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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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STAKEHOLDER WORKSHOP ON THE SECURITY

AND CONTINUED USE OF

CESIUM-137 CHLORIDE SOURCES

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TUESDAY, SEPTEMBER 30, 2008

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ROCKVILLE, MARYLAND

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The Workshop was held at the Bethesda North Marriott and Convention Center, Foyer C, 5701 Marinelli Road, at 8:30 a.m., Lance Rakovan, Facilitator, presiding.

PANELISTS:

PANEL 3:

GAMAL AKABANI

RICHARD BENJAMIN

CELSO BIANCO

KEVIN CHARBONNEAU

CATHY RIBAUDO

MELISSA MARTIN

RONALDO MINNITI

JOSEPH RING

PANEL 3.2

DEBBIE GILLEY

BLAIR MENNA

CONSTANCE ROSSER

PANEL 3.3:

PAUL MOSES

ROBERT PHILLIPS

MARY SHEPHERD

RUTH D. SYLVESTER

MICHAEL TAYLOR

PANEL 3.4:

RONALDO MINNITI

KAVITA MURTHY

RICHARD TOOHEY

PETER ZIMMERMAN

DAVID COPPELL

PANEL 4:

GRANT MILLS

RICHARD RATLIFF

ADELA SALAME-ALFIE

JERRY THOMAS

JOHN ZABKO

JOSEPH RING

RICHARD TOOHEY

PANEL 5:

LEONARD CONNELL

SAMEERA DANIELS

JOHN ERTEL

LYNNE FAIROBENT

RICHARD TOOHEY

ADELA SALAME-ALFIE

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

(8:31 a.m.)

MS. JONES: Good morning, everyone. Did the cheese blintzes settle well with everybody? They looked very good. I'm going to have mine after this morning.

Well, good morning. I'm Cynthia Jones. I'm the Senior Technical Advisor for Nuclear Security in the Office of Nuclear Security and Incident Response at NRC.

Let me first say that as the co-coordinator of this workshop I am just so pleased with the attendance we have. We had, as of yesterday, 169 attendees, and we are anticipating about 30 or 40 more today for the discussions.

Let me express my sincere appreciation for the wonderful exchange of information and ideas that we experienced yesterday at this workshop. It was exactly this type of stakeholder exchange that we envisioned and that we were hoping to achieve with this meeting in order to document the variety of views and help inform the Commission on this very important issue.

To advance our discussions today, let me share with you some key points on the issues that were

discussed yesterday. As an aside, I will note that this is only a very brief overview of the many discussions that took place. A full meeting summary and complete list of participants of this workshop will be posted on the cesium chloride website that is listed in both Federal Register notices and that I have again listed at the end of this summary.

Next slide.

So yesterday NRC management provided a brief overview of the history of increased security controls of Category 1 and 2 radioactive sealed sources that are licensed to the United States by both the NRC and agreement state regulators. We next heard from the National Academies, who provided an overview of its radiation source use and replacement report.

The main points of that report concluded that applications of radionuclide sources are important and beneficial. Area of denial and its costs must be considered in the evaluation of security risk from these sources. Non-radioactive nuclide replacements exist for nearly all radioactive sources, but not all of these are practical or economically attractive now, but most are improving.

We should take actions to implement near-term replacement of cesium chloride sources and adopt

policies that provide incentives to replace other Category 1 and 2 sources. Next, we were provided a summary of the conclusions of an interagency cesium chloride working group, which is an official use only report that I served on with John Jankovich as co-chair.

The report recommended that immediate phaseout of cesium chloride sources would not be feasible; stepwise phaseout could be feasible. Challenges would have to be overcome. Sufficient time would be necessary for replacement technologies to be established and for disposal pathways. Sequences and timeframes are critical, and interim security measures remain very important.

We then heard a speech from NRC Commissioner Lyons on his views on the safety and security of sealed cesium-137 sources, which has been, and continues to be, a top priority for the NRC. He reiterated that NRC has not made any decisions regarding the suspension of the use of high-activity cesium-137 chloride sources, and emphasized that the information gathered at this workshop will be combined with other studies embedded with the Interagency Radiation Source Protection and Security Task Force, which by the way is having its meeting tomorrow at the

NRC.

