that risk compared to the risk from an
21 unrelated donor goes down, but it is still
22 appreciable, 1 in 900 chance of this situation
23 occurring when you look in U.S. Caucasians, the
24 parent-child risk is about 1 in 500, sibling 1 in 900.
25 And in the unrelated setting, it is a 1 in 7,000

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1 chance that a recipient will get an HLA homozygous
2 product with a shared haplotype.

3 Since there are 14 million red cell
4 transfusions in the United States per year, that 1 in
5 7,000 translates to a large number of transfusion
6 recipients potentially at risk for this lethal
7 reaction, but we don't see this reaction that often.

8 So there are other mitigating factors, but
9 this number here is one of the reasons that many
10 editorials have been written about the advantages of
11 universal blood irradiation.

12 What are the blood components that can
13 cause TAGvHD? Any component that contains viable T
14 lymphocytes, red cells, platelets, granulocytes,
15 plasma. The clinical manifestations are very severe,
16 making TAGvHD hard to miss. The onset is 3 to 30 days
17 following transfusion, with symptoms of fever, rash,
18 liver function abnormalities, diarrhea, and severe
19 pancytopenia. In case that is not enough, the
20 diagnosis can be confirmed by skin biopsy and by HLA
21 typing where extra circulating haplotypes are seen in
22 the blood.

23 The outcome, unfortunately, the reason why
24 we are here is that it is universally fatal, nearly
25 the numbers are fatal. By the time the reaction is

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1 recognized, it is grade 4, and it's untreatable. And
2 the death is usually infectious due to severe
3 neutropenia.

4 So since we can't treat, the way
5 transfusion medicine specialists handle this is to
6 prevent TAGvHD. And the goal is elimination of all
7 viable lymphocytes and blood components.

8 There are physical methods available for
9 decreasing the number of lymphocytes and blood
10 components, including washing, freezing and thawing,
11 and filtration, but all of these steps have been
12 associated with the development of TAGvHD. They're
13 not enough. And so we have irradiation.

14 Prophylactic irradiation of blood products
15 prior to transfusion is currently the most efficient
16 way to eliminate the mitotic potential of passenger
17 lymphocytes and blood components and prevent TAGvHD.

18 The dose is simple. There is general
19 agreement that a minimum dose should be 2,500
20 centigray (cGy) targeted to the midplane of the
21 canister holding the blood product. Circulating
22 lymphocytes are, as this audience knows, among the
23 most sensitive of mammalian cells to radiation. And a
24 dose of 1 or 2 hundred cGy is enough to eliminate
25 mitotic potential. But in bulky, irregularly shaped

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1 blood components, there is a level of safety added
2 and, thus, the dose of 3,500 cGy.

3 As red cells are stored in the irradiated
4 state, they gradually lose viability with increasing
5 storage time, probably due to damage to other cells,
6 like granulocytes, which release molecules which
7 damage red cells. But because of this, transfusion
8 medicine services attempt to irradiate immediately
9 prior to the release of the issue and as close to
10 release as possible and not store red cells in the
11 irradiated state. Thus, irradiation is generally
12 performed in hospital blood banks, not at blood
13 centers. And so there is a need for hundreds of
14 irradiators or mechanisms for irradiation to be
15 situated in hospital blood banks.

16 How widely is blood irradiation practiced?
17 And is there a role for universal irradiation?
18 According to data I just got a couple of weeks ago
19 from the 2009 National Blood Collection Utilization
20 Survey, approximately 10 to 15 percent of red cell
21 units are currently irradiated in the U.S. irradiation
22 increases the average cost per unit by 65 to 70
23 dollars. And about 20 to 25 hospitals in the U.S.
24 practice a universal blood component to irradiation.
25 These tend to be comprehensive cancer centers and

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1 pediatric cancer centers.

2 Techniques of blood irradiation. You have
3 been hearing that for one and a half days so far. One
4 can use ionizing radiation, employing free-standing
5 blood irradiators, two types, one that uses gamma rays
6 with either cesium-137 chloride or cobalt-60 as the
7 source and one that uses X-rays, or one can use
8 radiation therapy devices located in the hospital.
9 These are mainly linear accelerators, irradiated using
10 X-rays, or one can use ultraviolet irradiation.

11 There are three main manufacturers of
12 freestanding cesium chloride irradiators in the U.S.
13 available to or currently used in the U.S. The CIS,
14 the first company listed there, no longer makes
15 irradiators, blood irradiators. That is a French
16 company. However, their device, an excellent device,
17 is the one that is probably present in highest
18 frequency in United States blood banks. That is the
19 IBL-437C.

20 Ninety percent of blood irradiated in the
21 U.S. in transfusion medicine services currently uses
22 cesium chloride techniques. And there are about 100
23 to more than 150 irradiators on sites in the U.S.

24 There is Best Theratronics that makes
25 Gammacell models. And there is the Shepherd Company,

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1 JL Shepherd and Associates, which makes numerous
2 different kinds of irradiators. And I can't list them
3 all here.

4 Again, the source is cesium-137 except for
5 a couple of types of devices made by Shepherd, which
6 use cobalt-60. The central strength of the source
7 determines the central dose rate and the amount of
8 time the blood has to be exposed to the radiation
9 source.

10 And one can load an irradiator with the
11 maximum capacity; for example, the CIS device provides
12 the cesium chloride as 3 1,700 pencil-shaped sources.
13 Fully loaded, 3 times 1,700 is 5,100, which gives one
14 a central dose rate of 1,200 cGy per minute for a
15 large chamber size of 3.4 liters.

16 And, similarly, with the other devices,
17 the Gammacells load with multiples of 600 curies. So
18 fully loaded, the central dose rate is between 900 and
19 1,800 for a fully loaded 2,500 curie source and
20 chamber size of from one to two and a half liters.

21 The half-life of cesium is 30.2 years. So
22 when I am giving a talk to blood banks, I say once
23 your pocket is hurt by the initial purchase of one of
24 these devices, you don't have to worry about it for
25 the rest of your professional life in blood banking.

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1 In contrast, cobalt-60 sources have a
2 shorter half-life than the prior replacement of
3 sources, which is difficult to accomplish. Delivery
4 of about 2,500 cGy requires only 2 to 3 minutes with
5 these devices.

6 This is the device we have in our center,
7 the IBL-437C, currently a service by Pharmalucence
8 Company in Boston. It is very heavy, 4,400 pounds.
9 So that one needs floor dispersing techniques.

10 When you move it, you need floor loading
11 and engineers, come by, see the floor. The elevator,
12 as you heard earlier this morning will tolerate this
13 load. And we had to put an aluminum or steel plate,
14 which you can see, underneath this irradiator to
15 disperse the waste so it wouldn't crash through the
16 parking garage underneath our blood bank.

17 The 3.8-liter canister, which you see if I
18 can get it, right here, holds up to 6 blood
19 components. And, although it is expensive, if I take
20 the price and divide it by the weight of the machine,
21 it is less expensive than a flow cytometer or a DNA
22 sequencer.

23 (Laughter.)

24 DR. LEITMAN: That's the way I find to
25 explain the process.

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1 If one looks down from the top of the
2 device into the device, one would see a cross-section
3 that looks like this. The canister holding the blood
4 product sits on a turntable.

5 You hit "Irradiate," and the turntable
6 starts turning. The entire platform rotates to the
7 rear of the device behind the double lead shields so
8 that the component, still turning, is exposed to the 3
9 pencil sources here, 3 1,700-curie pencil sources.
10 And the absorbed dose is then dependent on the time
11 that the blood component sits in this position in that
12 turntable exposed to these sources.

13 When that time has elapsed and the
14 operator sets the time, then that whole entire
15 platform rotates the canister to the front of the
16 instrument. And irradiation is completed.

17 This gets a fairly homogeneous dose
18 distribution, 100 percent of the setos in the center
19 and from 85 to 110 at the bottom and at the sides of
20 the canister.

21 Performing dosimetry to validate that the
22 dose you want distributed is, in fact, distributed
23 throughout the canister. It is fairly easy. One can
24 use radiation-sensitive films put into water or
25 various thermoluminescent dosimeter chips or MOSFETS

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1 embedded into plastic or lucite, put them inside your
2 canister, irradiate them, and send them off to be
3 read, not complicated.

4 What are the advantages of gamma or cesium
5 chloride irradiators? The irradiation is rapid, two
6 to three minutes. They're easy to use, easy to train
7 employees to use. They're efficient. They're
8 convenient. They're situated right next to your blood
9 sign-out station. They're reliable.

10 It is extremely rare to have mechanical
11 issues. In 18 years that we have had this irradiator,
12 we have had a couple of batteries go that had to be
13 replaced and one ball bearing that wore out. That's
14 an excellent record for an 18-year-old device.

15 Very low maintenance. Preventive
16 maintenance and dosimetry only have to be performed
17 once per year. Large capacity of 3.8 liters to the
18 canister since 6 components are irradiated at a time
19 and reasonably even dose distribution.

20 So there are alternative sources of
21 radiation, free-standing irradiators. And that is the
22 X-ray irradiator that you have heard a fair amount
23 about already.

24 The one available in the U.S. is the
25 Raycell, distributed by Best Theratronics in Canada.

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1 X-ray source, of course, doesn't require an NRC
2 license. And it weighs much less than the other
3 device. Those are favorable, 5-minute irradiation
4 time to give 25 gray, a smaller canister so that only
5 2 blood bags can be placed into it at one time.

6 But when one speaks with users of these
7 X-ray irradiators, even now -- and I think there is a
8 newer model -- you don't hear favorable things still.
9 It is unreliable. There are very frequent down times.
10 The power source is erratic and fails frequently.
11 These are all direct quotes from users.

12 It is high-maintenance. There are two
13 X-ray tubes or bulbs that are used. And they wear out
14 unexpectedly. And the more you use the device, the
15 more frequently they wear out.

16 One needs a constant cooled water supply
17 running at ten liters per minute constant pressure to
18 keep the tubes cool. The irradiator is off when not
19 being used. Turn it on. It takes five minutes to
20 warm it up, get the water moving. And then when you
21 irradiate for five minutes, it's a ten-minute cycle.
22 And that is a lot of wasted tech time.

23 The PM contract I am told is very
24 expensive, nearly \$90,000 over 3 years, which covers 2
25 PM visits per year. That is preventive maintenance,

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1 two power supplies in case they go, and one tube.

2 The door used to break easily. There are
3 other mechanical problems. And it has a short device
4 life span of six to ten years in a couple of cases,
5 contrasting with cesium chloride, which really lasts
6 the length of the half-life of the -- more than the
7 half-life of the cesium source.

8 One can also use linear accelerators to
9 deliver the dose. And these schematics are taken from
10 a study we did a couple of years ago looking at
11 dose-distributed and simulated components.

12 These are blood bags which had TLD chips
13 embedded in them in a water base. And we exposed the
14 blood bags to a certain dose using Linac, the
15 IBL-437C, and the Gammacell 3000. What you can see is
16 that the dose distribution is most homogeneous using
17 linear accelerator technology.

18 So that is good, but in order to use
19 Linac, the blood units must leave the blood bank for
20 an uncertain length of time with uncertain temperature
21 control, although we put them in containers that are
22 supposed to maintain temperature, very difficult to
23 coordinate delays. And if it's a patient that needs
24 treatment, that always comes before blood bags. And
25 so this is a very cumbersome method of irradiating

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1 blood components.

2 Ultraviolet radiation looked like a great
3 idea a couple of years ago, but we are no further
4 along now than we were 20 years ago. UVB, 290 to
5 320-nanometer wavelength abolishes lymphocyte mitotic
6 activity completely. This does not require an NRC
7 license.

8 It's safe, a couple of sun lamps,
9 equivalent of a couple of sun lamps, but big problem.
10 UV light does not penetrate the blood bank plasma.
11 And, further, it doesn't penetrate anything except
12 clear plasma. So it couldn't be used for red cell
13 units. So, really, this looked like a promising
14 technology, but we have not overcome the hurdles to
15 use it.

16 There are psoralen-based pathogen
17 inactivation systems that have been developed in the
18 last decade, decade and a half. These systems were
19 designed to inactivate viruses and bacteria in blood
20 components.

21 The one that is closest to licensure is
22 that using the amotosalen hydrochloride or S-59
23 psoralen systems called Intercept, manufactured by
24 CRS. It is licensed in Europe but not in the U.S.
25 yet. And the way this works is the amotosalen targets

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1 DNA or RNA and interpolates between pyrimidine basis.

2 When one activates the psoralen by shining
3 UV -- with UVA illumination, permanent cross-links
4 across nucleic acid strands, which is a very effective
5 way to have T-cell inactivation but not available in
6 the U.S. yet.

7 There is a lot of manipulation of the
8 component transfer from the collection bag to another
9 bag, transfer back. Blood bankers do not like
10 transferring solutions in between bags because of
11 sterility concerns. And there is a certain loss of
12 the component in doing that.

13 How do we protect cesium chloride sources
14 from misuse? You have heard about
15 irradiator-hardening initiatives to minimize risk and
16 maximize security and safety of sources. Background
17 security checks you have heard about.

18 Constant surveillance by security cameras
19 to detect and respond to unauthorized access,
20 retrofitting devices with security enhancements paid
21 for by the Department of Energy at every blood bank in
22 the U.S. that has an irradiator, has been accomplished
23 in the last two years.

24 Permanent welded closure of the rear of
25 the irradiator, making access to isotopes extremely

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1 difficult, if not wildly improbable, and securing the
2 irradiator itself in a locked cage or room.

3 So this is our blood bank now, our issue
4 area. And here is our poor hapless irradiator in its
5 cage.

6 (Laughter.)

7 DR. LEITMAN: I am making this a little
8 bit like a prison cell. And if you look carefully --
9 and I don't think anybody has spotted it yet -- there
10 are not one or two or three but four security cameras.
11 One is up here for the parting and entryway. The
12 other is here. And then there are two from the
13 ceiling here. And there is a fifth one, which would
14 be right where I am standing at the other entrance to
15 this area.

16 And since I am the irradiator custodian,
17 they are monitored as soon as something goes wrong.
18 Usually it's nothing, some door, entryway to this area
19 that has been left propped open. I get a call day or
20 night. So they are monitored 100 percent of the time
21 by our security at NIH.

