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## NUCLEAR REGULATORY COMMISSION

Title: Stakeholder Workshop on the Security and Continued Use of Cesium-137 Chloride Sources

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1	UNITED STATES OF AMERICA
2	NUCLEAR REGULATORY COMMISSION
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4	STAKEHOLDER WORKSHOP ON THE SECURITY AND CONTINUED
5	USE OF CESIUM-137 CHLORIDE SOURCES
6	+ + + + +
7	MONDAY
8	SEPTEMBER 29, 2008
9	+ + + + +
10	ROCKVILLE, MARYLAND
11	+ + + + +
12	The Workshop was held at the Bethesda
13	North Marriott and Convention Center, Foyer C, 5701
14	Marinelli Road, at 8:45 a.m., Lance Rakovan,
15	Facilitator, presiding.
16	PANELISTS:
17	PANEL 1:
18	ALBERT ALOY
19	DAVID COPPELL
20	MARK MAIELLO
21	BRAD PATTON
22	JOHN SCHRADER
23	LYNNE FAIROBENT
24	
25	
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1	PANEL 1.2:
2	LEONARD CONNELL
3	JOHN FIKE
4	JOSEPH KAMINSKI
5	WILLIAM MCBRIDE
6	JOSEPH RING
7	DAVID COPPELL
8	GRANT NIXON
9	
10	PANEL 2:
11	BILL FITZGERALD
12	JED GORLI
13	MARK SVAJGER
14	RANDOL KIRK
15	DEBBIE GILLEY
16	ORHAN SULEIMAN
17	STEPHEN WAGNER
18	JOSEPH KAMINSKI
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1	ALSO PRESENT:	
2	COMMISSIONER PETER B. LYONS	
3	ROB LEWIS	
4	KEVIN CROWLEY	
5	JOHN JANKOVICH	
6	CYNTHIA JONES	
7	MICHELLE KILLIAN	
8	CHARLIE MILLER	
9	TOM MORGAN	
10	BLAIR MENNA	
11	LANCE RANKOVAN	
12	MARY SHEPHERD	
13	TOM WASIAK	
14	ORHAN SULEIMAN	
15	MOJI MOSHAASHAEE	
16	JERRY THOMAS	
17	LES JARDINE	
18	BRIAN POWELL	
19	ED GERSABECK	
20	RONALDO MINNITI	
21	PAUL MOSES	
22	MIKE RYAN	
23	GAMAL AKABANI	
24	PETER ZIMMERMAN	
25	JERRY THOMAS	
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1	STEVE	ROGERS	
2	STEVE	FORASTE	
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1	PROCEEDINGS
2	(8:45 a.m.)
3	MR. RAKOVAN: Good morning everyone. I
4	got a little bit of reaction there. My name is
5	Lance Rakovan. I am a communications specialist at
6	the Nuclear Regulatory Commission and it's my
7	pleasure to facilitate this two-day workshop on
8	cesium chloride. The main focus of the meeting, of
9	course, is to have some discussions about the issue
10	at hand. But before we start those discussions,
11	there's a few presentations that we'd like to have,
12	just to give a little bit of background on the
13	subject.
14	Please note that we've extended the
15	comment period for written comments from September
16	30th to October 15th. The extension was published
17	in the Federal Register last week. Copies of this
18	Federal Register notice are also available outside
19	on the registration table.
20	As I said, we're going to start the
21	workshop with a few formal presentations. Following
22	the presentations, we'll proceed to the roundtable
23	discussions after a short break. We should be
24	starting with the discussions around 10:15, 10:30,
25	following Commission Lyons' address to the workshop.
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1	Again, at the registration table we had
2	copies of the Federal Register notice and the
3	agenda. There was also some copies of other
4	materials, and a feedback form that you can fill out
5	for us on our public meetings, if you'll just take a
6	moment and fill that out today, or you can do it
7	afterwards and drop it in the mail. It'll get to
8	us, there's no postage necessary, and that gives us
9	an idea of how we can improve these workshops.
10	So if you could take a moment to do
11	that, that would be a great help to us. If there's
12	not copies of all the presentations that you'll be
13	seeing today, we plan to post them on the Cesium
14	Chloride Workshop Web site following the meeting, so
15	that you'll be able to see them after the workshop.
16	I'll be back again before we start the
17	panel discussions, just to go over some ground rules
18	and such, but at this point, the agenda for the
19	morning, like I said, has some presentations, so I'm
20	going to turn things over to Rob Lewis. Rob.
21	MR. LEWIS: Good morning everybody.
22	It's always nice to have a big neutral zone between
23	the speaker and the audience. I'm Robert Lewis.
24	I'm the NRC's Director of the Division of Material
25	Safety and State Agreements. Together with the
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1	Office of Nuclear Security and Incident Response,
2	we're hosting this workshop. And welcome. It's
3	NRC's Workshop on Security and Continued Use of
4	Cesium Chloride Sources.
5	Now we do view those as two discrete
6	topics as you'll see in the agenda, cause I think
7	continued use or phaseout, or alternative
8	technologies need to be considered, together with
9	additional security measures that might be
10	complementary or achieve the same end objective.
11	Thank you, first of all, from NRC, for
12	preparing for this workshop and for your
13	participation in this workshop, especially those
14	roundtable participants and those that have traveled
15	some distance, including international travelers.
16	We have collected here today, I think a
17	wide-ranging set of expertise, and participants that
18	can speak authoritatively on cesium chloride, its
19	uses, and the impacts of any changes to its uses.
20	We have people from industry, the
21	source-manufacturing industry, device manufacturing
22	industry, the medical industry, including doctors
23	and administrators of hospitals, research
24	facilities, calibration licensees. We have
25	representatives from government, from Federal
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1	Government as well as state government. Several
2	different agencies across the Federal Government are
3	working on cesium chloride issues.
4	We have representatives form
5	nongovernment organizations, and I particularly want
6	to thank the National Academies for being here
7	today. Much of what we're doing here today is
8	resulting from recommendations they made in a report
9	earlier this year.
10	And we have I think also some
11	international participants. So thank you, again,
12	for traveling so far, and for your interest in this
13	topic, and congressional staff interest as well.
14	The participation reflects the
15	importance of this subject. If not approached
16	properly, I firmly believe that this activity has
17	the potential to impact the lives of patients in
18	hospitals, and also the way we do business in
19	research, in calibration.
20	I would like to use my time to talk
21	about NRC would like to accomplish from this two-day
22	workshop, and also describe a little bit about how
23	we got to this point.
24	In terms of what NRC would like to
25	accomplish, this is a workshop, it's not a seminar
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1	or a conference where we just have speakers come, a
2	procession of speakers, very informative maybe, but
3	this is a workshop where we are depending upon
4	active participation to get views.
5	I think, as I mentioned earlier, this
6	audience is very unique, and probably never been
7	assembled beforethe expertise and knowledge of the
8	uses of cesium chloride that is in this room right
9	now. And your participation of course is essential
10	in all of the topical areas. We want to
11	specifically hear what you perceive to be the
12	impacts of phasing our cesium and replacing it in
13	the future, for future devices, but also phasing out
14	cesium chloride and its use for existing devices and
15	replacing those devices with alternatives, be they
16	different sources, different types of source such as
17	cobalt, different form, chemical forms of cesium or
18	different technologies such as x-ray.
19	We also want to brainstorm alternatives
20	on security of cesium chloride. We have increased
21	security of these sources in their settings, quite a
22	bit in the last several years, and we're at a point
23	where we have a great deal of experience in what the
24	security has done, and it's time to reflect, I
25	think, upon how to improve that, perhaps as an
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1	alternative to replacing the existing sources.
2	It's also fair game to say that the
3	security that we have is adequate. So if that's
4	your opinion, let us hear that.
5	Now as the regulator, we don't have all
6	the answers here. We have been charged, I think,
7	with looking into alternatives as a regulatory
8	action, but we don't have the experience in the use
9	of the material or the experience as licensees, or
10	even as members of the public, that is necessary to
11	bear upon what would be the impacts of phasing out
12	such long-standing successful devices that have real
13	impacts upon people's health and safety, and
14	research, and the value of research.
15	No one group has those answers. In
16	preparing for this workshop, we've talked to many of
17	you individually, and I guess I would characterize
18	those discussions as everybody has their own little
19	anecdotes about whether x-rays or cesium chloride is
20	better, better in a business sense, better in a
21	technological sense. You know, all kinds of
22	anecdotes. Anecdotes about research that had been
23	done several years ago to replace them, and whatever
24	happened to that research.
25	What we need, though, for regulatory
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1	decisions is not anecdotes but a collective
2	consensus of the impacts. Regulatory impacts to
3	safety, to security, and to cost, and to the
4	environment.
5	Let me turn, briefly, now, to how we got
6	to this point.
7	Cesium chloride is of course a salt.
8	It's a powdery salt that is compressed and formed
9	into sealed sources, and used in large-curie
10	quantities, primarily in blood and research
11	irradiators, also calibration irradiators throughout
12	the world.
13	There is one manufacturer currently of
14	cesium chloride in Russia, and it produces the
15	world's supply, and then the sources are then sent,
16	manufactured and sent to device manufacturers of
17	various types.
18	There's three main vendors of the
19	irradiators in the U.S., but again, it is used
20	worldwide. Cesium chloride is a highly-dispersible
21	salt and it's very soluble. So in a lot of ways,
22	even putting security aside, it's not an ideal
23	material to make sources from, and, in fact, there
24	have been, over the years, many studies on replacing
25	cesium chloride, especially after the incident in
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1	Goaiana, Brazil, in the late '80s, when a cesium
2	chloride source was taken apart by some local people
3	and some very serious health effects occurred.
4	That really started the IAEA down the
5	road of looking at source safety and security, and
6	of course then we had the terrorism attacks of 2001,
7	which put additional focus on the security aspect.
8	That all resulted in development of the
9	Code of Conduct for sources, and the NRC has used
10	the Code of Conduct with the rest of the U.S.
11	Government to establish levels of security which
12	need increased controls.
13	The increased controls orders were
14	issued in 2005 to all the NRC licensees and to the
15	Agreement State licensees around the country for
16	large-curie quantities of cesium chloride. So blood
17	irradiators and research irradiators essentially all
18	got the increased controls requirements.
19	Those have substantially increased
20	security of the material, looking mainly at the
21	facility aspects and the personnel that use the
22	material, and providing security features to ensure
23	that the material is used properly and accounted
24	for.
25	Cesium chloride is, as I said, a part of
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the Code of Conduct and it's one of the many nuclides listed in the Code of Conduct. The Code of Conduct and source security measures were developed using a public health and safety perspective from the point of view of avoiding prompt fatalities from radiation injury.

So cesium chloride, in a way, is treated 7 like all other nuclides on that framework. There 8 are those who believe that cesium chloride, because 9 of its dispersibility and solubility, deserve 10 additional treatment, additional treatment from a 11 security perspective, not necessarily because a 12 certain curie amount could result in some kind of 13 fatalities from radiation industry but from costs of 14 15 cleanup, or contamination spreading. And socioeconomic issues associated with any terrorist using 16 cesium chloride. 17

The chemical form of the material being very soluble and dispersible, in those people's minds, puts it on a different frame of reference than the traditional frame of reference in the Code of Conduct.

23 So that's kind of why we're here today, 24 asking whether the increased controls which do 25 provide security in the frame of reference of

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1	safety, health and safety and prompt fatalities,
2	also provide adequate security from the
3	dispersibility aspect.
4	And the Energy Policy Act of 2005
5	established several activities to look at that very
6	issue. The first is the task force. It's called
7	the Energy Policy Act Task Force, which we'll hear
8	about. One of the co-chairs of a working group of
9	that task force, John Jankovich, is going to do a
10	presentation on their study.
11	Basically the task force owed a report
12	to Congress in 2006, produced that report which
13	said, essentially, that cesium chloride needs an
14	additional look.
15	The National Research Council of the
16	National Academies was also chartered by the 2005
17	Energy Policy Act to produce a study on alternative
18	technologies to radiation sources. They did produce
19	that study earlier this year, and Dr. Kevin Crowley
20	from the National Academies is here, and is the next
21	speaker, actually, to talk about what they found.
22	In their study, they zeroed in a lot on
23	cesium chloride, and in a lot of ways, their
24	recommendations in their study is consistent with
25	the findings of the Energy Policy Act Task Force,
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1	which I neglected to mention, the Energy Policy Act
2	Task Force is made up of 14 different federal
3	agencies, plus two state organizations.
4	More recently, in the last year, the
5	Department of Energy, and the Department of Homeland
6	Security, in cooperation with the NRC, has started a
7	project to look at a hardening existing cesium
8	chloride irradiators around the country. We issued
9	a regulatory information summary, announcing that
10	project. We have members of the National Nuclear
11	Security Administration which is part of DOE here
12	today, and also the Domestic Nuclear Detection
13	Office, which is part of DHS, here today, to talk
14	about those studies.
15	If anybody's interested, I can identify
16	the contacts to you. Those studies, as I said, the
17	increased controls are focused more on the facility
18	and the users. The hardening efforts by those two
19	agencies are focused on hardening the actual devices
20	to prevent a delay in the amount of time it takes to
21	remove the sources from those devices.
22	And we are all working together as a
23	federal agency, in the last year, more so than ever.
24	Let me conclude by quickly mentioning
25	how we're going to go about moving forward.
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1	We have taken several actions at NRC.
2	We have accelerated our inspections of the cesium
3	chloride blood irradiators at hospitals. We expect
4	to conclude all of our initial increased controls
5	inspections at our licensees this month.
6	We have visited all the vendors at their
7	sites and talked to them about how they have
8	considered, in the past, alternatives to cesium
9	chloride sources, whether it's a ceramic form or
10	glass form, and if a source was produced, would it
11	fit, would it physically fit in their device? Could
12	it easily be replaced? Those kinds of questions.
13	Those vendors are here today, so we've
14	kind of seeded the ideas with them of what we're
15	looking for in the workshop, and I hope they'll
16	participate in the workshop today.
17	The Energy Policy Act Task Force, Cesium
18	Chloride Working Group, is delivering their product
19	to the task force this week, and the task force will
20	then take that product and the task force owes a
21	report to Congress in 2010, but having the Working
22	Group product, if the task force were to endorse it,
23	the NRC would take the recommendations from that
24	Task Force Working Group and bring those up to the
25	Commission where any policy issues were highlighted.
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18 1 The irradiator-hardening effort started 2 in ernest in the last month or so, and we'll be 3 working together with NMSA and DNDO to go out to the 4 sites and to implement hardening efforts on the 5 irradiators. In conjunction with those hardening of 6 irradiators, which is no cost to the industry, by 7 the way, it's all paid by the Government--in addition to the hardening efforts, while the NMSA 8 and DNDO people are on site, they are offering 9 10 security-assist visits, where some security experts can provide advice on how to improve security. 11 Many, many different angles. 12 One thing about this materials industry 13 that's different from maybe the reactor industry is 14 the amount of communication between licensees is 15 very limited. 16 So the reactor industry, I think they 17 all line up behind how to do security, and materials 18 19 industry, it's not conducive to that, first of all, because of the disparate types of activities that 20 21 occur. But even among hospitals in a particular 22 city, it may not be communicating how to do 23 radioactive material security. Maybe they 24 25 communicate neonatal security, or something. But we **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	have to do some international outreach, going
2	forward, as well. As I said, there's one producer
3	of this material for the Free World, and that
4	producer, any impacts, anything that we do in the
5	U.Swe have a session about this tomorrowwe
6	certainly don't want to inadvertently cause security
7	to be decreased byfor example, when teletherapy
8	units in the U.S. became no longer economical to use
9	in the U.S. for medical purposes, teletherapy units
10	were shipped to developing countries.
11	In fact, Goaiana, Brazil happened
12	because of that type of situation. So we don't want
13	to create that type of situation and we need to
14	consider the international angle of this business sa
15	well.
16	All of this that I've been mentioning
17	about how we're going forward, is going to be
18	produced in a Commission paper. In the November
19	timeframe we owe the Commission options. The
20	feedback from this workshop is the keystone of those
21	options we're going to tell the Commission, because
22	we can come up with options today, but what we can't
23	come up with, without your help, is the impacts of
24	all those options.
25	So we look forward to a productive two
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1	days and thank you for your attention.
2	[Applause]
3	MR. RAKOVAN: Our first presentation
4	will be given by Kevin Crowley of the National
5	Academy of Science.
6	DR. CROWLEY: Well, good Monday morning,
7	everybody. I notice everybody's a bit subdued this
8	morning. People aren't quite awake yet.
9	My name is Kevin Crowley. I'm the
10	director of the Nuclear and Radiation Studies Board
11	at the National Research Council of the National
12	Academies.
13	I'm actually here today as a substitute.
14	My colleague, Dr. Micah Lowenthal, was the study
15	director for this project, but unfortunately, he
16	couldn't be here today. He's in Vienna because
17	we're releasing another report on international fuel
18	cycles.
19	So if it looks like I'm reading the
20	notes, I am reading the notes. There are some
21	points that Micah asked me to be sure that I made as
22	we went through the slides, and so I will try to do
23	that.
24	I also want to point out that, as I will
25	tell you in a minute, the work that I'm about to
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1	describe was done by an expert committee that was
2	appointed by the National Research Council. There
3	are at least three members of the committee here
4	today. I won't be with you for the full workshop
5	but they will so. So I want to introduce them to
6	you, and if they wouldn't mind standing up.
7	Steve Wagner from the American Red
8	Cross. Ruth McBurney who is now theis it the
9	executive director of the CRCPD? Okay. And I
10	understand that Len Connell is here. Len is from
11	Sandia National Laboratories.
12	So if you have questions or feedback on
13	the report, those are the three individuals that you
14	would want to talk to during the workshop.
15	Okay. Well, let me start this by saying
16	that what I'm about to describe was requested by the
17	United States Congress. The study was requested by
18	the United States Congress in the 2005 Energy Policy
19	Act. I will show you the Statement of Task for that
20	in a second. As we do for all requests that we get,
21	whether they're from Congress or a federal agency,
22	we put together an expert committee to do the study,
23	and I will show you the roster for the committee at
24	the end of this presentation.
25	But I wanted to let you know that the
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1	study was chaired by Dr. Ted Phillips, who is a
2	distinguished radiation oncologist at the University
3	of San Francisco. He's also a member of the
4	Institute of Medicine.
5	And the other experts on the committee
6	were from a number of different fields, including
7	accelerator physics, radiation protection and
8	regulation, medical physics, nuclear security, blood
9	pathogen research, material science, nuclear
10	engineering and public policy.
11	So we had a very broad committee that we
12	brought together to do this study. Next slide,
13	please.
14	Here is the study task, and I'm going to
15	read this to make sure that we all understand what
16	it was we were asked to do.
17	We were asked to look at current
18	industrial research and commercial, including
19	medical, uses of radiation sources, and identify
20	uses for which the radiation source can be replaced
21	with an equivalent or improved process that does not
22	require the use of radioisotopes, or can be replaced
23	with another radiation source that poses a lower
24	risk to public health and safety, if it is involved
25	in an accident or a terrorist attack.
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	23
1	The study should explicitly consider
2	technical and economic feasibility and risk to
3	workers from such replacements, and I want to make a
4	couple of important distinctions about this task.
5	We were asked to look at potential
6	replacements. We were not asked to look at security
7	enhancements. Now obviously that is something that
8	the Nuclear Regulatory Commission has to do as part
9	of its mission. That was not something that
10	Congress asked us to do.
11	The other thing that we were asked to do
12	was to look at high-risk radiation sources, which
13	are the IAEA Category 1 and Category 2 sources, and
14	in terms of cesium, because I know that's the
15	radioisotope of interest in this workshop, a
16	Category 2 source contains between 27 curies and
17	2700 curies of cesium, and a Category 1 source would
18	be anything larger than that. Next slide.
19	So what I want to do is just give you
20	the main messages from the report and then I want to
21	talk about the cesium because that's of interest in
22	this workshop, and then I will backtrack and talk
23	about some of the other recommendations.
24	So here are the main messages from the
25	report. They're sort of a mixture of findings and
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	24
1	recommendations. Applications of radionuclide
2	sources are important and beneficial. Area denial
3	and its costs must be considered in the evaluation
4	of security risk from these sources.
5	Nonradioactive replacements exist for
6	nearly all radionuclide sources. However, not all
7	of these are practical or economically attractive
8	now, but most are improving. There's a need to take
9	actions to implement near-term replacement of cesium
10	chloride sources, and here I want to make an
11	important distinction.
12	Replace cesium chloride sources. It
13	does not say replace cesium. Okay. And finally,
14	adopt policies that provide incentives to replace
15	other Category 1 and 2 sources. Next slide.
16	So let's now turn to some of the
17	messages in the report about cesium chloride
18	sources.
19	Really, two main messages. Because of
20	its characteristics and where the sources are
21	located, radioactive cesium chloride is a greater
22	concern than other sources for some attack
23	scenarios. Rob Lewis talked about some of the
24	characteristics of cesium chloride that make it a
25	concernits dispersibility, solubility, penetrating
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1	radiation, the high source activity for many of the
2	cesium chloride sources in use today, as well as its
3	presence across the United States in facilities such
4	as hospitals, blood banks and universities, many of
5	which are located in large population centers.
6	This fact is made worse by a lack of a
7	permanent avenue for disposal of these sources.
8	That is, there are some disused sources that are
9	sitting in licensee storage facilities and there's
10	really no pathway for disposal of these sources.
11	Next slide. So here is the recommendation that was
12	made.
13	It says that in view of the overall
14	liabilities of radioactive cesium chloride, the U.S.
15	Government should implement options for eliminating
16	Category 1 and Category 2 cesium chloride sources
17	from use in the United States, and to the extent
18	possible, elsewhere.
19	The committee had three options for
20	achieving this. First, discontinue licensing of new
21	sources. Second, put in place incentives for
22	decommissioning existing sources, and third,
23	prohibit the export of cesium chloride sources to
24	other countries except for the purposes of disposal
25	in an appropriate licensed facility.
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1	Rob Lewis mentioned to you the lessons
2	learned from the cobalt irradiators. The committee
3	took that lesson in making the recommendation about
4	not exporting cesium chloride sources.
5	The committee recognized that current
6	users and owners of cesium chloride sources might
7	need incentives to decommission their existing
8	sources because many of them still have value, and
9	of course there are fairly high decommissioning
10	costs.
11	The report provides some options for how
12	this could be achieved. For example, buying out the
13	remaining present value of sources, or changes to
14	DOE's offsite source recovery project's policy.
15	Okay. Next slide.
16	Let me now turn to some of the other
17	messages in the report.
18	These are not necessarily directly
19	relevant to cesium chloride. The committee noted
20	that there are approximately 55,000 Category 1 and 2
21	sources in 5000 devices, and that the sources have
22	very important uses for cancer therapy,
23	sterilization of medical devices, irradiation of
24	blood in laboratory animals, nondestructive testing
25	of structures and equipment, and exploration for oil
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1	and gas.
2	And so the committee's recommendation
3	was that replacement of radionuclide sources with
4	nonradionuclide radiation generators should be done
5	with caution.
6	There's a bit of a, what I might call "a
7	ying and a yang" in this report. The community is
8	saying proceed cautiously. On the other hand, the
9	committee is saying you really need to replace
10	cesium chloride. So there's a certain tension in
11	the report that I want you to be aware of.
12	I would point out that the committee is
13	made up of experts from fields that use radiation
14	for the benefits of society, and many of those
15	members use radiation in their own activities, and
16	so there was a lot of discussion within the
17	committee about how far they really wanted to push
18	on replacements, including replacements for cesium
19	chloride.
20	But in the end, I think the committee
21	felt that action was, needed to be taken on cesium
22	chloride. Next slide.
23	And some of the reasons for that are
24	shown in this slide. Security and safety risks
25	motivated the request for the study, and as Rob
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1	pointed out, radiation sources, including cesium
2	chloride sources, can pose significant risk to
3	individuals but are unlikely to cause deterministic
4	health effects to large numbers of people.
5	The committee concluded that the widest-
6	ranging and most long-lasting consequences from, for
7	example, a terrorist attack, would be economic and
8	social disruptions, not large numbers of individuals
9	dying, and the economic and social disruptions would
10	come from contamination that leads to denial of
11	areas, of land areas.
12	The committee noted that the IAEA source
13	categories, like Category 1 and 2 that I told you
14	about earlier, are based primarily on deterministic
15	health effects, that the Nuclear Regulatory
16	Commission and Department of Energy have looked at
17	contamination criteria, but the committee concluded
18	that those criteria, at their present state of
19	development, were not adequate.
20	The USNRC and DOE looked at
21	contamination, asked the question, Could a source
22	contaminate a half-a-square mile kilometer area
23	above the threshold that requires cleanup? But the
24	committee noted that for some sources contamination
25	could be much greater than half-a-square kilometer,
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29 1 and the committee recommended that the NRC and DOE 2 take the next step, and consider the area source a 3 radioactive source, potential to cause area denial. Next slide. 4 5 The committee noted that lower hazard replacements exist for nearly all applications of 6 7 Category 1 and Category 2 sources. However, at this time not all of the replacements are necessarily 8 practical or economically attractive. But most of 9 10 them are improving and many of them are viable now, and there are a number of examples in the report of-11 12 -in fact there are several chapters in the report, that go into some detail about potential 13 replacements. 14 For example, particle accelerators can 15 16 be signed to operate as radiation generator replacements. In some cases, such as self-shielded 17 radiators, which I know is a concern to this group, 18 19 x-ray tubes can replace some sources. Contract irradiators already use E-beam 20 21 irradiation for some applications, and an x-ray facility could be a feasible replacement for cobalt 22 60 gamma irradiation in some cases. 23 Linear accelerators for radiotherapy 24 25 have already replaced cobalt-60 teletherapy devices **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	in the United States, except for the gamma knife,
2	and LINAC vendors are trying to penetrate that
3	market as well.
4	The development of new technologies,
5	especially in some areas of ultrasonics and x-ray
6	sources, has provided alternatives to gamma
7	radiography for nondestructive investigation.
8	Neutron well-logging tools that use
9	americium beryllium sources are beginning to see
10	competition from accelerator fusion sources in
11	californium-252 sources. There are alternative
12	radionuclides for cesium chloride. Cobalt-60 can
13	sometimes be used in the place of cesium, and
14	alternative material forms such as metals, oxides,
15	and minerals, rather than salts. Specifically some
16	alternatives to radioactive cesium chloride include
17	radioactive cesium glass, and a mineral form of
18	cesium, pollucite. Next slide.
19	The committee recognized that these
20	replacements probably would not take place without
21	some government incentives. So the committee
22	recommended that the U.S. Government should adopt
23	policies that provide market, regulatory, and
24	certification type incentives to facilitate the
25	introduction of replacements and reduce the
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31 1 attractiveness and availability of high-risk 2 radiation sources. And again, there's a fairly indepth discussion of some of the possible incentives 3 4 that could be adopted. 5 For example, making licensees bear more of the full life cycle costs of radiation sources, 6 particularly for disposal of cesium chloride and 7 americium-241 sources. 8 9 Revising the requirements for decommissioning funds for Category 1 and 2 devices, 10 to increase the up-front costs for higher-hazard 11 12 sources. I mentioned this earlier. To enhance 13 DOE's offsite source recovery project, to include 14 15 the buy-back of devices that still have use value, 16 provided that the devices are replaced with lower hazard devices. 17 And of course the Government could 18 19 impose charges on all sources, or just new sources based on hazards or risks. 20 21 These are options for government agencies to consider, and I want to make an 22 important point here, which is we are a private not-23 for-profit congressionally-chartered organization. 24 25 We are an advisory organization. We do not make **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	public policy. The committee has made
2	recommendations to the government. It is not up to
3	the government to determine whether and how it
4	should implement those recommendations. And then my
5	final slide.
6	Just in closing, this is the committee
7	roster. These are the committee members who carried
8	out this study. Thank you very much for your
9	attention.
10	[Applause]
11	MR. RAKOVAN: Thank you, sir. And we
12	apparently have about 75 copies of the study on the
13	registration table. So get them while they last.
14	Our final presentation before we take a
15	quick break is by John Jankovich from the NRC, who's
16	going to be going over the Cesium Chloride Working
17	Group overview and general conclusions.
18	MR. JANKOVICH: Good morning. I am here
19	to present you an overview of the report, and I will
20	describe the relationship here of the group who
21	prepared it, the Cesium Chloride Working Group, and
22	they prepared it for the Radiation Source Protection
23	Security Task Force.
24	And as you notice, I am with the Nuclear
25	Regulatory Commission as co-chair of this Working
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1	Group. The other co-chair is Dr. Brendon Plapp from
2	the State Department. He's also here with us today.
3	A little background, and to put things
4	into perspective, I like to say a few words, how
5	this Working Group came about. We all go back to as
6	far as 2005, act of Congress established the task
7	force, Security and Protection Task Force, and
8	Congress also assigned the task force to write a
9	report by 2006. That report was delivered to the
10	president and Congress in August of 2006.
11	And one recommendation of that report is
12	about my Cesium Chloride Working Group, specifically
13	Recommendation 12-2, and this is a quoteimportant.
14	It says there should be a Working Group
15	and the Working Group should assess feasibility and
16	phasing out of cesium chloride in highly-dispersible
17	form.
18	This is a clear assignment and it has
19	three elements. I want to emphasize it because our
20	report, what we produced, clearly addresses these
21	assignment, specifically thego back a second.
22	We produced a study to assess
23	feasibility for phasing out cesium chloride in
24	highly-dispersible form. So when I come to the
25	conclusions, please note, that's what we are
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1	addressing here.
2	And let's go then to the next one,
3	please. I like to point out, really, how we came
4	about producing this report, and on this Working
5	Group there were ten government agencies involved,
6	because the scope of the work goes beyond the NRC.
7	And in addition, of course as you know,
8	the NRC in the agreement states regulate nuclear
9	material in partnership with each other. Therefore,
10	we had a representative from the Organization of
11	Agreement States on our Working Group. There were a
12	total there of 33 people working on it. We began our
13	work at the start of last year, in January, and we
14	finish this year in August, and we worked, meeting
15	for worktr sessions, every month on the average.
16	That means we were not just talking. We were
17	working on the report.
18	And we also didn't want to produce a
19	report which comes from an ivory tower. So once we
20	established the major issues to be addressed, we
21	prepared a white paper to outreach to stakeholders.
22	And this white paper was presented to
23	the government and industry sector, coordinating
24	councils. We asked them to distribute the white
25	paper to their members and give us comments. We did
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1	receive a number of comments, in writing, and those
2	are collected in one appendix of our report.
3	And we submitted our report to the task
4	force on September the 12th. I'd like to say a few
5	words about it.
6	Our due date was the end of August. We
7	were late only 12 days. Considering the complexity
8	of the issues, how many agencies were involved, how
9	many individuals were involved, I don't think it's
10	too much of a delay. Many of us who have some home
11	improvement projects going, we would be happy with a
12	12 day delay only as you know.
13	However, let's go back, be serious
14	again. This report is official use, for the
15	official use at the moment, and the recipient of the
16	report, the task force itself, hasn't briefed about
17	this one. But the task force members and the NRC
18	thinks that the work is of sufficient importance for
19	this workshop, and also not just that the report is
20	important. This workshop is important. That's why
21	the decision was made to present the results here,
22	even before the task force itself hears it.
23	One more comment, please. That this is,
24	the report is a product of these individuals. They
25	are technical experts in their field. They don't
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36 1 represent agency points of view from those ten 2 agencies, plus the Agreement States. And this is one mosaic in the overall picture that Rob Lewis has 3 4 presented earlier this morning. NRC, other 5 government agencies, have many initiatives going on, and this is just one element, one mosaic in the 6 overall picture. Next. 7 8 I want to put our report into perspective for you, and these are the caveats, 9 these are the limiting conditions, what you should 10 consider. 11 12 First of all, our assignment was primarily to address the domestic use. We have some 13 comments on international use. You will see that 14 later. 15 16 We restricted our considerations to our Category 1 and 2 sources, and dispersible and 17 soluble form. Again, I want to add one more point 18 19 of view to what we have heard from the National Academies. This form, what is used in the present 20 21 time, the physical form, is like the Tic-Tac candy, compressed powder, which is dispersible and soluble. 22 That's the issue. That's what we want to solve. 23 And as we proceeded in our work, it 24 25 became clear at the beginning, that there are **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	various applications for the use of cesium chloride
2	sources. They differ by the purpose, how they are
3	used. They differ by the activity level. They
4	differ by the facilities who are using them.
5	Therefore, we made the distinction,
6	clear distinction for research irradiators, blood
7	irradiators, and calibrators. And when we come to
8	our conclusions, we have this graded approach to the
9	conclusions.
10	One resolution doesn't fit all these
11	modes of applications, that's what I want to
12	emphasize, there are different modes, and the
13	solution to the problem also differs according to
14	these modes of application.
15	In our work we of course looked at the
16	current regulations. There are administrative and
17	physical requirements for security at the moment.
18	There are import/export regulations.
19	We were aware that the National
20	Academies produced its report. I want to put again
21	our work in perspective to the work, what the
22	National Academy has done. They had a much broader
23	assignment. As we have heard, they were to address
24	all users of radioactive materials and sources.
25	Here, we are limited only to cesium
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1	chloride. Even their final conclusions had a number
2	of suggestions about cesium chloride. We focused
3	only on this one isotope.
4	Now here we come to the point, how we
5	did our work. We developed a number of options. It
6	ranged from no action to complete ban. And we
7	reviewed and developed pros and cons, and
8	consequences for all these options.
9	Based on that, we went through a
10	screening process. Next slide, please.
11	Here, for using the proper word, I am
12	showing words considerations to reach conclusions.
13	These are the filters, the weighing factors of what
14	we used for each of those options. And these
15	factors are grouped into key considerations and some
16	additional factors.
17	Of course the key considerations are
18	focused on improving security, because that's the
19	purpose of our work here. And we realized from the
20	beginning, that there is competition between the
21	beneficial use of this isotope versus the security
22	requirements, and we had to overcome that.
23	And then let's define alternative
24	technologies. This was also one heavy weighing
25	factor in our analysis, and for the purpose of our
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39 1 report, we defined alternative technologies, you know, in different physical form. Less soluble, 2 less dispersible, or in other isotope like cobalt, 3 or completely new technology, just as we have heard 4 5 from the Academies' presentation. That's alternative technologies. 6 And for each of those options they 7 reviewed safe and security disposal questions. 8 In addition, of course there are other factors. 9 When 10 to introduce any change. That's very important. How to apply those changes to the various modes of 11 application, and there could be incentives by the 12 government to facilitate the process. 13 We looked at the transportation issues. 14 15 Transportation is important for a number of 16 reasons. As we know, there are no, sufficient 17 number of transportation packages for these large activity sources at the moment, and the costs are 18 19 also very significant, and our Working Group recognized that. 20 We looked if education and information 21 campaigns could facilitate the process. This is not 22 just for the public but also information campaign 23 for the professional community like us here in this 24 25 room.