The Commissioner noted that the NRC and its federal partners need very broad stakeholder input on the potential impacts of actions and the range of alternatives that could potentially address issues associated with the removal or increased controls of cesium chloride sources in use.

In addition, he emphasized that the NRC needs your stakeholder views on economic and societal costs associated with the replacement of these sources, or how your research would be impacted if they were not available. Additionally, NRC also needs to understand the affect on your programs if such sources could be replaced by X-rays or other alternatives.

He noted as we consider these issues we need to pay careful attention to both the consequences of our actions to avoid unintended consequences, both domestically and internationally. Commissioner Lyons' presentation will be posted shortly on NRC's public website, which is www.nrc.gov.

Slide 3 and 4. Slides 3 and 4 are just a summary of the questions that we went over yesterday in this session. On Issue 1.1, feasibility on the use of other forms of cesium-137, we heard from an Oak

Ridge National Lab representative regarding the U.S. historical information concerning the manufacture of cesium chloride in the 1970s, and the discussion of the amounts of specific activity that was manufactured at that time.

The REVISS representative discussed problems with the exact duplication of existing sources using forms other than cesium chloride, but believed that this process could be developed by Mayak, who is the sole source manufacturer in Russia after a feasibility assessment is performed.

Workshop participants familiar with the Mayak production facility stated that we will need to take theoretical concepts and studies that have been performed with surrogate -- in other words, non-radioactive material -- to Mayak to see if real sources can be made.

Time estimates of this assessment range from about one year for an economic and feasibility study for glass or ceramic. And then, if a specific path forward can be identified and agreed upon, perhaps another three to five years for retooling the production lines, or building a new facility to begin source production and cold testing.

Commenters stated that these actions would

require multi-national agreements between participating nations, which currently do not exist today.

Discussions also centered on questions concerning the term "dispersibility" and what would be acceptable for such retooled sources in the manufacturing process. Currently, there are no known entities in the U.S. or worldwide that engage in manufacturing sources with alternative forms of cesium-137.

Let's go to Slide 5. In Issue 1.2, we discussed the feasibility of the use of isotopes other than cesium-137. And regarding the use of cobalt-60, many organizational representatives provided excellent data and survey results from over 700 individuals at their user facilities on the perspective of their users on the potential impacts associated with replacing cesium with other radioactive material, such as cobalt or X-rays.

Several medical organizations stated that they are concerned that the prohibition or elimination of the use of cesium chloride irradiators could result in a decrease in the standard of medical care that exists in this country. They stated that limiting sources would have a major impact on medical research

in the United States, and that any transition to another modality would have severe impacts on the medical industry.

Slide 6, please. In the next issue, which was use of alternative technologies, we heard that many workshop participants agreed that there are specific issues to be resolved with any replacement technology, and that big differences exist between X-rays and gamma in terms of absorbed dose. While there may be alternatives to certain types of processes, such as blood irradiation using X-rays, these alternatives appear not to be suitable for many other types of biomedical research applications.

Given that the discussions by various user groups and the nearly 50 years of research that has been performed using cesium chloride irradiators, any change in protocols would have to be reconciled. Older studies that cannot be easily validated with newer and/or different sources would need to be investigated.

Given the numerous types of research performed today, there does not appear to be a one size fits all approach to addressing these issues.

We also discussed the use of cesium chloride used in calibration. Most participants

indicated that there is no replacement at the present time, and that most of the calibrators are located in secure locations.

Participants emphasized the need for considering risk-benefit and cost-benefit in the decisionmaking processes, and stated that there should be a need to balance the scientific facts and economic issues as well. They emphasized that the cost of alternatives need to include the cost of replacement, down time, calibration, and ongoing maintenance.

There was also a discussion of the issues concerning solubility, dispersibility, and the decontamination effort incidents of the past, such as Goiania, which was a cesium-137 source, and Juarez, Mexico, that involved a cobalt-60 source. Differences in the cleanup costs between these two events was noted to be significant.

Manufacturers stated that the use of cobalt-60 replacement, if possible, would need to be of different design due to the increased need for additional shielding, for increased source energy and structural design considerations for floor loading issues.