22 If you are located here, getting ready to
23 release a blood component, here is our platelet
24 storage, agitator. Here is our red cell storage, a
25 refrigerator. And then we irradiate, and then we

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1 release. Here is the computer, the sign-out computer.
2 So it is all very efficient.

3 You look up. And sometimes you feel like
4 you are in a casino and Big Brother is watching from
5 the ceiling. So you can see the surveillance cameras.
6 And the cage is bolted to the floor. You can see
7 those bolts.

8 So I want to end with the fact that the
9 cesium chloride irradiators remain the most reliable
10 and efficient means to accomplish blood irradiation.
11 Other options, X-ray, are improving.

12 The safety and security of cesium chloride
13 sources has been markedly strengthened in the past two
14 years through initiatives recommended and started by
15 the NRC for which we as blood bankers would like to
16 thank the NRC because we do feel much more safe, that
17 these sources are much more safe now.

18 These include the physical security
19 enhancements to all irradiators in the U.S. blood
20 banks, the enhanced environmental security, the
21 monitoring, and the locked access, and the robust
22 system for background security checks. And that's it.

23 (Applause.)

24 CONDUCT OF BIO-MEDICAL RESEARCH IN VIEW OF

25 Cs-137 IRRADIATION

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1 DR. NELSON: Hello again. My name is
2 Kevin Nelson. And if you came and were expecting me
3 to talk about the conduct of biomedical research in
4 view of the cesium-137 irradiation, I'm sorry, but I
5 am not going to be talking about that today.

6 My talk is very similar to what Dr.
7 Leitman just presented. As a matter of fact, we were
8 concerned about some redundancy. And I shared with
9 her our slides. And it was felt that maybe because of
10 this situation, because of the importance in blood
11 transfusion, that a little redundancy was perhaps
12 good.

13 Cathy Ribaldo from NIH gave an excellent
14 review I think yesterday on research use of
15 irradiators. So I apologize if you were expecting me
16 to talk about that particular topic.

17 Dr. Zubair, who is the Director of our
18 Transfusion Medicine and Stem Cell Therapy Program at
19 Mayo Clinic in Jacksonville, Florida, unfortunately,
20 was unable to attend. So I am going to do my best to
21 cover the medical aspects of this. And if you have a
22 question on the medical aspects that I can't answer,
23 I'm sure Dr. Leitman could probably answer that
24 question.

25 Again, we find use for the irradiator in a

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1 number of different situations. Dr. Leitman again has
2 covered these. This involves thousands and thousands
3 of patients annually. And certainly we care for these
4 types of patients at May Clinic and other hospitals
5 across the United States.

6 The graft versus host is the biggest
7 issue. And it's the viable lymphocytes that cause the
8 greatest amount of concern in a transfusion bag or a
9 unit of plasma. And you, in particular, have to be
10 concerned about severely immunocompromised patients.

11 In the graft versus host disease syndrome,
12 you will get fever, liver dysfunction, skin rash,
13 diarrhea, and hypoplasia. And the onset can occur
14 less than 30 days following transfusion. And, of
15 course, the bag thing, even though this is a
16 relatively rare event, is that it is fatal in 90
17 percent or more of patients that have graft versus
18 host disease.

19 The morbidity that goes with it is also
20 high. And there is no good therapy known for this
21 particular disease.

22 So how do we deal with that? Probably the
23 best way is through irradiation of blood products to
24 eradicate the lymphocytes that may be remaining.

25 And, again, as mentioned by Dr. Leitman,

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1 we want to do this as soon as we can. We want to be
2 able to give the blood to patients as soon as we can
3 after we irradiate the blood because we have noticed
4 an increase in potassium through leaky cell membranes,
5 which tend to occur after irradiation. So the sooner
6 that you can give the blood to the patients after
7 irradiation, the better.

8 Our gamma ray dose, acceptable gamma ray
9 dose, is fairly close to what Dr. Leitman had
10 mentioned, 15 to 30 gray, or 1,500 to 3,000 rads. And
11 some of the different types of sources that you could
12 use for gamma ray sources include cesium and cobalt,
13 although certainly cesium is the predominant isotope
14 of choice.

15 We irradiate our blood products to 25
16 gray, or 2,500 rads, at Mayo Clinic. Where I am doing
17 to diverge a little bit from the previous presentation
18 is a discussion of using irradiated blood products for
19 transplant patients.

20 You have seen a list of patients that need
21 irradiated blood. We would add to that list solid
22 organ transplants. This is somewhat controversial.

23 We do a large number of transplants at
24 Mayo Clinic in Florida. And there have been cases
25 that have been reported of graft versus host disease

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1 in solid organ transplants. So this started the
2 process of us looking at this more closely.

3 There are some other issues that are
4 working in favor of blood irradiation for solid organ
5 transplants. And they include, again, the use of
6 potent immunosuppressant drugs in transplant patients.
7 And also transplant patients, at least in the
8 population that we are seeing, tend to be older and,
9 therefore, tend to be more immunosuppressed.

10 We are a relatively new program as far as
11 transplant programs go. We started in 1998. And we
12 began universal irradiation of blood products in
13 January 2004. And this gives you sort of a history of
14 the number of transplants we have done and the types
15 of organs that we have conducted transplants in. We
16 are one of the larger liver transplant programs in the
17 United States. And we will talk about that in another
18 slide.

19 But this was we actually presented a paper
20 at the AABB meeting. And we found some interesting
21 results when we irradiated blood. Two of the key
22 indicators in transplant are one-year patient survival
23 and one-year graft survival as well as five-year
24 patient survival.

25 And when you look at the national average

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1 of 88.6 in one-year patient survival and compare what
2 has happened at our institution before and after
3 universal irradiation, you can see that we have
4 significantly improved our one-year survival rate and
5 are ahead of the national average.

6 And when you look at one-year graft
7 survival, you will see again a significant increase
8 after universal irradiation was implemented at our
9 facility. And, again, this puts us again above the
10 national average.

11 I mentioned that, even though we started
12 our transplant program in 1998, we have one of the
13 larger liver transplant programs in the United States.
14 And when you look at 2009 statistics, UCLA has the
15 largest program followed by Mayo Clinic in Florida and
16 then University of California at San Francisco.

17 Now, this is an important issue for us,
18 irradiate blood and do transplants. Bill Lew, who is
19 the RSO from University of California, San Francisco,
20 came out to be part of this program. We have other
21 people that are part of transplant programs that are
22 here because they are concerned about the possibility
23 of having cesium chloride being eliminated from our
24 treatment regimen.

25 And I think it is interesting that we

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1 talked about theoretical events occurring with cesium
2 chloride, even though none have occurred so far. Of
3 course, that doesn't mean that they couldn't occur in
4 the future.

5 I think all of us in the room are in favor
6 for enhanced security measures to protect these
7 devices. But eliminating cesium chloride from the
8 picture impacts patients right now. You are impacting
9 patient care right now.

10 I think one of the important messages that
11 I would want to leave for the commissioners and the
12 people that participate in the Task Force is that we
13 are all in favor for looking at alternative methods,
14 such as we heard from John in the previous session
15 about different types of cesium that might be useful.

16 But when we compare cesium with X-rays,
17 for large facilities, we see that there could be a
18 significant patient impact. And so when we are
19 discussing this, please remember that changes that you
20 might make, such as immediately removing cesium
21 chloride, will have a profound impact on patient care
22 settings. And I think that is very important to
23 remember.

24 So what are some of the issues that we
25 have with the use of X-ray irradiators? Capacity is

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1 certainly one of them. Uniform irradiation. I like
2 to do dosimetry as a health physicist. And I have yet
3 to see a good peer-reviewed prospective case study
4 comparing X-ray irradiation with gamma radiation. If
5 there is one out there, please see me after my
6 presentation. I would love to look at that and
7 maintenance costs.

8 So we look at capacity. We basically
9 irradiate all of our blood products at Mayo Clinic,
10 Florida. And so this amounts to about 18,000 units
11 per year.

12 The capacity, I know manufacturers,
13 including Best, are working at increasing the capacity
14 for the X-ray irradiators. But we would still have an
15 issue being able to irradiate that much blood in a
16 year, even if we purchase multiple X-ray irradiator
17 units.

18 Then we have the issue of uniform
19 irradiation. Cesium-137 is really nice, has one major
20 photopeak at 662 keV. X-ray spectra, however, are
21 different. There is a broad spectra. And there is
22 usually a peak somewhere in that broad spectra.

23 But depending again on the volume of the
24 bags and the number of bags in these X-ray irradiator
25 units, are you irradiating them to the point that you

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1 want them to? Are you being able to irradiate them to
2 25 gray?

3 Maintenance is a key issue. The Raycell
4 full-service contracts cost \$72,000 over 3 years.
5 And, as mentioned previously, this includes two power
6 supplies and one tube during the three-year period.

7 You have an optional PM visit per year for
8 an extra 15,000 over 3 years. And this is
9 recommended. And this is the definition used by
10 Raycell for machines, high-use machines, over 130
11 products per week.

12 This is from a form on the website called
13 Bloodbanktalk.com. I usually try not to spend a lot
14 of time looking at forms. I am busy enough without
15 having to do that. But in this particular posting,
16 there were a lot of issues.

17 Many issues identified related to the
18 maintenance. And they eventually had to scrap the
19 X-ray unit and go back to a cesium chloride
20 irradiator.

21 In preparation for this workshop, I did
22 literature research. And I did find one publication,
23 where X-ray irradiators were compared to gamma
24 radiation devices.

25 This was taken from the International

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1 Society of Blood Transfusion. And they did a quick
2 survey of a number of different countries, including
3 the United States, European countries, Far East
4 countries. And some of their conclusions were the
5 advice of the U.S. Nuclear Regulatory Commission task
6 force phase-out of cesium-137 irradiators, two years,
7 to prevent terrorists from using isotopes is at
8 present not followed in any country, although in
9 France, the national strategy agrees with this advice.
10 And, going forward, phasing out of cesium-137
11 irradiators is except in France not considered at
12 present.

13 So we are all enamored as Americans with
14 new technology. The medical arena is no different.
15 But when we look at some of these alternatives to
16 cesium chloride irradiators, have all the questions
17 been answered?

18 And I will stop my presentation again by
19 emphasizing the fact that we are talking about real
20 patients here. Removing cesium chloride irradiators
21 for blood transfusion products simply is not -- we
22 can't do that right now. And you are impacting
23 potentially. If you move forward by eliminating the
24 irradiators right now, you are impacting patient care.
25 And I think that is a very important message that

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1 large users of irradiators want to leave with this
2 workshop that has been put on.

3 Thank you.

4 (Applause.)

5 MR. TAYLOR: Hi. Michael Taylor from the
6 American Association of Physicists in Medicine.

7 I like the Pinto picture because that sort
8 of was my idea as to leading off when you purchase
9 anything. What is it you really look for when you are
10 looking for a car, a PC, or an extra radiator for your
11 apartment? You are looking for cost. You are looking
12 for reliability. And you are looking for known
13 results.

14 Right now we have that. We have a system
15 that works. It is simple. It is stupid. And it is
16 going to work for on and on with just small mechanical
17 changes.

18 Changing. Can we change? Sure. Yes, we
19 can change. But what are the costs going to be?

20 The last survey done by the AAPM as to
21 what type technologies were out there for performing
22 irradiation work, we had right at 300 responses for
23 types of irradiators. And 85 percent of them were
24 cesium, 9 percent X-ray, and 6 percent were based on
25 linear accelerators.

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1 What were the uses for the cesium iodine?
2 The society came back and said roughly 40 percent were
3 lead, 25 percent were material irradiators, and 25
4 percent were animal. And the group that I'm
5 representing is hospital and medical university. That
6 is sort of a background of population.

7 It has been stated very well by the two
8 previous presentations. And I can't improve on what
9 they have already said. You need to look at the
10 parameters by which you have to buy a piece of
11 equipment. Reliability of operation, a mechanical
12 turntable versus chilled water systems, single
13 three-phased power, known heterogeneity of an X-ray
14 beam versus a known single energy of cesium, the
15 reliability. Cesium wins on that hands down.

16 Throughput. They can make X-ray units big
17 enough. They could reach the cesium irradiators.
18 They are sort of close but not quite.

19 Simplicity of operation. It's pretty
20 simple to punch in three numbers and hit "Go." The
21 X-ray unit is going to be a little more complicated
22 but not overly.

23 Cost. We have to look at getting rid of
24 all of our equipment. And there have been several
25 talks earlier on how much, the cost of replacement

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1 units. We are looking at roughly about \$300,000 a
2 unit plus disposal costs plus installation costs.

3 Service. We have already seen this about
4 four times what the cesium device is right now. Cost
5 of operation to maintain chilled water systems isn't
6 inexpensive. That takes regular PMs plus utilities,
7 which isn't that great, but it still is a cost, plus
8 the changeout of X-ray tubes.

9 Dose mapping. I couldn't get any
10 information directly. I did look at sales brochures.
11 It appeared that it was somewhat close to what I have
12 seen from my known dose mapping from my gamma devices.
13 But, again, there is no article out there that I could
14 find either that would compare the two systems.

15 As far as calibration, there are
16 independent calibrations. So that is sort of a wash
17 as far as how you check the output of these devices.

18 The bottom line is we have something that
19 is simple, stupid. And when something is not broken,
20 why go out to fix it? Enhanced security measures that
21 have been put in place do provide I think the
22 necessary piece of mind that we all need for what
23 these devices could be used in a malicious way.

24 Thank you.

25 (Applause.)

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1 ISSUES IN CALIBRATION TECHNOLOGY IN VIEW OF
2 CS-137 SOURCES

3 DR. MINNITI: Good morning. My name is
4 Ron Minniti from NIST. NIST stands for National
5 Institute of Standards and Technology.

6 So I am in the Ionizing Radiation
7 Division. Our goal in the division is to develop
8 standards for radiation dose. We disseminate the
9 standards throughout the country.

10 The dissemination of standards is done
11 through the calibration of instruments. So in this
12 slide, it is a small sample of the types of radiation
13 instruments that exist. And in this slide, you see
14 survey meters, electronic dosimeters, PRDs -- I guess
15 I will try to use the mouse. That is a TLD. It is a
16 personal dosimeter.