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1	If everybody sees the goals clearly, and
2	sees the way to reach that, we can be much more
3	effective than otherwise. We analyzed the role of
4	the government for all these options, what are the
5	consequences, what are the costs.
6	Regarding the costs, we came up with an
7	itemized list of cost element, and we came up with
8	some estimated dollar values for all of those.
9	Results. I'd like to sum up here the
10	overall conclusions, and please note that this one
11	slide expresses, in condensed form, the total
12	findings of our Working Group.
13	So a week from now, if somebody asks you
14	what were the findings of the Cesium Chloride
15	Working Group, what their report contains, think of
16	this, and I like to point out here what these
17	results are.
18	Again, our assignment was assessment,
19	feasibility, cesium chloride dispersibility. So we
20	say immediate phase-out would not be feasible.
21	That's our conclusion. Because there are so many
22	factors involved, and timing and consequences are
23	very crucial.
24	However, stepwise phaseout, again I say
25	phaseout, in other form, could be feasible. Another
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1	conclusion. How we go about it. The goal here
2	challenges would have to be overcome. Challenges in
3	plain language, I would say are the preconditions
4	that must be in place before stepwide phaseout or
5	other phaseout could be implemented. And I talk a
6	little bit about these challenges.
7	Sufficient time is needed till
8	replacement technologies, which are well-established
9	and broadly usable, are available. And then
10	disposal pathways must be available. So for
11	stepwide phaseout, or other phaseout, these things
12	are crucial.
13	And these preconditions cannot be placed
14	randomly, they have to be in a sequence, and then
15	sufficient time must be given to them. And then in
16	the meantime, the interim security measures are very
17	important.
18	That slide presented the overall
19	conclusions. However, we went further, and we
20	provided step by step methods for the task force to
21	follow up, if they choose to. We call that the
22	Recommended Path Forward, and these six elements are
23	the major avenues that must be implemented to
24	achieve our goal.
25	I'd like to say a few words about each
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one of them.

2 One is the Working Group concluded that we need to continue the security upgrades to 3 4 supplement the existing requirements, and then 5 establish a process for determining additional 6 upgrades and the need for them. As you know, the 7 Department of Homeland Security and Department of Energy are implementing this voluntary initiative to 8 9 have a hardening project, and we encourage that. But in addition, we put here kind of 10 administrative term. Need establish a process. 11 12 that means the government should establish a process to continually evaluate the risks and take 13 appropriate action, if needs. 14 Our recommendation two, initiate 15 16 rulemaking or other processes. This is very 17 important, because the Commission has other means to achieve the goal, and, for example, issue a policy 18 19 statement or something like that. And the objective of this process should be to eliminate further 20 21 licensing or ban the exports. These two functions must go together. 22 Furthermore, we recommend that there is 23 need to develop a government-facilitated disposal 24 25 This is one of the most critical elements pathway. **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W.

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1	in the overall approach, because there is no
2	transportation package. There is no commercial side
3	where to take these sources. And we don't recommend
4	interim mass storage, because transportation to that
5	site involves risk. Storing a large number of
6	sources at a site involves risk. Further
7	transportation creates further risks.
8	We recommend to implement incentives in
9	a prioritized fashion, either for phasing out, or
10	obtaining replacement technologies.
11	We also support short-term and long-term
12	research, and because the alternative technologies
13	are not commercially available on a large scale,
14	they may not achieve the same purpose as the present
15	technology.
16	And finally, we make some comments,
17	quite a few comments about the international
18	considerations. Most of us who are working here in
19	the U.S. are not aware what the U.S. can do
20	internationally, and whatever decision, rule or
21	requirements we put in place here, will have
22	implication on other countries.
23	And having the State Department on the
24	Working Group was most useful, and we have a long
25	list of considerations for the international
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1	considerations. Thank you.
2	[Applause]
3	MR. RAKOVAN: We're going to take a
4	quick break and let you stretch your legs, probably
5	get started here about 9:55.
6	(Whereupon, the proceedings in the
7	foregoing matter went off the record at 9:39 a.m.
8	and went back on the record at 9:59 a.m.)
9	FACILITATOR RAKOVAN: Welcome back.
10	We're going to do a quick swap in the agenda real
11	quick. I'll be going over the ground rules right
12	before we start the discussions, but first we're
13	going to have the address by Commissioner Lyons.
14	And to introduce him, I'd like to
15	introduce Charlie Miller. He is the Officer
16	Director for the Office of Federal and State
17	Materials and Environmental Management Programs at
18	the Nuclear Regulatory Commission. Charlie?
19	MR. MILLER: Thank you, Lance. For
20	those of you that don't know me, I thought I'd take
21	one moment to just identify the different roles that
22	I play and how they're central to everything that
23	we're doing in the workshop.
24	We heard about the Energy Policy Act
25	Task Force this morning, which the legislation
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1	provided for the fact that the Chairman of the
2	Nuclear Regulatory Commission would chair that task
3	force. And I do chair the task force meetings on
4	the Chairman's behalf, so the overall task force
5	activities are very important to me.
6	Secondly, I'd like to point out that the
7	increased control orders that we do have in place,
8	that you've heard a little bit about, were done
9	under my purview. And I signed those orders out, so
10	I have a stake in that aspect of it also.
11	Thirdly, any rulemakings that would
12	result from our deliberations here, or proposed
13	rulemakings, would be done out of my office also, so
14	how the path forward from here is extremely
15	important to myself also personally.
16	And Rob had talked about the options
17	paper. One of the important things to remember from
18	the workshop is the fact that NRC is an independent
19	regulator. We do not promote or deny any
20	opportunities. We do not have a commercial interest
21	whatsoever in what's going on. It is our job to
22	make sure that public health and safety and the
23	appropriate security measures are put in place.
24	Finally, I'd like to point out that
25	because this is an issue that involves nuclear
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46 1 materials, our agreement state partners are 2 extremely important. Currently, between 80 and 85 3 percent of the nuclear materials regulation in the 4 United States are done by our partners in the 5 agreement states, and I'm happy to see a number of 6 representatives from those here today, as well as 7 our federal partners. It is important as we go forward that all our stakeholders are represented. 8 Finally, I'd like to have the pleasure 9 10 of introducing the Honorable Peter B. Lyons, who was sworn in as a Commissioner of the Nuclear Regulatory 11 12 Commission in January of 2005. During his tenure, Commissioner Lyons has emphasized that the NRC and 13 its licensees must remain strong and vigilant 14 15 components of our nation's integrated defenses 16 against acts of terrorism. And in that regard, he has been a consistent voice for security matters as 17 well as our partnerships with the agreement states, 18 19 who he recognizes as our partners in this activity. Commissioner Lyons has had a very 20 21 distinguished career at Los Alamos Laboratory, followed by service on the Hill. He was a science 22 advisor on the staff of U.S. Senator Peter Domenici 23 and the Senate Committee on Energy and Natural 24 25 Resources.

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1	He is a native of Nevada, and he
2	received his Doctorate in Nuclear Astrophysics from
3	the California Institute of Technology, and he
4	earned his undergraduate degree in Physics and
5	Mathematics from the University of Arizona.
6	He is a fellow of the American Physical
7	Society and was elected to 16 years on the Los
8	Alamos School Board, and spent six years on the
9	University of New Mexico Los Alamos Branch Advisory
10	Board.
11	He is a resident of Virginia currently,
12	and without further ado I'd like to introduce
13	Commissioner Lyons.
14	(Applause.)
15	COMMISSIONER LYONS: I am not sure which
16	mic I'm using at the moment. Is it this one? Yes,
17	let's just use that one.
18	Thanks, Charlie, for the kind
19	introduction. And some of you may have noticed in
20	what Charlie said, he mentioned 16 years on the Los
21	Alamos School Board. I sometimes think that being
22	on a School Board was the best preparation I could
23	possibly have had for serving at the NRC.
24	(Laughter.)
25	I am pleased to be here today, and I
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1	very much appreciate your willingness to participate
2	in this very, very important workshop. There can
3	simply be no question that the uses of cesium-137
4	chloride sources benefit the world's medical
5	research and industrial communities and the public,
6	and benefit them very substantially. However,
7	preserving these benefits, coupled with achieving
8	adequate security, is a very real challenge.
9	As I think you know, after this workshop
10	the NRC staff will be developing recommendations for
11	Commission deliberation. The discussions at this
12	workshop will provide highly valuable input for this
13	process. Because of the importance of these sources
14	to society, it is imperative that we hear from you
15	to help frame a strategy and a possible timeline to
16	address this issue.
17	I want to thank the NRC staff and all of
18	the participants who have worked so hard to make
19	this workshop possible.
20	I need to emphasize that I am providing
21	only my own personal views today, and certainly not
22	necessarily those of the Commission. I will keep my
23	remarks relatively brief, and I will be happy to
24	take a few questions. I might even be able to
25	provide answers, but at least I am happy to take
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1	questions, and we will see what I can do on answers.
2	I should begin by pointing out that the
3	NRC has not made any decisions regarding the
4	suspension of the use of high-activity cesium-137
5	chloride sources. The information gathered at this
6	workshop, combined with other studies, will provide
7	useful insight for the Radiation Source Protection
8	and Security Task Force's discussion and
9	consideration of the continued use of cesium
10	chloride sources. That task force is made up of 14
11	federal agencies and representatives from the
12	Organization of Agreement States and the Conference
13	of Radiation Control Program Directors.
14	The security of radioactive materials
15	has been, and continues to be, a top priority for
16	the NRC. Applying a risk-based approach, the NRC
17	has enhanced security of radioactive materials, and
18	has reduced the potential threat from an RDD or RED
19	type of attack. The security of these materials has
20	been enhanced through additional requirements on
21	access control, detection, trustworthiness,
22	accounting, and other measures.
23	Nevertheless, NRC continues to work
24	closely with its domestic and international partners
25	to continuously assess, integrate, and improve its
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security programs and, when deemed necessary, to make risk-significant radioactive materials still more secure and still less vulnerable to terrorists and terrorist actions.

5 One such example of this coordination is the government-sponsored -- through DHS and DOE --6 7 voluntary program to enhance the security of highactivity cesium chloride irradiators by making 8 design changes to further delay unauthorized access 9 to the sealed sources. This is referred to as the 10 11 hardening program. It is a voluntary program, and 12 the NRC and agreement states have notified the user community about the program through careful 13 communications. 14

The program, and its proposed changes to device designs, have been thoroughly vetted with the device vendors and the users, to ensure that the changes will have no impact on safety, maintenance, or operation of the devices.

The NRC has a number of initiatives currently underway to address security risks of cesium chloride sources, and to develop an integrated strategy towards its future use. I believe others have, and later will, cover several of these initiatives this morning, and certainly

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1	more discussion will be planned at this workshop.
2	However, I would like to briefly review
3	a number of points that I believe have relevance at
4	this workshop. High-activity cesium-137 chloride
5	sources, as I think everyone in this room knows, are
6	used for research and for industrial and medical
7	purposes and devices regulated by the NRC and the
8	agreement states. These devices include self-
9	shielded irradiators, research devices, and
10	detection and dosimetry calibrators.
11	Today, Russia's Mayak is the only
12	manufacturer of high-activity cesium-137 sources for
13	the international market. The commercial
14	distributor of the Mayak sources in the U.S., as you
15	know, is REVISS. The form of cesium-137 in such
16	sources is the chloride form, cesium chloride, which
17	is both very soluble and very dispersible.
18	Some research and development of
19	alternative forms for cesium-137 has been performed
20	and indicates that less soluble and less dispersible
21	materials may be able to be developed for use in
22	some cesium high-activity cesium sources.
23	However, Mayak will need time to develop commercial
24	production lines for sources that would use a less
25	dispersible form.

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1	We need your suggestions to determine,
2	and hopefully agree, on an appropriate balance
3	between increased control requirements and the
4	continued use of these sources, until alternative
5	forms can be made available or until feasible
6	alternative technologies become widely used.
7	Prior to 9/11, regulations of the NRC
8	and the agreement states contain both safety and
9	security components that were appropriate for that
10	time. After 9/11, the safety and security
11	requirements were enhanced through the use of
12	increased security controls that aligned the IAEA
13	Code of Conduct recommendations.
14	Concerns about safety and security of
15	radiation sources and devices have grown partly in
16	response to fears that radiation sources could be
17	used to make RDDs, or, as you know, referred to more
18	often as a dirty bomb.
19	Congress directed the NRC, through the
20	Energy Policy Act of 2005, to take several actions.
21	Among them, we were required to undertake a study
22	by the National Academy of Sciences to identify the
23	uses of high-risk radiation sources and the
24	feasibility of replacing them with lower risk
25	alternatives.
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53 1 The National Academy recommendations 2 called for stopping the licensing of new cesium-137 chloride irradiator sources, prohibiting the export 3 4 of such sources, providing incentives for 5 decommissioning of existing sources, and replacing existing sources with possibly a less dispersible 6 form of radioactive cesium -- with cobalt-60 or with 7 non-radioactive alternatives. 8 Others have called for the complete 9 replacement of cesium chloride sources, including, 10 as you are probably well aware, House Bill H.R. 11 12 6816, which is entitled the Nuclear Facility and Material Security Act of 2008, and consistent with 13 another recommendation of the National Academy study 14 entitled Radiation Source Use and Replacement. 15 16 I very much agree with the National 17 Academy that any effort to replace these radiation sources with alternative technologies should proceed 18 19 with caution in order to minimize disruption in vital areas of industry, medicine, and research. То 20 21 that end goal, as you know, the NRC is holding this public workshop to ensure that all stakeholders are 22 afforded an early opportunity to provide input on 23 any potential regulatory changes. 24 The Commission believes that a balanced 25 **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS

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1 consideration of stakeholder concerns is essential 2 to inform regulatory changes, and will help quantify 3 and possibly lessen any negative impacts of such 4 changes.

5 The task force that I discussed earlier has formed several subgroups, including ones on 6 cesium chloride, radiation sources, and alternative 7 technologies. The cesium chloride subgroup has 8 already issued its report within or to the task 9 10 force. The radiation sources subgroup plans for a fall 2008 report, so pretty soon. And the 11 12 alternative technology subgroup's report is due in 2009. 13

These studies, as well as other input, 14 such as, for example, the ongoing study of the 15 16 Advisory Committee on the Medical Uses of Isotopes, 17 on the efficacy of X-ray alternatives, will be used by the task force to develop recommendations in its 18 19 report to the President and to U.S. Congress, and that report is due in 2010. The 2010 report will 20 21 certainly include this issue, among a number of other topics. 22

As we consider these difficult issues, we need to pay very careful attention to the consequences of our actions, to avoid unintended

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55 1 consequences, both domestically and internationally. 2 Thus, any resolution, in my mind, would benefit 3 from an international consensus, to avoid driving 4 some applications offshore, and to prevent sources 5 of concern from becoming more readily accessible in 6 other countries. 7 It may be useful also during this workshop to discuss when security becomes 8 sufficient. For example, should nuclear powerplants 9 that use these sources be required to replace them, 10 despite the enhanced security that is in place at 11 12 such facilities? You could also offer valuable input to 13 two additional questions. How feasible is it to 14 15 stop licensing cesium-137 chloride sources now with a goal of complete replacement within 10 years? 16 And, second, what should be done with the replaced 17 sources and devices? How should we solve the 18 19 disposal issue? And should we prohibit export of these sources and devices, as the National Academy 20 21 suggested? As I noted earlier, the NRC and its 22 federal partners need broad stakeholder input on the 23 potential impacts of actions and the range of 24 25 alternatives that can potentially address issues **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	associated with removing high-activity cesium
2	chloride sources from use. We clearly need your
3	views on economic and societal costs associated with
4	replacing these sources, including the effectiveness
5	of replacements or in impacts-to-research programs,
6	if they are not available.
7	Additionally, we need to understand the
8	effect on your programs if such sources were
9	replaced by X-ray machines or other alternatives
10	for example, maintenance and efficacy issues and
11	cost issues. I, for one, very much look forward to
12	the staff's recommendations on the issues associated
13	with cesium chloride sources, and those
14	recommendations are going to be informed by the
15	dialogue of this workshop, as well as from input
16	from previous and also ongoing studies.
17	I do appreciate your attention. I hope
18	you have a productive, informative workshop, where a
19	variety of different points of view can be
20	discussed, debated, and better understood by all of
21	you.
22	With that, I am willing to take a few
23	questions, with the obvious caveat that I would be
24	speaking only for myself, and that this early in the
25	deliberations I will be fairly careful in what I
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1	say, too. If there are questions, I'll try.
2	FACILITATOR RAKOVAN: If you have a
3	question, please come to use the microphone.
4	MR. MORGAN: Hi. I'm Tom Morgan from
5	the University of Rochester. Most of what I have
6	heard today is in the purview within the purview
7	of the NRC. However, disposal doesn't appear to be.
8	That's a huge political decision. How do you see
9	this playing out disposal playing out versus
10	all the other regulations?
11	COMMISSIONER LYONS: Well, there is
12	certainly no question that the country now is facing
13	a real challenge on disposal options for all
14	sources. The closure of Barnwell certainly
15	complicated a system that was already strained.
16	There are some possible commercial
17	options that still may come online, but this may be
18	something that, depending on the feedback from this
19	workshop, depending on the success that some of
20	these newer commercial options may have or may not
21	have, it may be very reasonable for the Commission
22	to entertain direct communication with our oversight
23	committees in Congress to point out the concerns
24	raised by the lack of disposal options, and to, you
25	could say, ask or plead for congressional action to

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1	resolve those issues.
2	You are quite right that the NRC, per
3	se, does not have the necessary authorities to solve
4	this problem, but we are piece of any solution.
5	Congress may well have to be involved before this is
6	over.
7	Any other questions?
8	(No response.)
9	Again, I wish you great success for the
10	conference, for the workshop. It truly is a very,
11	very important contribution, and I appreciate your
12	taking the time from your schedules to provide that
13	input. So thanks very much.
14	(Applause.)
15	FACILITATOR RAKOVAN: Thank you, sir.
16	I would like to take a moment now to go
17	over some ground rules for the discussion panels.
18	The roundtable discussions will essentially follow
19	the five issues detailed in the Federal Register
20	notice, with one session devoted to each issue.
21	We're going to have some different panel members for
22	each discussion, and expect that those sitting at
23	the table will be the primary participants for each
24	session.
25	We received far more expressions of
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1 interest for serving as panel members than we could 2 accommodate, unfortunately, as we have attempted to 3 ensure a good balance between the various groups and 4 perspectives sitting at the table. Therefore, we 5 apologize that we could not put all those interested 6 parties on the panels. However, we are going to do 7 our best to make sure that all participants, whether they are seated at the tables or not, have an 8 opportunity to participate in discussions. 9 10 Now, I have got Cyndi Jones over here, 11 and I've got Michelle Killian over here, and they 12 are hopefully going to help us keep honest in terms of which panel members need to be up for which 13 discussions, and also make sure that those people 14 15 have their tents designating kind of their seats, and so we know who they are when they speak as well. 16 At the start of each session we may have 17 some initial statements made by participants. As 18 19 established before the meeting, these statements should take three minutes at the most, to allow 20 sufficient time for discussion on each issue. 21 I would really appreciate if you would help me keep to 22 If you start kind of going over the three-23 that. minute mark, I'm going to take some steps to kind of 24 25 -- well, please help me keep to the three-minute **NEAL R. GROSS** 

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1	mark.
2	(Laughter.)
3	If you have any PowerPoint presentations
4	for a presentation coming up, try to get it to
5	Michelle over here as early as possible, so that we
6	make sure that we have it on our computer.
7	Following any initial statements, we
8	will open up discussion for the designated issue.
9	If you are sitting at the table and you want to make
10	a statement, you can either raise your hand to get
11	my attention or you can put your name tent sideways,
12	assuming it will stay up. Again, I will try to get
13	to everyone in the order that I see you.
14	If you are in the audience and I will
15	try to go to the audience at specific times you
16	can see we have got a couple of mics in the center
17	aisle, and if you just want to approach the mic. Or
18	I'll be looking at the crowd a couple times, if you
19	just raise your hand, then I'll kind of give you a
20	nod.
21	But, like I said, we're going to try to
22	let everybody participate, but we are looking to the
23	panel members to be the primary people who are
24	having the discussions.
25	If things come up that aren't pertinent
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61 1 to the topic at hand, I'm going to put it on one of 2 these flipcharts over here. I think you will notice 3 on the agenda we've got some time for "parking lot issues," and hopefully we'll get to those towards 4 5 the end of the day, especially if they are important 6 topics that we want to discuss, but maybe they are 7 just not in the flow of what's being discussed at the moment. 8 Please note that this is a public 9 meeting, so we will be discussing only publicly-10 available information, asking that participants 11 please do not -- please do not discuss specific 12 security-related information about your facilities. 13 There also should be no discussions about specific 14 scenarios or additional security measures that 15 16 should be added to a certain device. This type of discussion could 17 potentially cross into safeguards or classified 18 19 information quickly, and they are not appropriate for this workshop. So I appreciate your help in 20 21 that. We are transcribing today's meeting to 22 fully document the discussions. So there is a few 23 things that you can help us out with in terms of 24 25 making sure that we get a clean transcript for the **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	meeting. First, if you are going to participate in
2	a discussion, please make sure you use a microphone.
3	When you do make a comment, please try to give us
4	your name and any organization that you represent,
5	at least the first few times that you make a
6	comment.
7	Also, hopefully with the microphones,
8	but let's try to keep one main conversation going at
9	any given time. Side conversations probably won't
10	find their way to the transcript, and they also take
11	away from whatever the main discussion is.
12	You can also help us cut down on
13	background noise by turning off or silencing your
14	cell phones or other electronic devices. Heard a
15	few of those going off already, so, if you could go
16	ahead and do that, that will really help us out.
17	We can take written statements that we
18	can include as part of the transcript. If you have
19	something that you'd like to submit, you can either
20	give it to me or any of the people that you see that
21	have been helping out at the workshop, or at the
22	registration table. All those will make their way
23	officially onto the transcript.
24	Both John Jankovich and Cyndi Jones, the
25	workshop coordinators, are going to be available
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63 1 throughout the meeting in order to answer any 2 questions you might have. 3 And let's just try to remember that we 4 are here to discuss these issues, not reach a 5 There's a pretty good chance that we're consensus. 6 not all going to agree 100 percent with what 7 everybody else says. And that's all right. When someone has the floor, please give them the floor 8 fully, and show them the respect that you yourself 9 would like. 10 A few logistic information -- if you did 11 12 park over here in the parking lot for the Convention Center, we do have free parking that we can give 13 you. Just stop at the registration table and let 14 15 them know, and you'll be able to park for free. They have got vouchers. If you haven't figured it 16 17 out yet, restrooms are down here and on your right. Obviously, you've probably noticed that 18 19 we've got lots of food going on. There will be food out pretty much during the morning and afternoon 20 sessions. Lunch, you're on your own. I believe 21 they've got a restaurant down here, but there is a 22 few restaurants that are within a quick walking 23 distance towards Rockville Pike as well. So when we 24 25 take a break for lunch, you are on your own for **NEAL R. GROSS** 

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1	that.
2	We do have this room for two complete
3	days. So if you want to leave some of your
4	materials, like in a specific chair, it should be
5	okay. I'm not sure that I would leave computers or
6	anything like that, but just in case you don't feel
7	like lugging your copy of the National Academy's
8	report home with you, if you set it on a chair and
9	put something with your name on it, or something, it
10	should be fine.
11	And, again, just one more plug, if you
12	could fill out the public meeting feedback forms. I
13	just signed out a memo the other day that publishes
14	the results that we had last year, and we do have
15	specific information, trends, specific comments that
16	were made, etcetera. So those really do help us
17	improve on our public meetings.
18	So having said all of that, let's go
19	ahead and move to the first panel and first topic,
20	Issue 1.1, which is feasibility of the use of other
21	forms of cesium-137.
22	Michelle, do you want me to go ahead and
23	read off the participants?
24	MS. KILLIAN: That would be good.
25	FACILITATOR RAKOVAN: Okay. The
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1	participants that I have listed for this are Albert
2	Aloy, and I apologize if I slaughter anyone's name,
3	David Coppell, Mark Maiello, Brad Patton, John
4	Schrader, Thadium Stirchanko, and Lynne Fairobent.
5	If you could all go ahead and come up and take a
6	seat. I think Michelle has specific places that she
7	wants to put you, so if you could try to match
8	yourself with your tent.
9	(Pause.)
10	Okay. I'm going to assume that we have
11	everybody up here that we need.
12	I have a statement that I have been
13	asked to read. It is from Abba Zubair, M.D., Ph.D.,
14	from the Mayo Clinic. Unfortunately, no one from
15	the Mayo Clinic was able to make it today, so I'd
16	like to read the statement that he had planned to
17	read. I've got the letter, and I'll just go through
18	it right now.
19	"It is regrettable that I will not be
20	able to attend the upcoming workshop that will
21	discuss the security and continued use of devices
22	that contain cesium-137 chloride. To supplement the
23	letter I previously sent you" and this was
24	addressed to Cynthia Jones "I would like to have
25	read into the record some of the important points
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1	that were brought up by my Mayo Clinic colleagues
2	regarding cesium blood bank irradiators.
3	"Bullet 1. Irradiation of blood is
4	medically necessary for some patients to prevent
5	transfusion-associated graft versus host disease.
6	The 2005 nationwide blood collection and utilization
7	survey reported over 2.5 million blood components
8	were irradiated in the year 2004.
9	"Next, cesium chloride blood irradiators
10	are the most reliable, efficient, and low
11	maintenance blood irradiators available. All
12	hospital blood banks are staffed 24 hours a day,
13	seven days a week. Therefore, with the recent
14	increased security requirements, we believe blood
15	bank irradiators are sufficiently secured.
16	"If the decision is to allow all cesium
17	chloride containing irradiators, then the ban should
18	be limited to new irradiators. The cost of
19	replacement of cesium chloride irradiators, with X-
20	ray irradiators, would create a hardship for many
21	hospitals and blood banks. At a minimum, the
22	government should provide the funding for removal of
23	existing cesium-137 blood bank irradiators.
24	"X-ray blood irradiators are the most
25	likely alternative to cesium chloride blood
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1	irradiators, but they are not currently as efficient
2	or reliable as cesium chloride irradiators, and may
3	not be as efficacious based on conflicting reports
4	in the literature. X-ray blood irradiators are
5	associated with relatively higher maintenance costs.
6	"The current manufacturing capacity in
7	the U.S. is not capable of replacing cesium chloride
8	irradiators in a reasonable period of time.
9	Therefore, the waiting time to purchase an X-ray
10	blood irradiator is over six months, and this will
11	significantly get worse if cesium chloride
12	irradiators are outlawed all at the same time.
13	"My assessment of opinions among
14	colleagues in the transfusion medicine community is
15	that existing measures taken to ensure security
16	blood bank irradiators are adequate. Any measure
17	that will limit their use should be enacted over a
18	reasonable time to allow for removal and replacement
19	of existing cesium chloride blood irradiators.
20	"Thank you for giving us this
21	opportunity to offer our opinions and suggestions.
22	We look forward to the outcome of the workshop and
23	NRC's decisions."
24	And it is signed Abba Zubair, M.D.,
25	Ph.D., Director, Transfusion Medicine and Stem Cell
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1	Therapy, Mayo Clinic.
2	All right. Did anybody time me? Was
3	that under three minutes?
4	(Laughter.)
5	Did I hope to my own okay.
6	If we could go around the table and have
7	the panelists introduce themselves briefly. To use
8	your microphone, that's all you need to do is hit
9	the center and it should come on. Lynne, do you
10	want to start us out, please?
11	MS. FAIROBENT: Lynne Fairobent. I'm
12	the Manager of Legislative and Regulatory Affairs
13	for the American Association of Physicists in
14	Medicine.
15	MR. SCHRADER: I'm John Schrader, REVISS
16	Services, and Vice President of North American
17	Operations, and also Radiation Safety Officer.
18	MR. PATTON: I am Brad Patton from Oak
19	Ridge National Laboratory, involved in cesium source
20	fabrication work.
21	MR. MAIELLO: Mark Maiello, Radiation
22	Safety Officer for the Pearl River, New York
23	facility for Wyeth Pharmaceuticals.
24	MR. COPPELL: And I'm David Coppell.
25	I'm Manufacturing and Technical Director for REVISS
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69 Services. 1 2 MR. ALOY: I am Albert Aloy from St. Petersburg Institute. 3 4 FACILITATOR RAKOVAN: Thank you, 5 everyone. Just switched to the lapel mic, so 6 hopefully you can all hear me. It sounds like I'm 7 8 coming through okay. 9 Why don't we go ahead and start with our discussion of 1.1. Michelle, do you want to put up 10 the first question, then, please? 11 12 (Pause.) Something go wrong? 13 MS. KILLIAN: Yes. 14 FACILITATOR RAKOVAN: Of course. Do we 15 16 have a paper copy that I could read it from? Do you have another copy? 17 (Pause.) 18 19 As we are waiting to do that, does 20 anyone have an opening statement that they wanted to 21 go through? Please. 22 I have some viewgraphs. MR. PATTON: FACILITATOR RAKOVAN: 23 Into the microphone, please. 24 25 MR. PATTON: I have some viewgraphs --**NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	FACILITATOR RAKOVAN: If you could
2	introduce yourself.
3	MR. PATTON: if you could put them
4	up, please.
5	FACILITATOR RAKOVAN: Could you
6	introduce yourself, please, the first couple of
7	times that you speak?
8	MR. PATTON: Brad Patton from Oak Ridge
9	National Laboratory.
10	FACILITATOR RAKOVAN: Thank you. Do you
11	have some viewgraphs?
12	MR. PATTON: Yes, sir, I do.
13	FACILITATOR RAKOVAN: Okay. Do we
14	does Michelle have them in the computer already?
15	MR. PATTON: Yes, she does.
16	FACILITATOR RAKOVAN: Okay. Well,
17	unfortunately, that might be we're experiencing
18	technical difficulties. Please stand by.
19	(Laughter.)
20	Thanks, Lynne.
21	All right. Question 1.1, are
22	manufacturers this is feasibility of the use of
23	other forms of cesium-137. The question is: are
24	manufacturers currently considering the use of other
25	forms of cesium, other than cesium chloride? If
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1	yes, what are such considerations?
2	Hey, look at that. Okay. Michelle, do
3	you have the charts? Can you put those up, please?
4	MS. KILLIAN: Is this for Lynne?
5	FACILITATOR RAKOVAN: No. This is for
6	Brad Patton.
7	(Pause.)
8	MR. PATTON: Can I get up here where I
9	can see?
10	FACILITATOR RAKOVAN: Yes. You can use
11	the podium if you'd like to while you're giving your
12	presentation. Certainly. Thanks.
13	MR. PATTON: I am Brad Patton from Oak
14	Ridge National Laboratory, and I would like to give
15	you some history of cesium chloride production at
16	Oak Ridge, which hopefully will put some of the
17	discussion in perspective later on in the day.
18	Next viewgraph, please.
19	ORNL produced cesium chloride from 1950
20	until 1989. Approximately 56 million curies of
21	cesium chloride were distributed over that
22	timeframe. And the specific activity of material
23	that we produced was always greater than 18 curies
24	per gram, and many times as high as 25 curies per
25	gram. And that is important as we go through the
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1	discussion I think, and getting a concentrated
2	source is very important to the discussion we are
3	having.
4	The cesium chloride we produced was
5	produced both in bulk material, breast pellets and
6	powders, which were distributed to other
7	manufacturers to produce sources, and we also
8	produced sources ourselves. And you see in this
9	photograph we had a different a number of
10	different source types that were produced at ORNL.
11	Next viewgraph, please.
12	Our process was very simple, and I think
13	that is why we are using cesium chloride. The
14	material the bulk material was separated at the
15	Hanford facility, the DOE Hanford facility. It was
16	shipped to ORNL, and the process simply was to
17	dissolve the material, to filter it, and then
18	solidify the material again into the cesium chloride
19	form, and then those were cold-pressed into pellets.
20	Again, this is a hot cell operation, and
21	this is the simplest way to produce the material,
22	and that is why cesium chloride I guess was chosen
23	as the source form of interest, plus the fact that
24	you get some very high specific activities
25	associated with the material.
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1	Next viewgraph, please.
2	During that period in the early 1980s,
3	ORNL did experiment with other source forms. And
4	pollucite, which has already been discussed today,
5	was one of those source forms. And we actually
6	produced cesium-137 material with pollucite.
7	Unfortunately, the specific activity is more like 10
8	curies a gram that we that we resulted from
9	this process, roughly half the specific activity
10	that we had in general in our cesium chloride.
11	Another source form that we make at ORNL
12	is californium sources, and this is a cermet, which
13	is a ceramic encapsulating a metal matrix, and it's
14	used commonly from ORNL now. It's a palladium and
15	cesium oxide cermet, and ORNL is experimenting with
16	cermets for spent fuel and proposes cesium-type
17	cermet, which both would be insoluble and also non-
18	dispersible.
19	As I put in the box here, these are all
20	more difficult processes, and all have to be done in
21	a hot cell environment.
22	Next viewgraph?
23	In summary, ORNL has a lot of experience
24	in handling cesium chloride, also experience in
25	other source forms. We have no plans to be in the
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1	cesium production business, but we are interested in
2	developing new source forms and reviewing source
3	forms developed by other agencies.
4	And based on our experience with how
5	easy cesium chloride is to produce, and the specific
6	activity that you get with cesium chloride,
7	alternate forms will be more difficult with lower
8	specific activities, and we believe the phaseout
9	would need to be driven by some sort of regulatory
10	requirement.
11	FACILITATOR RAKOVAN: Thank you, sir.
12	Did we have any other opening points for
13	this particular issue?
14	(No response.)
15	Okay. So let's just go ahead and open
16	to discussion, then. Anybody have a point that
17	they'd like to make on this particular issue, work
18	towards sir, please, if you could introduce
19	yourself, at least for the first few times.
20	MR. COPPELL: Yes, thank you. It's
21	David Coppell here again from REVISS Services. I
22	think many of you will know that REVISS works
23	closely with Mayak in a partnership for
24	manufacturing and distribution of radioactive
25	sources, including large cesium sources.
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75 1 And I just wanted to respond to the 2 first question, question 1.1, are manufacturers currently considering the use of other forms of 3 4 cesium? Well, the answer is, quite simply, yes. In 5 fact, I think it is probably common knowledge that other forms of cesium have been available for some 6 decades, not for this type of product. 7 8 And I think what has been explored at 9 the moment is the potential to extend and probably modify the manufacturing technologies for those 10 alternate forms, so that they could be applied to 11 12 the manufacture of large cesium sources for the applications that we are discussing. 13 The only thing I would say is that these 14 15 development programs are not very quick or very 16 I think as Brad pointed out in his easy. 17 presentation just now there are some technology challenges that we need to go through, and so at 18 19 this precise stage we are not quite in a position to be able to make some firm proposals. But I think 20 21 our expectation would be that within a very few months that would be possible. 22 FACILITATOR RAKOVAN: Okay. 23 Anyone want to piggyback on that, or make a different discussion 24 25 point? Sir, yes, if you could introduce yourself, **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W.