Replacement of irradiators with cobalt-60 would need to be changed more frequently -- every five

to 10 years -- versus cesium-137's current replacement time of 25 to 30 years. This raised additional concerns with: number one, about 99 percent of transport containers are not available for any type of Type B quantity of radioactive materials as of October 1, 2008, (which is tomorrow); increased -- number 2, increased possibility for transportation or reloading accidents from a safety -- radiation safety perspective; number 3, issues with disposal of cesium in general, since there are no current disposal pathways for these sources; and, number 4, increased risk for diversion during transport.

Clearly, transportation adds additional risk that would need to be considered in the overall framework, and that this should be studied from a total life cycle perspective in order to balance the risk and potential security concerns.

Please keep in mind that this was only a very short summary of the discussions from yesterday. The full transcript of this meeting, as well as the meeting summary, will be posted on the cesium chloride website in about 10 days.

If we could go to the last slide. And, in addition, as was mentioned yesterday, the summary of comments and issues that are raised from this

stakeholder meeting will serve to provide a range of recommendations to the Commission for consideration of a path forward. It is our expectation that you will have future opportunities to express your views well before any final decision is made.

Thank you.

FACILITATOR RAKOVAN: Good morning, everyone. Welcome back.

Before we get started this morning, I just wanted to do kind of an abbreviated version of the ground rules, just to kind of remind you on how to do things and also for people who are new today, to let them kind of have an idea of what to expect.

For those of you who are going to start out on the panel, if you want to go ahead and take your seats while I'm going through this, that will hopefully save us a little bit of time in the long run. So you can come up, and please take your seats.

One thing you've probably noticed if you were here yesterday is that there was not too much NRC participation above and beyond the presentations that were given in the morning, and I wanted to take a moment to address that. The reason that we had this workshop, the whole reason that we went ahead and did this, was to listen to the various stakeholders.

We did not want to spend a whole lot of time having the NRC talking and taking up time, so you'll notice we don't even have a person sitting at the table as a panelist on any of the panels, and that was done with forethought. So just wanted to let you know we're here to listen. That certainly doesn't mean that it's not important. Obviously, it's important, since we're having this workshop.

And if there are any questions that you have, there are certainly a lot of people here -- John and Cyndi certainly at the top -- that are willing to have discussions with you about the issues off to the side during a break. So I just wanted to address that.

I also wanted to remind you that the comment period has been extended until October 15th. Hopefully, that will allow you a little bit of time to digest what we've discussed at this meeting, and it should allow us some time to get the transcript out and posted, so that you might even be able to look at the transcript a bit and take that into account, in case you missed or forgot some of the discussions at this meeting.

So we're going to do pretty much the same thing that we did yesterday in terms of the

discussions. We have got a number of different panels and categories to get through today. We're going to start each panel with going through kind of an overview of what the Federal Register notice said. If any of the panelists wish to make opening statements or presentations, we will go ahead and let them do that. And then, we'll go ahead and open up for discussion.

Again, it's very important that you use a microphone if you are going to speak. Thanks to everyone who helped me out with that yesterday. I thought it went very well. And, thankfully, all the microphones seemed to be working and working quite well as well, so that's good.

I think we got a fairly good transcript yesterday, and hopefully we'll get another one today.

I wanted to remind you again on the public meeting feedbacks forms. I believe some of the conference people left them sitting interspersed on the chairs. There is a big box on the registration table that you can drop those into, or you can just drop it in the mail. Postage is free, and it will get to us.

Please note, again, that this is a public meeting, so we'll be discussing only publicly-

available information. That is especially important; I believe this afternoon we have a session on the security issues. So try to keep that in mind.

Again, please silence your cell phones or other electronic devices. That will help us make sure that we don't have any interruptions. And, actually, while I'm saying that I'm going to look at my phone. Okay. Manner mode, very good. It's pretty embarrassing if the facilitator has his phone go off during the discussion, so I wanted to make sure I had that covered.

Other than that, I think that we are just going to go ahead, like I said, and do things today pretty much the same as we did yesterday. Depending on how things go, we will be taking breaks and lunch. I know it was difficult to get you away from the food this morning, but it will be out there until 11:00, I'm told, so you should have plenty of time to grab something, and certainly grab something during the break that we'll take.