17 Just to put things in perspective,
18 soldiers in the Army are all provided with these
19 dosimeters. And they amount more or less up to a
20 quarter million. And then on the right we see
21 ionization chambers. And these are one of the most
22 robust and used for standards.

23 And I guess my point here is to say that
24 we calibrate -- well, not NIST but in the U.S., we
25 calibrate more than one million radiation measurement

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1 instruments of this type. And for all of this, cesium
2 is used.

3 So who are the users of these instruments?
4 Well, there is a broad spectrum of users. That
5 includes people in the Navy, Army, Air Force,
6 emergency responders. There's a suite of homeland
7 security applications. That includes Coast Guard,
8 TSA.

9 And, just for example, on the top, on the
10 left top corner, you see an emergency responder
11 entering a zone with his radiation detector. And,
12 again, that detector through a chain of traceability
13 has been calibrated. And what that means is that that
14 person relies on that instrument and knows that it
15 measures accurately. So if he goes into a dangerous
16 zone, he knows what the radiation level is and what is
17 the value of that?

18 So, again, I want to emphasize that the
19 purpose of calibrating these type of radiation
20 instruments is to ensure accuracy of the measurements.
21 And the bottom line is to ensure the safety of the
22 users of these instruments and the public in general.

23 So here is a picture. What I want to show
24 here is that there is a large number of applications
25 and where all of these instruments are used. And it

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1 goes from low levels, from environmental levels, all
2 the way up to industrial levels.

3 I want you to keep that in mind for a
4 second. And also if you look at the horizontal axis,
5 you see that in the middle of the energy spectrum with
6 cesium. And that is what all of the calibration
7 facilities use as the reference calibration energy.

8 I think, as Dr. Jankovich said yesterday,
9 the reason why this was chosen decades ago is because
10 most of the instruments -- I'll see if I can use the
11 mouse. I can use the laser pointer. Most of the
12 instruments in the low-energy range vary in the
13 response. And you need to reach the cesium range
14 because in that range, most of all the instruments
15 have a flat response. And that is where you want to
16 calibrate an instrument.

17 So that is one of the reasons. The second
18 reason is cesium is more energetic. So you have a
19 nice narrow energy spectrum, as opposed to an X-ray
20 beam, which is a broad spectrum.

21 So, anyway, basically to meet these
22 requirements, what do we use? We use cesium
23 irradiators. And the range of activity of these
24 irradiators varies from the millicurie range, which is
25 category 3, all the way up to 1,200 curies, which is a

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1 category 2 and is a matter of this discussion.

2 And in the picture, you see a gentleman
3 setting up I guess an ion chamber in front of cesium
4 irradiator. And he's about to calibrate that.

5 So these calibrations are
6 done in terms of two physical quantities. One is
7 exposure. The unit of exposures is roentgen. And the
8 other quantity is air kerma. And the units were kerma
9 as well.

10 So at NIST, we determined from fundamental
11 principles these quantities. We disseminated these
12 quantities through calibrations. And this is a
13 picture of -- I mean to show the network of
14 calibration facilities in the U.S.

15 So this network starts at NIST. And then,
16 as you see, these standards are disseminated through
17 the red dots, which correspond to secondary
18 calibration facilities. And these later calibrate
19 instruments for the end users. So, as you see, it is
20 a complete network throughout the whole country and
21 relies on the use of cesium irradiators.

22 In addition, there are lots of national
23 and international protocols and document standards and
24 guidelines that rely on cesium. So, for example, if
25 you just get ANSI 13.11, this document standard

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1 relates to the testing of personal dosimeters. And it
2 is written in there that you have to use cesium to
3 test this, again, in the same way you have other
4 standards as well that rely on the use of cesium
5 irradiators.

6 In addition, to make sure that all the
7 secondary facilities are doing a good job and they are
8 able to transfer calibrations and do measurements
9 correctly, there is a group of accreditation programs
10 around the country. One is run by the Health Physics
11 Society; another run by DOE; and another one by NVLAP,
12 which is the National Voluntary Laboratory
13 Accreditation Program. Basically what they do is they
14 go to these facilities. And they ensure that their
15 calibration they receive from NIST is used properly
16 for them to be able to do measurements. And, in
17 addition to that, they are blind tests performed
18 between the secondary facilities and the end users.

19 So I think that's it. Thank you.

20 (Applause.)

21 STATUS OF ALTERNATIVE TECHNOLOGIES

22 MR. DERMOTT: Good morning. I'm Brian
23 Dermott. My company is Precision X-Ray. We make
24 research X-ray irradiators, not blood irradiators,
25 because I want to be separated after hearing some of

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1 the negatives about blood irradiation.

2 (Laughter.)

3 MR. DERMOTT: Basically the X-ray
4 irradiators we manufacture are all based on radiation
5 therapy X-ray machines, those used for superficial and
6 orthovoltage X-ray.

7 We have heard things about the X-ray
8 tubes. One of the beautiful things about this, they
9 are metal ceramic tubes. There are many papers
10 published about their beam homogeneity and their
11 outputs. And that can be looked up at any time.

12 They are also highly reliable. One of the
13 things you heard with blood irradiation is the
14 unreliability of the tube. The tubes we use have got
15 a life in excess of ten years. One of the reports was
16 from the NIH that said they had negative results on
17 X-ray irradiator tubes.

18 We have many units at NIH. And to this
19 day, I don't think we have ever changed a tube. So
20 those are things that we have to make sure people
21 understand. There is a difference when you are
22 talking about research irradiators.

23 Now, for anyone that hasn't seen a
24 research irradiator, these are what they look like.
25 Now, our name is X-RAD. They range from 160 or 450

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1 keV. The most popular one of them is the 320, which
2 is based on an orthovoltage system. They are
3 self-contained.

4 You don't need a license. They're
5 idiot-proof. If you do anything wrong with them, they
6 can't turn on. You can't put in wrong parameters.
7 They are an alternative for gamma for research.

8 And the most important thing is over the
9 years how many we have sold. That is the customer
10 list for research irradiators in this country and
11 abroad. And, thanks to what is happening here, we are
12 actually selling more irradiators than ever now. And
13 it doesn't look as if it is going to slow down any
14 time soon.

15 So that is my presentation.

16 (Laughter.)

17 FACILITATOR BAILEY: Thank you.

18 (Applause.)

19 FACILITATOR BAILEY: At this time the
20 panel will entertain any questions or comments.

21 STATEMENTS & ROUND TABLE DISCUSSION

22 MR. REIS: Hi. Terry Reis from the NRC
23 staff.

24 This is primarily for the medical
25 panelists. You were very convincing. Thank you all

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1 for the presentations. They were very convincing,
2 very convincing arguments for why you just can't go
3 with the Pinto. I think I understand that.

4 What I didn't grasp out of that is for the
5 blood applications, we didn't seem to really touch on
6 cobalt as an alternative. Can somebody address that?

7 DR. LEITMAN: So you don't blood
8 irradiation to take a large amount of time. And so as
9 the source, of course, decays, it takes longer, the
10 exposure time is longer. And since cobalt has -- what
11 did I say? -- one-half of five or six years, after
12 five years, you have half the strength left. And so
13 if you were irradiating for four minutes, you are now
14 irradiating for eight minutes. And if you are
15 practicing universal irradiation, you are going to
16 have a staff person spending their entire day
17 irradiating. So it is the residual strength of the
18 source.

19 I think that the manufacturer -- maybe
20 Mary Shepherd if she is still here could address this
21 -- has the ability to swap the source. They brought a
22 portable hot cell with them, and you could swap
23 cobalt-60 sources, move the irradiator into their
24 device in some sort of system of trust, which had the
25 safeguards to swap sources. Is Mary here?

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1 But it is the accelerated decay. And one
2 needs twice-year dosimetry because of that, rather
3 than once yearly. So it's a little bit more costly.

4 MS. SHEPHERD: Some of the cobalt devices
5 are overloaded. So you have a very short dosimetry
6 time. There are two versions: the higher -- and the
7 reason we can't go too much higher is because of the
8 dose rates associated needed for blood irradiation and
9 the weights because cobalt machines are heavier than
10 cesium blood product machines. And you have to keep
11 the weights down to keep them in an accessible area in
12 the blood bank, rather than in the basement or the
13 ground floor.

14 Some you will have a changeover between 5
15 to 12 years depending on which source loading is
16 available. So you start out very high. And then
17 you've got like a 5 to 10-12-year crossover rate to
18 where you're achieving your cesium dose rates versus
19 30 years. A lot of people don't like that option.

20 We can do a -- right now we definitely
21 because of the transportation container issues and COC
22 for the cobalt blood irradiators has been retired. So
23 at present if you're going to reload a cobalt
24 irradiator, it's a portable hot cell. When the new
25 ones come on board, we are back to swapping out and

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1 shipping, you know, just doing an irradiated body
2 swap-out.

3 MR. REIS: Thank you.

4 FACILITATOR BAILEY: Thanks.

5 MR. TAYLOR: But I think you have to also
6 throw in your increased service contract because you
7 are now dealing with source changeouts, which are not
8 inexpensive.

9 DR. JANKOVICH: John Jankovich from the
10 NRC.

11 I would like to supplement the comments we
12 have received to the question. A simple change of
13 cesium sources to cobalt, that physically is not
14 really possible for a number of reasons.

15 One is, of course, technical. The
16 irradiators are designed differently. Sources cannot
17 be accessible in most of the cases. In addition, then
18 we would have to consider the activity level. The
19 same activity level for cobalt sources needs much
20 larger shielding. That leads to heavy debate because
21 of the energy spectrum of the cobalt.

22 In addition, there are the licensing
23 questions, too. The devices, the irradiators are not
24 approved for losing cobalt sources. Then there is the
25 site licensing question. And this makes the

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1 switchover practically impossible.

2 MR. LEW: Yes. On behalf of the
3 University of California system and particularly UCSF,
4 UCLA, thank you for your very thorough presentation.
5 I appreciate the comprehensive preparation you did for
6 your presentation.

7 This is so obvious. We say a footprint.
8 What that means is that these blood irradiators can
9 fit through an existing 36-inch door. Most people may
10 know that, but if you do not work around it regularly,
11 that may just simply be missed. So one dimension
12 won't fit through the 36-inch door, but these are only
13 -- you know, of course, a cobalt unit would not fit it
14 well.

15 FACILITATOR BAILEY: Please use the mike.
16 Excuse me. Please use the mike.

17 MR. LEW: I just want to make a comment,
18 too, that I concur on the NRC and the other agencies'
19 need for the common defense. So I look forward to
20 encouraging through the NRC the funding process to get
21 the private sector, perhaps get the national labs,
22 academics, whatever it takes, to develop machines.
23 Maybe I will come up with that breakthrough so we
24 could have the excellent machine source radiation and
25 perhaps through the information provided by the last

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1 speaker.

2 Thank you. Thank you very much. I want
3 to just express my deep appreciation for the NRC
4 making this forum available --

5 FACILITATOR BAILEY: Ms. Shepherd, did you
6 want to add --

7 MR. LEW: -- for UCSF.

8 FACILITATOR BAILEY: Ms. Shepherd, did you
9 still want to add your comment?

10 MS. SHEPHERD: Mary Shepherd, Shepherd and
11 Associates.

12 The cobalt blood irradiators are designed
13 to go through a standard 36-inch door. We pay very
14 close attention to that. But the weights are
15 considerably much higher. So unless your blood bank
16 is on grade, especially for the double-loaded ones,
17 you are not going to put them on a fifth floor blood
18 bank. They will end up in the basement without a lot
19 of structural support. And that is one of the
20 drawbacks.

21 People have bought some. And some have
22 been decommissioned. Some people want those reloaded.
23 It's all I think a matter of the blood bank directors'
24 personal and physicians' opinions on what they like to
25 see in an irradiator.

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1 Some are in place. I think we will sell
2 some more. FDA has done the 5/10k on both the cesium
3 and cobalts. But, again, swapping to a cobalt unit is
4 a complete new license application because they are
5 completely different units.

6 DR. LEITMAN: I want to comment on the top
7 of weight. Blood banks occasionally move from an
8 older facility to a new facility, which we did a while
9 ago. The hardest part of that move was engineering
10 the move of the cesium chloride irradiator.

11 Off the floor, every path that irradiator
12 took had to be checked out by engineers for robustness
13 of ability to support the -- it's like driving a small
14 car through that area of the 4,400-pound device. So
15 an even heavier device is -- that is a very
16 significant consideration.

17 FACILITATOR BAILEY: Thanks.

18 MR. RATLIFF: Richard Ratliff, Conference
19 of Radiation Control.

20 I just wanted to clarify for the record
21 that the state radiation programs do have to license
22 all of the X-ray irradiators. I see that
23 advertisement all the time. It is the license. And
24 so they are not licensed freely. They don't have
25 increasing controls, but they do have to be licensed.

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1 FACILITATOR BAILEY: Thanks.

2 MR. MILLS: Grant Mills with the North
3 Carolina program.

4 I just wanted to say that I have been
5 doing this a long time doing some inspections on the
6 blood irradiators. And I can remember over 25 years
7 ago when we loved to do them because we told the folks
8 up there the only way it could hurt them was if it
9 fell on them.

10 (Laughter.)

11 MR. MILLS: It's not true today. And I've
12 noticed that during the inspections, there are still
13 some concerns of the folks who actually operationally
14 use the devices. And during inspections is not always
15 a convenient time to ask the kind of questions I think
16 they want to ask, especially involving the security
17 Orders.

18 As you guys have your professional society
19 meetings -- and I am not sure what your organizations
20 are, but I am sure there are many of them -- remember
21 to reach out to either the Health Physics Society or
22 the law enforcement groups or whoever you think is
23 appropriate to come discuss the security culture with
24 your organizations so that those folks who are the end
25 users get an understanding of why they are required to

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1 do these things.

2 That's it. Thanks.

3 FACILITATOR BAILEY: Any additional
4 questions or comments?

5 DR. LEITMAN: I have a response to that.
6 So as 80 people or 30 people who needed unescorted
7 access to the irradiator in my center had to go
8 through a security clearance, that was probably one of
9 the single most difficult things.