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1	please.
2	MR. MENNA: My name is Blair Menna. I'm
3	from Best Theratronics. A question for Brad, I
4	guess, and it's probably just a yes or no question.
5	I gather from your presentation that it is very
6	feasible technically. We we have the technology
7	to develop a non-dispersible form of cesium.
8	MR. PATTON: Yes, we do have the
9	technology to produce those forms. But I guess the
10	question is whether we can get the specific
11	activities high enough to serve the uses that you
12	now have for the source materials. But, yes, I
13	think the source could be developed that are non-
14	leachable and non-dispersible, but you are going to
15	have to add have some additives there, and the
16	specific activity will be necessarily lower.
17	MR. COPPELL: Dave Coppell again here
18	from REVISS. Just to add a couple of points to
19	that. I agree with what Brad says. That's
20	certainly a challenge. It is not the only
21	challenge. I think in developing the alternative
22	forms we will need to understand more clearly what
23	the target is going to be in terms of solubility and
24	leachability, and also what the target is going to
25	be in terms of dispersibility.
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1	And then, having gone through the
2	technology development program, there will be a
3	matter of cost as well. We will need to come to
4	that at some stage.
5	MS. FAIROBENT: To both of you, what
6	sort of timeframe are we realistically talking
7	about? If we had an alternative form today that was
8	readily available, what timeframe could it be
9	brought into market to substitute out the cesium
10	chloride form?
11	MR. PATTON: Since we are really not in
12	the business right now
13	FACILITATOR RAKOVAN: Sir, I don't think
14	your microphone is on. Yes, red light is on when
15	it's on.
16	MR. PATTON: I would refer to REVISS on
17	that. Since we are really not the producers at this
18	time, that would be their their statement,
19	please.
20	MR. COPPELL: Okay. Thanks, yes. The
21	simple answer is I am not exactly sure. It will be
22	a few years. It is going to depend I think on
23	well, a number of factors, but particularly the
24	commercial viability. Obviously, this is going to
25	go faster if there is more funding available to
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1	support it, so there are a lot of factors involved
2	in making an assessment of time scale, but let's say
3	a few years.
4	FACILITATOR RAKOVAN: Please, if you
5	could go ahead and step to a microphone and
6	introduce yourself.
7	MS. SHEPHERD: Mary Shepherd, J.L.
8	Shepherd and Associates. With the having of the
9	of the output by going to a more indispersible form,
10	there would have to be consideration for either the
11	placement of the device because of the size of the
12	sources would be either double to replace the source
13	or to look at the technology. Is half a curie
14	output half a curie output feasible for the
15	replacing into existing devices? There is not the
16	physical size to put double a capsule that is
17	twice the size inside an irradiator.
18	And the question for REVISS would be:
19	would there be a means of replicating the current
20	curie output in the same size?
21	MR. COPPELL: Well, the simple answer
22	is, no, not really. The specific activity and
23	volume-specific activity of the replacement product
24	would be lower. There is no doubt of that. And
25	there are some other effects as well, such as self-
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absorption of the radiation in a larger and more dense material.

Having said that, it may be that the 3 physical size of the sealed source is not -- not 4 5 immensely larger than a current one of the same 6 activity. We've got a few estimates. I don't have 7 some figures with me at the moment, but I guess that what we believe is that for many instruments it is 8 possible to make relatively minor modifications to 9 the instrument in order to accommodate a slightly 10 11 larger sealed source. But we really need to discuss 12 that with equipment manufacturers and the industry more generally. 13

14 FACILITATOR RAKOVAN: Does anyone want 15 to expand upon that or -- please, if you could 16 introduce yourself.

17 MR. MAIELLO: Sure. Mark Maiello again from Wyeth Research in New York. There was the 18 19 representative from Best, I believe. This would be a question for you on this issue. Forgive me if 20 21 this is anecdotal information, but is it true that the existing irradiators would not be subject to 22 reloading, but, in fact, would have to be totally 23 replaced? We had heard that that was a real 24 25 possibility.

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80 MR. WASIAK: Obviously -- Tom Wasiak 1 2 from Best Theratronics. We haven't done very extensive analysis of that situation, but we looked 3 4 at it briefly. And I think the entire -- doing it 5 in the field would be probably prohibitive and 6 likely impossible. There might be an option of 7 doing something in the facility, kind of swapping the radioactive shielding component. That might be 8 an option. 9 I also would like to say -- kind of 10 11 follow up on the previous comment that the impact of 12 using different form of cesium varies, obviously, with the design of the equipment. And it's not the 13 same for all kind of equipment and all applications. 14 So in our case it might be easier in case of blood 15 irradiators -- obviously, you have to compensate in 16 17 some way for a loss of specific activity and possibly, you know, increased volume or increased 18 19 number of sources. But it might be possible, with some, you 20

21 know, medium size design changes. In other case, 22 more significant changes to the design of equipment 23 would be required, and probably loading these type 24 of sources to the existing pieces of equipment might 25 be impossible.

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1	FACILITATOR RAKOVAN: I've got a few
2	panelists who haven't made any comments yet. I'd
3	just like to open the floor, if they would like to
4	go ahead and step up and say something at this
5	point, after this gentleman speaks, of course. Sir,
6	if you could introduce yourself.
7	MR. SULEIMAN: Orhan Suleiman with the
8	Food and Drug Administration. You talk about reduce
9	specific activity. Twenty percent, 50 percent?
10	Give me a ballpark figure. And how would that have
11	what sort of an impact would that have in terms
12	of irradiation time for commonly-used applications?
13	Are we going to go from five-minute times to five
14	hours? Or are we going to go from five minutes to
15	10 minutes? That has a lot to do with the
16	practicability and the applicability of such
17	changes.
18	MR. PATTON: Well, you saw my
19	viewgraphs. In the pollucite, we really
20	basically was half what the cesium chloride was.
21	And I don't know if there's other experience there,
22	but I think half or lower may be depending on how
23	much again, we don't know what the requirements
24	are for dispersibility or leachability. I mean,
25	depending on what those requirements are, how much
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1	better is good enough, it would drive that specific
2	activity reduction.
3	MR. SULEIMAN: I know, but I can only
4	think one thing at a time, so I want to I want to
5	understand the reduced
6	(Laughter.)
7	activity and intensity, and then I
8	could worry about the other issues. But I think
9	is reducing the activity going to be so bad that it
10	can't be it won't be practical in the working
11	environment? And what are the average times for
12	using these irradiators for applications?
13	MR. COPPELL: Well, I'm not sure I can
14	add much to what Brad just said. If you're looking
15	for a typical number, think of half. Whether that's
16	still is still viable from an applications
17	perspective is really a question more for the
18	equipment manufacturers.
19	And I think we're all a little concerned
20	about getting numbers set in concrete too early, but
21	just for order of magnitude think of maybe half.
22	MR. SULEIMAN: Thank you.
23	FACILITATOR RAKOVAN: Sir, if you could
24	introduce yourself, please.
25	MR. MOSHAASHAEE: Moji Moshaashaee,
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1	Schering Corporation. I just had a question. When
2	you change the constituency of the cesium chloride
3	itself, you have additives. Does that change in any
4	way the gammas that are you know, the basically
5	beautiful gamma that we get from the cesium sources
6	that we get right now? Do we get uniform
7	uniform, actually, gammas?
8	MR. COPPELL: Provided you design the
9	material that you incorporate matrix material
10	that you incorporate this in correctly, the answer
11	is no.
12	MR. THOMAS: I'm Jerry Thomas of Via
13	Christi Regional Medical Center in Wichita, Kansas.
14	FACILITATOR RAKOVAN: If you could turn
15	the mic up a little bit, please.
16	MR. THOMAS: Oh, absolutely. Excuse me.
17	FACILITATOR RAKOVAN: Thank you.
18	MR. THOMAS: I'd like to give Orhan a
19	direct answer to your question, and that is how long
20	of the irradiation time. We currently are
21	irradiating at about 12 to 15 minutes for a source
22	pardon me, for a blood sample. Consequently, if
23	we double that time, the throughput is going to be
24	24 to 30 minutes per sample.
25	Consequently, to meet the workload that
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84 1 we currently have, we are going to have to have an 2 additional irradiator capability. I think that is 3 going to be the case in many large blood banks is 4 that the current irradiator capacity is not going to 5 be sufficient with the lower specific activity source in the irradiator. 6 7 MR. MOSES: Paul Moses, Best Theratronics. If you look at the different models 8 that we have in the gamma cell line, which holds the 9 10 cesium source, you are looking at the higher loaded units to be in compliance with the AABB and the FDA. 11 12 You would be looking at little over a minute to be in compliance with a fully loaded unit, GammaCell 13 1000. 14 The GammaCell 3000, which holds multiple 15 16 blood bags, you are looking at a cycle time of around two and a half minutes on a new unit fully 17 loaded. So after you've had a unit for it sounds 18 19 like -- in the gentleman's case here -- for maybe 20 20 years --21 PARTICIPANT: Fifteen. MR. MOSES: -- 15 years --22 (Laughter.) 23 -- yes, you are obviously -- your cycle 24 25 time is going to drop a little. But that just **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	speaks to the reliability and the longevity of this
2	kind of product in the marketplace.
3	FACILITATOR RAKOVAN: Do you want to
4	okay. Rob, do you want to go first?
5	MR. LEWIS: Rob Lewis from NRC. I would
6	like to hear, if I could, some additional words from
7	the panel about creating a market. And, in
8	particular, the panel seemed to indicate that there
9	wasn't a technological obstacle to a new form, but
10	there wasn't a market-driver. And, you know, a
11	regulatory action could create a market, of course,
12	to drive a new form for the U.S.
13	But, as we all said, this is a worldwide
14	business, and there is only one producer in the
15	world, which is Mayak. And would the regulatory
16	action in the U.S. also create a market for the rest
17	of the world, or or, you know, how can we do this
18	in isolation? Even is there enough market force
19	to sustain two different forms a cesium chloride
20	form for the rest of the world and a different form
21	for the U.S.?
22	MR. SCHRADER: John Schrader, REVISS
23	Services. We have had this discussion internally
24	quite a bit. It is going to depend on what the
25	costs are to make the changes, whether they are
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1	going to be able to pass a lot of costs on,
2	obviously.
3	We are looking at probably having to
4	develop a new process line to be able to develop the
5	new source material. Whether there is a sufficient
6	market out there right now to be able to maintain
7	two lines where you have cesium chloride on one and
8	where you have this new material on another
9	again, it's going to all depend on what the
10	development costs are and what the sales costs will
11	be.
12	FACILITATOR RAKOVAN: Please.
13	MR. ALOY: Excuse me. Because I am not
14	very fluent in excuse, maybe I speak in Russian and
15	use the
16	FACILITATOR RAKOVAN: No, that's fine.
17	That's fine.
18	MR. ALOY: I can I would like to
19	stress only that we have no technology for a new
20	alternative form. We have only the scientific
21	results and scientific resources and scientific
22	bases of different alternative materials, like
23	pollucite or glasses.
24	But technology means that equipment,
25	operational personnel, and hot cell installation.
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1	And so just only the first approach to the change
2	for a new alternative materials we have.
3	And also, in Russia we have the testing
4	in the with surrogate materials, not with the
5	real initial form. Initial form is cesium nitrate
6	is initial form to transform into the ceramics or
7	into the glasses. So we have no technology for
8	pollucite or alternate forms. We have only
9	scientific approach, and we need enough time to
10	implement the scientific approach into real
11	technology.
12	And also, we need to understand that the
13	cesium chloride, due to crystalline form properties
14	and physical property, has free volume into the real
15	sources. This is free volume in the design sources,
16	about 25 volume percent.
17	So we can use this additional volume to
18	receive the volume activity, specific volume
19	activity, equal approximately it's about 90
20	percent to the activity of the cesium chloride.
21	This is only just my remarks to the discussion.
22	FACILITATOR RAKOVAN: Thank you, sir.
23	MR. COPPELL: Yes. Can I just add my
24	support to that comment on behalf of the
25	manufacturers? I am trying to be careful to say
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1	that we believe that we can develop the technology.
2	But I support what Mr. Aloy says. We don't have
3	that technology right now. We have a track record
4	of use of non-dispersible versions for forms of
5	cesium going back some time, which leads us to
6	believe that it is feasible.
7	But, really, we need some more months,
8	as I said at the outset, maybe six to nine more
9	months, to to assure ourselves, and then be able
10	to make a proposal. And thereafter, then actually
11	industrializing that technology, bringing it to
12	market, assuming that the commercial environment
13	existed to justify it, would take a few years.
14	FACILITATOR RAKOVAN: If I could I'm
15	sorry, I had a gentleman who stood up earlier. If
16	you want to please. I cut you off earlier, and I
17	wanted to give you a chance. I'll get to you next,
18	sir, I promise.
19	MR. WASIAK: Just a brief comment. I
20	guess it some of the questions earlier it was
21	assumed that a 50 percent drop in specific activity
22	automatically means that the irradiation time would
23	have to be doubled.
24	It is true in some cases, but I think
25	by, you know, installing more sources where you have
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1	that capability, or in other means, this can be
2	compensated to some extent, and may not necessarily
3	mean drop of or extension of irradiation time
4	twice the previous value, right? So partial
5	compensation, if not full compensation, may be
6	accomplished by certain design changes.
7	FACILITATOR RAKOVAN: Yes. Sir?
8	MR. MAIELLO: Mark Maiello again from
9	Wyeth Research. You know, we are starting to touch
10	on the money issue now a little bit. And I'd like
11	to remind everyone here that even pharmaceutical
12	companies have budgets and
13	(Laughter.)
14	we are we are starting to hear
15	rumors. You know, again, I hate to bring up
16	anecdotal information, but, you know, we are hearing
17	rumors that new irradiators may cost, you know,
18	hundreds of thousands of dollars.
19	In the present economic atmosphere, even
20	companies like my own are struggling. And prior to
21	this, they were struggling on their own without the
22	present economic burdens, research lines and
23	research avenues in most pharmaceutical companies.
24	And I know there are some of my
25	colleagues here, so correct me if I'm wrong, there
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1	are those research avenues were drying up. So,
2	you know, budgets are rather tight. Unless these
3	new and with all due respect to the panel
4	members, unless these new sources are competitively
5	priced, with the non-isotopic versions, for
6	companies like mine that do not need a mono-
7	energetic photon beam, they will switch over.
8	That's what I'm hearing from my management and the
9	scientists that use these devices. They will switch
10	over to X-ray type devices.
11	Again, it is probably too early to
12	determine what the cost of these things will be, but
13	it is something to keep in mind.
14	MR. JARDINE: Let's see, Les Jardine, a
15	consultant. And I have worked the last 12 years in
16	Russia, including the Mayak site.
17	Just I want to add what is missing
18	and everybody should bear in mind the cesium
19	comes from an operating reprocessing plant. There
20	is one at Mayak. There is none in the U.S.
21	That plant purposely designed a process
22	to recover cesium nitrate. That doesn't exist in
23	France, where there is another operating plant. To
24	take that product, as Albert Aloy said, to another
25	form requires the scientific basis, which the
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91 1 institute has developed. But what's required are the engineering study to decide how to fit that in 2 an operating reprocessing plant in their hot cells. 3 And that is where this time comes in. 4 5 And it's my personal judgment, having 6 worked feasibility studies and others in Russia, 7 it's a five-year process to take it to another form in an operating plant at Mayak. That's why I'm 8 supporting the notion of three years, but it's not 9 -- and just bear in mind, in Oak Ridge, what could 10 they do? They don't have any cesium nitrate. 11 We 12 don't have the reprocessing plant. So somehow, you know, as an operating 13 reprocessing plant you have to develop a whole 14 15 remote operated production line and continue the scientific work. And it's a five-year timeline, is 16 17 my experience in Russia. And I should just add, because I may not 18 19 comment again, and there has to be the cooperative agreement between the governments to allow that work 20 to take place. That's missing. The U.S.-Russian 21 government to allow that work to happen is missing. 22 FACILITATOR RAKOVAN: Orhan? 23 If you could introduce yourself again, please. 24 25 MR. SULEIMAN: Yes. Orhan Suleiman with **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	FDA, but these are clearly my professional
2	questions. I have accepted the fact that the
3	activity, although reduced, could probably be you
4	can use more of it, and it will probably be
5	feasible. It sounds like industry is up to the
6	challenge.
7	The more fundamental issue is the
8	chemical, non-dispersibility form, and how that
9	works out economically I have no idea. But,
10	obviously, it is feasible. I just wanted to get
11	that clarified in my mind.
12	So it sounds like it is very, very much
13	possible to come up with a solid, non-dispersible
14	form of cesium, and it's probably with sufficient
15	activity, in larger amounts, that would fulfill the
16	tasks necessary. How that plays out economically,
17	as I said, I'm not going to participate in that
18	decision, because who is going to manufacture it,
19	who is going to put it together is a different
20	issue.
21	But the scientific issues, the technical
22	challenges, sound like they're soluble. I mean,
23	they're they can be resolved.
24	(Laughter.)
25	They can be resolved.
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1	Am I correct on those two points? We
2	probably could get a forum that would be adequate,
3	and we probably could get insufficient activity. I
4	mean, that's what I'm hearing. I don't really need
5	your answer. That's what I've come to the
6	conclusion myself.
7	FACILITATOR RAKOVAN: Anybody want to go
8	into that territory?
9	MR. SCHRADER: I was just going to say I
10	think it's a correct conclusion that it is a
11	solvable issue. I wouldn't go so far as to say,
12	yes, it's the money is you know, how much is
13	it going to cost? Is it we can solve the
14	problem, but can people afford it when we get it
15	solved?
16	Secondly, I would just kind of add that
17	everything is dispersible with enough exposure
18	behind it.
19	MR. PATTON: I guess I might make one
20	more comment. I guess it was mentioned that there
21	is some void volume in these sources, so there is
22	we could reduce the void volume in the cell I
23	mean, into the in the source and also decrease
24	or increase, I guess the amount of material in a
25	given volume.
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1 But I would like to caution that we do 2 want to keep safety in mind as well. And barium grows into these materials. It has different forms. 3 4 So we need to look at the thermal expansion and 5 make sure we don't develop a source that is not safe 6 in the process of changing the source form. So all of the testing, and so forth, needs to be done to 7 make sure that the source form is safe as well. 8 9 FACILITATOR RAKOVAN: Dr. Aloy, you had 10 MR. ALOY: We need to find not only the 11 12 physical forms, but also to provide the results -positive results after the testing of these forms in 13 optimal design, because we have after the studies 14 15 some ceramics or glasses, we provide the test for 16 compatibility, for fire, and for some additional tests for specificity. 17 And not -- we have good results after 18 19 this testing. So it's not only the problem to find the alternative forms and produce. It also needs 20 21 along the way for testing purposes alternative forms and the design of sources for specificity. We have 22 standards and -- followed by these vendors in all 23 the testing. 24 25 MR. COPPELL: Well, I think I'm at risk **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	of repeating what a number of other people have
2	said. I agree with the point that Brad made about
3	the we do need to take care of the question of
4	safety and allowing sufficient void volume in
5	cesium. But in estimating, maybe a half the content
6	activity in a source made to a new format, I think
7	we are making allowance for that. I don't really
8	want to complicate the issue by going into the
9	detail of what that means.
10	And I also agree with the comments that
11	Mr. Aloy made about, in terms of the performance of
12	these sources, there is a long road to go down to
13	convince ourselves that the improvement that is
14	delivered from a change in physical and chemical
15	form is adequate to meet everybody's needs and
16	expectations. And that is particularly true in
17	terms of dispersibility.
18	I think we have had a couple of
19	conversations and discussions about leachability or
20	solubility, if you want to call it that, and that's
21	a relatively simple term to understand. And it's a
22	relatively simple concept to measure and validate.
23	But when it comes to discussion about
24	dispersibility, which of course is another concern,
25	then I don't know that there is any very clear
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96 1 guidelines right now. And I think part of the process of developing the technology will be to 2 3 develop an understanding of what is acceptable in 4 terms of dispersibility. 5 FACILITATOR RAKOVAN: Anyone care to 6 piggyback on that, or make another point? Please 7 introduce yourself, sir. MR. POWELL: I am Brian Powell. I am 8 from Constellation Energy, nuclear power. And I 9 guess I am trying to get an understanding of this 10 11 from a practical perspective. So what I'm 12 understanding is that to calibrate our instruments, for example, we are going to need twice the 13 material. We'll basically have to replace our 14 15 calibrators, and that -- there is going to be some 16 increased cost with this new solid type of source. I don't know if there's a ballpark 17 number that it's going to be 10 times as much per 18 19 curie, or 1,000 times more per curie, or a million times more per curie, but that would be something 20 21 that I'd like to know. And the other thing is, which I'm 22 hearing some things being touched on, is industrial 23 safety issues. You know, does making these new 24 25 sources introduce other things that we are going to **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	need to be able to monitor for besides just
2	radiation? Chemicals leaching out, things like
3	that?
4	FACILITATOR RAKOVAN: Just wanted to
5	interject from that question. Just keep in mind
6	that, you know, we are having this workshop because
7	it's part of the process. We haven't made any
8	decisions on how we're moving forward on this at
9	this point. So just kind of wanted to throw that
10	out there. We're you know, we're just discussing
11	these issues.
12	Did anybody want to react to the
13	gentlemen's statements?
14	MR. COPPELL: On the subject of cost, I
15	mean, I think it's obvious to the industry that this
16	isn't going to work if the cost of the new
17	technology is that significantly greater, or, more
18	particularly, if the cost of the new technology is
19	more than alternate technologies. Then, clearly, it
20	is not going to be very attractive.
21	So that has got to be borne in mind, and
22	it is being borne in mind in terms of our
23	development activities.
24	I think, though, that you need to recall
25	that the costs will be split into two parts, really.
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98 1 The first part is a development cost, and that 2 could be quite significant to the industry, and, of 3 course, the risk is that that development cost will 4 have to be incurred before there is any revenue or, 5 indeed, any guarantee of any revenue. And that is 6 part of the discussion we need to have. 7 And then, there will be a manufacturing cost once the technology is developed and installed 8 and considered operational. And that is not yet 9 assessed, but we understand that it needs to be 10 realistic in terms of market accessibility. 11 12 FACILITATOR RAKOVAN: I am going to use a pause, since I see no hands. Lynne, do you want 13 to go ahead and give your presentation? 14 Michelle, if you could bring Lynne's 15 16 presentation up? She has just got some general information from the medical perspective that she 17 wanted to share. 18 19 MS. FAIROBENT: Thank you, Michelle. As I introduced myself earlier, I am 20 21 Lynne Fairobent with the American Association of Physicists in Medicine (AAPM). And since this issue 22 surfaced and the NAS panel had been charged with 23 their task, AAPM and the medical community has been 24 25 looking at this issue. **NEAL R. GROSS** 

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1	Next slide, Michelle.
2	AAPM's mission, just for those who may
3	not be as familiar with us as others in the
4	audience, is to promote the highest quality medical
5	services for patients while advancing the practice
6	of physics in medicine and biology by encouraging
7	innovative research and development, disseminating
8	scientific and technical information, fostering the
9	education and professional development of medical
10	physicists. And we currently represent about 6,000
11	medical physicists, primarily in the U.S., but we
12	also do have international members.
13	Next?
14	The use of radioactive materials in
15	medicine I think can easily be stated and not
16	disputed, that it has resulted in many lives being
17	saved that otherwise would not be. Cesium chloride
18	irradiators are just one example of the way in which
19	this occurs.
20	AAPM is concerned that the prohibition
21	or elimination of the use of cesium irradiators
22	could result in a decrease in the standard of care
23	that currently exists in this country. As a result
24	of that next slide AAPM conducted a survey in
25	August of this year to assess our members'
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1	experience with irradiators across the board.
2	The results of the survey are skewed
3	toward hospital-base or university-base irradiators,
4	but it should not affect the general overall
5	conclusions and trends.
6	Next slide.
7	The survey was distributed to all AAPM
8	members, as well as members of the RSO, the
9	Radiation Safety Officers' listserv, and other
10	medical organizations had access to this.
11	We received 363 respondents, 297 had
12	irradiators. 84.6 of those used cesium-137 as the
13	source. 9.3 percent used conventional X-ray units.
14	Six percent used medical LINAC accelerators or
15	LINACs.
16	The cesium units represented all of the
17	major vendors. Only 10 percent were purchased
18	within the last two years, and seven percent planned
19	on replacing the units within the next five years.
20	Next slide.
21	Twenty-five percent of the cesium units
22	had some malfunction, but most were repaired in less
23	than seven days. This is an issue that keeps coming
24	up as we discuss and debate the difference between
25	the cesium chloride irradiators and transitioning to
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1	the X-ray units.
2	Of the X-ray units, 35 percent had
3	malfunctions, with 44 percent being repaired in
4	seven days.
5	Next slide.
6	Of the cesium units, only 40 percent are
7	used for blood irradiation, and I think this is key
8	to keep in mind is the other irradiation uses of
9	these irradiators. With 25 percent used for
10	material, 25 percent for animal irradiations, and 10
11	percent was unspecified as other uses.
12	Of the X-ray units, 50 percent were used
13	for blood irradiation, 19 percent for material, and
14	32 percent for animals. Of the medical LINACs that
15	were used in this modality or use, 40 percent were
16	for blood irradiation, and 11 for animals, versus
17	the primary use of LINACs, of course, is to treat
18	patients human patients and veterinary patients
19	for the treatment of cancer.
20	Next slide.
21	In conclusion, we feel that both types
22	are usable. The conventional X-ray irradiators seem
23	to be fairly reliable. However, they represent only
24	a small minority of the irradiators currently in the
25	field, and they have slightly more down time than
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1	the cesium units.
2	The cesium units, on the other hand, we
3	know to be extremely reliable. Their users, in
4	general, have no plans to replace them unless there
5	is an external factor that is going to drive them to
6	that.
7	Next slide.
8	We believe that the forced removal of
9	cesium irradiators would result in a large loss of
10	resources, both radiation sources and funds, not
11	only from medical facilities but research
12	institutions as well.
13	Next slide.
14	In considering the cost of alternative
15	technologies, one needs to include not only the cost
16	of the replacement, but the calibration and
17	maintenance of the equipment, the cost of downtime
18	for the critical use equipment, such as the blood
19	irradiators. And a quantifiable cost for the
20	alternative blood sterilization during equipment
21	down time needs to be assessed and needs to be
22	possible, as well as the human cost for patients who
23	need blood.
24	In many cases, the comments we receive
25	from the survey, if an X-ray unit is being used for
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1	blood irradiation, and it is down, oftentimes the
2	backup is the cesium irradiator at someone else's
3	facility if they do not have one at their own
4	institution.
5	Next slide.
6	It is easily demonstrable that cesium
7	chloride sources utilized in blood irradiators have
8	a much more reliable performance record than
9	machine-produced technologies. And both the cost
10	and continuity of operation or failure should be
11	considered financially, and then the possible impact
12	on human life.
13	Over the course of the rest of today and
14	tomorrow, we actually will be sharing more data as a
15	result of a couple of the other questions that are
16	being asked. But there is a huge increase in
17	concern in the research community on the viability
18	of transitioning, for clinical trials work, from
19	using a cesium irradiator now to if one has to
20	transition to the X-ray unit, can one in fact
21	demonstrate the equivalency to FDA in order not to
22	jeopardize the clinical trials work that has been
23	done currently, and not have to go back and start at
24	square one.
25	Thank you.
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1	FACILITATOR RAKOVAN: Thanks, Ms.
2	Fairobent.
3	Michelle, if you could go ahead and
4	bring up the question again.
5	Anyone have any reaction to the
6	presentation that Ms. Fairobent just gave, or any
7	other issues that they'd like to throw around in
8	terms of question 1.1? Please.
9	MR. MAIELLO: Mark again from Wyeth
10	Research. Lynne, that was very good. The again,
11	the anecdotal information I will give you from my
12	institution. And, again, if my colleagues find that
13	this is inaccurate, please go to the microphone.
14	I'll step back a little bit about what
15	you know, about what I commented on earlier. The
16	pharmaceutical companies are a little strange. They
17	do things with research lines in mind, and that
18	research often changes.
19	In my own institution, the use of the
20	irradiators is basically two different types, one
21	for irradiating small animals, the other for
22	irradiating cells. The group that irradiates the
23	cells would agree with the equivalency issue that
24	you brought up, because when asked directly by me
25	they said, yes, it would be potentially troublesome,
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because the literature has used the -- the literature shows that researchers have used the cesium sources most frequently for irradiating cells. And perhaps research that was conducted with an X-ray machine, with its broad spectrum, would be questioned.