Hopefully, get you out of here on time, and we'll just see how things go.

So thanks again for your participation yesterday, and hopefully today will go well.

Why don't we start off by having the

panelists introduce themselves. Let's start on the far side of the room there.

MR. RING: I'm Joe Ring, representing Harvard University faculty.

MR. MINNITI: I'm Ronnie Minniti from the National Institute of Standards and Technology.

MS. MARTIN: I'm Melissa Martin representing American College of Radiology.

MS. RIBAUDO: Cathy Ribaudo, National Institutes of Health.

MR. CHARBONNEAU: Kevin Charbonneau representing Yale University.

MR. BIANCO: Celso Bianco representing America's Blood Centers.

MR. BENJAMIN: Richard Benjamin, Chief Medical Officer for the American Red Cross Blood Services.

MR. AKABANI: Gamal Akabani from the Food and Drug Administration.

FACILITATOR RAKOVAN: And I would ask the panelists that when you're not using your microphone, if you could turn it off. That helps cut down on feedback. We didn't have too many issues with that, but it did happen.

Also, specifically for the panelists, I

know it's something that's difficult, and I certainly won't call you on it, but when you speak, if you could identify yourself, both for the transcript and also I was told that a lot of people in the back can't see who is talking when they start talking. So if you could try to remember just to identify yourself before you speak, that will help out both with the transcript and with the people sitting towards the back.

We're going to start out today -- Issue Number 3 is possible phaseout of cesium chloride sources. And, geez, what do you guys think? Should I read the whole thing in the Federal Register notice, or have you all read it? Just give me -- I'm seeing -- okay, I'm seeing a lot of -- all right. So we'll just go ahead.

Issue 3.1, potential rulemaking issues and justification for regulatory change. I will read the question, though, just to make sure we have it on the transcript. Q3.1-1(a), what would be the medical consequences if cesium chloride was to be banned for medical, e.g. blood irradiators? (b), what would be the impact to existing and future biomedical research using these devices? And, (c), can alternative technologies be used for medical applications and/or biomedical research, research on animals and tissue?

I'm going to look to the crowd again, because I had a suggestion yesterday that I read all of the questions involved with a panel before the panel starts. Yes? No? Yes, okay. I'll go ahead and do that.

3.1-2(a), what would be the consequences if cesium chloride was to be banned for irradiators that are used for industrial and calibration purposes? (b), what is the impact on existing American National Standards Institute, or ANSI standards, and the licensee conditions that require the use of cesium-137 for calibration purposes?

3.1-3, what would be the economic consequences to users if cesium chloride was to be banned?

3.1-4, what would be the economic consequences to vendors if cesium chloride was to be banned?

3.1-5(a), should the NRC discontinue all new licensing and importation of these sources and devices? (b) what is the regulatory basis? (c) who -- NRC, DHS, or jointly -- should conduct the risk analysis?

So those -- that's -- those are the five questions, with a few subparts, that we'll be

discussing in this particular panel.

Start out, as usual, by asking if any of the panelists have statements or presentations that they'd like to make to start us off. Please. First hand I saw. Yes? Okay, maybe not.

MR. BIANCO: Well, thank you for the opportunity for being here. This has been a very stimulating and, I believe, productive discussion.

Next slide, please.

I represent America's Blood Centers. You could go through all of them. That's an association of blood centers in the U.S. that provides about half of the U.S. blood supply to hospitals, to about 3,000 hospitals. And the ABC members collect about nine million units of blood and components a year. And they vary in size from just 10,000 to about 800,000 a year, and they irradiate about half a million units of blood a year.

The next slide, please.

We conducted, before coming to this meeting, a survey of our members, and we got responses of 68 of the 77 members and -- which is a substantial portion of our collections. And we realize that the vast majority -- 65 of them -- have cesium chloride irradiators. Two have cobalt irradiators, and 13 have

changed in recent times to X-ray type irradiators.

Next, please.

And, obviously, there is a substantial change in terms of the costs, those that move to the X-ray, they have paid a much -- the third column -- average purchase price, and the average operating costs have been much higher.