10 So as the irradiator custodian for that
11 instrument for 20 years, I had to be fingerprinted
12 again. I had to prove my trustworthiness and
13 reliability and couldn't be grandfathered or
14 grandmothers into it. It was a little frustrating.
15 And so you find that a lot among employees who have to
16 go through this fairly onerous process.

17 FACILITATOR BAILEY: Thanks.

18 DR. JONES: Thank you very much. Cynthia
19 Jones with the NRC.

20 Just outstanding presentations. We can't
21 thank you enough for providing your information on
22 X-ray cesium medical use. It is extremely valuable
23 for the Commission to have sound science and basic
24 facts about how they're used on a daily basis and
25 nationally. And that is going to be extremely helpful

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1 when John and I and others take the comments from this
2 workshop and work it into the policy statement. So
3 thank you very, very much.

4 I will just make a note. One comment that
5 we saw earlier on a slide was a statement that NRC may
6 be phasing out cesium chloride within two years. And,
7 just to put everyone at ease, that is not correct. We
8 are not in the process of phasing out cesium chloride.
9 It may be that that was from an earlier task force
10 report or a subgroup report, but that is not the
11 current vision or motion that the Commission is
12 pursuing at this time.

13 With that being said, one of the comments
14 that I mentioned this morning in the summary meeting
15 which came from NIH yesterday relates to the first
16 comment and bullet up on the screen, which is "What
17 impact does the draft policy statement pose for each
18 of these applications?"

19 I guess I would look to the panelists.
20 One of the comments we heard yesterday was the cesium
21 chloride draft policy statement gives credit to your
22 research and the types of work that you do. However,
23 it was recommended that more needs to be added to the
24 policy statement on research activities in use.

25 And I would like if you could provide your

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1 thoughts on how the policy statement should be revised
2 or does it need to be revised to adequately reflect
3 the activities that you do and why cesium is needed.

4 Thank you.

5 DR. NELSON: I guess I will take a crack
6 at it first. Kevin Nelson from Mayo Clinic.

7 You know, I had a particular focus coming
8 to this meeting. And that was in trying to ensure
9 that my message regarding the use of cesium chloride
10 for blood irradiation was heard.

11 I thought that the policy statement did a
12 fairly good job of doing that, acknowledging that we
13 can't switch cesium chloride right now for a number of
14 very important applications, you know, but we are
15 going to continue to look at alternative sources. And
16 I have no concern over that.

17 I was concerned, however, regarding the
18 2010 Task Force report and the comments that I think
19 we heard from John yesterday regarding that. They
20 seem to be a little bit more aggressive in their
21 statements regarding removal of cesium chloride at a
22 more accelerated rate.

23 And so my message again would be I think
24 that the policy statement is good. It allows some
25 flexibility. But I am concerned that the other

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1 members of the Task Force may not understand the need
2 currently for cesium chloride and why we just can't
3 stop using cesium chloride.

4 DR. LEITMAN: I think the draft policy
5 statement got it right. In preparation for this
6 meeting, I thought the language was good. And it
7 listed the reasons for which cesium chloride is such a
8 useful radionuclide for these medical and research and
9 calibration purposes.

10 DR. MINNITI: I guess the only thing I
11 would add is that in the case of calibration of
12 instruments, cesium is needed because of what I said
13 in the talk, the fact that it is a mono-energetic,
14 potent source.

15 And if there is going to be a replacement,
16 it would have to be another form of cesium. We could
17 not use an X-ray source because of what I explained
18 before. An X-ray provides a broad energy spectrum.

19 So, other than that, I don't have anything
20 else to add.

21 DR. JONES: Thank you.

22 I think what we will certainly do is make
23 sure that the Task Force members who are represented
24 have an opportunity to be provided the transcript of
25 this meeting and certainly of your comments that you

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1 shared.

2 And I would on a personal note just
3 indicate that when I read the Task Force report, I
4 would agree with the comments that were just made. So
5 I could see how that could be read.

6 But we're all learning. Just as we were
7 two years ago, this is another workshop or an
8 opportunity for more knowledge in this area. And I
9 want to thank everyone for their comments and for
10 another very interesting session.

11 One opportunity for you all before lunch.
12 Any other questions or comments as licensees? Anyone?

13 (No response.)

14 DR. JONES: It looks like you are all
15 hungry and you want to go to lunch. Let's give our
16 panel members another hand.

17 (Applause.)

18 DR. JONES: So we will come back at 1:00
19 o'clock? Is that right, Ken?

20 FACILITATOR BAILEY: Yes, 1:00 o'clock.

21 DR. JONES: Very good. Thank you very
22 much.

23 FACILITATOR BAILEY: Enjoy your lunch.

24 (Whereupon, a luncheon recess was taken at
25 11:44 a.m.)

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

2 (1:03 p.m.)

3 ISSUE NO. 6: STATUS OF DISPOSAL

4 PANEL MEMBERS

5 FACILITATOR BAILEY: I hope you all had a
6 chance to enjoy your lunch. We will now begin the
7 afternoon portion with issue 6 for discussion. The
8 NRC recognizes that currently there is no disposal
9 capability for commercial cesium chloride sources.
10 The NRC considers it imperative to develop a pathway
11 for long-term storage and disposal of these sources,
12 whether or not they are alternative developments.

13 Again, I will allow the panel to introduce
14 themselves, beginning from the left.

15 MR. DANSEREAU: Bob Dansereau with the New
16 York State Department of Health.

17 MR. ZARLING: John Zarling, NNSA, GTRI.

18 MR. EDELMAN: Arnie Edelman, Office of
19 Environmental Management, Department of Energy.

20 DR. NELSON: Kevin Nelson, Mayo Clinic,
21 Jacksonville, Florida.

22 FACILITATOR BAILEY: And the first
23 presentation will be from Arnold Edelman, "DOE Update
24 on Development of Environmental Impact Statement for
25 Disposal Facilities."

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1 I apologize. Briefly, can you tell me --
2 can I get a show of hands for those people that's
3 catching the Metro and will need a ride to the Metro
4 station, Shady Grove Metro station?

5 (Whereupon, there was a show of hands.)

6 FACILITATOR BAILEY: Okay.

7 PANEL PRESENTATIONS:

8 DOE UPDATE ON DEVELOPMENT OF ENVIRONMENTAL
9 IMPACT STATEMENT FOR A DISPOSAL FACILITY

10 MR. EDELMAN: Well, good afternoon. I am
11 sure everybody had a wonderful lunch. And hopefully
12 you won't fall asleep during my presentation.

13 This morning when we were looking at the
14 different pictures of blood irradiators, I felt some
15 emotion when they showed the blood irradiator in the
16 cage and it looked like people were really concerned
17 about that.

18 We know within the Department of Energy
19 that there are blood irradiators that are not only
20 thin cages, but they are probably in basements in the
21 dark and in storage closets in the dark waiting for a
22 home.

23 We believe the best home is 30 to 600
24 meters underground or under several feet of concrete
25 and soil. So the Department of Energy is indeed

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1 working on coming up with a disposal methodology,
2 disposal approach for greater than class C waste that
3 includes cesium chloride sources.

4 The policy statement mentions that there
5 are two impediments to disposal. One is the high cost
6 for disposal of cesium chloride sources and also the
7 lack of a disposal facility. I am hoping that as a
8 result of DOE efforts, that we will be able to at
9 least solve one of those two problems, come up with a
10 disposal facility for future disposal of cesium
11 chloride sources.

12 Today I am going to be talking about where
13 we are in the Department of developing an
14 environmental impact statement (EIS) for the disposal
15 of greater than class C waste that does include cesium
16 chloride sources and also to solicit the folks in the
17 audience as well as the general medical community to
18 provide us input to the draft EIS that will be coming
19 out in the very near future.

20 We are going to be probably getting
21 hundreds, thousands of comments on the draft EIS, both
22 for and against the siting of a disposal facility.
23 And we encourage you to give us your input to be aware
24 of what is going on because that will help us make
25 decisions on where we need to go.

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1 So where are we and what are the basic
2 drivers for developing an EIS? Well, of course, we
3 have the congressional mandate. And, as you all know,
4 in general federal agencies are very responsive to
5 Congress. And we have two pieces of legislation:
6 Low-Level Radioactive Waste Policy Act Amendments of
7 1985 that require the federal government to develop
8 disposal for greater than class C. It require the
9 Department to develop a report to identify what are
10 the basic quantities out there, what are the basic
11 options. That report was done in 1985. And it also
12 established the GTRI program in terms of going out
13 after sealed sources.

14 Then we had the Energy Policy Act of 2005.
15 That specifically requested that we identify who
16 within the federal establishment develop the greater
17 than class C environmental impact statement. And that
18 was the Department of Energy.

19 The Department of Energy basically took
20 the assignment. The Office of Environmental
21 Management was given the responsibility to develop the
22 EIS.

23 Specifically -- and I wanted to point this
24 out that the ~~Low-Level~~Low-level Radioactive Waste
25 Policy Act Amendments, LLRWPA, not the easiest thing

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1 to say, basically indicated that the federal
2 government is responsible for disposal of
3 radionuclides that exceed the definition of class C.
4 It didn't say anything about B or C. It just said
5 that we're responsible for greater than class C.

6 I know there have been some questions in
7 the past and some discussion in the past about could
8 we take other waste, could we take B and C waste at a
9 disposal facility that we are going to be developing.

10 At least right now, based upon the
11 existing legislation, the only thing we are designing
12 is a facility for greater than class C waste.

13 In 2005, as I mentioned, the Energy Policy
14 Act, the Energy Policy Act not only gave the
15 assignment to DOE. It also required us to develop a
16 report on the development of an environmental impact
17 statement, giving an estimate of cost and the
18 schedule. We proposed initially 2008. And here we
19 are in almost 2011. And we hope to be out with the
20 EIS soon.

21 It also required us to report to Congress
22 before any final decision was made on where we would
23 be going with the greater than class C waste and the
24 creation of a disposal facility. So that is something
25 that we are working to and developing in the near

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1 future, an approach on dealing with what types of
2 waste, where we are going to be going with the waste,
3 and also preparing the report to Congress that will
4 authorize us to actually make a decision on where we
5 are going to put the waste.

6 We have the national security concerns.
7 There has been a lot of discussion today and yesterday
8 about the Task Force report and the Task Force
9 identifying the need for secure and safe disposal. We
10 have also talked about future programs that within the
11 Department of Energy, we have programs under NNSA for
12 the development of moly-99, development of a domestic
13 source of production for moly-99.

14 It is our understanding that many of the
15 industries that are looking at this issue don't want
16 to move forward until they have a disposal path for
17 the waste that will be coming out of the production,
18 which will be considered greater than class C waste.

19 We have also have green energy systems,
20 development of new nuclear reactors that will be
21 generating greater than class C waste. And we have
22 space exploration power sources that as we produce
23 those power sources, again, greater than class C waste
24 will be generated. And we really need to find a place
25 to put this waste and dispose of it.

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1 And then, finally, we have environmental
2 stewardship in the Office of Environmental Management.
3 Our basic responsibility is environmental restoration
4 and cleanup. We have a major site in West Valley, New
5 York, where there will be waste coming out of that
6 site. That would also be considered greater than
7 class C. There are plenty of drivers, plenty of
8 reason to move forward on the development of the EIS.

9 So what is the EIS really covering? One,
10 it's going to be covering and identifying the waste
11 types, identifying the quantities of waste that are
12 currently available for disposal and that would be
13 generated in the future. And in terms of generating
14 in the future, we are looking at a 60-year horizon for
15 the design of the facility and the calculation of
16 waste that will be generated over that 60 years.

17 It looks like a range of alternatives for
18 disposal, including methods and also looking at sites.
19 And we have various sites -- and I will be going to
20 that in a moment -- located throughout the country and
21 also part of an EIS that evaluates the potential human
22 health and environmental consequences of constructing,
23 operating, and closing a facility. And we're looking
24 up to at least out to about 10,000 years in terms of
25 doing those calculations.

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1 So what does it look like? We have waste
2 types. We have the sealed sources that include cesium
3 chloride sources. We have other sources that are used
4 not only in medical purposes but for, as you all know,
5 oil, oil drilling and looking at welds.

6 We have activated metals, which are
7 primarily from the decommissioning of nuclear
8 reactors. There is a small quantity of waste
9 currently out there right now. We anticipate that
10 over the next 40 to 60 years as power plants are
11 decommissioned or new ones come on line, there will be
12 additional cleanup. And then there will be additional
13 activated metals generated that will need to be
14 disposed of.

15 We are looking at probably a 30 to 40-year
16 horizon before a large quantity of those wastes get
17 generated. And then we have other waste, as I
18 mentioned, the waste from moly-99 from the power
19 sources and space exploration.

20 So we have all these types of waste out
21 there that we are going to be dealing with under the
22 EIS. And here is sort of an overview. In looking at
23 a 60-year horizon, looking at the information that we
24 were able to gather between 2005 and 2009, we estimate
25 that it is approximately 12,000 cubic meters of waste.

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1 Sort of a simple way to look at that is a
2 football field, about 7 feet high, full of low-level
3 radioactive waste if you want to get a visual of it.

4 About 25 percent of that waste total is
5 from sources of about 8 and a half percent, or 1,000
6 cubic meters, coming from cesium chloride sources.
7 The other you need about 1,800 cubic meters from
8 sealed sources, about 15 percent. We have activated
9 metals, about 16 percent, and then other waste, which
10 is primarily West Valley.

11 So when you look at the total quantity of
12 waste that we have, the sealed sources represent 25
13 percent, which is a pretty good, pretty large amount
14 considering that the other waste and the activated
15 metals are waste that may be generated in the future;
16 whereas, we know for sure that the sealed sources are
17 out there and will be continually generated over time.

18 So what are we looking at in terms of
19 coming up with a solution to the problem? Well, the
20 first thing I think is important is that the NRC
21 regulations under 10 CFR Part 61.55 basically say
22 greater than class C waste needs to be disposed of in
23 a deep geological depository unless other methods are
24 presented to the Commission and the Commission
25 approaches those methods.

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1 Now, it is my understanding that on a
2 case-by-case basis, the Nuclear Regulatory Commission
3 has indeed approved some disposal of greater than
4 class C waste at the bottom of existing disposal pits
5 and slit trenches. It's been very limited, has been
6 done, but that is not the solution to the overall
7 problem.