On the other hand -- and this was part 7 of my comment before -- the group that irradiates 8 with animals -- irradiates the animal lines would 9 probably not care. However, I will say this. 10 The researcher who I questioned, who was in charge of 11 12 the irradiator, said to me a few days ago it would be potentially feasible, if the money is there, to 13 purchase -- to keep the irradiator, assuming no 14 regulatory issues arise, and buy an X-ray machine at 15 16 the same time, and use it exactly the way you described it -- as a potential backup for the X-ray 17 machine if the X-ray machine fails, and we have 18 19 heard about the higher maintenance and potentially higher breakdowns. And so the irradiator would 20 21 still be there, assuming, of course, that no regulatory issues arose to force us out. 22 So the situation is never quite clear. 23 It is always gray. And when given a choice, people 24

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will often take the choice, especially if -- I have

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1	to say it if the money is there, they will take
2	the choice.
3	FACILITATOR RAKOVAN: Okay. A few more
4	comments, and then we're going to move on, please.
5	MR. McBRIDE: I'm Bill McBride from
6	UCLA. I'm a radiobiologist. I'm representing ASTRO
7	here. It's the American Society of Therapeutic
8	Radiation Oncology.
9	Yes, I'd like to say that there are
10	actually you know, from a radiobiological point
11	of view, I'll state the obvious. An X-ray is not a
12	gamma ray. There is a big difference between them.
13	I think the you know, whenever it
14	comes to the usage of these machines, they are all
15	used for different purposes. And, actually,
16	switching I mean, I disagree entirely that small
17	animal users could switch easily to X-rays. That
18	just isn't true. I think that it would take a lot
19	of effort. Most of the work that has been done with
20	small animals have used cesium.
21	I think that in particular for things
22	like whole body radiation setups cesium is a much
23	better kind of for all kinds of technical
24	reasons. I think making that change is going to be
25	expensive, it's going to use more animals, you are
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1	going to get into a whole new recalibration system.
2	And I think it is not just a simple matter of, you
3	know, taking the animals and saying, "Okay. Let's
4	use X-rays." I don't think it's going to be that
5	easy at all.
6	So I think there are disadvantages,
7	certainly, to using X-rays for many studies, not all
8	certainly. There are some situations where the
9	transition can be made without a great deal of
10	difficulty, but they are other situations where it
11	is just going to be very difficult indeed.
12	FACILITATOR RAKOVAN: One more hand,
13	please?
14	MR. NIXON: Grant Nixon with Best
15	Theratronics. As the world's leading manufacturer
16	of self-contained irradiators, in both the X-ray
17	technology form and in the cesium form, I would
18	agree wholeheartedly with that comment. The use of
19	X-ray technology does not port well to the research
20	irradiator applications, specifically with regards
21	to irradiating animals. There is a big difference
22	between the mode of dose deposition.
23	When you're dealing with low-energy
24	photons that are inevitably part of the X-ray
25	spectrum, you will end up with a lot of photo-
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1	electric differentiation in terms of the absorbed
2	dose. So unless you can genetically engineer a
3	mouse not to have any bones
4	(Laughter.)
5	you are going to be you are going
6	to be stuck with using a high-energy gamma research
7	irradiator for the foreseeable future.
8	Thank you.
9	MR. KAMINSKI: Hi. Joe Kaminski, NIH,
10	but I'm not speaking on behalf of the NIH. I'm a
11	radiation oncologist. Again, we treat with X-rays,
12	high-energy X-rays, and, of course, you know, a
13	mono-energetic 660KeV gamma that's cesium is
14	useful. But certainly other sources, such as
15	cobalt, could be used, which would more mimic the
16	high-energy X-rays which we used clinically.
17	So to disregard X-rays and, again, we
18	can use LINACs for some animal use, although it is
19	expensive. But there are alternatives, such as
20	high-energy X-rays. So
21	MR. SVAJGER: Hi. I'm Mark Svajger with
22	Fluke Biomedical. We are a large calibration
23	facility. I just have a statement and a question.
24	First of all, the statement. Any changes will cause
25	the price of calibration to go up. And we are
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1	already probably one of the most costly facilities
2	right now, at, let's say, \$200 an instrument.
3	So when we're talking about, like the
4	gentleman from Constellation Energy, is it going to
5	be 100 times more, a million times more? That will
6	all impact us as we use our equipment to survey our
7	facilities.
8	Number two, my question is, if we change
9	this is more or less for Brad, I guess. If we
10	change from a powder form to more of a ceramic form,
11	are there any more inherent errors or variables with
12	that?
13	MR. PATTON: Maybe others can I think
14	there might be some self-shielding, but I think
15	someone mentioned earlier that the energy of the
16	gamma is going to be the same in these different
17	forms. And there might be some self-shielding if
18	you bring in some cermats, you bring metals or other
19	things into it. But I think you will get the same
20	type energies, which I would think would be of
21	interest to you.
22	MR. ALOY: I can say that because the
23	ceramics or glasses contained only elements with the
24	atomic weight, the self-absorption is not will
25	not change very sharply from the cesium chloride.
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1	So the properties will be very close to cesium
2	chloride.
3	MR. MAIELLO: If I might just get back
4	to that issue briefly about the use of both machines
5	at a facility. First, let me say, don't shoot the
6	messenger. I'm only repeating what the scientists
7	tell me.
8	And maybe the confusion bespeaks more to
9	the where we are about this than anything else.
10	And if they haven't researched it very well, then
11	they are making statements about using both kinds of
12	machines, you know, with one as a backup. On the
13	other hand, the end point that we used the machine
14	for is simply the knocking down of the immune system
15	of the animal. It is not to do anything else.
16	Now, whether that you know, certainly
17	a mono-energetic photon is not needed for that, but
18	the it is true that the broad spectrum of the X-
19	ray machine may induce some secondary effects that
20	scientists have not considered. But, again, that is
21	because of where we are in this entire issue. They
22	are hearing these things, that these cesium sources
23	may go away and they are beginning to explore
24	whether or not the alternatives are available.
25	Now, I do know I have made contact
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with a few other scientists at other institutions, and they use the machine the X-ray machine for
and they use the machine the X-ray machine for
exactly the same reason we do to knock down the
immune system of the animal, so that oncological
compounds can be tested on the tumors that the nude
mice grow rather quickly.
FACILITATOR RAKOVAN: Sir, I'm sorry.
I'm going to interrupt real quick. Right now, I'm
just trying to bring us all in. We're focusing on
feasibility of the use of other forms of cesium-137.
If you'd like, I can't put like in a parking lot
kind of the X-ray stuff, because we are going to hit
on that later. Do you want me to put it up there,
or do to
MR. MAIELLO: As I understand, that is
going to be another question.
FACILITATOR RAKOVAN: Yes, yes. We're
going to get to that.
MR. MAIELLO: We can hold that off until
then.
FACILITATOR RAKOVAN: Okay. I just
wanted to kind of bring us back.
Lynne, I saw you had your tent up
earlier?
MS. FAIROBENT: I think the only comment
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1	I wanted to make on with regard to a LINAC being
2	used instead of cesium chloride, while we are
3	awaiting development of an alternative form of
4	cesium perhaps, is that in many of the medical
5	institutions where they may use the LINACs for blood
6	irradiation, they have to schedule the blood as if
7	they were scheduling a patient for treatment. And
8	oftentimes the LINAC may not be available, because
9	patient treatment tends to take priority, as I think
10	most of us would agree it probably should.
11	So if there is if the X-rays are
12	being used and there is down time on that, and the
13	LINAC is the backup, it may not be available due to
14	patient treatment schedules.
15	FACILITATOR RAKOVAN: As you've noticed,
16	we've put the other the next question up, which I
17	think we've been covering anyhow. It's question
18	1.12, is the use of other forms of cesium feasible?
19	If so, please describe desired methods, and discuss
20	any benefits or obstacles. Again, I think we have
21	been covering this, unless if someone has a
22	specific additional topic.
23	Sir, if you can introduce yourself one
24	more time.
25	MR. MENNA: Yes, Blair Menna again from
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1	Best Theratronics.
2	I just want to key in on the word
3	"benefits" there. And one of the things that I
4	think potentially may be feasible and would
5	certainly be extremely beneficial is, if we went
6	into reprocessing cesium, wouldn't it be wonderful
7	if we were reprocessing the existing cesium
8	chloride? So the benefit would be that we we
9	would essentially defer the disposal problem. We
10	wouldn't have to find an immediate storage solution
11	for that.
12	Assuming that the specific activity
13	drops off, and assuming that there is a switch to
14	alternative technologies all together, I am
15	wondering whether or not we couldn't essentially
16	reprocess cesium, have enough return from the field
17	that then would be returned for applications in a
18	less dispersible form.
19	So I see it being a benefit. I don't
20	know whether any of the source manufacturers could
21	comment on the feasibility of doing that.
22	FACILITATOR RAKOVAN: If you'd like to.
23	MR. COPPELL: Okay. Well, just briefly.
24	Yes, I understand, Blair, what your proposal is
25	there, and it does sound attractive, doesn't it?
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There are one or two obstacles that we may have to overcome before we could recycle cesium that is currently in circulation, not least the fact that a lot of that material is quite old already. Cesium has a half-life of around 30 years. And so material which is well into one half-life may be 15 or 20 years old. It is really questionable whether that would be reusable anyway. We are already looking, as we have described, at the potential reduction in specific activity of an alternate form of maybe a factor of If you make that worse by using 15-year old two. cesium, or 20-year old cesium, I'm just not sure it is practical. But it is -- it is something that is

15 being considered.

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16 MR. ALOY: Excuse me. It's -- maybe I 17 do not speak in good English, but I would like to say that besides cesium-137 we have this table. I 18 19 support cesium-133. And when we use the decay of cesium-137, the ratio between stable isotope and 20 21 radioactive isotope changed, and the stable isotope equivalence in the -- for the second review of this 22 radioactive isotope. So this is not feasible to --23 24 to process the spent sources to separate cesium-137, 25 because the ratio will be not good for the -- using

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1	their radiation sources.
2	MR. COPPELL: At the risk of getting
3	into too much detail, I agree with that. But, of
4	course, the cesium-137 decays to barium. The barium
5	is can be separated after the cesium, so it in
6	effect, the effective specific activity of the
7	material doesn't decay with the same 30-year half-
8	life as the cesium-137 does. You can recover some
9	of this lost activity by removing the barrier.
10	FACILITATOR RAKOVAN: Please introduce
11	yourself.
12	MR. JONES. Yes. Rick Jones, just
13	private citizen. I represent myself.
14	(Laughter.)
15	Just hearing the dialogue, it what
16	I'm hearing is the users are expressing criteria
17	that has to be met. Manufacturers are kind of
18	responding to that, and these are kind of drivers
19	from both sides to inform the decision.
20	As a path forward, something to
21	consider, not making more work for federal agencies,
22	but it would seem a getting together of the users to
23	create the criteria that they need in the different
24	uses of these sources, and then compiling that, and
25	then communicating that to the manufacturers, gee,
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116 1 how would you meet these criteria, would really go 2 to help inform what can and can't be done and in 3 what timeframe, how much money would it take, how 4 many years of development. 5 If it's five years just to create the 6 product line, how many years of testing would it require to accept the product in the different users 7 for blood irradiators, for your radiation of 8 animals, cells? You know, how many years of just 9 testing of the new product to make it acceptable to 10 11 the user community? 12 But I just -- in listening to this, it seems like a collection of user needs communicated 13 to the manufacturers to then respond to see what 14 15 they could do. And perhaps that could be something 16 the federal agencies could do in informing the answers to these questions over time. 17 Thank you. 18 19 FACILITATOR RAKOVAN: Thank you, Mr. Citizen. 20 21 (Laughter.) I'm going to go ahead and try to get 22 through a few of the questions. 1.13 I believe we 23 have up already. Would the affect of density 24 25 loading, with different forms of cesium, preclude **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	the use their use in existing devices? And also,
2	would it require modification of existing devices?
3	If anyone has any specific points that haven't been
4	made on this topic, now would be a good time to
5	interject.
6	Sir, please, step in.
7	MR. ALOY: Just only from the scientific
8	point of view, not as a producer, because
9	unfortunately I represent a different Mayak site.
10	And as the people from Radio Institute note, I had
11	an opportunity to participate in this very important
12	meeting.
13	But from a scientific point of view, I
14	can say that that feasibility study, we need to
15	have in at once to change the technology. And this
16	is a task for optimization. From one point of view,
17	this is a safety, then cost, then technology
18	availability, and the physical and allegation
19	properties, and all together we need to combine
20	have good initial data based on the scientific
21	research and development technology, and then
22	calculate all of this in the optimization option
23	for optimization option.
24	And, of course, we need to move to each
25	from one site, the users from other sites,
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1	distributors and producers and scientists and
2	technology specialists. So we need to understand
3	also about the secondary risk when we use the new
4	technology, which accompanies a new process.
5	And this is will be a more
6	complicated process, but from very simple answer
7	for this question. I think this is my private
8	opinion that, yes, we can develop a very good new
9	ceramic or glass forms, with good density of cesium-
10	137, which will satisfy the user's needs.
11	But we need to move to each okay.
12	FACILITATOR RAKOVAN: Thank you, sir.
13	Anyone else want to build off of those
14	comments, or give another perspective? Sir, if you
15	could introduce yourself again, please.
16	MR. WASIAK: Tom Wasiak from Best
17	Theratronics. I guess I may repeat the previous
18	comment, but I guess this question specifically asks
19	so speaking about our family of irradiators,
20	GammaCells, if you read the question as, would it
21	preclude their use in existing devices, without
22	absolutely any changes? I think the answer would be
23	yes.
24	But if you look at it, you know, with
25	some small to medium to large design changes, the
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1	answer would be it would be possible, and different
2	forms of cesium would not be precluded in this
3	application.
4	FACILITATOR RAKOVAN: Thank you.
5	MS. SHEPHERD: Mary Shepherd, J.L.
6	Shepherd and Associates.
7	FACILITATOR RAKOVAN: Could you bring
8	just go ahead and bring the microphone down. There
9	you go.
10	MS. SHEPHERD: Okay. Better?
11	FACILITATOR RAKOVAN: Much better.
12	Thank you.
13	MS. SHEPHERD: Mary Shepherd, J.L.
14	Shepherd and Associates. I think it would have to
15	be a cooperative effort with the source
16	manufacturers and the irradiator manufacturers to
17	develop sizes that would be interchangeable or
18	requiring different kinds of modifications. I think
19	it's way too soon to say a yes or a no at this point
20	in time, because we don't know what the new forms
21	are going to be, what the sizes will be, or if they
22	would be interchangeable.
23	FACILITATOR RAKOVAN: Very good point.
24	Please introduce yourself, sir.
25	MR. GERSABECK: My name is Edward
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1 Gersabeck. I'm with U.S. Department of Agriculture. 2 We currently own and operate nine Huseman Category 3 1 irradiators that we use primarily for sterilizing 4 insects. And in our line of work we simply can't 5 tolerate too much of an increase in time, which you're sort of implying if you had increased --6 7 decreased your activity by about a half, because in our line of work the time is critical because we try 8 to destroy the gonadotropic tissue in the insects. 9 But if they are in those irradiators too long, we 10 start getting secondary damage to the insect. 11 So -- and I'm not sure if -- maybe if 12 there is someone from NRC here, if we had to 13 redesign the Huseman to accept a higher amount of 14 15 material, would that imply having to get a new license as well for those? Because we also own the 16 license to the Huseman irradiator. 17 Thank you. 18 19 FACILITATOR RAKOVAN: Any further discussion on this particular question before we 20 21 move on to the next? 22 (No response.) Okay. Michelle, 1.14. Is it feasible 23 24 that high activity, e.g. IAEA Category 1 and 25 Category 2, cesium sources will be available in **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	alternative material forms? If so, what is the
2	estimated timeframe for manufacturing?
3	Please, go ahead.
4	MR. COPPELL: Well, I think to some
5	extent we have covered that already. I think the
6	answer is probably, though we need a few more months
7	to come up with a firm proposal. And with regard to
8	timeframe, well, a few years. Don't know quite what
9	that means, somewhere between two and five I guess,
10	probably nearer five.
11	FACILITATOR RAKOVAN: Okay. Please.
12	MS. SHEPHERD: Mary Shepherd from J.L.
13	Shepherd and Associates.
14	FACILITATOR RAKOVAN: If you could speak
15	up just a little bit. Do your best.
16	MS. SHEPHERD: I'm freezing.
17	(Laughter.)
18	Mary Shepherd from J.L. Shepherd and
19	Associates. One thing we haven't discussed is what
20	we did with the chloride sources, that the DOE did
21	was a 100-year accelerated aging test, and I
22	don't know what the timeframe would be on that
23	before, you know, any licensing could be performed.
24	I just I didn't know what if we had even
25	thought about those yet.
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1	FACILITATOR RAKOVAN: Want to take a
2	stab? You seem to be a very popular guy at this
3	panel, so
4	(Laughter.)
5	maybe I should just assume that you
6	are going to be addressing the questions.
7	MR. COPPELL: It's a good point, Mary,
8	and you it is one of the issues that we need to
9	consider, as well as the question of
10	solubility/dispersibility, the third element that I
11	would probably cite as being a technology issue,
12	which we need to include in the development program,
13	is to work out how stable these materials are over a
14	period of time in the matrices that we developed for
15	them.
16	It's easy enough to say, well, they
17	should be okay, because we've had we've had a lot
18	of ceramic and glass materials with cesium in them
19	around for 30 or 40 years. But I'm not sure how
20	much evidence or data there is about how they
21	perform once they are 20 or more years old. So it's
22	an issue. We do need to do some accelerated
23	lifetime trials on them, but it's assumed to be part
24	of the program. We have not forgotten it.
25	FACILITATOR RAKOVAN: Further discussion
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1	on these issues? Please. If you could introduce
2	yourself, sir.
3	MR. MINNITI: Yes. I am Ronnie Minniti
4	from the National Institute of Standards and
5	Technology. I have a question. When
6	FACILITATOR RAKOVAN: Could you turn up
7	the mic?
8	MR. MINNITI: Yes.
9	FACILITATOR RAKOVAN: Just bring it up
10	closer to you. You can just turn you can move
11	it. There you go.
12	MR. MINNITI: Okay.
13	FACILITATOR RAKOVAN: Don't be afraid.
14	MR. MINNITI: Yes. The summary that was
15	made at the beginning classified the different
16	applications in three basically, right? Research
17	irradiators, blood irradiators, and calibration. So
18	I think I speak on behalf of the people that need
19	calibration of instruments.
20	So the question is we are talking
21	about here about periods of time, a few years,
22	right? And I think I heard this morning saying that
23	it will depend on the market and how many
24	irradiators will be needed. So, hypothetically, if
25	some of the for these for some of these
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1	applications, like blood irradiators, it's decided
2	that other forms other alternatives are going to
3	be used.
4	And then, the only people who would need
5	another form of cesium would be the calibration
6	facilities. This is approximately something between
7	10 and 20 percent of the current irradiators in use.
8	So in that case, would the manufacturers be
9	interested in pursuing this? I guess that's the
10	question, because then that would increase cost of
11	making sources, right? As opposed to do you
12	understand the question or
13	(Laughter.)
14	Yes. Well, it looks like you are going
15	to
16	(Laughter.)
17	MR. COPPELL: I think if I can I
18	reinterpret the question? I think what you're
19	saying is that if a number of the applications for
20	cesium sources dropped off the list
21	MR. MINNITI: Yes.
22	MR. COPPELL: and other technologies
23	were used for them, would that increase the cost of
24	the remaining
25	MR. MINNITI: Yes.
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1	MR. COPPELL: smaller volume of
2	cesium sources?
3	MR. MINNITI: Yes.
4	(Laughter.)
5	Well, no, that's obvious, but what
6	concerns me is that, okay, well, if this is not I
7	guess it's a comment more than a question. But if
8	that's the case, then will there be a replacement
9	a possible replacement for calibration of
10	instruments? If it's decided that, okay, we cannot
11	pursue the manufacturers of sources are not going
12	to pursue another form of cesium, because then the
13	cost is too high for just a few users, right? Which
14	is maybe 100 out of currently 1,500 calibrators out
15	there. Then, that would become a problem, right,
16	for those for that particular application. So I
17	guess it was just a comment.
18	FACILITATOR RAKOVAN: I think we are
19	going to get into some of those issues later in the
20	panel.
21	One last comment before we move on to
22	the next question? Sir, if you could introduce
23	yourself again, please.
24	MR. POWELL: Yes, Brian Powell,
25	Constellation Energy. So I'm representing nuclear
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1	power.
2	And just looking at this question up
3	here, is it feasible that high activity, IAEA
4	Category 1 and 2 cesium sources will be available in
5	alternate material forms? And it's just a comment.
6	In the current cesium-137 form, cesium chloride, we
7	are already covered, as far as safety and security
8	and these sources. We have taken all our steps to
9	make sure that those are protected.
10	And that wouldn't change if those
11	sources were in a different form. So I'm kind of
12	looking for the benefit of spending all this time
13	and energy to follow this path when we already have
14	things in place to protect them. And we are going
15	to do the same thing, regardless of the form that
16	this source is in.
17	FACILITATOR RAKOVAN: Okay.
18	MR. KAMINSKI: Joe Kaminski. To address
19	that question, I guess, is the concern is the

solubility of the cesium-137 chloride. Just I'm

also on the emergency preparedness side, and 21 22 dispersibility, and the ability to leach into 23 concrete, and so forth. So if it gets released, for example, in the City of New York, let's say, while 24 25 you're talking about economic impact, that could be

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1	billions of dollars. That could be underestimating
2	it.
3	So, I mean, it is a real potential, and
4	that's why there is concern. And, again, I don't
5	speak on behalf of NIH. So
6	FACILITATOR RAKOVAN: Okay. Any further
7	discussion before we move on to the next question?
8	Okay.
9	MR. ALOY: Unfortunately, we have not
10	the standards for dispersibility properties of these
11	materials. We have standards for leachability, we
12	have standards for the mechanical properties study,
13	for fire testing, but we have not IAEA regulation
14	hasn't standards for dispersibility. What does it
15	mean?
16	Because any materials may be dispersed
17	in small particles with action from explosion, for
18	example, or from other mechanical forces. So maybe
19	we need to develop these standards or testing
20	testing procedure for dispersibility, to meet these
21	requirements. It's my opinion.
22	FACILITATOR RAKOVAN: Okay. Yes,
23	please.
24	MR. COPPELL: Yes, I agree. Maybe I
25	I think we all understand that the risk is that this
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1	this gets close to the security issue. But I
2	think we we are going to have to work out what we
3	mean by "dispersibility," how exactly are you going
4	to try to disperse it before you can do anything to
5	assess its performance in those circumstances and
6	compare it with other options. It's tricky. I
7	don't know how we go about that, but we need to find
8	a way.
9	FACILITATOR RAKOVAN: Okay. We've got
10	two more questions I'd like to get through before we
11	go out for lunch. Question 1.15, since all of the
12	cesium chloride is manufactured in Mayak, Russia, is
13	it known if the cesium source producer can modify
14	its production processes? I think I know kind of
15	who this question might be focused on.
16	(Laughter.)
17	Are you okay with addressing it, sir,
18	or
19	MR. COPPELL: Yes, okay. I mean, but I
20	think we have more or less addressed it a couple of
21	times. It is the answer is, in principle, we
22	think so. It depends on just what the technology
23	involves. As Dr. Aloy has said, you know, it the
24	technology development must include development of
25	facilities for production, must ensure that we have
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1	validated the product to make sure it does what we
2	think it does, as well as just the scientific
3	element of, can we make this material in a less
4	soluble, less dispersible form.
5	I think, you know, that the view within
6	the industry is the answer is probably. We need a
7	few more months to come up with some firm proposals,
8	and then we need to look at whether it is
9	commercially viable.
10	FACILITATOR RAKOVAN: Dr. Aloy?
11	MR. ALOY: It is well known that new
12	forms, like the pollucite or glasses, you need to
13	use a higher temperature. It is a high temperature
14	process. During this high temperature process, the
15	cesium alterations have made will be higher, and
16	we will have more secondary waste in comparison with
17	cesium chloride production.
18	So this is the task for optimization of
19	the process. And, of course, we need this is my
20	own opinion. Mayak all the time go ahead and
21	develop a new technology, but we support this study
22	by R&D in the institute. And so I think that in the
23	near future they can do new forms.
24	MR. PATTON: This is Brad Patton again.
25	It was pointed out earlier that we, in this
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1	country, aren't doing reprocessing, but there is a
2	lot of research going on about reprocessing now.
3	And some of those flow sheets include separation of
4	fission products.
5	I think we need to consider looking in
6	the long term, if we are separating cesium-137 and
7	developing waste forms for cesium, we need to think
8	about the applications here for irradiators, and
9	perhaps some waste forms that we might develop could
10	also be used for irradiation sources.
11	So I think as we begin to develop new
12	waste forms and look at reprocessing in this country
13	we need to consider the use of some of those
14	materials for irradiation sources.
15	FACILITATOR RAKOVAN: Any additional
16	points before we go ahead and move on to the final
17	question on this topic?
18	(No response.)
19	Okay. I think it's already up there
20	already, but question 1.16, would other entities in
21	the U.S. or worldwide engage in manufacturing
22	sources with alternative forms of cesium-137?
23	Anyone have any thoughts that they'd like to share
24	on this particular issue? Stab in the dark? Lynne?
25	MS. FAIROBENT: Brad, I have a question
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1	for you. You said Oak Ridge was not interested in
2	getting into the production mode for cesium. But
3	has there been discussion among the broader DOE
4	community as to one of the other labs stepping up
5	into this role?
6	MR. PATTON: Of course, we all work for
7	the Department of Energy, so it's up to the
8	Department of Energy to task us with production
9	material. But I guess, again, as rightly discussed
10	earlier, we aren't doing reprocessing in this
11	country. The cesium we have, which is significant,
12	is older. And we could remove the barium, but we
13	still have the inert cesium that's in the material.
14	And so it's a lower specific activity, which would
15	be lowered further by some of these source forms.
16	So it would be up to DOE to decide that,
17	and I don't see anyone, you know, discussing it at
18	this time.
19	FACILITATOR RAKOVAN: Please.
20	MR. COPPELL: Yes. I guess the issue is
21	that a lot of the costs involved in this,
22	effectively entry costs for establishing a facility
23	or a plant to manufacture these products. And for
24	somebody who doesn't manufacture them right now, the
25	entry costs are higher than extending the capability
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1	for somebody who does. I guess that's the issue.
2	FACILITATOR RAKOVAN: Okay. Any further
3	discussion on any of the topics involved with
4	Issue 1.1, feasibility of the use of other forms of
5	cesium-137, before we take a break for lunch?
6	(No response.)
7	I know, it's very encouraging for
8	everyone to rush up with a comment, isn't it?
9	(Laughter.)
10	Okay. Let's try to get started promptly
11	at 1:00. The next panel will be feasibility of the
12	use of isotopes other than cesium-137. If you are a
13	panelist, please just come right up and take your
14	seat at the table. We'll start again promptly at
15	1:00.
16	(Whereupon, at 11:54 a.m., the proceedings in the
17	foregoing matter recessed for lunch.)
18	FACILITATOR RAKOVAN: Why don't we go
19	ahead and get started.
20	ISSUE 1.2: FEASIBILITY OF THE USE OF ISOTOPES OTHER
21	THAN CESIUM 137
22	The next topic that we will be
23	discussing is Issue 1.2, Feasibility of the Use of
24	Isotopes Other Than Cesium 137. Why don't we start
25	by going ahead and having our panelists introduce
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133 1 themselves if we could start over here on the left 2 please. MR. CONNELL: My name is Leonard 3 I study radiological and nuclear terrorism 4 Connell. 5 at Sandia Labs and I was the lead on the Red Teaming 6 Analysis, the attack videos which some of you may have seen on looking at the vulnerability of the 7 cesium chloride machines and also led the team that 8 designed the upgrade kits for those cesium chloride 9 irradiators. 10 MR. FIKE: I am John Fike, the 11 12 University of California at San Francisco. I'm a radiobiologist. I'm here on behalf of the Radiation 13 Research Society. 14 MR. KAMINSKI: Joe Kaminski, National 15 16 Institutes of Health. I'm a radiation oncologist and previously in my other life also head of a 17 laboratory and I'm involved also in the emergency 18 19 preparedness side. MR. McBRIDE: I'm Bill McBride, UCLA, 20 21 Radiobiologist. I'm representing the American Society for Therapeutic Radiation Oncology and I 22 also lead a CMCR which is one of the center for 23 countermeasures at UCLA. 24 25 MR. RING: I'm Joe Ring, Harvard **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	University Radiation Safety Officer. I am
2	presenting a summary of my faculty's comments.
3	MR. COPPELL: I'm David Coppell. I
4	didn't get any calls over lunch. So I'm still
5	technically Manufacturing Director for REVISS
6	Services.
7	(Laughter.)
8	MR. NIXON: I am Grant Nixon. I'm a
9	Senior Radiation Physicist for Best Theratronics and
10	in a former life NDS Nordion. We are the largest
11	manufacturer of self-contained irradiators both in
12	terms of x-ray, technology and cesium chloride.
13	FACILITATOR RAKOVAN: Thank you,
14	gentlemen. Before we dive into the questions, I
15	believe a few of you had statements or presentations
16	that you wanted to go through. So if you would like
17	to go first, that would be fine.
18	MR. FIKE: John Fike, representing the
19	Radiation Research Society. I'd like to make a very
20	brief statement primarily regarding the scientific
21	impact and potential consequences of banning, in
22	particular, cesium sources.
23	As I said, I represent the Radiation
24	Research Society which is about 1500 members. It's
25	a multidisciplinary group of biologists, physicists,
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1	chemists and clinicians and while there are multi-
2	faceted and extensive interests across these people,
3	there's a common goal of advancing the understanding
4	of radiation effects and advanced of radiation
5	medicine.
6	The work by these individuals is
7	supported in a big way, hundreds of millions of
8	dollars, by a variety of governmental sources and
9	nongovernmental sources, NIH, DOD, DOE, NASA, DHS,
10	NSF and others. So it's a big component of
11	federally-sponsored research and I'd like to just
12	summarize the concerns of the Radiation Research
13	Society in just three major points.
14	We did a poll a couple months ago and
15	about 80 percent of the members indicated the cesium
16	irradiators were used by them and over half of them
17	were critically dependent on it and when I say this,
18	80 percent of the people said that the loss of these
19	irradiators would be either major or catastrophic to
20	their research efforts.
21	The second point is, and may Bill
22	McBride will speak more to this in a moment,
23	Radiation Research members play in a central role in
24	the development of medical countermeasures to meet
25	the threat of radiological nuclear terrorism. If
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1	cesium irradiators were eliminated, this development
2	would suffer a serious setback and made our country
3	more vulnerable and I mean that in the context of
4	the timely development of effective countermeasures.
5	And, lastly, Radiation Research members
6	are actively involved in the development of
7	innovative cancer treatments involving all types of
8	radiations. Cesium irradiators are critical to much
9	of this work and if they are eliminated, this could
10	have a very significant impact on the advancement of
11	radiation medicine.
12	That's my statement.
13	FACILITATOR RAKOVAN: Thank you, sir.
14	MR. McBRIDE: Just on behalf of ASTRO
15	(American Society for Therapeutic Radiology and
16	Oncology) I would like to echo John's comments and
17	expand on a little bit of that. I mean, I think
18	there really is in terms of the countermeasures
19	program the majority of the eight centers of which
20	UCLA is one use cesium sources as the main kind of
21	workhorse for all of this activity and this is a
22	major program which has been undertaken by the
23	government to try and counteract exactly the kind of
24	terrorists' acts that we're really thinking of in
25	this forum.

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1	I think that we should also realize that
2	there's a lot of radiation research which has been
3	done which is not totally directed towards a kind of
4	terrorist attack, but from the point of radiation
5	protection for the population as a whole since
6	really the last war and before even. And also in
7	the medical kind of sphere using radiation in a
8	therapeutic sense really has saved many, many lives
9	and it's a major cancer modality. Over 50 percent
10	of patients with cancer get treated with radiation
11	and are cured. So limiting our sources, limiting
12	our availability of these sources, really is going
13	to have a major impact upon the research which goes
14	on.
15	I'd like to just kind of stress that
16	there are lots of user groups out here and we hear
17	from blood bank users which are an important group.
18	We've also heard someone talking this morning about
19	zapping mice to knock down the immune system. The
20	radiation research is a lot more sophisticated than
21	that. We're dealing with the effects of radiation
22	on many different organ systems and tumor systems
23	and this requires a lot of different kind of
24	approaches, the uses of radiation, and cesium is one
25	of the major ways in which we do this kind of

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1	research.
2	We have a record of well over half a
3	century if not a century of research using these
4	kind of sources and it's the transition to any other
5	kind of modality, whether it be x-ray or cobalt, is
6	not going to be trivial.
7	MR. KAMINSKI: Again, this represents
8	only my professional opinion and I'll just pose a
9	question first and it's obvious. But should we
10	pursue safer forms of cesium-137 or technologies
11	assuming they exist and are economically viable to
12	the enduser and I think all of you would agree that
13	we should because if we don't the potential impact
14	of not doing so could be substantial as already
15	mentioned.
16	I'm certainly not arguing for any one
17	single solution. We need alternative forms of
18	cesium-137. If they are currently available, then
19	we should look into that and x-rays obviously are
20	another potential form, another potential source,
21	and potentially even other radionuclides. Of
22	course, this should be done over many years and it
23	needs to be carefully orchestrated so it doesn't
24	interrupt research in blood banks, for instance.
25	Thank you.
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1	MR. RING: Could I have Joe Ring's
2	slides please?
3	I've attempted to collect a wide variety
4	of input from my faculty and it's very important for
5	us to stress that much of the work that we do is
6	basic scientific research and it is used to develop
7	therapeutic interventions for disease among other
8	things.
9	We work in primary areas. Next slide
10	please. I was trying to get going. Cancer therapy,
11	blood transfusions, DNA damage studies, space
12	travel, molecular biology, immunology, stem cell and
13	radiological terrorism effects, a very wide range.
14	We're using it for a very wide range of research and
15	that means that many of things that we're
16	identifying may be slightly different.
17	One thing I did come to find out is I'm
18	not going to argue with a Harvard faculty member
19	when he tells me or she tells me that there are
20	differences. Cesium-137 is the instrument of choice
21	for much of the research. It is the standard. It
22	is the standard because it has uniform irradiation
23	effects. It has very unique cell interactions.
24	This is one of the areas where I got
25	very clear guidance from my faculty. They want me
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to show you this book. This book documents, it's a long-standing reference, the unique effects from cesium and from radiation. The cell damage ends when the irradiation ends and it's very important to most of our faculty. It has very well characterized interactions.

7 If you go into PubMed and you look for DNA damage since 1998, you will find that there's 8 almost 7500 references or studies that used cesium 9 10 radiation in the last ten years. That's only 11 looking at DNA damage. You can look at many of 12 these other studies and you can get similar numbers. Generally I found when I did it and I gave up 13 overload there were 3,000 on most of the subjects at 14 15 the minimum. So it was extensively used. Next 16 slide please.