And as I said before, most of them have been bought more recently, and average, most of them, around 2005 and more recently.

The next slide.

And many have still a number of years of remaining usefulness.

Next, please.

We did an estimate of what it would mean to phase out all of the cesium irradiators. And we came to a -- to estimate that it would be over $20 million for that replacement, in terms of the remaining value, in terms of the decommissioning cost that is quite high.

The purchase cost of X-ray instrumentation, we did not include here the facility changes that are required for the -- like water and electricity and all of that, and the additional operating costs in terms of maintenance, X-ray tubes,

and all of that.

The next slide.

This is my last slide, and I'd like to mention, what are the obstacles that we see in terms of a conversion when we ask the question, "Should we convert?"

The first is the cost and financial issues. All of the acquisition, facility modifications, maintenance, recalibration, replacement parts, and there is -- since those are highly regulated activities for us in everything, and blood transfusion is highly regulated, a lot of employee training and a lot of QC as part of the good practices.

There is a complexity of decommissioning, and many of us have gone through decommissioning irradiators in our lives, and this was always an experience, done in secret, done with a lot of LOCA requirements. We had a lot of firewalls in New York, so you can imagine what it was to move an irradiator in the city of New York.

Loss of use of the current instrument, and, finally, a lack of perception of risk. I think that all of the ABC members have complied with the recent increased control requirements by NRC,

including physical location, controlled access, security clearance of personnel.

And they feel -- and I agree with them personally -- that it's the elimination of the cesium chloride irradiation is an extreme action. And the comparison that I would make is if after 9/11 we had eliminated air travel, we saw that this would be an impossible task, just to go back to what we did many years ago with boats and trains and cars, and that we compensated that for a substantial increase in safety and security, that has so far been quite appropriate and served for us to retain something that is fundamental for our daily activities in the 21st century.

Thank you.

FACILITATOR RAKOVAN: Thank you.

(Applause.)

MS. MARTIN: Thank you very much for allowing us to participate in this workshop today. My name is Melissa Martin. I'm representing the American College of Radiology (ACR).

Next slide.

Just for those that may or may not be aware of us, we -- the American College of Radiology is a professional association with approximately

32,000 members. Our membership consists of radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists. Our mission is to basically serve our patients with -- and society and maximize the value in doing so.

Our headquarters are local. They are over in Reston, Virginia, and with the government relations office here in Washington, D.C., and a clinical research office in Philadelphia.

Next?

Why is the American College of Radiology worried or concerned about the use of cesium chloride? Well, because it very definitely affects the operations of the ACR community. The ACR membership -- we use the cesium chloride sources for patient care and for biomedical research applications. Medical physicists, such as myself, are involved with many of the radiation safety aspects of cesium chloride sources in both medical and scientific settings.

Personally, I serve as RSO at two rather large hospitals in Southern California now. And so having gone through some of the increased controls, from the medical perspective I am very well aware of what is involved in this from a medical

community/hospital operation point of view.

Obviously, the radiation oncologists and many of our radiologists also serve as radiation safety officers in their own facility as well as using these cesium chloride sources for research purposes. We have many million dollars worth of research grants that are tied right now to the cesium chloride irradiators for their basis.

Next.

The pertinent questions that we thought we should respond to, and that we solicited input back from our membership, concern just three of them. Question 1 was the -- what would be the medical consequences if the cesium chloride was to be banned for medical purposes? And what would be the impact of future -- existing and future biomedical research? And, (c), can the alternative technologies be used for medical applications?

We heard many of these answers yesterday, so this basically will serve as a -- to reiterate and reinforce what has already been said from those in attendance. Most of the research is done on -- for both clinical and commercial viability of the alternatives to cesium chloride irradiators is just not there yet. Other groups have discussed the

implications from a biomedical research -- and I will let that be covered by the other groups.

And our membership felt that basically the alternatives may not be feasible right now. We heard that again this morning as one of the summaries, and I'm sure we'll hear that reiterated throughout the day, that the alternatives may come, but they aren't here right now.

Next?