8 So we're looking at deep geological, at
9 WIPP, the Waste Isolation Pilot Project located in New
10 Mexico. And then we are looking at other land
11 disposal locations throughout the United States,
12 including DOE facilities where there is an existing
13 mission for disposal, such as Savannah River, Los
14 Alamos National Laboratory, Idaho National Laboratory,
15 the Nevada test site, where the national -- let's see
16 -- Nevada -- no, not a national security site, that's
17 a brand new name -- Hanford and Idaho National
18 Laboratories.

19 So we are looking at those sites. And as
20 we look at those sites, we are looking at conditions
21 of geology, the hydrology, the soil conditions,
22 socioeconomics, the environmental justice issues, the
23 air, land, other water issues. So we are evaluating
24 all of their sites.

25 So, in addition to those, we have a

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1 no-action alternative that we can take or we can look
2 at commercial. And we also did an examination of
3 potential commercial sites back in 2005, we solicited
4 input from the commercial industry to see if they
5 would be interested in creating a disposal site for
6 greater than class C waste, received some preliminary
7 thoughts from a few of the commercial establishments,
8 but nobody raises their hand. But, in spite of that,
9 we figured that we ought to be covering that within
10 the EIS.

11 So we evaluated potential locations
12 throughout the four NRC regions, looking at humid
13 areas, semi-humid areas, arid, semi-arid areas, and
14 evaluated, were evaluating, whether or not indeed
15 there could be commercial disposal at the sites.

16 So once we look at our sites, we are
17 considering it could be a potential selection of
18 multiple sites. And we could also combine methods.

19 Now, what are some of the methods? Well,
20 we have four basic methods: one, the accepted method
21 that the NRC states in regulations, which is a deep
22 geological depository over 600 meters below the ground
23 surface. We are looking at an above-grade vault, an
24 intermediate depth borehole and enhanced near-surface
25 trench.

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1 Pretty much for the borehole trench and,
2 of course, geological depository, we have really good
3 experience in dealing with similar waste being
4 disposed of at that site.

5 WIPP, of course, is transuranic waste.
6 The cesium chloride waste is not transuranic in terms
7 of our definition. We have others, sealed sources,
8 that are indeed transuranic. And they potentially
9 could go to WIPP.

10 WIPP is currently operating under the Land
11 Withdrawal Act. The Land Withdrawal Act specifically
12 defines the mission of WIPP to be defense transuranic
13 waste. So it cannot take at this point in time any
14 non-defense transuranic waste or any non-actinide
15 waste.

16 So if WIPP were to be potentially selected
17 as a preferred alternative, there would need to be
18 some legislative changes and also an agreement by the
19 State of New Mexico and the Department of
20 Environmental Protection in the State of New Mexico to
21 allow that waste to go there.

22 We do have experience. As I mentioned,
23 NRC has approved on a case-by-case basis a disposal of
24 greater than class C in slit trenches below, 30 meters
25 below, surface. And, of course, on top of it was a

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1 lot of low-level waste. I think it was at Barnwell or
2 U.S. Ecology. I think that is where it was approved.

3 And then we have -- out at Idaho, we have
4 had -- yes, at Idaho, we have had some experience with
5 intermediate depth boreholes in the disposal of
6 greater than class C-type waste. I'm sorry. It's at
7 Nevada test site.

8 So we are looking at these methods. We
9 are looking at these sites. The final conclusion when
10 we come to coming up with a preferred alternative,
11 which we are not right now looking at, it could be a
12 combination of the methods, could be a combination of
13 the sites, and it could be a combination of the waste
14 types.

15 So we could take cesium chloride and put
16 it in a borehole. We could take potentially cesium
17 chloride with legislative changes, put it in WIPP or
18 we could put it in the trench. And we could do it at
19 Nevada. We could do it at Savannah River. We could
20 do it at a combination of sites. It just depends on
21 what type of conclusions you make based upon the
22 analysis.

23 So where are we in terms of our schedule?
24 We are hoping to issue the draft EIS January of next
25 year. That is our target date. It is currently

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1 undergoing review by senior management. And we are
2 hoping by the end of the month that we will get to
3 ahead and actually publish the document.

4 We will be having public hearings at the
5 sites that I mentioned in the March, April, May time
6 frame. We will be soliciting from the public their
7 perspective on the alternatives, the methods, and
8 considerations for selection of a preferred
9 alternative.

10 So as a medical community, as sealed
11 source producers, you know, your input could be very
12 valuable here to us in terms of what are the criteria,
13 what are the considerations we ought to be taking as
14 we move forward in the selection of a preferred
15 alternative and finalizing that preferred alternative
16 and moving forward.

17 We are hoping to issue the final EIS in
18 2012. And at that same time, we need to submit a
19 report to Congress. That report to Congress we need
20 to identify basically what we have in the EIS. What
21 are the quantities of waste? What are the options for
22 disposal? What are the legislative changes or
23 regulations that need to be developed? What are the
24 costs associated with each of those methods? And we
25 also need to present to Congress, how can we recoup

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1 the money for the construction and operation of that
2 facility?

3 It basically says in the legislation that
4 those who benefit from the operation of these
5 facilities will need to pay for them. How that is
6 done, what those options are we still have to develop.

7 Once that report goes to Congress,
8 basically before we can make a final decision, we have
9 to hear back. We need to await congressional action.

10 That could take a lot of forms. It could
11 take a letter from Congress, from the Congress, from
12 the Committee, from individual site congressional
13 delegations supporting, not supporting, agreeing to
14 legislative changes, agreeing to funding to help us go
15 forward and build the facility. But we cannot move
16 forward until we hear back from Congress.

17 So we are hoping that Congress pays
18 attention to this issue in 2012. And I'm sure there
19 are other issues that they will be looking at, but
20 hopefully we will pay attention to this issue in 2012.
21 We will be able to issue a record of decision and then
22 implement the record of decision.

23 So a fairly quick, big picture overview.
24 In 1985, we had the Low-Level Radioactive Waste Policy
25 Act Amendments. 9/11/2001. We had the notice of

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1 intent in 2005. And now we are working to issue the
2 draft EIS with the hope that, indeed, we will have
3 that draft out in January and finalized in January of
4 2012.

5 In that little green box up there, that's
6 hopefully 2019, 2020 is when the facility will actually
7 be online. You sort of see there is a blank in
8 between the draft and the final EIS. There are a lot
9 of things that are going to need to take place. We
10 are basically taking the United States and winnowing
11 down to a facility or facility and a method or
12 methods.

13 And then after we do that, we are going to
14 then need to go to that specific site and do further
15 analysis. We are going to need to do site
16 characterization. We are going to need to look at the
17 detailed geology. We're going to need to do and
18 modify any existing NEPA documentation that is out
19 there, be it a site-wide EIS or site-specific EIS.
20 We're going to need to work with the NRC on best
21 approach to licensing.

22 You know, are there regulations right now
23 out there that will cover these facilities and the
24 construction of these facilities or will NRC need to
25 develop new regulations, new procedures, new policies?

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1 That is unknown. NRC is going to need to look at this
2 EIS or hopefully the NRC folks out here have their
3 reading glasses on for January. It's 1,500 pages
4 approximately is the EIS. So, you know, we are going
5 to have to look at that.

6 Then once we get the ~~site-specific~~
7 ~~site-specific~~ EIS's done, the site characterizations done,
8 and they go through their public hearing, public
9 comment, and then we are going to have to go through
10 the license application, license approval, and then
11 construction, we estimate it is going to take about
12 two and a half to three years to construct a new
13 facility. Yet, we are building a new facility. If
14 we're using an existing facility, then we are
15 risk-constrained by legislative changes.

16 So we had challenges and opportunities for
17 us in coming up with a disposal approach. We need to
18 get stakeholder input, evaluation, and support. As I
19 mentioned, we are going to need you to help us come up
20 with a preferred alternative or alternatives. We need
21 NRC to evaluate the EIS to look at the methodologies,
22 the conceptual designs we have developed and determine
23 whether or not those can be approved under existing
24 conceptual design and what type of regulations we need
25 to be developed.

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1 One comment I have on the draft policy is
2 that right now the draft policy focuses on the
3 Commission to actively support the storage of greater
4 than class C waste. And I would like to see that
5 extended to not only support the storage of greater
6 than class C waste but also the disposal of class C
7 waste. And that is something that we are really going
8 to need NRC because we are not going to be able to get
9 there without NRC's approval and licensing of the
10 facility.

11 Well, that is my name. And there is our
12 EIS website. We are hoping, again, that the EIS will
13 be out in January. And we look forward to your input
14 and your advice and your suggestions on how to move
15 forward with this EIS.

16 And then just one quick last one. That is
17 the Department of Energy, not an eye test. John
18 Zarling is going to be talking about GTRI. He is over
19 on the left. And then we are over on the right in the
20 Office of Environmental Management. I'm in the
21 Disposal Operations Group.

22 And, even though we are separated by a
23 whole lot of boxes, we actually know each other's
24 phone number and e-mails, and we talk to each other.
25 And, in a way, the GTRI program and what we are doing

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1 in the EIS are really closely aligned.

2 Thank you very much.

3 (Applause.)

4 LICENSEES' PERSPECTIVE ON STORAGE AND

5 DISPOSAL OF CsCL SOURCES

6 DR. NELSON: Good afternoon again. My
7 name is Kevin Nelson. I am the RSO at Mayo Clinic in
8 Florida. And I will guarantee that this is the last
9 time you will have to hear me at this workshop.

10 (Laughter.)

11 DR. NELSON: Again, I appreciate Dr. Jones
12 reaching out and asking me to talk on this very
13 important topic as a licensee. And of the
14 presentations that I have prepared for this workshop,
15 this was the easiest one to prepare because there are
16 so few answers.

17 As a licensee, I have to keep reminding
18 myself this is a process. Waste disposal is a
19 process. And it involves a lot of stakeholder
20 involvement. It involves a lot of regulatory review.
21 All of these are very important in finding disposal
22 sites or disposal for cesium chloride sources.

23 So I think the most important thing as a
24 licensee you can do is if you buy a new source,
25 whether it is cesium chloride or any other device

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1 containing radioactive material, is to see what kind
2 of support you can get from the vendor in returning
3 that specific source.

4 Some of the issues we have with cesium
5 chloride -- and I am going to be speaking specifically
6 as a licensee that has a blood bank irradiator -- is
7 that sometimes the vendor may go out of business
8 before you really have to dispose of the device.

9 Our particular device was originally
10 purchased in 1993. And, even if they did have
11 agreements in place at that time, who really honors
12 agreements once you get 15, 20, 25 years out as a lot
13 of these irradiators have a long, useful life span?

14 When we looked for disposal sites, we
15 really don't have any option if you're out of compact
16 for class B or C waste. As licensees, currently we
17 don't have an option for GTCC, greater than class C,
18 although we certainly endorse what DOE has been doing
19 and encourage their work. But we really think that
20 probably in the short term, that we are looking at
21 storage on site. And that in itself can bring its own
22 set of safety and security issues.

23 I think we would much rather prefer to
24 have these sources in one or two or three locations
25 across the United States versus having them at

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1 individual sites.

2 So as far as the classification of waste,
3 it depends on the activity and volume. And cesium
4 chloride sources would span the spectrum. For some of
5 your low-activity sources, you might be looking at a
6 class B. Certainly for blood bank irradiators, you
7 are looking at greater than class C type of waste.

8 What is the volume that we are looking at?
9 Are we looking at the source capsule? Are we looking
10 at the source capsule plus the radiation shielding?
11 Are we looking at the whole unit in consideration of
12 volume?

13 The classification and the requirements
14 for class B and C waste, for land disposal are listed
15 under 10 CFR 61.55. And I have extracted table 2 from
16 that section to show you that on the bottom there, you
17 see cesium chloride. And a class B source would be
18 somewhere between column 1 and column 2, 1 to 44
19 curies per cubic meter.

20 And a class C would be somewhere between
21 44 and 46 hundred curies per cubic meter. And greater
22 than 4,600 curies per cubic meter would be your
23 greater than class C waste for cesium chloride.

24 As I mentioned, most blood bank
25 irradiators would be classified as greater than class

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1 C-type devices. I did a quick calculation on our
2 particular device. And it would have to be less than
3 probably about 570 curies to be considered class C
4 waste if I look at the volume being a source container
5 and the shielding itself.

6 Well, as mentioned previously and in the
7 draft policy statement, there are no disposal options
8 for commercial cesium chloride since the closure of
9 Barnwell, South Carolina in July 2008 for
10 out-of-compact waste.

11 We just heard an excellent presentation
12 about what DOE is planning to do for greater than
13 class C waste in their EIS, environmental impact
14 statement.

15 There may be a commercial option with
16 waste control specialists in Texas. And I will talk a
17 little bit more about that in a couple of slides.
18 But, although I keep telling myself this is a process
19 and a long process, it just seems that there is a lack
20 of political will to move this forward.

21 Certainly there are questions that parties
22 are asking that should be answered, but I told myself
23 when I first started my career as a health physicist
24 over three decades ago when the Low-Level Waste
25 Compact Act was passed, I thought, "Wow. This is

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1 great. This is going to be the answer." Well, three
2 decades later, I am still waiting for that answer to
3 appear to me in the State of Florida.

4 We did back in 2007, a little over three
5 years ago, when I was the President of the Health
6 Physics Society, provide comments to the DOE on their
7 proposed EIS for greater than class C low-level waste.
8 And I will highlight some of the things that we
9 responded to in this letter.

10 Probably the most significant thing is
11 lack of greater than class C and non-greater than
12 class C waste disposal option for unwanted sealed
13 radiological sources that both security and public
14 health concerns will continue to increase the number
15 of orphan sources. So the longer we go without a
16 pathway for these sources, the more at risk these
17 sources become.

18 We also did ask the DOE if they would
19 consider including class B and C in their
20 environmental impact statement. And it was true that
21 they did not have a mandate in the Energy Policy Act
22 of 2005 for doing that, but when we looked at it, they
23 may not have had a mandate, but it didn't say you
24 couldn't do it.