There's been lots of discussion about 17 potential alternatives. That raises an awful lot of 18 19 angst and concern for my faculty. They say there is very different biological mechanisms which mean a 20 21 lot to them when they work at basic science. They're working at very small levels in the cells 22 and there's a picture that shows you there. 23 Just graphically, you can see that it's different 24 25 response mechanisms. I don't want to go into the

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1	details. But the alternative sources give different
2	effects because their effects vary with the energy
3	of the sources. They see very strong differences
4	in the irradiations done between x-rays and strong
5	differences between cobalt and cesium irradiations.
6	The chemical agents really react by a
7	very different methodology that presents them a fair
8	number of problems. Chemical reagents react by
9	diffusion. Therefore, they see a gradient across
10	whatever they're trying to study in reactions and,
11	even more, there is no clear endpoint. That
12	endpoint continues after a period until the chemical
13	agent wears down and that chemical agent has
14	different effects in the cells. So they see very
15	different reactions from chemical agents that are
16	different by substantial means from other
17	irradiation sources and radiation sources in general
18	vary amongst the energies.
19	The faculty really is looking for a way
20	to move forward. They're very concerned about the
21	grants and contracts which are federal money and the
22	impact on that and the ability to continue
23	competitive science research. They are very
24	concerned that this will drastically impact science
25	and that we need to look at alternative studies and
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1	whether or not they can be correlated. There is a
2	huge dataset out there of studies that have been
3	done over the last 40 or 50 years that cannot be
4	correlated with new studies done by another
5	mechanism. So we have a validate or cross validate
6	that historical dataset.
7	We should investigate alternative
8	physical forms to cesium so that we can minimize
9	that risk. One of the things that they recommend
10	very strong in the short term is to look at
11	hardening of the sources. I know there is some
12	discussion with that.
13	I got an awful lot of interest from my
14	faculty and I will tell you that they really made a
15	point. Harvard faculty don't usually get involved.
16	They demanded that I have a meeting and they
17	demanded that I show up to talk to them and they
18	presented significant volumes of scientific data to
19	show this is different and it is of importance to
20	them.
21	Thank you.
22	FACILITATOR RAKOVAN: Before we move to
23	the questions, any further statements by the
24	panelists? I have one on the far side. Are you
25	going to use the podium?
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1	(Off the record discussion.)
2	MR. CONNELL: Again, I'm Len Connell
3	from Sandia Labs and my role has been on the
4	National Academies to really help inform the
5	committee on the differences in the risk, the
6	radiological terrorism risk, between the different
7	radionuclides. So I brought this. I don't have a
8	presentation.
9	But this is cesium chloride and if we
10	filled up to about this level, that's about 1,000
11	curies of cesium chloride. As was mentioned in most
12	sources, it's a packed powder, but packing it into
13	pellets doesn't really effect the dispersability
14	very much. This is about 1,000 curies of cobalt and
15	since we're talking cobalt-60 I thought this was
16	kind of to frame the debate between two, about 7
17	grams of cobalt.
18	Now we have two very interesting
19	accidents that have occurred with both of these
20	types of material. The one was mentioned before was
21	in Goiania in `87 and it involved about 1400 curies
22	of the cesium chloride. We know from that accident
23	that because of the solubility of the cesium when it
24	got onto the ground it went into solution, it mixed
25	with dust particles, the dust went onto the tops of
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144 1 those nice Spanish tiles and, as was mentioned 2 before, you can't just rub it off. It actually 3 chemically bonds with these building surfaces. So a 4 huge expense in clean-up. A large difference 5 between that and cobalt. Seventy grams of the 6 cesium chloride in that teletherapy unit in Goiania produced roughly 70 tons of rad waste that had to be 7 disposed. 8 9 About a year later, a cobalt teletherapy 10 machine in Juarez, again similar problem. It was abandoned and people stole the material and sold it 11 12 to a junkyard for scrap metal. Now the cobalt in the teletherapy 13 machines, it's not this slug. It's actually little 14 BBs about a millimeter in size. Some of those also 15 16 qot dispersed in the city. In that case, it was a 17 matter of the responders going around with the radiation detector, finding the pellets, picking it 18 19 up, putting it in a pig and the problem was solved, a huge difference in the consequence. Not even 20 21 looking at the radiological terrorism and all the different mechanisms of dispersal, we know from 22 those two datapoints there's a very significant 23 difference in the consequence. 24 25 So that's what has driven my concern **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	about the cesium chloride. By switching to cobalt,
2	we don't completely solve the problem as was
3	mentioned by others. Anything can be dispersed if
4	you work hard enough at it. The difference with the
5	cobalt of course is there's much more work that has
6	to be done.
7	I hope that that frames the debate a
8	little bit. Thank you.
9	FACILITATOR RAKOVAN: Thank you.
10	MR. KAMINSKI: I just want to make one
11	comment that I didn't totally agree with. I
12	certainly don't agree with the mechanism of action
13	being different between x-rays and cesium.
14	Certainly, the depth dose profiles are different in
15	small animals and so forth. It might be more ideal
16	to use a cesium source than, for instance, like
17	cobalt source where it d-maxes that 0.5 centimeters
18	where you might need to use bolus. But certainly
19	the mechanisms are the same.
20	MR. NIXON: I'll show you if I could
21	make a comment on your comment. In terms of dose
22	deposition, even though the depth dose profiles even
23	if you were to find similar profiles in water, it's
24	very different in terms of the way it interacts with
25	the matter. X-ray tubes generally produce a broad
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1	spectrum. A significant portion of that spectrum is
2	in the low energy sector and that's up to and
3	including say up to 150 kilovolts, KeV.
4	Most of these photons interact
5	differently when they come into contact with atomic
6	constituents that are of higher atomic number. They
7	react via the photoelectric effect and that's why
8	when you get an x-ray radiograph you get this
9	contrast that appears between bone and tissue. Even
10	though you get a similar depth dose profile in terms
11	of the total attenuation of the beam throughout the
12	sample, the actual deposition in the individual
13	constituents inside that ensemble is quite
14	different. In fact, if you're going to go below 320
15	kilovolts it could be as high as two to one.
16	FACILITATOR RAKOVAN: All right. Hold
17	on. The topic at hand is feasibility of the use of
18	isotopes other than cesium-137. We are doing
19	opening statements. If you'd like we can put this
20	topic in the parking lot. You just have to tell me
21	what I'm supposed to put up there. I'm all right
22	with that. Do you guys want me to put it in the
23	parking lot?
24	MR. NIXON: I think that would be for
25	the next session.
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1	FACILITATOR RAKOVAN: Okay. Can you
2	hold on to discuss it until then?
3	MR. NIXON: Okay.
4	FACILITATOR RAKOVAN: Okay. I thought
5	we had one more opening statement here to do.
6	Correct?
7	MR. NIXON: Yes.
8	FACILITATOR RAKOVAN: If you could wait
9	until you get to the podium to make sure that we
10	have you on the transcript.
11	MR. NIXON: Presentation Number one.
12	So, as I said earlier, we are the My name is
13	Grant Nixon. I'm a radiation physicist with Best
14	Theratronics and formerly NDS Nordion. So as such
15	we are the largest manufacturer of blood
16	irradiators, both x-ray and cesium based, in the
17	world. Next slide please.
18	In terms of a quick summary of some of
19	the questions and our position, as a manufacturer,
20	we would say that for most of our applications that
21	we sell units for cesium chloride could possibly be
22	replaced with cobalt-60 energies or sources for most
23	applications from a radiation physics perspective.
24	Unfortunately, for current designs of self-contained
25	irradiators this is not always easy because of the
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1	shielding requirements of cobalt are much greater.
2	Next slide please.
3	As such, we can look to other isotopes
4	that differ from cobalt-60 such as europium-152.
5	This isotope has received considerable press as a
6	possible substitute for cobalt-60 due to the cost of
7	cobalt-60. The problem with europium is it's a
8	fairly broad spectrum radioisotope and although it
9	has a good long half-life there are issues
10	associated with its handling, manufacturing, the
11	availability in terms of manufacturing as well, and
12	more difficulties in terms of the filtering of the
13	low energy components.
14	Cobalt-60 is the only isotope as a
15	manufacturer that we would consider as a possible
16	substitute for cesium chloride in self-contained
17	irradiators. But as a simple hand-waving argument
18	or scaling argument can demonstrate, the shielding
19	requirements are approximately two to one and the
20	use of tungsten or depleted uranium which nobody
21	wants to touch anymore will not alleviate that basic
22	fact by very much.
23	Now in terms of attendant risks
24	associated with the transport of cobalt sources,
25	because cobalt has a 5.27 year half-life versus a 30
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1	year half-life of cesium-137 most units will have to
2	be resourced over a period of five to ten years if
3	they are to meet the requirements that they are put
4	to initially. So with that transport comes other
5	issues, security of the transport, possible
6	accidents, etc., and, of course, all the ALARA-
7	associated risks that health physicists like to jump
8	all over.
9	Thank you.
10	FACILITATOR RAKOVAN: Thank you, sir.
11	Okay. I think we might as well go ahead
12	and go to the questions. We could do this similar
13	to the way we did the discussions this morning. For
14	those of you at the table, if you just want to give
15	me one of these (Indicating) or put your tent up,
16	then I'll try to go to you. For those of you in the
17	audience, the same kind of thing. If you give me a
18	wave or if you want to approach the mike, I'll try
19	to go to people in the order that I see them.
20	I thought that this morning went very
21	well in terms of a back and forth and we had very
22	good participation. So I'm hoping to keep that
23	going.
24	As we have 1.1 up there or 1.21(a), can
25	cobalt-60 be substituted for a radioactive cesium
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1	chlorine for any applications, (b) if so, what types
2	of applications, and (c) if not, why not? And there
3	are only three questions for this panel. So we'll
4	see how much time we need to discuss each. So don't
5	be shy.
6	MR. KAMINSKI: The answer is yes. It
7	could be substituted. Whether it's better, it could
8	be in certain situations such as if it's a large
9	animal where a 660 KeV may not be penetrating enough
10	to give a homogenous dose if you're radiating a
11	monkey or something like that. But in those cases
12	probably most academic facilities have LINACs that
13	could be used on the weekends or potentially at
14	night.
15	MR. McBRIDE: Yes. I mean, the answer
16	is yes. You can use cobalt. Do we have the
17	facilities in most academic places? Probably not.
18	I think also there are issues. Certainly if you're
19	doing a monkey, I think cobalt is fine. If you're
20	doing mice, there are other kind of issues in terms
21	of set-ups and things like build-up that you
22	mentioned in terms of depth doses and so on.
23	One of the great things about cesium is
24	that non-radiation physicists and biologists can use
25	it without any problem at all. It's a very simple
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machine, a very reliable machine. Whenever you start moving into cobalt machine for doing the same kind of things, you need a lot more back-up. You need better dosimetry. You need just a different kind of set-up completely from what we have at the moment with cesium.

7 And so actually putting that in place is as I said not trivial. I mean, in radiation 8 oncology, they got rid of most of our cobalt 9 There are not all that many left. There machines. 10 are a few of the old kind of style of DOE kind of 11 panoramic cobalt machines around the place. 12 But really overall, I really don't think that we have 13 the facilities to replace cesium in almost all of 14 15 the academic centers certainly and I can't talk 16 outside of that.

17 MR. FIKE: I'd like to expand on that a little bit. For those of you who don't do animal 18 19 research like Bill and I do, I'm talking now about small animals, rodents mainly, and most universities 20 now are going to transgenic facilities within their 21 institutions which are behind the barrier. These 22 are specialized secure areas. People have to gown 23 up and so forth. 24

The point is that, and all I can speak

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1	is for the University of California, San Francisco
2	(UCSF) and I'm not on their space committee, but
3	nevertheless the idea of putting in a much bigger
4	room heavily shielded that would be required for
5	cobalt would be very problematic. A) There's not
6	space there and B) just the idea of renovating a
7	whole room and getting a very heavy, big, shielded
8	cobalt unit behind a barrier like that I think would
9	be very problematic, not only economically but
10	practically, and I think that has to be considered,
11	at least, from the research perspective. I can't
12	speak for blood irradiators. Maybe it's the same
13	issue. I don't know.
14	MR. CONNELL: Can we hear from JL
15	Shepherd? Mary, can you talk about whether there
16	are cobalt-60 mouse irradiators existing and how
17	feasible that is? I spent several years working
18	with the manufacturers on all these different
19	applications. So I just wanted to hear from them.
20	MS. SHEPHERD: Mary Shepherd, JL
21	Shepherd and Associates. Not a lot of people using
22	cobalt are using them for small animal research.
23	It's mostly large animal research. When you go to
24	large animal research, you need to have a shielded
25	room like the teletherapy rooms. Most of those have
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1	disappeared from this country. So the cost for
2	doing a completely shielded facility to do large
3	animals is quite expensive.
4	Cobalt primarily is used now for
5	biologicals, CDC research, all the real nasty
6	biologics that are dose rate dependent. I'm not
7	going to go any further than that.
8	The weight of a cobalt machine is not
9	such that a replacement cobalt machine could not go
10	into an animal facility that is not on the ground
11	floor because buildings cannot take the weight.
12	You're talking a replacement for like a Mark I that
13	can go anywhere from 4,000 to 6,000 pounds. You're
14	talking 14,000 pounds on a little bit larger
15	footprint and therefore the entire animal facility
16	would need to be relocated. Most of them are not on
17	the ground floor for security reasons and for other
18	like PETA and other issues like that. So the whole
19	institution would have to change the whole facility
20	plan or build a whole new secure facility just for
21	the replacement.
22	MR. KAMINSKI: And again, this is my
23	professional opinion that I would not switch from a
24	cesium-137 source for small animals to a cobalt. I
25	think that would be a mistake because again the
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1	cobalt-60 d-maxes at 0.5 centimeters. So certainly
2	you wouldn't be getting a homogenous dose through
3	the animal.
4	MS. MOSES: Paul Moses, Best
5	Theratronics. Formerly, we used to be Atomic Energy
6	of Canada and then we turned into MDS Nordion and
7	very recently we became Best Theratronics. Going
8	back to even Atomic Energy of Canada, we had access
9	to probably more cobalt than anybody in the planet
10	just based on our nuclear reactors.
11	We looked at both cobalt for research
12	applications and, of course, for the blood
13	community. It would have been very easy for us to
14	use cobalt. It was easier for us to get and less
15	expensive. But the thing is when you actually look
16	where blood banks are located and we did that.
17	Being in marketing, you sit and say where is it
18	going to go, how is it going to get there, how much
19	is it going to cost and you look the money
20	associated with that.
21	So if you look at most blood banks,
22	they're on a $3^{rd}$ or $4^{th}$ level. You have to go up in
23	an elevator. So you go to the elevator and you say,
24	"Okay. How much can this accommodate" and you very
25	quickly realize that cobalt's not going to fit into
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1	the blood bank communities partly because they're
2	huge. It has a half-life of 5.2 years. Cesium is
3	30.2. So you're looking at constant replacement.
4	There's a lot of issues like that,
5	business issues, that are a concern when you start
6	looking at cobalt to replace a cesium unit. But,
7	once again, weight is a big concern as to where they
8	would go and you can't get a cobalt unit up on a
9	third or fourth floor when they weigh 6,000 or 7,000
10	pounds.
11	MR. MORGAN: Tom Morgan, University of
12	Rochester. I just wanted to put an underlying
13	exclamation point. Not all irradiators that are
14	being used in research are self-shielded
15	irradiators. A number of us have irradiators that
16	are in shielded rooms because we need to be able to
17	irradiate parts of animals. So if I had to change
18	out the source to cobalt-60, that room isn't
19	shielded for cobalt-60.
20	PARTICIPANT: I must say joke. All
21	irradiators are not created equal. We all know
22	that.
23	(Laughter.)
24	I had actually a scientist who came to
25	me and he said, "I want to irradiate just the head
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1	of the mouse." So being an engineer and being a
2	health physicist, I designed a real good shield
3	around the body and left the head exposed to cesium-
4	137. Can you do that with cobalt-60? Absolutely
5	with the high energy that's cobalt-60 and I could
6	accomplish that.
7	MR. SVAJGER: Just to add to I'm
8	sorry. Mark Svayger of Fluke Biomedical. Just to
9	add to the open air exposures and not a shielded
10	device, 11 meters, 2,000 curies of cesium requires a
11	meter of high density concrete walls and that's on
12	the ground level. So if a hospital has three
13	levels, you have your floor and your ceiling to
14	account for. So that's an added expense.
15	Also to put it in perspective, it costs
16	us \$250,000 in 1999 to design this new facility and
17	at that time it was going to cost us just \$500,000
18	just to tear it down. That's just the concrete and
19	the structures themselves. Thank you.
20	MR. POWELL: I am Brian Powell again.
21	Constellation Energy. Looking at nuclear power and
22	what I'm thinking about is the radiation protection
23	aspects of the cesium versus the cobalt or an
24	alternative source. And from my perspective or from
25	our industry's perspective, we use cesium to
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calibrate our instruments for a reason because we have cesium being produced in the reactor. We need to have a way to see what kind of dose our workers are getting so we can give them good reports at the end of the year that this is how much exposure that you received.

7 So all our instruments are calibrated towards cesium for that reason because we produce 8 it. It also has the lower energy which is more 9 representative of the range of isotopes that we have 10 in the power plants and obviously the 30 year half-11 12 life lends itself to what I would call a stable study. So the cesium is our base source, a thing 13 that all of our documentation and all our research 14 is based on from the instruments that we use to go 15 16 out and try to find the radiation to the instruments that we use to check people when they're exiting the 17 radiologically-controlled area. 18

I'm looking to hear how the NRC, for example, who is looking at our application of our instruments and our research and all that towards the cesium would -- We would have to potentially change our entire radiation protection program to go after something else.

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MR. COPPELL: Yes, Dave Coppell here

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1	from REVISS Services again. This may be a statement
2	to the obvious I suppose, but the incentive for
3	considering cobalt as an alternate to cesium
4	chloride really goes back to the presentation that
5	Len Connell made about the potential dispersability,
6	solubility, clean-up costs and so on.
7	The question in the Federal Register
8	specifically refers to a comparison between cobalt-
9	60 and cesium chloride. I guess the question we
10	ought to ask ourselves is how do you stack up the
11	comparison between cobalt-60 as one option and a
12	less dispersable form of cesium-137 as another
13	option.
14	MR. McBRIDE: If nobody is going to
15	answer that, I'll say the latter.
16	(Laughter.)
17	FACILITATOR RAKOVAN: Anyone? Please.
18	MR. CONNELL: I'll make a comment about
19	that. That's a very good point and I've talked a
20	little bit with John Schrader and David about the
21	dispersability issue and whether if we were to start
22	with pollucite form whether we could design it in
23	such a way that it minimized certain dispersable
24	effects. So one good thing about designing it from
25	scratch is we could try to build some of those
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1	aspects into it.
2	But as was mentioned I think before,
3	there really are two properties we're looking at
4	here. One is the solubility issue which is what you
5	really are solving when you go from the chloride to
6	the pollucite or if you go to cobalt.
7	And the other one is dispersability and
8	that's a much more difficult aspect because the
9	question is what do you mean, like was discussed in
10	the earlier session, by dispersability. How
11	dispersable? What kind of a particle size are you
12	trying to prevent? And we end up quickly getting
13	into classified information. But that is something
14	that we have to consider. And by going to
15	pollucite, you really do solve mainly the solubility
16	issue and a pollucite behaves in terms of an
17	explosive dispersal similar to ceramics and that
18	really doesn't completely solve our dispersal
19	problem.
20	As we're looking through these different
21	alternatives, again as I mentioned in the
22	introduction, if we go to a radionuclide alternative
23	to cesium we are reducing the risk because we're
24	actually making it more difficult to disperse, but
25	we're not eliminating the risk. The only way to
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1 eliminate the risk is to go to an non-radionuclide 2 alternative like the x-ray machine. And being from 3 my perspective, not being a user, but being a 4 student of radiological terrorism, that would be my 5 preferred option. As we look through these things, I'd 6 7 like to really understand much better where we could use x-ray machines, where we couldn't. If it's a 8 cost issue, that's something the government can 9 balance. Because the other thing we need to look at 10 as we talk about cost is we need to look at the cost 11 12 of maintaining cesium chloride in the U.S. and that's an additional cost for security as most users 13 probably already realize. 14

But it also involves an increased cost 15 16 to try to train the police department in trying to respond to a terrorist incident and it involves the 17 cost of if a terrorist actually does acquire this 18 19 source and disperses it. What is the cost of a terrorist incident using that material? And you 20 have to weight that based on the probability of that 21 and nobody really knows what the probability of that 22 is. 23 But after 9/11 we got a lot of 24

complaints that the government didn't connect the

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1	dots. So here's a case where we're really trying to
2	connect the dots and look where the holes are in our
3	security, where our gaps are, and trying to plug
4	them and that's one of the reasons why we're trying
5	to look at other options for cesium chloride.
6	MR. SULEIMAN: Orhan Suleiman from FDA.
7	Limiting myself to the question, the feasibility of
8	the use of isotopes other than cesium-137, you're
9	obviously talking about other energies and if you're
10	talking about calibration, cesium is ideal for some
11	applications. It's absolutely terrible for others.
12	So you limit yourself by taking cesium.
13	Are you talking about eliminating cesium
14	from all commerce for all calibration applications
15	just because of its chemical and mechanistic form? I
16	think you would be doing the scientific community a
17	disservice by taking this specific nuclide out of
18	the picture completely. If you're talking about
19	terrorism and being afraid of things, I deal with
20	explaining risk to people every single day. And so
21	at some point, when do you block yourself up in a
22	corner with a wall and just not expose yourself to
23	anything?
24	The NRC has a tough task here. There
25	are societal benefits of cesium. There are
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1 scientific benefits of cesium with its unique 2 energy. It's used as the nuclide for many, many calibration applications. But then again, in its 3 current form, it also raises some risks. But I 4 5 think in terms of the specific question, isotopes other than cesium-137, you're going to create a hole 6 7 if you eliminate cesium-137. 8 MS. DANIELS: Sameera Daniels, Ramsey This is addressed to Dr. Decision Theoretics. 9 Connell. I read through NA's, National Academy, 10 report. What confused me a little bit, maybe it was 11 12 because of the way it was presented, from, let's say, a period from 1999 to 2003, I think, or 2005, 13 that was a time range where incidents occurred and I 14 15 was wondering if you could just summarize the number 16 and what kinds of incidents that you have been concerned about. 17 MR. CONNELL: Do you mean terrorists 18 19 incidents? 20 MS. DANIELS: Yes. 21 MR. CONNELL: This is not a very good venue for discussing that, but what we've learned is 22 that terrorists are getting more knowledge about 23 these radionuclides and what's important. I mean 24 25 you can go to the Jihadi websites and read about it **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	and they've read the same things that you've all
2	read in the papers that come out of USA Today and
3	The Washington Post and NGO type reports that have
4	discussed these things and so we are concerned.
5	Then we see incidents in London with
6	doctors being terrorists and that kind of raises the
7	flag again about what's the vulnerability at
8	hospitals and universities for these things. These
9	aren't places that typically have a real strong
10	security culture. So that raises our concern about
11	risk.
12	When we talk about calibration machines
13	that are at nuclear power plants, again that's not
14	the same kind of a risk factor.
15	FACILITATOR RAKOVAN: Ma'am, if you're
16	going to speak, I'm going to have to ask you to use
17	the microphone.
18	MR. CONNELL: I hope I answered your
19	question, but there's not much more I can say about
20	that. I'm not trying to scare people, but when we
21	look and do these studies we look at all the
22	different radionuclides out there and we try to find
23	out where are the risks and that's what we did with
24	the National Academy study and that's why we ended
25	up with the bigger concern with cesium chloride
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because of the past experiences with accidents that involved cesium.

MR. MINNITI: I am Ronaldo Minniti from 3 4 National Institute of Standards and Technology. 5 Anyway, to answer that question, I guess I talk on behalf of all calibration facilities and I think 6 7 most of the people will agree with me that for calibration purposes and when I say "calibration" I 8 mean calibrating the radiation detector instrument, 9 cesium cannot be replaced by cobalt because we rely 10 on the energy. Energy of cesium is 662 keV and 11 energy of cobalt is much higher. So the answer to 12 that is no, it cannot be replaced and then it's B. 13 If so, what type of applications of calibration of 14 15 instruments. If not, why? I think I answered that. I guess I had a comment for Len about 16 17 the security. So I'm done with the question and this is the comment or question. If we would 18 19 increase the security in the facilities that have

nerease the security in the facilities that have
cesium chloride, then as you say there would be a
terrorist which would like to get a hold of cesium.
Now if he has increase security, would he prefer to
get something else, cobalt for example? I
understand that because the cost to clean up cobalt
would be much less, but still do you have still the

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165 1 psychological or social impact? Thank you. 2 MR. CONNELL: Well, that's a concern 3 that you want to have a risk balanced across the 4 spectrum. But again from my perspective, I'm 5 looking at where the long pole is in the tent right 6 now. Where are the high risk factors right now? 7 What do we need to do in the near term to try to reduce that? 8 9 The stop gap was one of the things that was discussed earlier that Commissioner Lyons 10 mentioned, this hardening program, where we're 11 12 trying to go back in and retrofit these machines and we've done the Red teaming assessment. 13 We know where we would attack them and so we're trying to 14 cover up those zones that are vulnerable and make it 15 16 more difficult for someone to gain access to the machine and that actually enhances the increased 17 controls which it kind of fits together well with 18 19 that in that we want time delay. We want time for the police departments to be able to get there and 20 21 prevent that kind of a thing. If that forces the terrorists to move to 22 cobalt, well, we already have the increased controls 23 with cobalt and, as I mentioned, cobalt, anything 24 25 can be made dispersable, but it takes more skill. **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W.

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1	It takes a larger team, more equipment, more money
2	and more time and the time is of the essence.
3	That's the critical factor here. If you steal it
4	and then you have to use it, that takes time.
5	That's why cobalt is less risk.
6	MS. MOSES: Just a quick one. In a
7	comparison between cesium and a biological disaster,
8	biological terrorism, how you would relate or what
9	would be worse?
10	FACILITATOR RAKOVAN: I think we should
11	just maybe move on from this. Remember we're here
12	to talk about the feasibility of the isotopes other
13	than cesium-137. I have one person I need to go to
14	first.
15	Ms. Shepherd, please.
16	MS. SHEPHERD: Mary Shepherd, JL
17	Shepherd and Associates. One area we haven't talked
18	about is non-proliferation and tracking of plumes
19	like Chernobyl-type power plant accidents. Cesium
20	is your recognizable peak and the Cesium technology
21	I don't think will be replaceable with cobalt or
22	other methods. It's non-proliferation power plant
23	accidents and we would lose a significant tool.
24	MR. KAMINSKI: Just one remark. Again,
25	it's my professional opinion. I won't say that
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1	again, but I agree. I think we definitely need
2	cesium-137, just alternative forms.
3	MR. MINNITI: One thing I forgot to
4	mention, regarding replacements I think for
5	calibration purposes again, in the case of a
6	radiological incident, we count on emergency
7	responders, police, firefighters, police personnel,
8	walking into this incident with a calibrated
9	detector. They rely on that to know that they're
10	going to ensure safety for them and for the public.
11	So I guess my point is again cesium has
12	been established as the workhorse for 40 years and
13	if we would look for an alternative, it would have
14	to be something that has similar energy. So maybe
15	another form of cesium could be a possible solution.
16	Cobalt as I said before no. I guess what I'm
17	trying to say now imagine if we are not careful
18	about the replacement. If we remove cesium away, I
19	guess the impact for this particular case is you
20	would have emergency responders walking into a
21	radiological incident with non-calibrated
22	instruments and we would be creating a new risk. So
23	it would defeat the purpose of this whole ruling
24	anyway.
25	MR. CONNELL: Ronnie, can I ask you a
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1	question about calibration?
2	MR. MINNITI: Yes.
3	MR. CONNELL: Because we really didn't
4	pay it as much attention in the National Academy
5	study because again we only have 100 of these out
6	there and they are usually much lower curie
7	quantity.
8	But can you explain to me? Do we really
9	need 100 of these outside in the commercial
10	facilities? Can we draw them back in to maybe just
11	a few labs and have smaller quantity? Do we really
12	need 400 curies or more to do your calibrations?
13	MR. MINNITI: The reason high activities
14	are used is again there are three manufacturers here
15	that can correct me if I'm worry, but I think that
16	most of the sources that are used for calibrating
17	instruments go all the way up to most of them 400,
18	500 curies and there are a couple for the nuclear
19	power plants that go up to 1200 curies.
20	The reason, you can ask why is it so
21	high. These detectors are measuring a broad range
22	of exposure rates. So this is why you need these
23	high activities because you want to calibrate at the
24	low end of the scale. But also you want to reach
25	rates of 100 R per hour for example or in the case
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1	of the nuclear power plants, they put these
2	teletectors very close to the source and they want
3	to shoot over that range.
4	I think if someone would ask me
5	personally if we can live with what activities we
6	could live in the instrument calibration community,
7	I would say that probably with 1200 curies and below
8	would be fine. So that would limit the Category 2
9	range. Right? I don't know if that answers your
10	question.
11	MR. CONNELL: I had one more hand and
12	then I'm hoping to move onto the next question.
13	MR. SVAJGER: Mark Svajger with Fluke
14	Biomedical. To answer your question, we calibrated
15	in the range of up to 100 R per hour so that it will
16	exceed your 400 curies statement. Plus we also
17	calibrated in hour per second for, for example,
18	nuclear power plants.
19	MR. CONNELL: Okay. So let me ask you.
20	If I'm interested in doing a very high dose rate,
21	could I use cobalt for that and just use cesium,
22	cobalt and a lower energy nuclide to kind of give
23	you the spectrum, the response function?
24	MR. SVAJGER: Once again, cobalt-60 is
25	about 1.1-1.3 MeV and cesium is 0.6 MeV. So many of
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1	the detectors are also energy dependent. But
2	certain things can be done with cobalt-60. But most
3	everything we do is cesium-137. And to take an
4	account most radiation measurement instruments, they
5	have a wide range from low keVs in the 10s and 20s
6	to upper 1.4 to 1.3. Thank you.
7	FACILITATOR RAKOVAN: Okay. One more
8	comment from someone who promised he'd be brief.
9	(Laughter.)
10	MR. MINNITI: To answer your question,
11	the detectors are TLDs. These are thermal-
12	luminescent dosimeters and people use this, I don't
13	know, probably most of the people are familiar, but
14	for radiation protection and there are hundreds of
15	thousands of those in the U.S., probably more than
16	one million. I came up with this number just by
17	talking to only a few of our people we interact
18	with. That's basically the Navy, Air Force, Army
19	and a couple other private sectors.
20	But anyway TLDs are The readers that
21	are used for TLDs are calibrated with cesium and I
22	just thought you were asking why and these are
23	calibrated at doses of 5 gray. This is the highest
24	dose. We're talking 100 Roentgen (R).
25	The reason why you used the high
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1	activities which was your question is you want to
2	irradiate these TLDs in a reasonable amount of time.
3	I mean you could irradiate these doses per days,
4	but you have to do this. These are large amounts.
5	FACILITATOR RAKOVAN: I'm sorry. I
6	think we're going to have to move onto the next
7	question.
8	1.2-2 and I think we've gone into this a
9	little bit, but can the shielding challenges for
10	cobalt-60 be addressed by switching from lead
11	shields to more effective tungsten or depleted
12	uranium shielding? And there was a note. Consider
13	that tungsten shielding is more expensive than lead
14	and manufacturing depleted uranium shielding is a
15	very specialized, expensive operation that requires
16	NRC or agreement state licensing for its entire life
17	cycle.
18	Shielding discussion. No one in the
19	mood to discuss shielding. All right. We have a
20	couple people.
21	MR. MENNA: Blair Menna from Best
22	Theratronics. I'll just take a quick stab at it.
23	Tungsten is very expensive. The metals market
24	recently has just been going crazy. The subject of
25	home renovations came up earlier in the morning.
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1	You know if you're been pulling wire in your house
2	extension that it's gone up. Copper has gone up
3	hugely. Tungsten, we've seen huge leaps in the
4	price.
5	We are worried about the cost of
6	redesigning an irradiator to accommodate a larger
7	cesium source. Thinking out loud, I would suggest
8	that it would be cheaper to redesign a lead unit to
9	accommodate a larger non-dispersable season source
10	than it would be to make one of the irradiators out
11	of tungsten. The cost would be prohibitive.
12	MR. AKABANI: Depleted uranium by itself
13	
14	FACILITATOR RAKOVAN: I'm sorry. Could
15	you identify yourself?
16	MR. AKABANI: I'm My name is Gamal
17	Akabani. I used to work at Battelle Pacific
18	Northwest and one of my main projects was depleted
19	uranium and the depleted uranium by itself does
20	carry out a confounding factor because of the fact
21	that it produces lots of x-rays and therefore it
22	will be something that has to be taken into
23	consideration when you irradiate either animal
24	experiments or things like that. I know it's very
25	heavy, contains some of titanium. However, it's by
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itself, I would consider it to be probably not cost effective.