25 So that was those were some of our

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1 concerns. Obviously if they were to include class B
2 and C in their environmental impact statement, this
3 would require legislative approval for them to be able
4 to pursue that.

5 It has been projected that from an
6 activity standpoint going into the future, that the
7 majority of the activity is going to come from greater
8 than class C waste.

9 So our thinking was, if you are preparing
10 a site to hold greater than class C, certainly you
11 could hold class B and C waste there, probably a
12 little less of a security issue. Plus, from a volume
13 standpoint, it wouldn't be adding significantly to
14 what DOE is trying to cover.

15 I will have to say I do commend DOE again
16 for their efforts in trying to help us out as
17 licensees to get a disposal pathway for the cesium
18 chloride irradiators.

19 Now I want to talk a little bit about
20 Waste Control Specialists out in west Texas. They are
21 a private company. And they are working with the
22 Texas Compact, which includes the State of Texas and
23 Vermont.

24 In 2009, they were licensed to receive
25 low-level radioactive waste. And they disposed of

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1 about 750,000 cubic feet of radioactive material
2 generated at Fernald, Ohio during the Cold War. They
3 project that in 2011, they will be able to start
4 accepting class A, B, and C waste from the Texas
5 Compact and also accepting class A, B, and C waste
6 from DOE.

7 And depending on how things go, depending
8 on the regulatory environment, who knows? Maybe down
9 the road they might be able to accept class A, B, and
10 C waste from outside of the compact.

11 We, being the Health Physics Society, have
12 a position statement on continued federal and state is
13 needed for better control of radioactive sources. And
14 if you are interested in getting this position
15 statement, contact me. And I am certainly happy to
16 send it to you.

17 The specific items that we identified
18 under waste in this position statement included that
19 we want Congress to take some action to ensure
20 accessibility and safe options for disposal of
21 radioactive sources, especially category 1, 2, and 3
22 sources, which we -- well, we have been predominantly
23 talking about category 1 and 2 sources at this
24 workshop.

25 We further recommended that federal and

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1 state agencies work with professional organizations,
2 such as HPS or it could be AAPM, to develop and
3 implement programs to better inform licensees on
4 source disposal.

5 Looking at short and long-term solutions,
6 as I mentioned, there is a document on the same
7 website that was used by the previous speaker that
8 shows that through 2062, it is asymptote that the
9 total activity of greater than class C and greater
10 than class C-like waste will be seven times greater
11 than class A, B, and C. So certainly we need to start
12 looking at this sooner, rather than later.

13 Long term hopefully DOE will be able to
14 get to identify a site and get through all of the
15 regulatory hurdles that are needed and review. And
16 hopefully we will have that site available to us
17 sometime while I am still working as a health
18 physicist.

19 For the Texas site, maybe at some point in
20 the future we might have an option for disposing of
21 class B and C waste out of the compact. Short-term,
22 however, again, I believe that on-site storage is
23 probably going to be our only option. And, again,
24 that has its own safety and security risks in itself.

25 And my final question or my final slide is

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1 a question to the audience. And, Mary, you already
2 stole my thunder on this this morning. So how much
3 does it cost to move a cesium chloride blood bank
4 irradiator ten miles in a type B container: a) a
5 month's mortgage payment? How many of you think a
6 month's mortgage payment?

7 (No response.)

8 DR. NELSON: No hands. How about all new
9 kitchen appliances, something that I am going through
10 right now?

11 (No response.)

12 DR. NELSON: No hands. How about a new
13 Lexus?

14 (Whereupon, there was a show of hands.)

15 DR. NELSON: All right. And then a
16 median-priced house in Jacksonville, not to say that
17 you would move to Jacksonville, but it is a nice place
18 to live. Well, in our particular case, the answer is
19 a new Lexus. Just a cost to move it ten miles down
20 the road was \$30,000. The rigors were extra. And so
21 it is not inexpensive just to move these devices. And
22 you have to consider that I think also, as Mary had
23 gone through that this morning.

24 That is my presentation. Thank you.

25 (Applause.)

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1 DISPOSAL OF CsCL SOURCES THROUGH DOE'S OFF-SITE

2 MR. ZARLING: My name is John Zarling. I
3 am here to discuss the disposal issues that we see in
4 the recovery and disposal of the cesium plus other
5 sealed sources as well.

6 Yesterday a colleague from GTRI did
7 discuss a couple of the -- well, especially the
8 in-device delays of the cesium chloride irradiators
9 plus the physical upgrades at the sites. And that's
10 two of the pillars.

11 You know, we have the three pillars of the
12 GTRI mission are the convert, remove, and protect.
13 The convert is more nuclear. Obviously the remove and
14 protect deals with the radiological. And what I am
15 here obviously to discuss is the remove portion of it.

16 So I am from Los Alamos National
17 Laboratory. And we are here stationed at D.C. working
18 on the GTRI. I have gone on a lot of recoveries. So,
19 as this slide says, every year thousands of sources
20 become disused and unwanted. I think Ioanna said
21 yesterday it's about 3,500 sources that we have
22 registered every year on our website.

23 This kind of goes back to what the
24 previous speaker said. While secure storage is a
25 temporary measure, the longer sources remain disused

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1 or unwanted, the chances increase they will become
2 unsecured and abandoned.

3 So permanent disposal -- and so we at GTRI
4 don't think storage is an option. Disposal is what we
5 need. And that is also what was said as well.

6 If you have sources -- I am going to say
7 this right now. And it doesn't matter. We are here
8 talking about cesium today, but any disused, unwanted
9 sources, you can go to our osrp.lanl.gov website and
10 register those sources. That is the only way that
11 program knows that these sources are disused and
12 unwanted.

13 The website is secured. It's behind a
14 firewall. So your information won't get out to anyone
15 else other than the employees at Los Alamos.

16 Again, yesterday Ioanna said we have
17 recovered over 26,000 sources. That's domestically
18 plus an additional thousand sources from I think 18
19 countries, U.S. origin sources, to date.

20 The initial -- OSRP started recovering
21 plutonium-239 that was an AEC loan/lease program.
22 Then it kind of expanded after 9/11 to include larger
23 activity sources.

24 We work with the NRC to prioritize the
25 recoveries. The higher the activity of cesium or

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1 cobalt, the higher priority that it will receive for
2 recovery.

3 Currently, as of -- I did check this
4 morning. And we have recovered 48 large cesium
5 chloride devices to date.

6 Here is a graph. The first thing I guess
7 on the left is -- and it's from the sealed sources, a
8 national security program. I thought it was very nice
9 that the Task Force report was out on the table this
10 morning and this afternoon. So you can go into that
11 Task Force report and actually read the problem
12 statement that was developed from the subcouncil at
13 NGCC and NSCC over the past year and a half I think
14 the group worked together.

15 I am not going to sit here and read it.
16 You can read it yourself. It does tie in. At the
17 bottom, it says, "However, there are 14 states
18 currently that have commercial disposal." I am going
19 to show you a graph.

20 Since we are here talking about cesium,
21 currently right now the pie graph on the right is just
22 the number of sources we have registered as excess,
23 not just cesium.

24 So approximately 470 sources are currently
25 registered as disused and unwanted, over 100 curies.

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1 And approximately 1,000 sources, over 10 curies are
2 registered and disused and unwanted on our database.

3 As cesium, right now we have approximately
4 14,000 sources registered as disused and unwanted,
5 totaling approximately 74,000 curies. That's decayed
6 activity.

7 On the bright side, if there is a bright
8 side on that one, 13,000 of those sources are under
9 one curie. But that still totals almost 1,000 curies.

10 On the upper end, we have 91 sources
11 between 100 and 1,000 curies of cesium, registered, a
12 total of 36,000 curies. And we have 15 sources or
13 devices, totaling 35,000 curies, registered as disused
14 and unwanted.

15 Now the disposal. As was mentioned, we
16 have 14 states currently that have disposal in the
17 United States. There's the Rocky Mountain and
18 Northwest Compact plus the Atlantic Compact with South
19 Carolina, New Jersey, and Connecticut.

20 Hopefully, as you saw in the last
21 presentation, Texas and Vermont will be open.

22 While this is great that there is disposal
23 there, however, it is very limited disposal there. In
24 the New Jersey, South Carolina, and Connecticut, the
25 disposal limit is ten curies, which doesn't help with

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1 the blood irradiators. You know, it's somewhere
2 between class A and class B waste.

3 So Northwest Rocky Mountain Compact, it's
4 unknown what the disposal limit is. If you follow the
5 branch technical position paper, you would have to
6 believe it is 30 curies.

7 However, we are working with CRCPD. And
8 hopefully after -- the licensee, American Ecology and
9 Hanford, right now are on hold. They aren't issuing
10 disposal license until later on, I guess in the
11 springtime of 2011.

12 But we are going to work CRCPD and try to
13 come up with a plan to dispose of the higher activity,
14 something greater than 30 curies at Hanford to see if
15 it is possible to do. We aren't sure if it's
16 possible, but we are going to look at it.

17 And from what we have heard -- and we
18 don't know this for sure -- the Texas Compact is going
19 to be very similar to the 30-curie limit that's in the
20 [**1:48:34] position paper.

21 So, again, there are at least some options
22 in these 14 states, hopefully soon to be 16 states,
23 but it's still not a solution.

24 We as GTRI, OSRP do recover
25 higher-activity sources, but we also -- in both

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1 actinides and other sources, but once we recover them,
2 we take ownership, but we have very limited disposal
3 access as well. So that is not a solution either.

4 As my colleague from DOE EM said, we are
5 working with DOE EM and NRC looking at the problems
6 that we face right now. And, actually, it ties in
7 nicely. So you can see, yes, we can do recoveries.
8 And if you do have sources, you know, please contact
9 OSRP website.

10 We do work with NRC, as I said, to
11 prioritize these recoveries based on location and
12 activity. But this is not the only problem that we
13 have. You know, disposal is one problem, but,
14 actually, even moving the material to the disposal
15 site is another problem.

16 I wasn't here this morning to hear what
17 Mary had to say. However, Los Alamos with the -- Los
18 Alamos and GTRI are working on a new type B container.
19 Right now there is a very limited number of type B
20 containers in the United States that can move. And
21 that is part of the problem where the \$30,000 comes
22 from and not only the limited number of type B
23 containers. There's also a limited number of people
24 that can work on the devices as well.

25 So Los Alamos I guess in September of 2009

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1 let a contract for a new type B container. And AREVA
2 won that contract. It was originally designed for the
3 long-term storage shield, which is the use with the
4 IAEA mobile hot cell.

5 And the other part of it was hopefully we
6 could contain other use with other devices. What
7 should be noted about this type B container is it's
8 limited in size. Since it's going to be used with the
9 long-term storage shield, we didn't want a huge
10 container. We were limiting the total weight to
11 10,000 pounds. So it does have the limited.

12 We had a pre-designed public meeting with
13 the NRC on August 25th. And I will get on that.
14 Submitted a detailed design to the NRC. Hopefully
15 it's going to be this month. Full-scale testing,
16 March 2011. Review package, May 2011. And a
17 container approval, entry of a COC, March 2012.
18 That's the time line.

19 The picture you can see on the right is
20 the long-term storage shield. That would go inside
21 the new type B container. And the one on the bottom
22 is a possible internal support concept. And that
23 would be used for other devices, for cesium or cobalt
24 devices, large devices.

25 Now, during the meeting with the NRC, they

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1 were a little concerned with taking credit for
2 shielding of the device. They did say, you know, we
3 would have to look at that by a case-by-case basis.
4 And AREVA is working on that currently, but it is a
5 problem.

6 So from there, it says including a list of
7 specific -- so we're looking at it. It says,
8 "Including a list of specific models and devices with
9 design drawings and analysis."

10 So, I mean, there are hundreds of devices
11 out there. And a lot of them, you know, it has been
12 said, both yesterday and today, some of these devices
13 are no longer being made and the company is no longer
14 in business.

15 And some of the devices, when they are
16 shipped, they are shipped as type B shipments. That
17 is that certificate is probably expired. Who knows
18 where the design drawings are. And we have been told
19 by a couple of people that some of the design
20 drawings, they were submitted, but the as-built may be
21 a little bit different. And how do you prove and how
22 do you prove that the shielding is going to remain
23 intact during transportation?

24 So, as we were thinking about that
25 problem, we maybe start working on a new type B. The

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1 large B is what we are going to call it, where it is
2 going to be a much larger container that, instead of
3 taking credit for the shielding or the device, we are
4 going to look at shielding for the large -- you know,
5 build a container, a 10-160B-type large container or
6 the GE2000 large-type container with a lot of
7 shielding.

8 However, there might be issues with that,
9 you know, oversized load and things like that, that we
10 have to take into consideration.

11 This is very early in the design. We have
12 no contracts out yet about this. Los Alamos is still
13 looking at what it is going to take and what we can
14 take within that container. If the container, we find
15 out, okay, we design this 100,000-pound container, it
16 can only transport 10 curies of cobalt, is that worth
17 \$5 million, \$10 million to pursue that option?

18 So that is what we are looking at. So,
19 you know, it's been said many times in the last two
20 days that disposal isn't a huge problem right now, you
21 know, even for DOE taking ownership. We don't have
22 the solution to that. That's not just greater than
23 class C that DOE EM is working on but class A, B, and
24 C waste as well. You know, since they're sealed
25 sources, you know, the small sealed sources don't even

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1 have an option at Envirocare in Utah since they are
2 sealed sources and you can't dispose the sources
3 there.

4 So we have to look at issues and solutions
5 to the other sources. I wish I had the solution for
6 these. So we are looking at both disposal solutions
7 and looking at ways of transporting these once they
8 become disused and unwanted, which hopefully will help
9 not having these stored in unsecured locations. And
10 once we take ownership of them, we do have a secure
11 storage site pending disposal.

12 Thank you for your time.

13 (Applause.)

14 DOE/NNSA RECOVERY PROGRAM

15 ISSUES ASSOCIATED WITH PICK-UP OF SOURCES

16 MR. DANSEREAU: The problem with being
17 last is I have a lot of information here that is
18 redundant. I will try to avoid that, though, to spare
19 you.

20 We look at the NRC's draft policy
21 statement as it relates to disposal. I think it is
22 well-done because we talk about the need for long term
23 developing a pathway for long-term storage as well as
24 disposal.

25 We look at the Task Force's challenges and

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1 recommendations related to disposal. They're really
2 talking about disposal. They don't address the
3 long-term storage issue.. But NRC has captured the
4 need for the disposal. And we do see that for the
5 presentation, DOE is working towards finding a
6 solution and developing capacity for disposal.

7 So what are some of the general issues
8 that as a regulator we see with disposal of cesium
9 chloride? Well, one option for disposal would be to
10 transfer it to an authorized recipient. We don't see
11 a lot of that except with some smaller devices, small
12 instrument calibrators, millicurie quantities. But,
13 nonetheless, that is one path for reuse.

14 What I haven't heard much about is the
15 potential to recycle cesium chloride. What happens to
16 some of these disused sources where the capsule cannot
17 be used further? Because they have decayed away to a
18 level they are not useable. Is anybody looking at
19 means to recycle the cesium chloride, rather than to
20 start with virgin material or add more cesium chloride
21 to what is available out there?

22 I think I heard from one of the speakers
23 that there is some firm in Germany that recycles
24 cesium, but I haven't heard anything here and I don't
25 know if that has really been evaluated and if so how

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1 much that would really reduce some of the disposal
2 issues or quantities for disposal, I should say.

3 So right now in New York, we have had a
4 number of licensees who have been able to take
5 advantage of the Off-Site Recovery Program. We are
6 very fortunate to have that.

7 Some issues with that, there is a high
8 demand. You heard there is a long list of sources on
9 that register. And it can take some time before these
10 sources are actually removed.

11 There are issues with the shipping
12 containers. You heard the availability of them.
13 There are very few shipping containers. So that takes
14 time.

15 Currently we have -- well, in the next
16 slide, I will show you that, but bids have to be put
17 out, contracts signed, and so forth, for the vendors.
18 There are very few vendors that do this work.

19 Who prioritizes these disposals? If a
20 facility registers a source, they wait to hear until
21 there is a roundup in their area or they are going to
22 be selected for pickup.

23 Of course, everything is related to
24 funding. DOE Off-Site Recovery Programs, like
25 everybody else, they're limited by their funding.

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1 We have a unique case in New York, leaking
2 -- I should say suspected leaking sources in the
3 Gammacell 40 unit. If this had been actually -- I put
4 the wrong date here thinking that was the anniversary.
5 That happened one year ago today, not 2010. Today is
6 the anniversary of that event being reported to us.

7 Very unique. We have very few cases of
8 leaking sources reported to us. There are certainly
9 no sources of this type of activity.

10 The technicians, engineers working on the
11 unit noticed some corrosion on the source drive
12 mechanisms. They did some wipe testing and found
13 activity. That was later identified as cesium-137.

14 The quantity on the leak tests did exceed
15 the leak tests, regulatory leak test limits. So we
16 are considering these leaking.

17 According to regulation, leaking sources
18 have to be taken out of service. They can be put back
19 into service if they are repaired. I'm not even
20 certain who would do repairs. I've never heard of a
21 source of that magnitude being repaired. These things
22 are in the regulations, but sometimes we don't
23 question them until we encounter the situation.

24 And who can repair sources? What would
25 that cost? And is it even a viable option for

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1 something like this? These are questions they raised
2 I have no answers to.

3 Obviously the research is affected at this
4 facility. That is a decision they will have to make
5 as to how they are going to continue their research.

6 And also we have heard some people talk
7 about the life cycle of these units. Obviously this
8 is a premature end of that life cycle. The unit has
9 been in service since 1975 and, as far as I know,
10 still has a lot of life left to it, service life left
11 to it.

12 The leaking source, just to touch on the
13 leaking -- I don't have a slide for this on the
14 leaking source -- again, a very unusual occurrence for
15 us to hear about that. We got some information
16 through the NRC from Southwest Research Institute.
17 Now, Southwest Research Institute has about 50 years'
18 experience of decommissioning sources. They have I
19 think collected nearly 3,000 sources. They found six
20 to be leaking, though I don't know what information on
21 what activity sources.

22 They also indicate that 25 to 50 percent
23 of sources had contamination on them. And that
24 contamination in some cases exceeded the leak test
25 limit.

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1 However, they determined that those
2 contaminated sources are not from leaking. Rather,
3 they were from leaching, cesium and other materials
4 that were trapped in the weld during manufacturer.
5 There is weeping or sloughing off over time.

6 So what do we do? Oops. I've got my
7 slides out of order here.

8 So just, in summary, you know, I think in
9 the New York State perspective, we are very fortunate
10 to have the Off-Site Recovery Program in place.
11 Otherwise, a lot of these sources, including the ones
12 I just spoke about, would remain there indefinitely.
13 And that is not a good situation.

14 It does take time to make these
15 arrangements. Our licensee who has the leaking
16 sources is still storing those, although I believe
17 that pretty soon those will be picked up by the
18 Off-Site Recovery Program.

19 After these sources are picked up, I think
20 there is a need to assess the sources to determine are
21 these leaking? And that can only be done by very
22 limited -- there is very limited capability for that.
23 And I believe Southwest Research Institute will be
24 looking into that issue.

25 The phenomenon of leaching was new to me

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1 and I think probably new to quite a few people. I
2 think we need a little more research and understanding
3 of that process or that phenomenon.

4 I think there are certain records on the
5 way to identify permanent disposal options. We just
6 heard about that. Then again I'm not really certain
7 I've heard much or anything, really, about recycling
8 of the material or repair of such sources to get them
9 out of at least the immediate disposal need,
10 eventually disposal need but the immediate need.

11 Thanks.

12 (Applause.)

13 FACILITATOR BAILEY: Once again, at this
14 time we are going to entertain your questions if you
15 have any, and we will entertain your comments.

16 STATEMENTS & ROUND TABLE DISCUSSION

17 MR. WAGNER: Steve Wagner, American Red
18 Cross.

19 I have a question. I am not sure who to
20 direct it to, but it seems to me like it's going to
21 take a fairly long time before there is some permanent
22 disposal option that has been clearly identified and
23 that would be able to be put in use.

24 I guess my question is, has anyone been
25 doing any thinking about intermediate term storage for

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1 disused or abandoned sources in such a way that it
2 could be held in a secured fashion, perhaps protected
3 by the government, perhaps taking advantage of the
4 fact that there are Department of Defense facilities
5 that might be able to guard these sources, unwanted
6 sources, better than civilian organizations? And has
7 there been any thought about how there might be some
8 intermediate solution prior to putting into place a
9 long-term disposal?

10 MR. ZARLING: I can try to answer that.
11 And I can give you an example. The GTRI OSRP program,
12 if we are notified of the unused/unwanted source --
13 and I'll use an example of in New York City, recently
14 we recovered a irradiator from a hospital that went
15 out of business.

16 So we do take -- you know, if we find out
17 things like that, we will work with the state
18 regulators, NRC, and we will go and recover that
19 disused, unwanted source. And we do have secure
20 storage.

21 And, as I said during the talk, there is
22 -- we do have limited disposition capabilities, but we
23 don't have -- we can't dispose of absolutely
24 everything. So we do -- at Los Alamos plus other
25 secured storage sites, we do take some of those

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1 sources in if we do know that they are there, going to
2 be unprotected.

3 MR. WAGNER: Because there are a lot of
4 irradiators that are beginning to get close to 30
5 years old. I imagine that the facilities may either
6 want to replace them with similar sources or perhaps
7 go to X-rays. But we can't just keep on accumulating
8 these sources in these buildings that have certain
9 lifetimes. There has to be some at least
10 intermediate-term solution.

11 MR. ZARLING: I agree. The only thing I
12 can answer about that is these are -- as they come to
13 the end of their life, please do register them at the
14 OSRP website database so we know that they're disused
15 and unwanted.

16 If we don't know or if someone else or the
17 manufacturer doesn't know or anyone doesn't know these
18 are disused and unwanted, then, you know, at that
19 point, I think, as you are saying, they become
20 unsecured.

21 And so I urge anyone in the audience to
22 tell people that you know that these disused and
23 unwanted sources do register with the OSRP. And we
24 will get into contact with you.

25 And we will prioritize, you know,

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1 especially going out of business. And let's say we do
2 work with the NRC. If they're going out of business
3 or if it's already out of business, we will work and
4 make that a high priority to recover that and secure
5 it.

6 MR. WAGNER: A lot of these places are
7 still in business but cannot afford disposal and may
8 not even be able to afford transportation costs.

9 MR. ZARLING: Yes.

10 FACILITATOR BAILEY: Thanks.

11 MS. FAIROBENT: Lynne Fairobent with AAPM.

12 I just want to second what you were saying
13 as far as registering not only the disused and
14 unwanted sources but sources that meet the SCATR
15 criteria.

16 Without having the data in the database,
17 we cannot appropriately lobby Congress for funds or
18 for a solution given that we have so few states who
19 have disposal options. And that data is absolutely
20 critical as we look to move forwards with the program
21 and working with GTRI and the Conference of Radiation
22 Control Program Directors.

23 MR. ZARLING: And I forgot to mention that
24 during my talk. We also do work with CRCPD in the
25 SCATR Program. And the way that is working right now

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1 is in states with disposal options, SCATR Program will
2 collect the smaller, lower-activity sources and in
3 all-radium I'm going to say in all-radium because
4 radium does have disposal at American Ecology up in
5 Hanford.

6 The only way we know and CRCPD knows about
7 that, they do work again with the OSRP at Los Alamos
8 in their website. So it is the same registration
9 process.

10 You've got to go online to osrp.lanl.gov
11 and register it. Then they will forward that
12 information to CRCPD so they have that information and
13 they can start working with the licensees to recover
14 those sources.

15 FACILITATOR BAILEY: Thank you.

16 Mary?

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

19 Maybe I've addressed some of the issue. I
20 have to collect my thoughts. There are a lot of
21 things going on here.

22 The manufacturers that are in existence, I
23 believe Nordion, if you buy a new irradiator, you have
24 the option of sending the old one back to your
25 manufacturer.

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1 There are some costs involved in that.
2 They are not a free service, like OSRP is,
3 unfortunately. But the costs to sending an old one
4 back or if you want a private disposal is well within
5 the financial surety that every licensee has had to
6 put up to the disposal of an irradiator. And I don't
7 think we have ever exceeded those costs.

8 It is interesting. I come from a
9 different perspective because I think a cesium
10 chloride source and an irradiator is a product. Just
11 because it is an unwanted product or an unneeded
12 product at that time and we as a company have never
13 considered those as waste, it should be something,
14 recycling is something that we have been allowed to
15 do.

16 Our license allows us to do it. We have
17 been doing it for years. Again, you can't compete
18 with free, but it is an option. It is a very good
19 option. It reduces your full cesium footprint
20 throughout the entire country. You are allowed to
21 recycle a source. You are not bringing lots more
22 sources in and looking to do a land burial. It is
23 unwanted at that point in time.

24 It comes to a secure facility. Our
25 company is involved in increased controls, and we are

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1 doing the GTRI upgrades. At that point in time when a
2 new source goes out, it goes out to a client that is a
3 licensee who also meets the increased controls.

4 As I spoke yesterday, we make sure we ask
5 the licensees and don't ship until they have assured
6 us that their increased controls are in place. It's
7 just not the building that is finished, but your
8 increased controls are in place before you receive a
9 large cesium source.

10 Besides cesium chloride, there are other
11 sources: Cobalt-60. I believe I4 has a program where
12 they like to -- I don't know how well they have been,
13 how established they are doing it -- to reactivate
14 spent cobalt sources. That is a domestic program.
15 So, again, you are taking unusable cobalt and making
16 it reusable and reactivate it and make it into a new
17 product.

18 There are recycling options available. As
19 I said, you know, since we are commercial, it is not
20 free. So we can't compete with free.

21 The nice thing about a recycling, you're
22 transferring the source to a specific licensee in that
23 transfer to -- like somebody with a license, whether
24 it's a facility that transfers it to another
25 university and a hospital, you don't have the

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1 continuing liability. The person who gets that source
2 has the residual liability for that source.

3 One of the reasons why transferring
4 between licensees doesn't happen a lot is because of
5 the licensing, the process. People that need to get
6 rid of a source, they may not have the six to nine
7 months or longer to wait for the recipient licensee to
8 get their source. So if you go back to the
9 manufacturer, we take on that liability and wait until
10 there is a use for that source. That is why you don't
11 see a lot of the licensee-to-licensee transfers going
12 on, which is because by the time in my personal
13 experience, people don't have the time to wait for the
14 new license to come.

15 And we already talked, somebody had
16 questions about the costs for moving. The type B
17 containers are very expensive to move. You just can't
18 use commercial mode of freight to do a relocation
19 anymore.

20 There are transportation security
21 requirements. You have to have certain bedded trucks
22 to use. All of that is it's a soy use truck. Soy use
23 truck is like chartering your own airplane, you know,
24 your own private jet. It is not an inexpensive
25 process, plus the rigging.

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1 And rigging is always interesting. It
2 depends what it takes to get it out and get it to you.
3 And sometimes that can be very easy and very
4 inexpensive. Sometimes that can cost you thousands
5 and thousands of dollars. It just depends on each
6 individual facility.

7 The irradiator is a big, heavy piece of
8 equipment. They have to be moved safely. Nobody
9 wants to put one on an elevator and watch the
10 irradiator go five floors to the basement without an
11 elevator operator working it. You know, that's not
12 anybody's objective in life, is to have an incident
13 like that. It probably will survive the drop test,
14 but headaches would be just astronomical, plus all the
15 reviews and the television coverage and not a good
16 thing to do.

17 For OSRP, doing a versatile-type fee
18 package is not an easy process. I have been through
19 it. It is fraught with things they never tell you
20 about. There is no guideline that gives you all of
21 the little ins and outs for a type B package until you
22 actually get into the modeling. And what looks good
23 on paper, what looks good engineered, the modeling
24 will totally trash that design, like eight models into
25 incidental transport requirements. So that gets

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1 interesting. And the cost to develop new packages is
2 very high. It is not an easy process.