3 MS. SHEPHERD: Mary Shepherd, JL 4 Shepherd and Associates. Tungsten is a very long 5 lead time item now. If you go to a manufacturer trying to obtain it, it's sometimes six to nine 6 7 months out for large quantities and depleted uranium 8 besides the licensing problems has a bad reputation with a lot of countries around the world and at one 9 point there was much more restriction towards its 10 use as a lead alternative for shielding and so there 11 would have to be some kind of regulatory interface 12 to be able to use depleted uranium. But it is very 13 expensive and it's also still a strategic material 14 15 in the Unites States. It used to be up to a couple 16 years ago. 17 FACILITATOR RAKOVAN: Anyone want to expand upon those comments or make a new point? 18 19 (No verbal comment.) Okay. Let's go ahead and move onto the 20 21 third question then, 1.2-3. What are the attendant risks associated with cobalt-60 source 22 transportation? The note: Consider the shorter 23 half-life of 5.27 years of cobalt-60 radiation 24 25 It would require that they would be sources. **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W.

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1	replaced more frequently than cesium-137 which
2	entails the transportation of both fresh and used
3	sources. I think this was brought up someone
4	previously, but transportation.
5	MS. SHEPHERD: Mary Shepherd, JL
6	Shepherd and Associates. You exponentially increase
7	your risk for a transportation accident with the
8	more shipments you have on the road.
9	I don't think we have time to go into
10	all the transportation issues now, but tomorrow 99.9
11	percent of all U.S. transport containers are no
12	longer useable.
13	There are two basically nuclear waste
14	containers, two models, that are certified in the
15	U.S. market. Some of the international containers
16	are in applicable for U.S. domestic use with the
17	NRC, but that's not granted yet. We filed
18	extensions for special permits and we have a new
19	container in testing. That's a very long and
20	expensive process.
21	So right now, as of tomorrow, there is
22	very little domestic options for any kind of source
23	transport for Type B quantity of radioactive
24	materials.
25	MR. RING: Joe Ring, Harvard. If you
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175 1 tried to replace the sources in transgenic facilities with ones that are shorter, you have a 2 significant issue with changing the source out and 3 4 bringing it in and out of the transgenic facility. 5 It's very important that those facilities stay biologically clean for the purposes of the residents 6 and that certainly is against what we need in the 7 transgenic facility. 8 9 MR. JARDINE: I'm Les Jardine, 10 Consultant. I just add to our memory here. This will add to the waste disposal problem for which 11 there is no answer. Yes, it's five years half-life, 12 but it generates a lot more waste all these 13 operations for where there is no endpoint. 14 FACILITATOR RAKOVAN: Further discussion 15 16 on transportation issues or for that matter any issues associated with feasibility and the use of 17 isotopes other than cesium-137? 18 19 Charlie, I'll get to you in a second. I had a hand back there first. 20 I'm sorry. 21 I would like to go back for MR. WASIAK: the moment to the comment that I think Len made 22 regarding different forms of cesium that the 23 pollucite or ceramic would only address part of the 24 25 problem meaning the solubility, not necessarily the **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	dispersability. Could you give us an idea or your
2	opinion? If addressing both aspects would it fix
3	100 percent of our problems. Addressing the
4	solubility problem only, how much of an improvement
5	would that be if we only address that part with
6	alternate forms of cesium?
7	MR. CONNELL: That's a real tough
8	question to answer, Tom. Again, if you look at the
9	Goiania incident, the solubility was a big factor in
10	the way the material spread itself around and got
11	bonded to surfaces. So I think it's a big
12	improvement. How I would quantify that, I mean,
13	that's just Because there are so many different -
14	- I mean, what we really need to go through and
15	maybe this will come up tomorrow when we talk about
16	risk is we need to look at all the different
17	pathways by which a terrorist can use this material
18	and think through all those different paths and try
19	to look at the relative probabilities of those and
20	then see what the impact is of changing the
21	dispersability.
22	It's a complicated process, but I would
23	relate it to like a PRA-type analysis. You look at
24	the different, you know, a thought tree and then try
25	to assign probabilities and look at the different
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1	progression. But I think there's a way to do it. I
2	don't know if you can come up with an exact number.
3	But I do believe that the solubility
4	issue is a big issue and if we remove that it takes
5	a big chunk out of the risk. It doesn't remove the
6	fact that you have to go around and Now if you
7	have an oxide that's not soluble and if you still
8	have very, very tiny, you know, 100 micron particles
9	of oxide, you have to go around and pick them up.
10	But, at least, it's not chemically bonded to the
11	concrete. So that makes it feasible to mechanically
12	remove it. It still would be expensive, but it
13	won't be impossible to clean up in a nondestructive
14	way.
15	MR. WASIAK: I guess the reason for that
16	question was primarily to kind of assess the
17	viability of the alternate form of cesium. Because
18	if it doesn't really help us that much, then it's
19	really maybe not worth doing. But my expectation
20	was that addressing the solubility problems
21	significantly and dispersability to some extent
22	would get us quite a significant part of the way
23	there.
24	MR. CONNELL: I think it does a good
25	job. I don't think the government has really sorted
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1	through the complete effect of that yet. I think
2	that a lot more analysis needs to be done to look at
3	the impact of having a material that's not soluble,
4	but it's still dispersable.
5	MR. MILLER: Thanks, Lance. This is
6	Charlie Miller from the NRC. Lance, I would like
7	you to get a couple of things in the parking lot.
8	FACILITATOR RAKOVAN: Can you speak a
9	little bit more into the mike.
10	MR. MILLER: As I listen to the
11	discussion thus far, there's a number of things I
12	would just like to throw out for consideration for
13	the rest of the workshop. One is that we've had a
14	lot of good discussion over the course of the day
15	concerning cesium chloride, various forms of cesium
16	chloride alternatives, some alternatives, cobalt so
17	far or x-rays.
18	One of the things that the NRC has to
19	ponder when formulating our decision makings is to
20	where we go with this is how far do we go as a
21	regulator. Okay. Nothing that we're going to do is
22	going to give zero risk except complete elimination
23	of radionuclides. I think that's recognized. So
24	the question becomes what is an acceptable risk and
25	that's something we should be thinking about as we
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1	go through and formulate our comments.
2	Some stakeholders here are coming at it
3	from a security perspective. Like Lance, some are
4	coming at it from the manufacturing perspective.
5	Some are coming at it from a research perspective.
6	Some are coming at it from a medical perspective.
7	Some are coming at it from an industrial calibration
8	perspective.
9	The other piece that I'd like to get a
10	little bit better handle on, we've kind of talked
11	around it some, so if anybody has any insights to
12	this especially the manufacturers and distributors,
13	is it's obvious from the discussion so far based
14	upon the stakeholders' input that one size doesn't
15	fit all. So therefore if we were to look for
16	alternatives, what percentage, for example, of the
17	cesium chloride would be eliminated if we went to
18	alternatives for various utilization, in other
19	words, for blood irradiators versus calibration
20	versus research aspects of it so that if we do make
21	decisions that are different for each how much are
22	we really reducing the risk by the actions that
23	we're taking?
24	And I guess finally I would just like to
25	We don't live in a zero risk society. We're not
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1 going to get there as I said. So therefore if we 2 are to promulgate, if we were to go forward and promulgate, some kind of ruling-making on this 3 4 activity, part of our rule-making activity requires 5 a regulatory analysis which has to factor in cost/benefit of the actions that were taken. 6 It's important for us to have that information so that we 7 make informed decisions as we go forward. 8 9 Those are some things that I would just 10 like to put in the parking lot and hope that we can 11 get better information on as the workshop goes on 12 and is concluded or anyone who wants to issue written comments or supply comments to us after the 13 workshop these are important considerations for us 14 15 as we go forward and make recommendations to the 16 Commission as the NRC staff. 17 Thank you. MR. McBRIDE: Can I just ask you a 18 19 question before you go away? MR. MILLER: Absolutely. 20 MR. MENNA: You said getting rid of 21 radionuclides. Are you talking only about the high 22 level or what level or --23 MR. MILLER: Yes, if you're going to 24 25 talk about complete, if you were removing the risk **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	completely of using cesium chloride or cobalt or any
2	radionuclide, the only way you eliminate that risk
3	completely is not to use it at all from a
4	radionuclide perspective. So there's a recognition
5	
6	MR. MENNA: But get rid of low level
7	radionuclides as well?
8	MR. MILLER: That's all it's going to
9	take. Yes, any utilization of it at all in any form
10	is going to give some form of risk. The question
11	becomes what's that accepted level which I think is
12	the point that we're trying to ponder.
13	MR. RYAN: Mike Ryan. I'm a member of
14	the ACRS, Advisory Committee on Reactor Safeguards.
15	Charlie, I couldn't applaud you more for bringing
16	up the issue of risk. On the one hand, we've talked
17	a lot today about how cobalt-60 can be used to
18	replace cesium in an irradiator which kind of
19	presumes the question we've decided cesium doesn't
20	work. How about we ask the other question? What
21	would it take to make a cesium irradiator have a
22	risk profile that was acceptable by whatever metric
23	you wanted to use?
24	Asking the alternate question is a way
25	to analyze how do you make it better rather than
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1	what can we substitute and I think when you do that
2	in a risk-informed way and think about all the
3	risks, the risk of a terrorist, the risk of them
4	getting to the material, the risk of them getting it
5	and doing something bad with it and all those things
6	which is the event side and then thinking carefully
7	and systematically about protections that you have
8	or don't have now or should have or might have, we
9	can really kind of sort it out.
10	This last question on transportation to
11	me comes in from left field. What does this have to
12	do with irradiators? Transporting cobalt or cesium
13	on its own merit has a risk and I'm sure you're
14	concerned about Type B casks sort of going away.
15	Three of my favorites expire tomorrow. So that's a
16	whole different question.
17	But I would just urge that we focus on
18	the risks. What are the risks we're trying to
19	mitigate and how can we systematically mitigate them
20	and then how do we ask the questions? Instead of
21	presuming cesium has to go away, we can say if we
22	really want to keep cesium, what does it take to
23	give it the risk profile that would be acceptable
24	from a risk-informed regulatory view?
25	MR. KAMINSKI: I haven't heard anybody
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183 1 including the NRC or NAS advocating elimination of 2 cesium-137, but I think at least according to the 3 NAS report they do suggest eliminate of cesium-137 4 chloride, at least, category 1 and 2 and just one 5 reason is just due to the solubility and that's a 6 significant economic impact it would have on society 7 if a terrorist event happened. MR. RYAN: It is true it is soluble. Ι 8 agree 100 percent. It is salt. But where is the 9 10 evidence that says on a risk metric that that's the most important thing about cesium-137? If it's 11 12 properly secured, properly confined, properly contained, by whatever mechanism you want to think 13 up so that it prevents that action, that solubility 14 15 may become less significant from a risk point of 16 view and I think we're giving that up too quickly. 17 MR. KAMINSKI: I agree with you, but can we mitigate the risk and is it still economically 18 19 viable? MR. RYAN: That's exactly the question 20 we're posing. 21 22 MR. KAMINSKI: That's our question. Exactly the question. 23 MR. RYAN: I think we need to systematically think that through 24 before we throw it away. 25 **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W.

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1	MR. CONNELL: I thought Charlie brought
2	up some points about the different modalities here.
3	If you look at calibration machines and they're at
4	nuclear power plants, you have one security risk.
5	If you have cesium chloride at a university with
6	graduate students that are foreign, you have another
7	kind of risk. Hospital, blood banks, a different
8	whole spectrum. So you look at each one differently
9	and maybe you can come up with different solutions.
10	Maybe for the blood banks for those that
11	are not using a very high through-put, an x-ray
12	machine is a good option. For United Blood Services
13	or the Red Cross where they have a lot of through-
14	put, maybe you consolidate your cesium chloride
15	there and you increase the security and really beef
16	it up at those facilities. There are different ways
17	of dealing with this problem in terms of risk
18	reduction.
19	MS. SHEPHERD: Mary Shepherd, JL
20	Shepherd and Associates. I think the risk
21	associated with transport is probably when
22	radionuclides are at their most vulnerable that's
23	why it should be looked at significantly, much more
24	so than in a secured facility and that's being
25	addressed through other modalities. But I think
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1	it's a reason why that was brought up here.
2	And regarding the solubility and
3	dispersability, ever since we've had above-ground
4	testing we've had cesium all over the world and I
5	don't think we've cleaned up everything we've done
6	from our own above ground tests, much less everybody
7	else's besides Bikini Atolls and different areas
8	like that. It's there. It's part of the
9	environment.
10	FACILITATOR RAKOVAN: Any further
11	discussion on feasibility of the use of isotopes
12	other than cesium-137? Mr. Suleiman.
13	MR. SULEIMAN: I think I want to sort of
14	second the previous comments because if cesium-137
15	is so long-lived you just don't change it out very
16	frequently. So it's transported less frequently.
17	It's accessed less frequently. That has to figure
18	into the risk probability paradigm somehow. So, in
19	some ways, you could make an argument that cesium-
20	137 is actually more secure because it doesn't have
21	to be handled or it doesn't have to be changed out
22	or replaced as often.
23	You really have to look at this thing
24	from the total life cycle from manufacturing to
25	eventual storage or elimination. If you phase them
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1	out, then you have to get rid of all these all over
2	the country or you'll just let them decay away. So
3	you just have to identify all the variables and
4	assign some guesstimates into the risk.
5	MR. KAMINSKI: Just one comment. Having
6	worked with a cesium irradiator a few years ago and,
7	of course, measures have been implemented to
8	increase security and so forth since then, it's not
9	too difficult and if I wanted to I could have gotten
10	a hold of it back then.
11	FACILITATOR RAKOVAN: Go ahead.
12	MR. COPPELL: Sorry. David Coppell from
13	REVISS Services again. I guess I'm not sure what to
14	contribute to this discussion from a manufacturer's
15	perspective. We, of course, make both cobalt
16	sources and cesium sources.
17	This is inevitably about balance and
18	risk. Of course, it is and I guess everybody
19	understands that. I hope we're not going to ban
20	cars in order to reduce road accidents. What we're
21	looking at is whether or not here there's an
22	opportunity to fit air bags or whatever and I guess
23	for me with one set of demands which is reduce the
24	risks associated with how a terrorist might handle
25	cesium-137, but another set of demands from users
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1	who say it's really not very easy to substitute
2	cesium-137 with any other isotope. Then I guess that
3	we are trying to plan a furrow of finding a way of
4	manufacturing cesium sources that meet both sets of
5	requirements and that's just what we hope to come
6	back with in a few months.
7	MR. POWELL: Brian Powell, Constellation
8	Energy. As far as I understand, the sources of
9	concern already, Category 1 and 2 sources of
10	concern, already, are required to have a
11	transportation security plan. So I guess I'm asking
12	the panel what is the difference between the Is
13	there a new proposed transportation security plan
14	for cobalt-60 that's different than the cesium-137
15	one or any of the other isotopes are concerned or
16	are we already covered sufficiently by the existing
17	plans that we've implemented?
18	MR. RING: Joe Ring, Harvard. I would
19	like to respond to that in the general security. I
20	think the real issue with cobalt-60 is that you have
21	to replace it much more frequently. Therefore, it's
22	on the road an awful lot more. Cobalt irradiators
23	can last a comparatively short time as compared to
24	cesium.
25	And I would like to make a comment about
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1	the security of the current irradiators. I've gone
2	from a few thousand people having access to them to
3	400 people who now coordinate the access and I will
4	tell you that those 400 people think it is extremely
5	difficult to get access to an irradiator these days
6	and when they go through the process and they have
7	to have an escort by a security guard through
8	multiple systems, it is difficult for them and it
9	really has greatly impacted their research.
10	MR. KAMINSKI: Just to make one comment
11	about cobalt and, of course, I think cesium needs to
12	be used in certain cases for animal research also.
13	But the specific activity tends to be higher with
14	the cobalt source and you can load more also at the
15	time. So at least according to an NAS report, they
16	estimate replacement about every 15 years instead of
17	every 30.
18	FACILITATOR RAKOVAN: Okay. Another
19	one. Maybe we should just get you a lapel mike like
20	the one I have.
21	(Laughter.)
22	MS. SHEPHERD: I'm sorry. In regard to
23	shipment security, Mary Shepherd, Shepherd and
24	Associates. In regard to shipment security, there
25	was a Federal Register announcement that did not go
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1	into the safeguarded areas, but there will be more
2	security for all kinds of aspects starting out with
3	manufacture and distribution licensees that will
4	probably filter down through the whole licensing
5	community and I think it's I don't remember the
6	number, but it came out in August.
7	FACILITATOR RAKOVAN: Any further
8	discussion or should we go ahead and take a half
9	hour break?
10	(No verbal response.)
11	Okay. We'll come back in a half an hour
12	and start promptly a few minutes before 3:00 p.m.
13	with Panel 2. Off the record.
14	(Whereupon, at 2:26 p.m., the above-
15	entitled matter recessed and reconvened at 3:00 p.m.
16	the same day.)
17	MR. RAKOVAN: Okay. Let's go ahead and
18	get started again.
19	We're going to move on to Issue No. 2,
20	which is use of alternative technologies. If we
21	could really quick just go and have the new panel
22	members at the table or we might as well go ahead
23	and ask everybody who's at the table regardless of
24	whether you're new or not to introduce yourselves,
25	starting on the left there.
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1	MR. FITZGERALD: Yes, I'm Bill
2	Fitzgerald. I'm from the National Institute of
3	Environmental Health Sciences. I'm the Radiation
4	Safety Officer there.
5	MR. GORLI: Jed Gorli, Medical Director,
6	Memorial Blood Center, speaking on behalf of the
7	American Association of Blood Banks, or AABB.
8	MR. SVAJGER: I'm Mark Svajger,
9	Radiation Safety Officer and calibration service
10	manager for Fluke Biomedical, and I hope this is
11	employed. It's really just nonactive here.
12	(Laughter.)
13	MR. SVAJGER: Yeah, we're hurting right
14	now. Thanks.
15	MR. KIRK: Yes, I'm Randol Kirk from Rad
16	Source Technologies.
17	MS. GILLEY: Good afternoon. My name is
18	Debbie Gilley, and I'm with the Advisory Council for
19	the Use of Medical Isotopes for the NRC.
20	MR. SULEIMAN: I'm Orhan Suleiman. I'm
21	with the Food and Drug Administration's Center for
22	Drug Evaluation and Research. I also wear a dual
23	hat because I also participate with the Medical Use
24	Advisory Committee for the NRC.
25	MR. WAGNER: Hi. Good afternoon. My
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1	name is Steve Wagner. I'm with the American Red
2	Cross. I'm a scientist at the Holland Laboratory.
3	MR. KAMINSKI: Joe Kaminski, NIH.
4	Again, I only represent myself.
5	MR. McBRIDE: Bill McBride, again,
6	representing Astro.
7	MR. RING: Joe Ring, Harvard,
8	representing the summary of our faculty.
9	MR. NIXON: Grant Nixon, radiation
10	physicist, representing Best Theratronics.
11	MR. RAKOVAN: Thank you all.
12	As usual, I think we might have a few
13	statements to start the panel out with. So if
14	anyone has a statement they'd like to make now.
15	Okay. Start at the end there.
16	MR. FITZGERALD: Again, I'm Bill
17	Fitzgerald. I'm the Radiation Safety Officer at the
18	National Institute of Environmental Health Sciences,
19	and I'm representing the researchers at the NIHS.
20	You can go on to the next slide.
21	The NIEHS is one of the 27 institutes
22	and centers of the National Institute of Health. We
23	also are home of the National Toxicology Program.
24	We focus on environmental influences in the
25	development and progression of human disease. We
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1	are located in Research Triangle Park, North
2	Carolina.
3	Next slide.
4	We have a J.L. Shepherd Mark-431. This
5	is kind of a model, or Mark-168(a). It has about
6	22,000 curies of cesium in it when it was purchased.
7	It has been in service for more than 30 years. The
8	dose rates we were able to achieve when we first
9	purchased this were greater than 113 gray per
10	minute, and we have more than 40 ongoing research
11	projects.
12	There's been hundreds of research
13	projects using this irradiator over the last 30
14	years, but ongoing right now we have about 40.
15	Next slide.
16	So I spoke to each of the researchers
17	who used the irradiator and then tried to break down
18	their uses of it into classification, and I have
19	five classes here to let you know how to use it.
20	And then I also asked them for some
21	alternatives. What would you do if you lost the use
22	of the irradiator? What would you do as a means of
23	getting your work done or your research done?
24	So I broke it up into these five
25	classes: feeder cell, oxidation of proteins, loss
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1	of bone marrow viability, chromosome aberration, and
2	DNA study and repair states.
3	The first one with the feeder cells, the
4	doses range usually from about 30 to 80 gray. This
5	research has been going on for about 30 years.
6	The alternatives to that is you can use
7	X-ray. Some of the researchers said that this may
8	be an issue and that there's such a spectrum with
9	the X-rays, but they thought that they can overcome
10	that by hardening up the beam a little bit.
11	You can also use chemical treatments.
12	It is widely known that you can use chemical
13	treatments to stop the production of these cells.
14	The problem though is that when you're doing basic
15	cell research, some of this is genotoxic and so it
16	kind of nullifies what you're trying to accomplish,
17	and so in some cases you may be able to use some
18	chemicals, but in most of the cases where we're
19	looking at basic research, you're not going to be
20	able to.
21	But this is an alternative that they
22	brought forward and said in some areas they would be
23	able to do that.
24	The next slide, please.
25	The oxidation of proteins is something
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1	that has come out recently. We've been doing this
2	for about five years. The thing with this is that
3	you're trying to form hydroxyl radicals and
4	concentrations enough to oxidate the proteins, and
5	these dose rates that you need are really large.
6	They're around 23 gray per minute.
7	And, again, this research is only about
8	five years ongoing. You need ranges from about 100
9	to 2,800 gray, which are just really long doses, but
10	the researcher really kind of reached in and said,
11	well, he might be able to use some laser flash
12	photolysis to do this kind of work, but he said it
13	may change the type of work they're doing, but if he
14	lost the irradiator he may be able to do that.
15	Next slide, please.
16	The bone marrow viability, this is
17	something, again, that has been going on for a long
18	time. You're talking about doses five to ten gray.
19	It has been going on for about ten years. Again,
20	they thought you could use X-rays to take care of
21	this. There are chemicals that you could also use,
22	but again, here we go. When you're using a
23	chemical, it is also toxic to other organs in the
24	mouse or the animal that you're working with, and so
25	that may be a problem.

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1	So it may work for some research, but
2	not for others.
3	Next slide.
4	And in the chromosome aberration, again,
5	five to 40 gray here, about 30 years of research.
6	Again, even before the radiator that we had on site
7	that used X-rays for some of this work, most of what
8	we're doing this in is lower forms of animals. So
9	we're using flies, nematodes, and things like that.
10	The nematode people said that they
11	thought they could use a UV cross-linker. There's
12	some research that says that might work. It may
13	not, depending on the thing, but that's mainly
14	limited to the worm community. And, again, the
15	chemicals is also limited to the worm community.
16	The next slide, please.
17	With regard to our DNA repair studies,
18	this is what this research is about. We're looking
19	at research that's specific to direct ionization of
20	direct effects of low ionizing radiation. It deals
21	with double strand breaks and resection of randomly
22	broken DNA.
23	We use yeast to model that because yeast
24	has about 500 fewer times less DNA than on a human
25	cell. So we knew more about yeast a long time ago,
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1	but that means you have to have a higher dose to do
2	that. So that's been ongoing.
3	The high dose rates are needed for a
4	short time because the repair starts, and just a
5	point about the animal studies. The animal strains
6	that we use are specific. We make it specific to
7	the radiation dose. We know what the outcome is.
8	If we had to go to another form of radiation, we'd
9	have to recharacterize that, and that would take
10	many years of research.
11	And then finally, the last slide,
12	please.
13	And it's basically our clinical points
14	are that for some researchers we feel that there are
15	alternatives to gamma radiation, but for most of the
16	research we're looking at direct effects of
17	ionization, and we don't think there is any
18	alternatives to gamma radiation because that's what
19	we're studying. So I just want to make that point.
20	Thank you.
21	MR. RAKOVAN: Thank you.
22	MR. GORLI: Next slide.
23	I'm speaking for the American
24	Association of Blood Banks (AABB), and I just wanted
25	to make some over arching comments at first.
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1	AABB is not tied to any specific single
2	technology. That said, the details do matter. We
3	need to use irradiation to achieve a specific end.
4	That end is to prevent transfusion associated graft
5	versus host disease, which once it happens in a
6	patient is generally fatal and not treatable.
7	Irradiation consistent with AABB
8	standards has shown to be 100 percent effective in
9	the prevention of this complication.
10	Next slide.
11	Leaving X-rays to the subsequent slides,
12	cobalt is less desirable in that you've already
13	heard about its increased shielding requirements.
14	At least in half of our applications they're in
15	hospitals where the blood bank is generally opposite
16	the operating room, not the morgue.
17	Linear accelerators are generally not
18	uniformly available around the clock.
19	I do want to make the point that
20	pathogen inactivation has been shown in vitro to
21	largely abrogate the need to irradiate product. So
22	down the line when products are available, these DNA
23	cross-linking reagents may be a viable alternative,
24	and I don't think we're part of the worm community.
25	Next slide.
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1	That said, since there was a request for
2	quantitative data, we did do a survey of all our
3	constituents. It was done with a pretty short lead
4	time. So we did not have uniform response. We did
5	get 345 responses from 195 centers. We very
6	specifically called the list and did not call the
7	ABC or the Red Cross centers because they were
8	having their own direct surveys, which you will hear
9	about from their representatives shortly.
10	Next slide.
11	The preponderance of centers do, in
12	fact, use the cesium devices for the reasons you've
13	heard, reliability throughput and economics. Some,
14	and only a relatively small number, have X-ray
15	irradiators, and this becomes relevant in the
16	statistics.
17	Next.
18	Now, there was significant difference in
19	the down time reported cesium versus the X-ray
20	devices. For cesium, less than five percent had
21	more than 30 days down time versus 21.4 percent. In
22	fairness to the X-ray devices, that was a relatively
23	small number of centers, however.
24	Next slide.
25	The economics, again, are not equal.
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1	Although a cesium irradiator may be slightly more
2	expensive up front, the maintenance costs have been
3	estimated to be more than 300,000 over the lifetime
4	of a cesium device, and this is from the National
5	Academy report.
6	Next slide.
7	And hence, in recommendations, if you
8	can see in the background, that is a balanced scale.
9	So we want to balance both the risk and benefit as
10	well as cost and benefit. If cesium irradiators are
11	replaced, economic considerations should be not only
12	the cost at time of disposal, but the availability
13	of replacement devices and reimbursement of all
14	additional costs.
15	Thank you.
16	MR. RAKOVAN: Okay. Anyone else on the
17	panel have an opening statement or presentation?
18	I guess we'll just keep on moving this
19	way.
20	MR. KIRK: Good afternoon. I am from
21	Rad Source, and Rad Source makes a new type of X-ray
22	emitter, which has very, very high dose rates, and
23	the abilities to do things that have never been able
24	to be done with a point X-ray source.
25	Next slide.
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200 1 We have built a number of different 2 configurations using this emitter. Probably the 3 most successful one so far is the one up in the 4 right-hand corner, the RS-2400. The IAEA has just 5 completed a review of that unit and has begun the 6 process of getting an article accepted for publication, and that should be out probably three 7 or four months, and it talks about its application 8 in SIT. 9 The one that we have labeled the RS-3400 10 there is actually a new type of blood irradiator 11 12 which has just been submitted for the 510(k) review. I'm not going to say anything else about that right 13 now other than that it's in process, and it is 14 actually kind of a vertical version of the RS-2400. 15 16 So hopefully one of these days you'll be seeing it 17 around. Next slide, please. 18 19 Based on all of those products, we can pretty much match any application. I don't think I 20 21 mentioned. I forgot the highest dose rate unit there does ten kilogray per hour as far as output. 22 So if you think about that, that's considerably more 23 than you would expect from a conventional X-ray. 24 25 Reliability, the one thing that's **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS

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1	changed since we designed the first X-ray irradiator
2	about ten years ago is that we now have an emitter
3	that actually can be repaired. You don't have to
4	throw it away if it goes bad. You can open it up.
5	You're going to replace the filament. You can do
6	whatever is necessary, pump it back down, and
7	recycle it into the unit or another unit.
8	Thirdly, I think if you start
9	considering the fact that you have to consider the
10	disposal costs when you're thinking about
11	irradiators and you think about having a tube that
12	you don't have to replace, that cost becomes
13	competitive.
14	That's it. Thank you.
15	MR. RAKOVAN: Ms. Gilley.
16	MS. GILLEY: On behalf of the Nuclear
17	Regulatory Commission's Advisory Committee on the
18	Medical Use of Isotopes (ACMUI), Subcommittee on
19	Cesium Chloride Alternatives, I would like to
20	provide the following opening remarks and a little
21	bit about our draft report that we'll be providing
22	to NRC next month.
23	Cesium chloride irradiators are
24	responsible for saving lives. The standard of care
25	that exists in this country will be compromised if
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1	the use of cesium chloride is prohibited or
2	eliminated.
3	The members of the subcommittee are
4	Darrell Fischer, who is a patient advocate; myself,
5	as a member of an agreement state; Ralph Lieto, who
6	is a medical physicist; Orhan Suleiman, who is a
7	representative from FDA and is sharing the table
8	with me today; Dr. Bruce Tomadsen, who is a
9	radiation medical physicist; Dick Vetter, who is a
10	radiation safety officer at a large, major
11	institution; and Dr. James Welch, who is a radiation
12	oncologist.
13	The National Research Council's report
14	made several assumptions that seemed questionable to
15	the ACMUI. The subcommittee investigated these
16	concerns and raised the following comments by the
17	ACMUI.
18	Our concerns, first, are the need for
19	cesium chloride irradiators. We're also interested
20	in the liability of alternatives that are available
21	out there, and we also would like to bring to the
22	table and discuss the current security requirements
23	that our licensees have had to go forth and do in
24	order to maintain adequacy for their license.
25	The original report that approximated
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203 1 ten percent of the blood that was used in the United States was irradiated. We've had discussions with 2 3 the hematologists and oncologists who indicate that 4 for their particular practices, the values range 5 between 15 and 40 percent. These patients that are 6 involved have depressed immune systems and need the irradiated blood. 7 The lower number probably comes from a 8 higher fraction of trauma cases where irradiation is 9 irrelevant. 10 For animal irradiation for research, 11 12 research on stem cells and other systematic therapies increasingly requires whole body 13 irradiation of the animals, usually mice, before 14 15 infusion. This research is growing and may soon 16 lead to treatments for current untreatable conditions. 17 Without irradiators available -- next 18 19 slide -- hematology and oncology patients would suffer potential death for the lack of irradiated 20 21 blood. Without irradiators available, much of the stem cell systemic drug research would not be able 22 to proceed. 23 We looked at the alternatives for cesium 24 chloride irradiators. These alternatives are 25 **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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204 1 conventional X-ray units and linear accelerators. 2 Both have been and are used for blood, animal, and material irradiation. 3 4 Throughput is lower for the X-ray units 5 that are currently available out there. With 48,000 6 blood product units, X-ray tubes, and 50 units per 7 day operations would replace the tube every 3.7 years, adding to the cost of running the unit. 8 9 Issues with the X-ray unit for animal irradiation -- next slide. We're behind -- would 10 include the different RBE compared with the Cesium-11 12 137, possibly of a factor of two for the lower energy units, and the dose rates can have an effect 13 on the biological effectiveness as well as the 14 anesthesia, more difficult. 15 Penetration may require irradiating the 16 animals from several different directions. 17 MR. RAKOVAN: Can we make sure we've got 18 19 the right slide for you up there? I think we're a little lost. 20 21 MS. GILLEY: Okay. Next slide. Next slide. 22 There we go. Medical linear accelerators are another 23 option. I apologize. If the radiotherapy 24 25 department's accelerator is used, time available for **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	blood in animal irradiation becomes a problem.
2	These linear accelerators are used for the treatment
3	of cancer and are usually very busy. Many
4	institutions run two shifts a day in order to
5	accommodate patients.
6	And if it's not being used in the radio
7	therapy department, accelerators because of their
8	price tag become a problem at \$1.5 million as the
9	starting, getting in price for an accelerator.
10	Next we'd like to talk about security.
11	Since the National Research Council's report raising
12	the concerns about these units, several things have
13	changed that are not a part of that report. One is
14	the security of the users has been enhanced through
15	the requirement of background checks and
16	fingerprinting, and this is in response to orders
17	issued by NRC, increased controls and security in
18	orders or amendments by the agreement states.
19	The security of the facilities has been
20	enhanced following the directives of the Nuclear
21	Regulatory Commission. That means we've gone in and
22	required the facility to make additional security
23	capabilities to prevent access to these devices, and
24	it has also been enhanced and should be enhanced
25	through a hardening situation where we can actually
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1	go in and prevent the source from being removed from
2	the irradiator.
3	Next slide, please.
4	Following these three security
5	enhancements, the units present little hazard for
6	unauthorized source removal or disruption. The lack
7	of such security was a major factor for the
8	production of the original national academy of
9	science report.
10	In summary, we feel that irradiation
11	facilities are essential for irradiation of blood
12	and research. We believe that forced replacement of
13	Cesium-137 base units would force many facilities to
14	stop irradiation because of the large expense.
15	Since most of the facilities are nonprofits and have
16	few resources for funding new X-ray units and
17	maintaining the units.
18	And if not leading to the termination of
19	irradiation, the replacement would put a large
20	financial burden on the facilities which use and
21	have little funding.
22	Thank you.
23	MR. RAKOVAN: Okay. We might as well
24	continue this way. Anyone else have statements that
25	they'd like to start out with?
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1	MR. KAMINSKI: I'd just make one
2	statement just about the mechanisms of X-rays.
3	MR. RAKOVAN: Could you get a little
4	closer to the microphone, please?
5	MR. KAMINSKI: The mechanisms of X-rays,
6	low energy X-rays and higher energy, for example,
7	photons or X-rays. I just jotted down some stuff as
8	we were talking, but the mechanism of knocking out
9	electrons is different between low and high photon
10	energies, for example, photoelectric and Compton,
11	respectively. But the damage is primarily done by
12	double strand breaks, as you all know out there.
13	The reason why we see bone at low
14	energies is due to the extra-celluosseous matrix,
15	but indeed, there are dosimetric concerns at the
16	osseous interface and depth dose issues with lower
17	energies. But, again, I don't think in the majority
18	of the cases these are relevant too much to animal
19	research as they can be factored into the picture,
20	and that's pretty much what I wanted to say.
21	But, again, I think cesium, getting back
22	to it, cesium does have a good depth dose profile
23	for small animals and I don't personally think we
24	should advocate eliminating it. Just the form of
25	cesium 137 should be changed.
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1	MR. RAKOVAN: Any other panelists want
2	to make initial statements?
3	MR. NIXON: Hi. This talk was prepared
4	with my colleagues, Tom Wasiak and Paul Moses and
5	Blair Menna.
6	Next slide, please.
7	So just to give a brief perspective from
8	our view as a manufacturer, we are a manufacturer of
9	both X-ray and cesium chloride irradiators. So we
10	have dogs in both sides of the fight. We come out a
11	winner no matter which way this works out.
12	(Laughter.)
13	MR. NIXON: So we like to consider
14	ourselves more or less an independent broker, to
15	give you the straight goods. I mean, we offer both
16	technologies. We want to do what's best for our
17	customers.
18	So are they already commercially
19	available, X-ray units to substitute cesium chloride
20	or cesium-137 and cobalt-60? Well, it depends on
21	the application, of course, and it depends on what
22	you mean by "substitution."
23	Currently, we have models available for
24	low volume, low throughput, self-contained blood
25	irradiators in X-ray form. We offer the Raycell,
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1	which is the $510(k)$ approved modality available to
2	the U.S.
3	No, in terms of high volume, high
4	throughput, self-contained blood irradiators, and in
5	terms of a comparison with the gamma cell 3000 Model
6	II.
7	And in terms of research irradiators
8	used for stem cell research and so forth, as a
9	manufacturer, we do not feel that existing units
10	available in the marketplace today can supplant the
11	use of cesium chloride or cesium-137 based self-
12	contained irradiators on account of the voltages
13	being too low at this time.
14	In the near future or in a few years'
15	time perhaps we will have prototypes available. At
16	this time, because of the low energy components, you
17	get too much dose differentiation between tissue and
18	bone, and as my colleague expressed, you get these
19	interface effects that lead to overdosing, and these
20	overdosing effects vary from one specimen to the
21	next on account of the shielding issues associated
22	with low energy photons.
23	Next slide, please.
24	Are X-ray units cost effective
25	considering initial capital costs, et cetera? Well,
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1	if they weren't cost effective people wouldn't be
2	buying them. So I would say, yes, they're cost
3	effective, but as most people realize that are in
4	the business, there are more costs associated with
5	that modality by its very nature.
6	Life spans of typical X-ray units, at
7	least from the history we have to date, is that they
8	can be used or serviced and used over a period of
9	five to ten years or as cesium units. We have
10	cesium units that are 40 years old out in the field
11	today that are still running.
12	There's more servicing of auxiliary
13	components associated with X-ray technology.
14	Calibration of the beam, very difficult from a
15	dosimetry perspective. I worked in dosimetry for
16	ten years, and most of the tubes out there use an X-
17	ray, cabinet X-ray equipment are of the order of 150
18	kilovolts or around 60 kilovolts. Very challenging
19	to properly characterize and to find consensus, and
20	even the experts in the field are constantly
21	revising their recommended protocols.
22	Next slide.
23	And is there any indication that
24	performance of the alternatives will improve or
25	worsen with respect to Cesium-137? I think
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1	technology usually advances forward. Things tend to
2	improve.
3	On the other hand, there will always be
4	an inherent limitation because of the extra
5	complexity. Like any process, you want to make it
6	more lean. You want to have fewer components that
7	can go wrong in order for it to be more reliable.
8	In the case of X-ray generation, more
9	things can go wrong and will, and there's no getting
10	around that.
11	Tubes have been manufactured for over
12	100 years, and almost the same could be said for
13	high voltage power supplies. There's only so much
14	that can be done.
15	Next slide, please.
16	And in terms of alternative
17	technologies, what time frame? What's the time
18	frame future availability of each alternative? And
19	what's the cost, capital cost, operational cost, end
20	user costs?
21	Very, very early in the history of the
22	use of these kind of technologies, way too early to
23	tell what the overall cost will be; very difficult
24	to estimate. A lot depends on developments that are
25	going to occur in the near future.
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1	I'll leave it at that. Thank you.
2	MR. RAKOVAN: Thank you.
3	Please.
4	MR. McBRIDE: I'd just like to add a
5	little bit to that. I mean, I think the cost
6	depends to a certain extent on the applications.
7	Astro did a breakdown of the costs of X-rays
8	compared with cesium units for research
9	applications, and they reckoned that it's probably
10	going to cost about five times as much to run an X-
11	ray machine as the cesium source.
12	A lot of this actually goes into physics
13	time. The actual calibrations, the maintaining the
14	machine, and just, you know, getting goods at a
15	homogeneity of fields and other issues which are
16	really important if you're doing, for example, you
17	know, small animal work, which is tough, I think,
18	for X-rays anyway, but it does depend to a certain
19	extent I would say upon the application. You
20	certainly are looking at a higher cost, also bigger
21	supporting.
22	MR. SULEIMAN: I want to just add a few
23	points that needed to be emphasized. Radiation is
24	the only prophylactic treatment for graft versus
25	host disease. There aren't any alternative
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1 methodologies. I've been assured by some of my 2 colleagues, actually Dr. Phillips of the Center for Device and Rad Health, who will be on one of the 3 4 panels tomorrow, that basically in terms of FDA 5 clearance, hardening of these irradiators shouldn't 6 impact on us in any way, shape or form in terms of 7 getting them cleared. So this has come up in other types of 8

discussions where people have accused FDA is going to -- this is going to cause significant slow-down of the process, but this should be transparent to us.

And the third thing I want to mention is 13 my entre into this whole area a few years ago, and 14 15 what bothered me then -- so I'm going to share that frustration with you -- I was very much involved 16 with the decision to use radiation to render the 17 mail safe after anthrax issue, and I won't tell you. 18 19 It's a long story. It's a very long story, but within 24 hours of convening a task group, the 20 21 decision was made to use accelerators, and I was accused of being a cobalt advocate, and I said 22 absolutely not. I thought we ought to put all of 23 the irradiators or all of the sources on the table. 24 25 We're dealing with large volumes of mail, large

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1	intensities, and so on. We needed to know the dose
2	that would do what we wanted to do.
3	And the fear was that any explosion
4	would basically cause contamination, and I
5	unsuccessfully argued that, by gosh, if there was
6	going to be an explosion, I'd just as soon have it
7	in a nice, shielded room than elsewhere.
8	But it was obvious I was clearly
9	outnumbered. In a democracy you know when to sort
10	of back off, but that phobia and I would be very
11	concerned professionally and individually to
12	basically make some decisions without having all of
13	the scientific risk and all of the advantages and
14	disadvantages of all of these technologies on the
15	table.
16	And there are clearly alternative
17	technologies, but the economic issues and questions
18	haven't been answered, at least to satisfy me, but I
19	suspect it hasn't answered a lot of other people
20	either.
21	MR. RAKOVAN: Okay. Real quick, before
22	we continue, I just wanted to go ahead and read kind
23	of the intro to these questions that was in the
24	Federal Register notice.
25	An alternative technology is defined in
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215 1 the context of this document as a technological 2 process that provides the same societal benefits as the devices that utilize cesium chloride at the 3 present time, but without the use of radionuclides. 4 5 Some of the potentially feasible alternative 6 technologies include such processes as X-ray irradiators or electron beam irradiators. 7 Previous reports, such as those prepared 8 by the Radiation Source Protection and Security Task 9 Force and the NAS referenced above addressed the 10 issue of alternative technologies to a limited 11 extent. A more extensive examination of the 12 feasibility of these and other alternative 13 technologies is needed. 14 Therefore, in considering Issue No. 2, 15 use of alternative technologies, there are four main 16 issues that should be considered and discussed. 17 The first one we have up here, Question 18 19 2-1, are X-ray generators already commercially available as substitutes for applications that do 20 not require the gamma rays with Cesium-137 and 21 Cobalt-60? 22 MR. KAMINSKI: I can answer at least for 23 the Cobalt-60. The answer is yes. I mean, we do it 24 25 clinically every day. For Cesium-137, again, for **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	small animals that energy is ideal, but X-rays, I
2	think, in many cases would be satisfactory.
3	MR. RAKOVAN: Further discussion?
4	MR. WAGNER: Thank you.
5	The American Red Cross uses Cesium-137
6	irradiators. We have 32 units in the field. We
7	also have seven X-ray devices. There are seven
8	Raycells and one RS-3000. We have 32 regional blood
9	centers.
10	The X-ray devices are 510(k) cleared,
11	and so they're available for use for irradiating
12	blood. So we use both devices.
13	MR. RING: Joe Ring, Harvard.
14	One of our faculty members in a foreign
15	laboratory that he runs, he has been able to use X-
16	ray machines to inactivate mitosis in cells.
17	However, he's found them problematic in that he has
18	to actually have two instruments so that he can do
19	his work, which basically doubles the cost.
20	MR. RAKOVAN: I had a gentleman who was
21	standing at the second mic. If you could introduce
22	yourself, please.
23	MR. MORGAN: Tom Morgan, University of
24	Rochester.
25	We're a Level 1 trauma facility for
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1	seven counties in central-western New York. We
2	choose to irradiate all blood products. That's 28
3	to 30,000 units a year.
4	So my question for the manufacturers
5	are: how many of your irradiators would I have to
6	purchase to meet that 28 to 30,000 units a year,
7	assuming a rate of 75 to 90 units a day, you know,
8	365 days a year?
9	MR. RAKOVAN: Somebody want to take a
10	stab at that one?
11	Please.
12	MR. WAGNER: I'm not a manufacturer, but
13	I know that the irradiation time for one of the X-
14	ray devices is about five or six minutes, and you
15	can fit basically three blood bags in at a time. So
16	I'm a little bit slow at math, but I guess you can
17	go through it yourself and sort out how many you
18	would need for your facility.
19	MR. KIRK: I'm not going to comment on a
20	510(k), but the device that we use to develop the
21	unit would probably do somewhere around five, 500 mL
22	bags of blood in the three minute range. I don't
23	know exactly what that calculates out to, and I'm
24	not sure that's what the submission says, but I know
25	from the IAEA work that's about where it would be.
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1	MR. GERSABECK: My name is Edward
2	Gersabeck. I represent the Department of
3	Agriculture.
4	I think we take the lead in small
5	animals because our insecteries produce anywhere
6	from 1.5 to two billion sterile small animals per
7	week for release both in the United States and
8	overseas. We actually own all three technologies.
9	We have several cobalt based irradiators. We have
10	several Husman cesium based irradiators. We
11	actually own some of the X-ray technology, and I
12	know you've asked for non-anecdotal type of
13	information. So let me give you our perspective.
14	Over the last three years, we've
15	invested over \$1.6 million in three X-ray machines,
16	and we have found them so unreliable that we this
17	year purchased for three-quarters of a million
18	dollars a cobalt machine for in insectery in Panama
19	and just over a million dollar machine for our
20	Moscamed facility in Guatemala.
21	Our position is at least for insectery
22	type uses, that we're probably at least two years
23	away for the technology to actually be usable or to
24	be recommended, but for our department we have
25	chosen not to pursue X-ray technology in our
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1	facilities overseas.
2	One thing we became aware of is as these
3	machines age and go off warranty, we'll have to
4	establish our own engineering staff to rewire or
5	replace the filaments in the machine, which means
6	have to establish a workshop. We have to train
7	personnel.
8	So besides the increased electrical
9	costs in operating these machines, there's ongoing
10	additional labor and training to keep these machines
11	in operation.
12	Thank you.
13	MR. NIXON: If I could interject to the
14	discussion, can we speak to the specifics as to what
15	technologies are available for what applications
16	today?
17	MR. RAKOVAN: Anyone want to step in and
18	address? Please.
19	MR. SVAJGER: Maybe someone in the NRC
20	staff can tell me this, but there's got to be a heck
21	of a lot more licensees than just blood irradiators,
22	and this morning I heard 1,100 facilities using
23	blood irradiators. So there has got to be tenfold,
24	100-fold more licensees than just that.
25	So what I'm saying is let's not just
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1	focus totally on blood irradiated entirely. There's
2	a huge percentage of cesium chloride as well.
3	With that I'll sign off.
4	MR. McBRIDE: Well, I guess I have a
5	non-blood irradiator. I'm a cell irradiator and an
6	animal irradiator.
7	You know, I think that we are kind of
8	trying again to put everything into one kind of
9	bucket here, and I agree with you, you know, that
10	really there are different irradiators for different
11	purposes, and as a radiation biologist who kind of
12	spends my life, and, you know, irradiating and
13	looking at cellular, molecular and whole animal
14	processes, you know, it's important to have that
15	availability of resources.
16	So I use cobalt. I use X-rays, and I
17	use cesium sources, and I use them under different
18	circumstances for different purposes, you know. And
19	to break that down, I's probably need an hour
20	lecture to actually explain the complexities of
21	doing all of these different types of studies.
22	If you're looking at the rapid molecular
23	assays for radiation end use responses or DNA
24	damage, that's a very different thing from looking
25	at the response of gut or brain in a mouse or a rat.
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1	So you really need the flexibility, but whenever it
2	comes down to it, you know, the cesium sources are
3	the work horses for all of this.
4	This is the kind of big base. They can
5	be used by people who have no knowledge of radiation
6	and no knowledge of physics. They can just walk in
7	and irradiate their cells, their feeder layers or
8	whatever, walk out again and, you know, it is very
9	easy, very low cost, really no backup almost. I
10	mean, it really is a very cheap process.
11	Going to X-rays, you've heard about the
12	lack of reliability. They are a lot more costly,
13	and the lost of cost, as I say, goes into physics to
14	actually get good dosimetry whenever you're trying
15	to do, in particular, animal radiations is tough, in
16	particular if you're doing small bits of animals,
17	you know, rather than your whole body irradiation.
18	I think the availability of X-rays and
19	cobalt is a big problem. You know, we've got five
20	cesium sources at UCLA. We have got one X-ray
21	source which isn't working. We've got two cobalt
22	sources, one of which we use for big animals, but
23	you know, we would have to replace all of those
24	cesium sources with X-ray machines, which as we
25	said are not really all reliable whenever it gets

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1	down to it.
2	And also are not user friendly for the
3	people that just want to walk in, irradiate some
4	cells, and walk out again. It's more complex than
5	that whenever it comes to the considerations of
6	using X-rays.
7	So I think that, you know, it's really a
8	big mistake to kind of limit the sources in any way
9	at all. We really need to kind of maintain all of
10	these sources really for different purposes, you
11	know, and certainly there are some of these purposes
12	that people will use cesium because it's available
13	and it's easy and they could use another source, but
14	there are other purposes where we can't do that.
15	Cesium is essential.
16	There are other purposes where X-rays
17	are better. You know, that's the way it goes. It
18	just depends on what you want to use the radiation
19	for. So we can't lump all of these together.
20	MR. KAMINSKI: I just want to say I
21	agree. We definitely need Cesium-137. Again, we
22	need to seek out alternative forms. I think it's
23	important.
24	MR. RAKOVAN: Sir, if you can introduce
25	yourself, please.
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1	MR. ZIMMERMAN: Peter Zimmerman, King's
2	College, London, retired.
3	I am a physicist, and I do do numbers
4	fairly well. The gentleman behind me from Rochester
5	suggested that he needed to do 30,000 units of blood
6	a year. Thirty-six thousand five hundred would be
7	100 units a day. So let's take that number.
8	One of the source manufacturers said he
9	could do five bags in three minutes. He needs to do
10	20 times that to keep up with a day. Twenty times
11	three minutes is an hour. Let's take another hour
12	for in and out time. That means that basically
13	between two and three hours of duty a day on the X-
14	ray machine is perfectly adequate. I seriously
15	doubt that you'll have to buy more than one blood
16	irradiator to handle that load.
17	I was very disappointed with the
18	attitude that I heard on a couple of people's part,
19	but mostly of the Advisory Committee on Medical
20	Uses. Nobody is actually talking necessarily about
21	taking away your cesium gamma spectrum. We're
22	talking about taking away cesium chloride, and let
23	me point out that the only nuclear or pardon me -
24	- radiological terrorist scenarios you can dream up
25	that kill a lot of people use and exploit cesium
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1	chloride.
2	I'm not at liberty to discuss what those
3	are, but they're pretty bad.
4	You've talked about security. Well,
5	security is not just in the fingerprinting or even
6	in the locks and keys. It's in an ongoing security
7	check that prevents good employees from going bad.
8	I could mention the name of Aldrich Ames and Hansen,
9	just to name a couple of good employees who went
10	real bad.
11	So to say that you've implemented the
12	security measures is not to say that those security
13	measures can ever be considered adequate unless you
14	have really intrusive, ongoing personnel monitoring.
15	I think we are going to have to face the
16	fact that cesium chloride in a water soluble form is
17	going to have to come out of circulation.
18	Now, I'll make two points about
19	reliability. First is as far as skills needed,
20	every dental technician can run an X-ray machine.
21	It's not that hard to build an X-ray machine that's
22	got a switch on it, on and off. It really isn't.
23	When I was a grad student, a post doc,
24	and a professor doing high energy and nuclear
25	physics, many accelerators were considered the most
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1	unreliable instruments ever built by the hand of
2	man. They are now one switch on, one switch off,
3	operated by a technician in medical treatment
4	centers.
5	Yes, they do break down, and yes, they
6	have to be repaired, but that's true of almost
7	everything.
8	Thank you very much.
9	MR. KAMINSKI: I just want to echo your
10	thoughts. I agree with everything you've said
11	concerning alternative forms of cesium-137. We have
12	to look at those, and I think it's critical to
13	remove cesium chloride from common use.
14	MR. SULEIMAN: Yes, I always have
15	trouble interpreting questions, but I'm looking at
16	2.1, and if it's a question of 662 keV photons, I
17	don't see X-ray or anything else replacing it. So
18	for some types of application, scientific radiation
19	biology, whatever, I don't think there would be if
20	you were to eliminate it completely.
21	And I also think the issue is going to
22	translate less into what's the alternative for
23	cesium as to what's the alternative for the
24	chemical, you know, physical form of how the cesium
25	is. I mean, that's my sense of where we're going.
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1	MR. POWELL: Brian Powell, Constellation
2	Energy representing nuclear power again.
3	As far as the question, I'd like to
4	answer it from our perspective in a broader sense.
5	When we were faced with the regulations that asked
6	us to take a security of our radioisotopes, we took
7	that very seriously, and it would be a real
8	challenge for someone to get into any of our plants
9	to try to get a hold of something that they
10	shouldn't.
11	We have the full background and the
12	fingerprints and the ongoing security investigations
13	that were mentioned before, and we're at the point
14	now where we're looking at alternatives not just to
15	things that are up for discussion today, the cesium,
16	but you know, some of the other isotopes of concern
17	that were used, for example, the ones that we need
18	for the radiography.
19	We're looking at replacing the iridium,
20	cobalt, selenium with the pulsed X-rays for the
21	smaller diameter piping. So it seems like, you
22	know, we could increase the security measures to a
23	level where we could be patient until these
24	alternatives to the cesium chloride were available,
25	then I think we would be happy to replace them as
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1	they became available, but they're not available.
2	We're doing what we can in the meantime,
3	and we're taking a bigger and broader look at
4	eliminating all of our sources of concern if we can.
5	Thank you.
6	MR. RAKOVAN: All right. The gentleman
7	right next to the please.
8	MR. THOMAS: I'm Jerry Thomas, Wichita,
9	Kansas.
10	Focusing specifically on X-ray
11	generators and nothing else, when we look at the
12	quality assurance required as well as the
13	calibration that's been pointed out by others, my
14	focus is specifically on the hospital and the blood
15	bank arena. I ask the question: do we have the
16	qualified and trained and skilled individuals?
17	Yes, I recognize you can turn them on
18	and off, but the comment on the linear accelerator
19	is there's a substantial quality assurance program
20	associated with an accelerator before you turn it on
21	with a patient every day.
22	That same type of program would have to
23	be in place for any use of X-ray sources, I would
24	think, in the irradiation of blood products.
25	Consequently, not only do we need to think about
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1	this as an alternative, but do we have the resources
2	available across the country in the heartland of the
3	country and the west of the country where we don't
4	have necessarily the level of expertise that is
5	sitting in this room or in our universities?
6	And I recognize that industry has made
7	this pretty much turnkey in their current products,
8	but again, there is a quality assurance issue that I
9	think needs to be looked at very critically before
10	one jumps into the X-ray source as the only source.
11	MR. FITZGERALD: Just to go back to the
12	question that's up there, are there alternatives
13	where you don't need cesium or cobalt gammas? I
14	mean, I think our researchers at NIHS said yes,
15	there are applications where that's true, but for
16	the most part, the majority of our research does
17	require the cesium-667 or whatever keV. That's what
18	they want and that's what they need.
19	So we do have people who would be
20	willing to use an X-ray source if we had it for some
21	mechanisms to do some of the work, but the majority
22	of our work requires the cesium irradiator.
23	MR. GORLI: Jed Gorli, AABB.
24	I'd just like to point out that lean and
25	disaster preparedness are inimicable. While we try
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1	to have as efficient systems as possible, and I
2	cannot gainsay the elegant mathematics of our recent
3	presenter, we do not function as a constant steady
4	state manufacturer, but rather we need to be
5	prepared for the bus accident and generating a lot
6	of stuff fast.
7	So in certain cases, but no means all,
8	there may be reasons either for reliability or
9	throughput that one might need additional X-ray
10	devices. This is not a matter of feasibility. This
11	is, however, a matter of economics.
12	MR. NIXON: I just want to speak a bit
13	to some of the points or opinions raised by Peter
14	Zimmerman.
15	In terms of manufacturing X-ray
16	equipment, one has to understand that although X-ray
17	technology is not new, it has been around for 100
18	years, the application used when you do blood
19	irradiation, it's different from the history of
20	development of the X-ray tube the way it was used in
21	the past. The new operational modality involves
22	irradiating cycling in periods, say, five minutes at
23	a time, first as a continuous operation, say, in an
24	X-ray scanner instead of an airport or the odd
25	explosions out of a hospital. That's brief.
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1	So speaking to that point, when you
2	change the application and how a device is used or
3	how a technology is used, very often you find
4	yourself facing many problems.
5	And I want to speak to another aspect,
6	too. With regards to cesium chloride having to be
7	banned because it's bad, bad, bad, until there's a
8	viable alternative form of cesium-137 available on
9	the marketplace, I mean, the best one should expect
10	from reasonably thinking, reasonably calculating
11	people in terms of risk analysis, in terms of cost
12	and so forth is that you mitigate as much as you can
13	until something is available.
14	Now, the nuclear industry is the most
15	heavily regulated industry in the world. When you
16	compare that with the proliferation of X-ray
17	technology, for instance, you have to consider that
18	there will be terrorism uses of X-ray technology as
19	well. I mean, one can envision a portable generator
20	being put into a truck or on a float and driven
21	through crowds, maybe this happening 100 cities at a
22	time. You know, how are you going to stop that?
23	So where is the regulation being applied
24	to, say, that alternate form of technology?
25	So you have to think outside the box
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231 1 sometimes and, you know, do the best you can, put 2 your money and your resources to attacking the 3 biggest problems. 4 MR. ZIMMERMAN: I am certainly aware 5 that the blood irradiation problem is different from the tooth irradiation problem. Nevertheless, we are 6 7 talking engineering in what is, indeed, a mature science with mature technology. It is not something 8 you will have tomorrow, but if the decision is made 9 to do the replacements, you'll have it on the market 10 in a small number of years, easily totable, easily 11 12 tabulatable on the fingers of one hand. Now, as to your questions about thinking 13 outside the box, believe me, those of us who have 14 15 done for the last five years a lot of worrying about 16 radiological terrorism, we are aware that you could 17 take an X-ray machine and put it on a float, but we would question the ability of you to get a power 18 19 supply to make it reliable and so on. We would suggest that right this minute cesium chloride 20 21 powder looks a higher hazard that portable X-ray machines in the hundreds of kilovolt range with very 22 large beam currents. 23 We would say spend the money right now 24 25 to begin exploring alternative forms of cesium. **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS

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1	Yes, I know you want to preserve the spectrum of the
2	photons from cesium because if you do not, you have
3	to do a lot of research to calibrate a spectrum of
4	let's just say 500 kilovolts against 680 kilovolts,
5	and you don't want to do that if you can avoid it.
6	I'm a physicist. I understand that, but
7	I also understand the other risks that we run with
8	cesium chloride as the source of the cesium photon.
9	MR. KAMINSKI: And I think the greatest
10	risk is probably damage to the infrastructure and
11	not so much to people. I mean, of course, you'll
12	have long-term effects, but acute effect in
13	radiation dispersal device would be minimal. It's
14	just billions of dollars to clean up if someone
15	decides to release it in New York or any other large
16	city.
17	I mean, you're talking a major economic
18	disaster. You think what we're going through now is
19	bad.
20	MR. RAKOVAN: I had a couple of hands I
21	wanted to get to. I think you had yours up.
22	MR. LIU: I'm Bill Liu with University
23	of California, RSO.
24	A question for the American Red Cross.
25	In the case of your machine irradiation of blood
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1	products, in the places where there's a single
2	machine and that machine is not working and perhaps
3	it takes a week to bring back into service, how is
4	that problem remedied?
5	MR. WAGNER: We have several sites that
6	only have X-ray devices and no gamma irradiators.
7	In the Red Cross we have the ability though to ship
8	blood pretty efficiently. Otherwise we wouldn't
9	have regional centers.
10	I guess now is as good a time as any to
11	talk about breakdown just for a moment. Among our
12	32 cesium-137 chloride irradiators, there have been
13	51 instances of breakdowns during the last three
14	years. For the X-ray devices, there have been 21
15	occurrences of breakdowns of the Raycells in the
16	last three years.
17	Of course, we have fewer devices, and
18	when you do it per device and figure out the
19	breakdown rate, there's about a 66 percent increase
20	in the breakdown rate when comparing the Raycell
21	devices to the cesium devices.
22	For the most part, in 66 percent of the
23	breakdowns the device could be repaired within one
24	day, usually by on-site staff or a local contractor.
25	However, two repairs took 26 and 37 days to
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234 1 complete and probably involved off-site, non-local 2 service. The average time for repairs that were greater than one day was 15.5 days, plus or minus 3 4 12.2 days, and this compares to 37 percent of breakdowns that could be repaired in one day for the 5 6 gamma irradiators. And in addition, those irradiators took 7 more than one day to repair, averaged 15.4 days plus 8 or minus 12.3 days for the gamma irradiators, again, 9 indicating probably that off-site service was 10 necessary, and of course, this makes sense because 11 as we know, the gamma irradiators are a regulated 12 device with safety concerns and require specialized 13 staff many times to fly in sometimes from other 14 15 countries to repair the device. MR. RAKOVAN: I have two hands in the 16 17 back of the room that I wanted to go to. MR. WASIAK: Tom Wasiak from Best 18 19 Theratronics. I have a couple of comments regarding 20 21 the information provided by the gentleman who put an amount on the back of the napkin or maybe in his 22 head and compared the, let's say, blood irradiators 23 to the X-ray equipment. I think part of that was 24 25 the dental X-ray equipment, let's say. **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W.

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235 1 As we kept hearing from many people 2 around here, the current state of technology is such 3 that X-ray equipment for blood irradiation, for 4 example, which is the main application, most units 5 being used right now, is not quite there as where 6 cesium is. It may not be there for a long period of It will be improving. No doubt about it, but 7 time. in comparison with dental X-ray, I think we'll get 8 there, but there is significant differences in 9 technology, although it's all the same X-ray. 10 The major differences are just listed, a couple of 11 12 numbers. Dental X-ray equipment uses in terms of 13 power probably a couple hundred watts. Blood 14 15 irradiators use about, you know, 6.4 kilowatts, In terms of high voltage, dental equipment 16 right? uses 30 kilovolts, let's say, or low energy. We are 17 using 160 kilovolts. 18 19 In terms of irradiation time, they are only on, actually tubes, for a split of a second for 20 21 dental X-ray. For blood irradiation, they run continuously for five, six minutes. 22 Yes, it's still the same technology. 23 However, technological differences are big enough to 24 25 cause certain technological troubles. That's **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

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1	unfortunately the current state of technology. It
2	will improve. It will take time.
3	Another little point, I just wanted to
4	clarify the numbers. I think the gentleman
5	referring to the numbers mentioned that there is an
6	X-ray irradiator that can irradiator five bags at
7	the same time with irradiation time, two minutes.
8	Unless I misheard it, I'm not aware of that X-ray
9	irradiator, though I'm aware of cesium blood
10	irradiator that can meet these numbers.
11	The only blood irradiator that is
12	currently on the market irradiates two to three bags
13	at the time, and it takes five to six minutes. So
14	if you do that math, including 50 percent for
15	loading or additional 100 percent of time for
16	loading/unloading, irradiating 100 bags a day would
17	take ten hours of continuous operation with breaks
18	for loading, unloading and so on.
19	So just a point for clarification.
20	MR. MOSES: Paul Moses, Best
21	Theratronics.
22	In speaking to the Red Cross, I'm very
23	familiar with the Red Cross account, and we would
24	have probably the largest number of units within the
25	Red Cross family of sites.
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1	When you speak and talk about breakdowns
2	and different numbers, I think you have to take into
3	consideration that some of the Red Cross units have
4	been out there for 25, almost 30 years. So when a
5	unit is that old, what will happen and it has
6	happened. I could name specific sites but they
7	have actually broken down. We've had to fly down,
8	fix them, and this is like a unit 25 years old,
9	mention to them, you know, this unit paid for itself
10	22 years ago.
11	(Laughter.)
12	MR. MOSES: And it might be a good idea
13	that you just bought a new one.
14	And the thing is that when you start
15	looking at the numbers, you have to be mindful of
16	when you're talking of an X-ray unit that's only
17	been out there for a short time versus a cesium unit
18	that's been out there forever.
19	MR. WAGNER: Paul, I agree with you
20	totally. Just for information, of the 32 irradiator
21	devices that we have, I know the age of 27 of them,
22	and the average age is 15 years basically, plus or
23	minus five years. So if you want to make a donation
24	to the Red Cross, we can
25	(Laughter.)
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1	MR. WAGNER: purchase some units.
2	Also, what Paul did not bring up, but
3	which I think is important, is that no one really
4	knows what the lifetime of these X-ray irradiators
5	are. You know, the manufacturer, we've heard ten
6	years, but there's no data out there that says how
7	long they will last, and until they last 30 years
8	they're not equivalent at least in terms of lifetime
9	presumably as the irradiators.
10	And so it's possible you would have to
11	go and replace them possibly more frequently. I
12	don't know because there's no data out there.
13	MR. SULEIMAN: I've got to add balance
14	back to this discussion. Those of you who
15	understand X-ray technology, some of the high output
16	computed tomography X-ray tubes, the reproducibility
17	and accuracy of modern medical imaging technology
18	and output, the technology is clearly here and has
19	been here for many, many years. So to imply that
20	the technology is not capable to put reproducible
21	output over a period of time is, in my opinion, just
22	wrong.
23	However, maintenance and quality
24	control, if you neglect a high quality car, it's not
25	going to last as long as a less expensive car that's
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1 maintained on a regular basis. So the issue with 2 electronic products more so than the radioactive 3 sources is to require long-term maintenance and 4 calibration and so on.

5 But to imply that the technology is not 6 up to the task is wrong. It's the human factor, the 7 maintenance, the calibration. So there's little doubt in my mind. Energy aside, unless you can come 8 up with an X-ray source that can generate a 662 keV 9 photon, that for scientific applications the non-10 radioactive technology is clearly, you know, 11 12 capable. And, again, I'm not addressing economics. I'm not addressing the market for this sort of 13 product. You sell a lot more CT scanners than you 14 do blood irradiators. 15 16 MS. GILLEY: Debbie Gilley. 17 In our review in our report from the

ACMUI, we indicated that 48,000 blood product units per X-ray tube, and if you did 50 units a day, that would be about 3.7 years per X-ray tube. Then it would need to be replaced.