3 For recycling, I think Joe Ring yesterday,
4 cesium and cesium sources, cobalt sources, they're an
5 asset. They're an asset until somebody no longer
6 needs them. And just because somebody doesn't need
7 them, I don't think they need to be referred to as --
8 they're an asset. They're an unwanted asset, but
9 they're something that is still highly useable.

10 And, regarding Southwest, I'm sure they
11 are going to look at those sources. That project is
12 going forward. I think what they will find is that it
13 is a contamination problem and not a leaking source
14 problem because we found the same things at our
15 facility.

16 Very rarely will you find a leaking
17 source. And it is even rarer that you find a large
18 leaking source if it's by Oak Ridge or one of the
19 national labs. There are very, very few instances of
20 that.

21 And another point I wanted to make. On
22 our sources since we have been doing this a long time,
23 the legal shipping limit used to be .05 microcuries.
24 That's what you were allowed to distribute years ago
25 when you are talking about the old sources. You will

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1 often see 0.5 microcuries, which was legal at that
2 time.

3 Since we have gone to .005 microcuries,
4 sometimes that raises alarm bells with people. And
5 that is another reason why leaking sources are
6 sometimes reported but aren't actually leaking
7 sources, like in this case, I think this is above that
8 and probably well above. But that is also something
9 everybody should take into consideration of all the
10 sources.

11 FACILITATOR BAILEY: Thank you.

12 Any other questions or comments?

13 MR. DANSEUREAU: A question here. I would
14 like to ask Mary Shepherd that. When I was referring
15 to recycling the cesium, I really didn't mean the use
16 of the source or the disassembly of the source for
17 another purpose to incorporate in a different product.
18 It could even be -- I don't know if this is feasible
19 to use that cesium chloride for the different forms,
20 ceramic or other forms. That is really what I meant
21 by recycling, not reuse.

22 For example, a leaking source, could you
23 recapture that cesium chloride and use it for the new
24 source?

25 MS. SHEPHERD: Mary Shepherd, Shepherd and

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1 Associates again.

2 It is definitely possible. Cesium, what
3 we do for recycling is actually reencapsulations. We
4 do not take out the cesium chloride for reuse or
5 reblending. For the activity levels that we deal
6 with, we would become a Superfund site, and that is
7 not our intention. We really need to be a
8 government-type facility to do that with those kinds
9 of protections.

10 The smaller cesium source manufacturers do
11 do that. And that is a possibility. I think Eckert
12 and Ziegler, GSA Global, I think those two, at least
13 as far as I know, they were doing some small-scale.
14 And it's just not cesium, isotope recycling.

15 FACILITATOR BAILEY: Cyndi?

16 DR. JONES: Cyndi Jones with the NRC.

17 One point of clarification. I want to
18 make clear that "disused and unwanted" sources does
19 not necessarily mean "unsecured." I think the NNSA
20 person from GTRI can confirm the source that was
21 picked up from that hospital was not abandoned and
22 unsecured. It was awaiting pickup by GTRI program.
23 Can you also confirm that, please, for the record?

24 MR. ZARLING: John Zarling from NNSA.

25 That's correct. The hospital was going

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1 out of business. And it made it top priority to
2 recover that source so it wouldn't become abandoned in
3 that hospital.

4 DR. JONES: Right. But in that case, the
5 licensee, as we have heard the last few days and also
6 before, has a responsibility to keep it secured in
7 storage at that facility. And we appreciate the
8 efforts of GTRI to be able to pick that up, but that
9 was a coordinated, planned pickup, not abandoned in
10 place and then picked up. I just wanted to make that
11 clarification.

12 One question that I have for -- I think
13 it's you, John. You mentioned that there were 48
14 large cesium chloride sources that were recovered by
15 GTRI. Can you clarify -- were those U.S. sources --
16 what the categorization was?

17 It may be on your slide with the pie chart
18 that we saw earlier and also if there were
19 prearrangements, plans to have these sources picked up
20 by GTRI. In other words, they had been registered on
21 your site for pickup, but they weren't abandoned and
22 unsecured.

23 Thank you.

24 MR. ZARLING: So all 48 sources were
25 recovered here in the United States, so U.S. origin.

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1 This is since 2006. This is where I went back. There
2 were previous sources, a bunch of cameras that were
3 recovered historically.

4 I don't know for sure, but I would hazard
5 to guess that none of them were abandoned. These
6 large sources, you know, I don't think -- I have never
7 heard of a large source, cesium chloride source, being
8 abandoned. There have been -- you know, we have seen
9 small iridium sources that have been abandoned but
10 never -- when I say "smaller," I'm talking millicurie
11 of iridium sources, odd stories where a doctor took it
12 home because of the hospital event and he kept it in
13 his barn for 40 years and he died and no one knew
14 about it. And that's -- but not a cesium source. So
15 no.

16 DR. JONES: That's our understanding as
17 well. I just wanted to clarify it for the record in
18 case a question came up.

19 And if any of the panelists could, just
20 for the record and for our knowledge as well and for
21 the individuals that will read this transcript in the
22 future, you said that there was a very limited number
23 of type B containers in the U.S. Can you give us a
24 ballpark figure of what "very limited" means? Is that
25 less than ten? Is it less than 100? Is it two? Just

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1 kind of a ballpark figure would be good I think for
2 the Commission to have on hand.

3 Thank you very much for your
4 presentations.

5 MR. ZARLING: I guess I am going to try to
6 answer that one again. Currently in the United
7 States, you know, I will say Best Theratronics has
8 containers for all their devices. So that is not an
9 issue. It is all the other devices out there.

10 And JL Shepherd currently has a container,
11 the 20WC, that is under special permit that they can
12 use. GTRI tried to get a special permit on 20WC, and
13 we were denied. So we rely on industry.

14 So, I mean, in the United States, for a
15 licensed container that can carry sealed sources, you
16 know, essentially it's the 20WC right now is about the
17 only thing out there. The 10-160B they cannot do
18 sealed sources until they remodify their certificate.

19 There are other containers out there that
20 can do sealed sources but only sealed sources. I
21 don't know. When I say, "only sealed sources," I'm
22 not talking devices, you know. That's why the
23 20WC-type container, DOC spec 20WC-type container was
24 a great container because you can do a device. Some
25 of these other type B containers out there, certified

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1 type B containers, the cavity size is not large enough
2 to accommodate a lot of the cesium chloride devices.

3 And, as you can guess, trying to do a
4 field transfer into a container of a 3,000-curie
5 cesium source is not the easiest thing in the world to
6 do either. And you don't want to be doing that at a
7 hospital or in public. It is possible. I am not
8 saying it is not impossible, but that is not an ideal
9 solution.

10 So, to answer your question, for here in
11 the United States, domestically, as I said, Best and
12 -- I don't know -- for the Gammacell 40 and the GC1000
13 and 3000, they have containers. So there are the
14 three there, the 20WC. There are four.

15 I know Best can transport some of these
16 devices, but they only have an import and export
17 license. So if they do the recovery, the device has
18 to go back to Canada or outside the United States. So
19 that's why I said it is very limited.

20 I would say that truly for the application
21 that GTRI does, it's the 20WC right now. There is the
22 GE2000, but that's a scheduling nightmare on that.
23 There are only three of those total in existence, and
24 they are heavily used by GE to move their material.
25 So you may have a two-week period of time once every

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1 three months to use the container. So it's not an
2 option for a recovery, an emergency recovery.

3 MR. DANSEREAU: This is Bob Dansereau, New
4 York Health.

5 In regard to the New York City Hospital,
6 whenever an hospital closes or merges in New York,
7 they have to file a closure plan. And those plans
8 always include disposition of radioactive materials.
9 So the Department of Health, my program needs to close
10 out that license as just one component of shutting
11 down the hospital.

12 FACILITATOR BAILEY: Any additional
13 comments from the audience or questions at this time?

14 (No response.)

15 FACILITATOR BAILEY: Okay. If we could
16 one more time give the panel a round of applause?

17 (Applause.)

18 FACILITATOR BAILEY: I would also like to
19 thank each panelist that participated throughout the
20 past two days and to the audience who helped
21 contribute to the comments and the questions that will
22 help the NRC better prepare the draft statement.

23 Now I would like to introduce Mr. Rob
24 Lewis -- he is the Director for Materials and Safety
25 and State Agreements -- for the wrap-up and the

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1 closing.

2 WRAP-UP AND CLOSE

3 MR. LEWIS: Okay. Good afternoon. I have
4 the honor of closing what I think was a very
5 successful meeting. I am not going to try to
6 summarize the discussions in the fashion that Cyndi
7 did this morning for yesterday's discussions. As much
8 as I would like to, I don't have the memory capacity.
9 And also it conveniently allows me to avoid talking
10 about waste. So I won't do that.

11 Also, first and foremost, I wanted to
12 thank all the participants. This was a very important
13 meeting for us, as was the meeting, very similar, two
14 years ago. I cannot overstate how much that meeting
15 weighed upon the Commission's decision to issue the
16 draft policy statement in the way that they did. And
17 in the same manner, the discussions and the
18 transcripts from this meeting will be very valuable to
19 the Commission as they decide on the final policy
20 statement. We owe it to them in April, shortly after
21 April.

22 Also, I would like to thank you for your
23 time. I know that your time is very valuable. And to
24 be here, you took away from your businesses or even in
25 some cases from patients. And that's very significant

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1 for me personally but also for all of NRC. So we very
2 much value your views here today.

3 I also wanted to thank Cyndi and John and
4 Sarenee and Ken for finding this facility for us and
5 all the work and the logistics in creating a good
6 agenda for us and bringing everyone together. So if
7 you could join me in a round of applause for them?

8 (Applause.)

9 MR. LEWIS: We had a wide representation
10 from regulators, other parts of the government, from
11 users, medical users, research users, and calibration
12 people, from all the major manufacturers of both
13 sources and devices, and also from professional
14 societies. So I think that in these two days, we
15 really spent all the aspects of use of cesium chloride
16 quite thoroughly.

17 You know, as narrow a type of activity
18 this is in the great scheme of things, it is such
19 widely used by many different types of uses and many
20 different users that it is just starting.

21 We walked through the agenda. Our eight
22 points in our policy statement kind of mirrored our
23 agenda. And I guess I will summarize what I will
24 bring back to the Commission and to the NRC senior
25 management.

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1 I didn't really hear anything that will
2 cause a major course correction, us to recommend a
3 major course correction in what is in the policy
4 statement that is here. In fact, I heard a lot of
5 things that affirmed what is in the policy statement.
6 Although there are some things that we want to look at
7 and tweak, I would characterize them as minor.

8 A couple of those types of things, in
9 terms of where we are today versus two years ago or a
10 couple of months before two years ago, when the
11 National Academy's report first came out, I think that
12 we have much more quantitative information versus
13 anecdotes. And that is the place we really need to be
14 for the Commission to make good public policy and a
15 fully informed decision on that policy.

16 There are about 1,100 radiators at 650
17 locations, most of which, of course, are in Agreement
18 States, but because a lot of the irradiators are used
19 in federal facilities, it isn't the same fraction as
20 some of the other types of licensee, but,
21 nevertheless, they are most in Agreement States.

22 We got a lot of good feedback in the last
23 couple of days on the increased controls in Part 37
24 and how those activities fit into what we say in the
25 policy statement. And I think we have to look there

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1 to make sure we're saying everything the right way.

2 The timing is good in that respect because
3 Part 37 public comment period ends in December for
4 both the rule and the guidance. And please do put
5 comments in on that.

6 DR. JONES: January.

7 MR. LEWIS: In January. Thank you, Cyndi.
8 Excuse me.

9 This policy statement's comment period
10 ends December 17th is what I meant to say. And the
11 Part 37 is shortly after that. So the timing actually
12 works very well. Please submit comments in both
13 places so that we can formally consider them in both
14 places as well.

15 I think there are also some issues we need
16 to look at in terms of what is out there in the field
17 in existing devices versus what we can do for new
18 devices. We didn't talk a lot about that in the last
19 couple of days, but the policy statement did make it
20 clear that for new devices, we think we can do better.
21 We can add design improvements.

22 You heard Mary just make a comment, from
23 JL Shepherd, about arrangements to retake the -- think
24 about the end of the life of the device before it's
25 purchased and put in place, such as returning to

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1 vendor. I think there are some issues we can explore
2 there on what we have in the policy statement,
3 distinguishing between existing devices in the field
4 and new devices in the future.

5 The path forward will really be defined by
6 the Task Force and by the policy statement. Those two
7 documents will be working in conjunction. We will
8 deliver the draft policy statement to the Commission
9 in April.

10 The Task Force, as John mentioned in his
11 talk and as you can see from the copies out back, has
12 several recommendations related to cesium chloride
13 that we will be working over the next four years.

14 As NRC, we have been striving to put the
15 Task Force as the primary vehicle to move these issues
16 forward across the government because the fact of the
17 matter is across the government, there is a wide range
18 of views about this material. And that is not going
19 to end. I mean, there is going to be continued
20 detention on cesium chloride and what we are doing
21 about it. Meetings like this are the best way to show
22 what we are doing about it.

23 We will, at NRC, move forward in a very
24 deliberative way and fully consider the uses. And
25 everything the Commission said today has been very

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1 clear about that. We have to consider the uses, the
2 beneficial uses in any decision about the future uses
3 and, as we heard this morning, the real benefit to
4 patients versus the theoretical detriment to other
5 actions. And we are very mindful of that. We hope we
6 are. If we are not, tell us.

7 Also, I think that the expectations across
8 the government will, as I mentioned, continue to
9 evolve. Expectations from Congress on this particular
10 issue will continue to evolve. We will be asked, you
11 know, what has the government done in response to the
12 National Academy study? How have we dispositioned
13 their findings, if we have? All those questions are
14 ahead of us.

15 So it is a long story. What I can commit
16 is that as we move forward, we will continue this
17 engagement because it is one thing for NRC staff to
18 say this is the way it should be, but it is a totally
19 different matter for the Commission and all the
20 policy-makers for users, for us to say, "Here is what
21 the user said this will cost." And that is where we
22 have got to be. And this meeting was very good for me
23 from that point of view.

24 So thank you again very much. Safe
25 travels home for everybody. And that concludes the

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1 meeting.

2 (Applause.)

3 (Whereupon, the foregoing matter was
4 concluded at 2:37 p.m.)

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