22 MR. KIRK: Randol Kirk from Rad Source. 23 Look. With an X-ray machine, you have 24 to treat the tube as a consumable. It is. There's 25 no getting around it. It's no different than the

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1	light bulb in your house. If you leave it on 24
2	hours a day, it's only going to last half as long as
3	if you only run it at night.
4	So anybody who doesn't think about that,
5	who doesn't, quite frankly, manage up front or
6	preemptively look at tubes, power supplies, that
7	sort of thing, to have them switched when they need
8	to be is always going to have down time. It has got
9	to be a joint effort in order to make sure that you
10	are ahead of the curve with an X-ray machine because
11	it's always going downhill.
12	MR. RAKOVAN: I think we've already kind
13	of gone into the next question already. Michelle,
14	if you want to bring it up, Q 2-2. Are X-ray tubes
15	cost effective considering the initial cost,
16	operating costs, and requirements for more
17	maintenance, for periodic calibration and
18	replacement than radioactive sources?
19	I figure since we were talking about it,
20	we might as well have it up there. Anybody want to
21	continue on that particular question topic?
22	MR. KIRK: Randol Kirk again.
23	Actually we think we have hit on a
24	relatively good solution. It's a matter of having
25	the availability of being able to open up the tube,
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1	repair it, close it up again and reuse it. Again,
2	this is a brand new concept.
3	The best we've been able to do so far is
4	somewhere less than 1,000 hours of use. We think we
5	can get considerably higher than that, but even at
6	1,000 hours, if you think about the calculations
7	that were just done here a little while ago, two
8	hours a day or whatever they were, 1,000 hours is a
9	year and a half before you have to do anything to
10	the tube, and that's a huge, huge operation to
11	irradiate that type of blood. I would guess only
12	the Red Cross would come close to those kinds of
13	numbers.
14	MR. RAKOVAN: I'm hearing some
15	disagreement from the crowd. If somebody wants to
16	take that to the microphone and explain it.
17	MR. GERSABECK: Yeah, this is Ed
18	Gersabeck with USDA again.
19	We're operating our irradiators, our two
20	gamma cells and two Husmans in Guatemala 22 hours a
21	day, seven days a week, and even with the guarantee
22	of 2,000 hours on the rad source tubes, the best
23	we've been able to get is about 700 hours, and even
24	if you got 2,000, that would only be 80 days or less
25	than three months. So we'd be into this continuous
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1	rebuilding the tubes.
2	And we've been quoted a price of if you
3	didn't have your machine shop capabilities, if you
4	just go out on the street and buy a new tube, the
5	last price we were quoted was \$50,000 which got us
6	interested in starting to set up our own machine
7	shop and training our own engineers to actually
8	replace these tubes.
9	So there is a lot of hidden cost and, as
10	I say, in a continuous operation, I'll give you an
11	example. If we're irradiating 300 million flies per
12	day, which is basically what USDA is doing, at a
13	cost of \$1,500 to \$2,500 per million, to have a
14	machine go down, we are losing a horrendous amount
15	of money per day until we get that machine back up.
16	Our down time on the Husman irradiators,
17	even the gamma cells has never been more than one
18	shift, six to eight hours, and a lot of that is just
19	going into town and getting a new motor for the
20	mechanics of it.
21	So in our industry, in our protection of
22	agriculture where we're sterilizing insects, the
23	reliability has to be there. You know, every day,
24	seven days a week we can't shut down or we just
25	start losing a lot of because you can't shelve
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243 1 living animals. You can't just put them on a shelf 2 for a week until you get a part in. I mean that's 3 the reality of what we're doing. 4 Thank you. 5 MR. KIRK: I would like to remain professional about this, but --6 MR. RAKOVAN: Please do. 7 (Laughter.) 8 MR. KIRK: -- I really feel that some of 9 10 the circumstances represented there are not accurate, and I'll just leave it at that. 11 MR. RAKOVAN: Any further discussion on 12 this question? Yes, please. 13 And thanks to you three guys on the end 14 there for all sharing the mic. I appreciate that. 15 16 MR. SVAJGER: Regardless of the use of 17 X-ray tube or you need to replace a tube or reload a cobalt safety source, they're both pretty expensive 18 19 as opposed to cesium which goes on and on and on. MS. SHEPHERD: Mary Shepherd, JL, 20 21 Shepherd & Associates. Red Cross is not the only 24-7 user of 22 blood irradiators. Every major metropolitan 23 hospital with an oncology department, and if you're 24 25 a large metropolitan area, multiple hospitals **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	operate in this modality. I think UCSF is one of
2	them, and there are many, many centers across the
3	country that especially if they're doing oncology.
4	Neonatal work, UCLA does not outsource
5	blood irradiation. Their protocol is in house only,
6	and I think there's a lot of other places that are
7	like that. It's imperative that it's not just a
8	couple of hours a day. It really depends on the
9	center and what the work they're doing.
10	And bone marrow irradiations, also
11	extremely complex and patient demanding.
12	MR. KIRK: I just wanted to ask what
13	kind of numbers of units that that the 24 hours a
14	day doesn't answer the question. It's what kind of
15	units does it.
16	MR. WAGNER: In the Red Cross, for
17	fiscal year '08, 475,000 units were irradiated, and
18	we believe that demand for irradiated blood has
19	increased by about ten percent in the last year, and
20	I might also comment that I believe that there's
21	probably more blood irradiation at the hospitals
22	than there are at the Red Cross, and there are some
23	good medical reasons for this, for red cells. When
24	you irradiate red cells, they release potassium and
25	that released potassium can be harmful to neonates.
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1	And so the hospitals prefer to irradiate
2	the blood at site so that they can get the blood red
3	cells at least to the patients who need it soon
4	rather than later during storage.
5	For platelets, they could be irradiated
6	at centralized facilities, but the hospitals already
7	have gamma irradiators.
8	MR. GORLI: The AABB collects data via
9	the NBRDF. Over two million blood products were
10	irradiated in 2006. There's over 20 million blood
11	products produced annually. Therefore, that's the
12	genesis of the about ten percent figure. Obviously
13	it's a higher proportion of platelets.
14	Wearing my MBA hat I would simply point
15	out that Paul Moses has pointed out that the market
16	answers the question. They're for sell and they're
17	selling. That said, the Red Cross data, the ABC
18	data, and the AABB data, all find that they're about
19	ten percent of the total irradiators out there.
20	So they're selling, but if they were as
21	cost efficient obviously they'd be selling more.
22	MR. RAKOVAN: Any further discussion on
23	this question in terms of cost effectiveness before
24	we move on to the next?
25	(No response.)
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1	MR. RAKOVAN: Okay. Let's go ahead and
2	put Question 2-3 up there. Is there any indication
3	that the performance of the alternatives will
4	change, improve or worsen, with respect to cesium-
5	137?
6	We may have touched upon this already,
7	but does anyone have something that they'd like to
8	continue the discussion on this?
9	Please.
10	MR. MINNITI: Yeah, it's Ronnie Minniti
11	from NIST.
12	This question is probably for Mr. Kirk.
13	Correct me if I'm wrong, but I believe the maximum
14	voltage, the state of the art today, is around 300,
15	400 kilovolts for X-rays, and that translates if you
16	filter such a spectrum to get a monochromatic
17	spectrum, you can get maybe up to 200-something, 250
18	keV. So can you go higher than that?
19	And if not, what do you think about that
20	in the future, if that's possible or not?
21	MR. KIRK: Well, hint, hint, we have
22	written a grant request to put together a machine
23	that will operate at 500 KeV, and at 500 KeV with
24	this new technology we're using, you have enough
25	photons that you can filter very, very hard and
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1	still have enough left to do something with.
2	So, yes, we believe it's possible. Is
3	it today? Is it tomorrow? No, it's probably in the
4	same time range as anything else.
5	MR. MINNITI: Okay, I guess, but what
6	would be the main energy then? We would be talking
7	around 400 tops, right, or maybe even less than
8	that?
9	MR. KIRK: Yeah, if you were to go to
10	500, then you would probably have a distribution
11	from maybe 275 to 380 or depending on what you were
12	filtering with and if you could optimize that.
13	MR. MINNITI: So is it correct to say
14	then that the technology is not there today or
15	MR. KIRK: Oh, no, I'm just saying it
16	will be three to four years before you can even get
17	to that level.
18	MR. MINNITI: To that level, but not to
19	600 KeV.
20	MR. KIRK: I think that
21	MR. MINNITI: I think that it's a fair
22	question since this morning when we were talking
23	about the other alternative about the cesium form,
24	right, we were asking, okay, if this would be
25	available and we had an answer for that. So I think
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1	we should explore that question, too, for this other
2	alternative.
3	MR. KIRK: I think it would be difficult
4	to go much beyond 500 keV as a peak.
5	MR. MINNITI: As a peak.
6	MR. KIRK: As a peak.
7	MR. MINNITI: Yeah, okay.
8	MR. KAMINSKI: That would just be for a
9	standard X-ray tube. I mean, certainly there are
10	other ways to increase the energy, such as LINACs,
11	linear accelerators and so forth that we use
12	clinically so that 18 mV or whatever, of course, if
13	you need to go that high, but it's much more
14	expensive.
15	MR. MINNITI: Yes.
16	(Laughter.)
17	MR. RAKOVAN: Got a question in the
18	back. If you could introduce yourself, please, sir.
19	MR. ROGERS: Yes, sir. Steve Rogers,
20	U.S. Army Primary Irradiation Standards Laboratory.
21	I noticed most of the discussion so far
22	has been on irradiations. I'm from the calibration
23	side of the house. Between ourselves and the
24	secondary laboratories beneath us, we calibrate tens
25	of thousands of survey instruments and dosimeters
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1	per year, and we have noticed a significant
2	difference in instrument response between
3	calibration of X-ray and calibration with cesium-
4	137.
5	Now, I know we're talking specifically
6	about cesium chloride, but if cesium-137 were to
7	disappear in any form and be replaced by X-ray,
8	we're talking about a lot of instruments that would
9	have to be recalled for recalibration out of cycle
10	at significant cost and adverse impact to our
11	soldiers trying to accomplish their missions, as
12	well as manpower in the calibration labs themselves,
13	and at several of our facilities we're short handed
14	already.
15	Thank you.
16	MR. RAKOVAN: Further discussion on
17	Question 3?
18	(No response.)
19	MR. RAKOVAN: Okay. Let's move ahead on
20	to the final question, 2-4, regarding the
21	availability of alternative technologies. (a) What
22	is the time frame of future availability of each
23	alternative, and (b) what is the cost for each of
24	the alternative technologies, capital cost,
25	operational cost, cost to users?
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250 1 Again, I think we've kind of talked about this a little bit, but if there's further 2 discussion on this issue or any of the other issues 3 that we've covered in terms of use of alternative 4 5 technologies. There's been a lot of talk 6 MR. NIXON: 7 about the availability of technologies in the context of prototypes. As a manufacturer who has 8 lived the life cycle of starting with a prototype 9 and working into a marketable product that has an 10 acceptable or semi-acceptable degree of reliability, 11 12 there is a big difference, and there could be a fairly long learning process involved. 13 So I just wanted to caution people into 14 thinking in terms of time to market of a viable work 15 16 horse X-ray technology to supplant the use of cesium-137. We're talking several years down the 17 road, and that's after the prototype comes to 18 19 market. MR. RAKOVAN: Further discussion? 20 MR. GORLI: 21 Pathogen inactivation for plasma and platelets is actually licensed in Europe, 22 but it probably can't catch on until all cellular 23 products have a licensable treatment. Red cells is 24 25 still probably several years away, but Dr. Wagner **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	could probably comment more accurately.
2	MR. WAGNER: I think red cells are back
3	to square one with respect to clinical trials, and
4	as you know, you have to go through a number of
5	clinical trials successfully and then regulatory
6	review. So I don't see that around the corner soon
7	in the States.
8	MR. RAKOVAN: Further comments? See on
9	the end, please.
10	MR. FITZGERALD: With regard to
11	alternative technologies, I just want to say that at
12	the NIH as a whole, there are over 20 cesium
13	irradiators. So jus the capital cost of just
14	replacing those alone, I understand that the
15	government is going to write a big check hopefully
16	in just a couple of days, but that kind of puts
17	pressure on the rest of us to hold down cost. So I
18	just want to make sure that's understood.
19	MR. RAKOVAN: Please, if you could
20	introduce yourself.
21	MR. CONNELL: Len Connell at Sandia.
22	With all of the discussion about cost,
23	and I know
24	MR. RAKOVAN: Sir, is the microphone on?
25	MR. CONNELL: Is it on?
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1	MR. RAKOVAN: Yes. Please just stay
2	that close if you would.
3	MR. CONNELL: Oh, yeah. Okay. Just a
4	discussion about cost. One of the things we also
5	brought up in the National Academy's report and it
6	was just discussed here about the market right now
7	has shown that there's a ten percent, you know,
8	intrusion in the market with X-ray machines, but one
9	of the things we noticed in the National Academy
10	study was that a lot of the costs are not actually
11	seen by the user and particularly the disposal
12	costs.
13	Again, it's hard to judge what that cost
14	is because we don't have a real disposal capability
15	right now. All we're doing with the off-site source
16	recover program is we're taking your cesium sources
17	and we're storing them.
18	If you started to look at the true cost
19	of disposal and if we were to really ask your users
20	to pay for that, I think you might see the market
21	change a little bit. So that's one aspect I don't
22	want you to forget, is that the user cost is not the
23	true cost to society, that all of us as taxpayers
24	are ultimately going to have to pay to dispose
25	ultimately of these sources.
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1	And we already mentioned about the
2	terrorist cost. You know, we don't really know what
3	the probability of one of these events are, but as
4	has been mentioned, if you had a terrorist event
5	involving cesium, the economic consequences could be
6	pretty high.
7	Thanks.
8	MR. RAKOVAN: And actually I think we'll
9	be talking about some of those issues tomorrow in a
10	few of our panels. So that's a good advertisement.
11	Thank you, sir.
12	(Laughter.)
13	MR. MORGAN: Tom Morgan, University of
14	Rochester.
15	I asked a vendor about how much it would
16	cost to dispose of the cesium-137 blood irradiator.
17	He quoted me \$35,000 to pick it up and dispose of
18	it and \$70,000 for rental of the Type B container
19	for shipping. So there's a particular cost point,
20	and that's one month old.
21	MR. RAKOVAN: Sir, sir, sorry. Go to
22	get to a mic.
23	MR. MORGAN: I asked this individual,
24	"What would you charge me to take this thing off my
25	hands?" And he told me it was \$105,000, broken out
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1	as I just said.
2	MR. RAKOVAN: All right. Any further
3	discussion on this particular issue? I've got one
4	more or two more hands.
5	MR. COPPELL: Yes, hi. It's David
6	Coppell from REVISS here.
7	I just wanted to comment on the issue of
8	disposal cost for cesium-137. I agree it's
9	difficult to work out what they are because there is
10	no disposal route right now. We're all in the
11	situation where we have to adopt long-term storage
12	techniques.
13	However, my understanding is that pretty
14	much all of the Cesium-137 that's used in the world
15	is actually separated from spent fuel. So this
16	material isn't generated particularly for this
17	purpose. It exists anyway, and the responsibility
18	and the task of storing it and ultimately disposing
19	of it will exist whether or not we use it for this
20	application.
21	MS. SHEPHERD: Mary Shepherd, Shepherd &
22	Associates.
23	One thing we did not talk about was the
24	carbon footprint of using a gamma irradiator versus
25	alternate technologies, the expense of the
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1	electricity, the amount of electricity that it takes
2	to run these machines, whether that be a PET or an
3	X-ray or linear accelerator, and in today's
4	uncertain world with fuel what it is, it's an
5	important point to bring out. What does it actually
6	cost to run all of this different technology
7	electricity-wise?
8	MR. RAKOVAN: Go ahead.
9	MR. WAGNER: Yeah, we've done some
10	calculations for the Raycell for blood bank. I
11	really can't speak for all of the other applications
12	because obviously they're different for every
13	application, but for one site that uses two
14	Raycells, a single Raycell instrument with its use
15	was estimated to cost about \$2,000 per year per
16	instrument, and so if we had to replace every gamma
17	irradiator with a Raycell, I think it would cost us
18	about \$60,000 a year more in electricity and water
19	and sewage cost.
20	MR. RAKOVAN: Okay. We seem to be kind
21	of moving in that general direction anyhow. So why
22	don't we go ahead and take a look at the parking lot
23	issues since we've got about a half an hour left of
24	today, if that's all right with everybody.
25	Charlie, I think the first three came
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1	from you. Did you want to address those or did you
2	just want me to throw them out as conversation
3	topics?
4	If you're going to talk, I need you on a
5	mic, man. Sorry.
6	MR. MILLER: You know, the intention of
7	my comments were to try to capture that as part of
8	the default process for the parking lot, and I think
9	it's going to take the full discussions of the whole
10	conference before we can ferret those out
11	completely.
12	MR. RAKOVAN: Okay.
13	MR. MILLER: So they were intended to
14	just keep people's consciousness as to some of that.
15	The other comment I'd make, while it's
16	not on the parking lot, is for the benefit of
17	everyone in the room, although I know many know
18	that, currently the Nuclear Regulatory Commission
19	has no regulatory authority over X-rays, but the
20	states do, and so suddenly if that were the only
21	technology available, it would solve the Nuclear
22	Regulatory's problem, but it certainly wouldn't
23	solve the state's problem.
24	(Laughter.)
25	MR. MILLER: So I just wanted to make
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1 sure that people were aware of the fact that , you 2 know, as we ponder the alternatives, the NRC has to ponder also what's within our regulatory purview and 3 4 what do we do about what's in our regulatory purview, and I'll let the states speak for 5 6 themselves, although they do have to deal with this 7 from those things that we do regulate. The states regulate that with a compatibility in a way that we 8 do. 9 10 Thank you. I wanted to just reiterate 11 MR. NIXON: 12 when we talk about cost, outside the security issues the cost to patient care not only here in the 13 continental United States, but in the rest of the 14 world if the use of cesium or cesium chloride today 15 16 were to be banned, patient care would be compromised all over the world. Many countries do not have 17 reliable power supplies and so forth. We construct 18 19 our cesium irradiators with back-up power supplies so that they can operate in times of power outages 20 21 and so that patient care is not compromised. So that is a relative major advantage of 22 cesium based technology over electrically generated 23 irradiation. 24 25 MR. RAKOVAN: Mr. Wagner? Your tent is **NEAL R. GROSS** COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. (202) 234-4433 WASHINGTON, D.C. 20005-3701 www.nealrgross.com

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1	up. So did you? No? Okay. Sorry.
2	Any additional discussion? Please, if
3	you could introduce yourself if you would.
4	MR. JARDINE: Would it be appropriate to
5	comment on 1.1 again?
6	MR. RAKOVAN: Right now as far as I'm
7	concerned, I think the whole day is open for
8	discussion.
9	MR. JARDINE: I just want to come back
10	to the question since the manufacturers were not
11	here from Mayak, primarily to our U.S. visa control
12	problem, but having worked with Russia and having
13	done seven of these engineering studies with
14	Russians on different parts of plutonium processing
15	basically and three at Mayak, I wanted to make this
16	statement that we have to realize that cesium comes
17	from the one reprocessing plant in the world that
18	designed a process, separate cesium nitrate. It
19	cannot be done in France or Japan. The U.S. has no
20	capability.
21	The Russians have been looking in the
22	past at alternatives to cesium chloride, and they're
23	looking today at alternatives, and it's basically a
24	glass and a ceramic. I will not be specific. Those
25	options exist. The Russian process, as I said,
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1	would take about five years.
2	What it consists of is parallel
3	engineering studies and design with the scientific
4	development and science and R&D, and it's basically
5	a one year technical economic feasibility
6	engineering study that compared two options, glass
7	and ceramic.
8	In parallel, the scientific institutes
9	prepare data on what these forms are in the glass
10	and ceramics so that the engineers can decide which
11	option is best after one year.
12	The next step if they're able to select
13	one option is to go to the next step of engineering,
14	which is one year in parallel as the R&D continues
15	on the one form or two forms.
16	But I have a problem, and the Russians I
17	think would, of deciding which form because there's
18	different issues fabricating a powder, a ceramic or
19	a glass, and the range of capsules that have to be
20	filled for the different customers that Mayak has.
21	You cannot pick a single option. These technical
22	and engineering feasibility studies will identify
23	these issues in collaboration with the Russian
24	institutes.
25	Quite frankly, it's my opinion our U.S.
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1 laboratories would not be very useful to this 2 process because they don't really know how to 3 contribute and often, quite frankly, can't work with 4 the radioactive materials.

5 During the second one-year engineering 6 study is when they specified equipment and start 7 procuring it, and it's called an open ended 8 justification investment. After two years then they 9 will start the construction of the facility or the 10 refurbishment of an existing facility at the RT-1 11 reprocessing plant, and that will take two years.

12 In parallel, again, the scientific R&D is continuing along with the qualification tests 13 that have to be done. You heard Aloy talk about the 14 fire test, the mechanical strength test. They have 15 16 to refill these containers or capsules, and that's why you come up with about four years until you have 17 your facility ready to operate, and then the fifth 18 19 year you hopefully are in a position to begin what I would call cold and hot tests and start producing 20 21 these capsules in a production line so that you could get serial samples, and it's very difficult to 22 see how it could go faster than that. 23 It will involve, you know, the collective Russian team doing 24 25 this work, and they're prepared to do it.

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1	I'm aware that they're thinking about it
2	and they're doing it, but that's the time line and
3	the basis for five years, and they do have options
4	of glass and ceramic to be decided upon, and that
5	first year study will determine the cost and then
6	verify it's feasible from the engineering standpoint
7	at the Mayak facility.
8	Thank you.
9	MR. RAKOVAN: Okay. Ms. Fairobent.
10	MS. FAIROBENT: Yes. I have a question
11	for you. During the time that they may be retooling
12	to look at the ceramic or glass, are they still able
13	to to produce the cesium chloride form? or would
14	they be shut down out of production and if so, what
15	sort of stockpile do we have if we're not pulling
16	cesium chloride out of use until an alternative form
17	is available?
18	MR. JARDINE: I think she said during
19	the first year. They would continue, my assumption.
20	I'm not Mayak. My assumption is they would
21	continue to produce the revenue generating cesium
22	chloride until they were in a position to make a
23	decision how will they best proceed to install the
24	new facility or processing line, next door in a
25	different hot cell, different building or have to
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1	fabricate a new one.
2	So I anticipate they're now market
3	driven. They'll continue to produce these sources
4	and find a way to bring on the second process, which
5	is high risk and may not work. It's not a known
6	technology.
7	MR. RAKOVAN: If you could introduce
8	yourself, please.
9	MR. FORASTE: Yes, good afternoon. My
10	name is Steve Foraste. I'm representing QSI Global.
11	We're a manufacturer of cesium products
12	for industrial uses, and we don't use cesium
13	chloride except for as a feedstock, but I have been
14	to the plant in Russia where our sources are
15	manufactured, and we make a few thousand of these a
16	year, but what we're making are things that are
17	about three orders of magnitude below a blood
18	irradiator source.
19	One of the problems with scaling up our
20	process to handle the blood irradiator is
21	disbursability. The cesium when it's put into the
22	glass is raised to such a temperature that a lot of
23	it is actually lost in the plant. A big part of the
24	quality control in manufacturing this is trying to
25	optimize the yield in the plant.
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1	So while I understand that cesium
2	chloride is a very large danger as far as
3	disbursability in a terrorist scenario, if we were
4	to scale up our existing process today at Mayak, we
5	would have a disbursability issue at Mayak.
6	They're famous for a large one about 51
7	years ago, but I wouldn't want to repeat that today.
8	I know David made a presentation on behalf of
9	REVISS on where cesium glass is today, but I can say
10	that our glasses are not up to the task yet for
11	blood irradiation.
12	MR. RAKOVAN: Very good. One thing that
13	I wanted to point out, I apologize. I forget who
14	brought this up to me, but the question to keep in
15	your head that I put on the parking lot, the
16	gentleman said during the lunch break, I believe, or
17	one of the breaks, would it be great for NRC to have
18	an Advisory Committee for this and what the thoughts
19	were on that. So he asked us if I'd put that under
20	the parking lot and I wanted to do so.
21	So just something to have in your head.
22	He said this is a complex issue. So there's an
23	advisory committee of some sort needed for it.
24	MR. RAKOVAN: Sir.
25	MR. MORGAN: Tom Morgan, University of
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1	Rochester.
2	I brought that up, and the Advisory
3	Committee on the medical use of isotopes I'm sure
4	has been very useful to the NRC, and this is such a
5	complex issue. There are so many stakeholders, so
6	many different paths that we have to walk to make
7	sure we get it right that that was my recommendation
8	for the committee.
9	MR. RAKOVAN: Please. If you could
10	please introduce yourself.
11	MR. PHILLIPS: Bob Phillips, FDA.
12	This morning the people from Russia were
13	indicating that they had a long development program
14	to develop alternate sources. They're also the only
15	source of cesium iodide chloride in the world.
16	Given the resurgence of nuclear power in the United
17	States because of our energy problems, does anybody
18	see any future for reprocessing to come back to the
19	United States?
20	MR. RAKOVAN: Anybody want to touch that
21	one?
22	(Laughter.)
23	MR. SULEIMAN: It's above my pay grade.
24	(Laughter.)
25	MR. NIXON: I'll just make a small
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1	comment. I wouldn't profess to speak for anybody in
2	the U.S., but cesium is usually extracted as part of
3	a bomb making project, right? It's a separation
4	when you're extracting plutonium from spent fuel.
5	So those are the conditions that lead to
6	the production of cesium as far as I know it.
7	MR. RAKOVAN: Any further discussion?
8	Please, sir.
9	MR. ALOY: Albert Aloy from Radium
10	Institute, St. Petersburg, Russia.
11	I would like to correct you because it's
12	the cesium that's the byproduct from reposition
13	(phonetic) of spent nuclear fuel, not recovered from
14	plutonium. Now we have developed the new, simplest,
15	purest process which oriented only for uranium
16	extraction from the spent nuclear fuel, and
17	plutonium is not now the main valuable product, and
18	our approach is because we use only the mixture of
19	new plutonium and the transfer uranium elements in
20	future, and the reactor is a fast reactor.
21	So I would like to correct you because
22	our purpose is not plutonium extraction during the
23	processing, but of course, we have also very old
24	vests, the same vests like in the Hanford site or in
25	Savannah River where the cesium is a byproduct like
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Strontium-90 collected in a big amount, and because of this different tanks with different history, the Mayak people can study the ratio between stable isotope of cesium and Isotope-135 and the long-lived cesium isotope and cesium-137 and select the same product which corresponds mainly for the purpose of irradiation, of irradiation sources.

And so the different vests which 8 collected from the old time is a product or a 9 byproduct for cesium extraction now, and of course, 10 we know that cesium chloride is dangerous, very 11 12 soluble, dispersible form, and we start to work, R&D work for replacement of this salt even in former 13 Soviet Union, but now it's more and more in phases, 14 15 made more in phases for the study now.

And if you say about the risk from my point of view, from Russia, from rare countries this risk may be going. I think that in the United States or in Europe we have a good controlling system for the sources, the users, and so the risk is very, very low level.

But developing country and country with developing economics, they cannot use the LT-90 for like an X-ray installation because more expensive, operational personnel, additional with high

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1	educational level.
2	And so I think that the main risk is on
3	the border of the country. It is terrorists may use
4	outside from USA cesium chloride to spread it inside
5	in the country, and because inside the country it's
6	too difficult and control use of these sources.
7	This is my opinion.
8	(Laughter.)
9	MR. ALOY: But main risk, main level of
10	risk, of course, from using cesium chloride outside
11	of developed country, of Europe or USA, Canada.
12	But cesium chloride very attractive for
13	this developing country, for cost and for long-lived
14	service.
15	MR. KAMINSKI: Just to make one fast
16	point, you know, what worries me is having cesium
17	chloride in these Third World countries and then
18	shipping it over in a lead cased container or
19	whatever, and we know the ports aren't monitored
20	very well, I mean, and it's not that difficult to
21	conceive of an event here in the U.S. either.
22	MR. ALOY: I'm sorry. I am not
23	understanding what you said.
24	(Whereupon, translator spoke with Mr.
25	Aloy.)
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1	MR. ALOY: But I think the revised case
2	involves a controlled system in Russia, and the
3	control is very strong, on the top level. Yes?
4	MR. COPPELL: Maybe just to repeat the
5	question, I think the point you were making was the
6	bigger risk may be the cesium chloride that's
7	somewhere in use in a developing economy might be
8	appropriated, shipped into the U.S. or into Europe
9	or anywhere else disguised essentially, and
10	encapsulated in some shielding material that makes
11	it difficult to detect.
12	MR. RAKOVAN: Sir, if you're going ot
13	say something, I'm sorry. I'm going to have to ask
14	for your mic to be on.
15	MR. COPPELL: Yeah, so I think everybody
16	recognizes that, and I think it's the reason why
17	this is an international issue really. I mean, of
18	course, here in the U.S. what you can address is
19	what you can control in the U.S., but equally
20	everybody else has to participate because this is an
21	international concern, and we need to find a way of
22	resolving it in a way that minimizes the risk
23	internationally.
24	I was just going to say one thing about
25	the comments earlier regarding time scales for
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269 1 development of a potentially alternative technology 2 for cesium at Mayak. This morning I made the point that there is a program; there is a project which is 3 4 receiving a lot of attention at Mayak and which the 5 general director of the whole of Mayak is fully aware of and very focused on. 6 The reason why I think we're being a 7 little bit unclear about time scales is because 8 they're not very clear about them yet. So I really 9 don't think it's particularly helpful for us to 10 actually try to fix in our mind an exact time frame 11 12 right now. It's going to be a few months before 13 we're in a position to actually make a clear 14 15 statement about what's going to be involved, how 16 long it's going to take and what the other implications, for example, cost implications might 17 be. 18 19 I realize that everybody is focused on this issue right now, but I think if we could just 20 21 have a little patience, give our colleagues in Russia until maybe spring or early summer next year, 22 I'm fairly confident they'll come back with 23 something that is detailed to the extent that we can 24 25 use it. **NEAL R. GROSS** 

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1	Thanks.
2	MR. SULEIMAN: This is a really, I
3	guess, stupid question, but if you take powder and
4	put it in some epoxy, I guess it's going to cook or
5	whatever, but where are the chemists? Could
6	somebody explain what would happen with that kind of
7	effort to solidify the powder?
8	MR. RAKOVAN: Anybody up for talking
9	epoxy?
10	MR. SULEIMAN: Wouldn't it affect the
11	disbursability? I mean, I'm sure this has been
12	looked at, but I'm just curious. Somebody has got
13	to know the answer to that.
14	Why is making it a non-powder so
15	difficult?
16	MR. MORGAN: Tom Morgan, University of
17	Rochester.
18	I'll try and take a shot at that. Epoxy
19	is an organic compound. With that much amount of
20	radioactivity you're going to have tremendous
21	radiolysis, and it's going to break down. It isn't
22	going to work in an epoxy.
23	MR. COPPELL: Sorry. I agree with that,
24	absolutely. You generate an awful lot of radiolysis
25	products, which means that it's pretty difficult to
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1	encapsulate it in anything, and pretty soon, you end
2	up with a kind of gooey black mess, which is going
3	to be
4	MR. RAKOVAN: What's wrong with that?
5	MR. COPPELL: Well, it's going to be
6	pretty disbursable and fairly soluble. The cesium,
7	if it's put into the mixture, let's call it, as a
8	salt, which is usually chloride, but it doesn't have
9	to be; it could be sulfate or nitrate. Then either
10	way, by the time you've broken down this epoxy
11	compound which isn't going to take very long, then
12	you've just go soluble cesium left.
13	So it really needs to be in a matrix
14	which can withstand a significant amount of
15	radiation damage without changing its nature, which
16	is why everybody talks about either ceramics or
17	glasses.
18	MR. ALOY: I would like to say again
19	about the testing of the performance of the sources.
20	Because we have the double encapsulated in
21	stainless steel sources with welding each capsule,
22	and some capsules we need for testing for fire.
23	It's 800 Centigrade at half hour. During this
24	testimony, epoxy raising or as an organic compound
25	will be decomposed with high pressure inside, and
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1	welding area will be destroyed.
2	So it is impossible to use any compound
3	containing organic or water inside in the capsule.
4	So only ceramics or glasses, inorganic materials may
5	be used, and we compare these properties as a
6	feasibility study because one material may be easy
7	for production, but other material may have more
8	performance properties for resistent to
9	reachability.
10	So we must compare and now all studies
11	performed on surrogate materials, and maybe after
12	one year you'll hear data to compare properties with
13	the real Cesium-137.
14	Maybe I not understand your questions
15	correctly.
16	MR. RAKOVAN: Last comment of the day.
17	MS. SHEPHERD: Mary Shepherd.
18	The testing that we're discussing is a
19	special form capsule testing that's usually required
20	for transportation and for licensing issues.
21	There's special form and there's NASI testing that's
22	involved with the manufacturer before you're allowed
23	to distribute or transport. And that's a whole
24	other factor that's trying to be addressed, and
25	those are real requirements unless the IAEA and the
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1	other governmental agencies change those
2	requirements for the production of any kind of
3	source, special form.
4	MR. RAKOVAN: Okay. Looking at the
5	agenda for tomorrow, we've got registration starting
6	at eight. I'm sure we'll have more food out. We'll
7	be starting promptly at 8:30, starting on Issue 3,
8	and then we'll move on to four and five tomorrow.
9	So we'll see you all tomorrow. We'll be
10	in the same room.
11	(Whereupon, at 4:53 p.m., the workshop
12	was adjourned, to reconvene at 8:30 a.m., September
13	30, 2008.)
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