The second question, what would be the economic consequences to users if cesium chloride was to be banned? Well, we basically can come back with questions to the answer to the question. Potential answers are going to vary depending on, obviously, a number of factors. What are the circumstances of the ban if it happened? Is it a long-term phaseout, or is it going to happen suddenly? And I think these are all factors that we're looking for answers for.

What are the costs of the premature decommissioning, storage, disposal, of existing sources? Most medical centers are not swimming in money right now and do not have the ability to absorb the significant cost, as we illustrated earlier by the blood banks. We are all in the same position.

What are the scientific investigators

saying about financial and opportunity costs of discontinuing access? I think we heard this yesterday. No one has money sitting around right now, unless there is a -- quote, "a significant bailout that might pass both Houses of Congress."

(Laughter.)

Next.

And question number 3 that we got answers from our members on was, should the NRC discontinue all new licensing and importation of these sources and devices? And, again, this question really can't be answered until all the information is collected from the stakeholders, which is the purpose of this meeting today.

Other groups, such as the ACMUI, have obviously conducted their own evaluations, and these evaluations will obviously be further explored. And if, after reviewing all of this available information, a ban for new licenses is determined, we really have to figure out federal compensation or financial incentives if licensees are going to be forced to transition to the alternatives.

Next.

We would like to put our ACR contacts in. Again, I'm a member. I serve on the American College

of Radiology's Commission on Medical Physics, and the Government Relations Committee. Gloria Romanelli is our Senior Director for Legislative and Regulatory Relations, and Mike Peters is our Regulatory Affairs Specialist.

Thank you again for the opportunity to participate in this conference.

(Applause.)

FACILITATOR RAKOVAN: Thank you.

MR. MINNITI: Good morning. My name is Ronaldo Minniti, and I'm from NIST, the National Institute of Standards and Technology.

First of all, I want to thank the organizers of the workshop for letting me speak today.

For those of you who are not familiar with activities of NIST, we maintain the standards for radiation dose from X-rays, cesium, and cobalt-60 beams. What I'm going to be talking about today is the use of cesium-137 exclusively for instrument calibrations.

Next, please.

So in the United States there is a large number of users of radiation detector instrumentations. I listed just a few there, and there is a large variety of radiation detector

instruments that are used, including survey meters, personal dosimeters, like TLDs or electronic dosimeters, ion chambers, etcetera.

There is a nice picture on the left corner that you can see a couple of them.

The users -- the list of users includes the Navy, the Army soldiers, and the Air Force. Within the Department of Homeland Security we have Coast Guards, Customs, TSA. There are also radiation workers at hospital clinics, and so on.

I guess just to put this in perspective, the Navy, by itself, has about a quarter million soldiers badged with passive dosimeters, just to monitor the radiations when they are working in submarines or aircraft carriers. I believe there is about around 70 to 80 submarines in the country. All of them have these dosimeter readers that are tested with cesium routinely.

And I could go on, but I don't have the time, so next slide, please.

So the question is: what is the impact on instrument calibrations if cesiums are banned? The short answer is, okay, it would be catastrophic. And why? Because the safety of all these users of radiation detector instruments really relies on the

calibration of these instruments using cesium-137.

For those of you that are not familiar with calibrations, the typical activities that are used do not exceed 1,200 curies, and maybe in some -- for some special applications there may be higher activities, but mostly that is the range. So basically, for instrument calibrations, I would say that most of the calibrators fall in the Category 2.

Next slide.

So this is just a partial list showing you where some of the calibration facilities are located in the U.S. And all of these calibration facilities have cesium irradiators or test their systems using cesium irradiators. As I said, the Navy has about 10. I think the Army -- and I believe there is some gentleman here -- may correct me if I'm wrong, but they have about 20, and so forth.

I just want to point out that all those facilities, all those red dots that you see on the map, they calibrate their instruments -- and there are about a million instruments out there in the U.S. -- using cesium. And a calibration ensures that an instrument measures correctly, and that's the only way that these users can ensure the safety of them and people in the public.

And the way that is done is all those measurements are traceable to the national standard, which is held at NIST. And I'll talk a little bit in the afternoon in the international section about how NIST compares to other countries.

Next.

So another thing I wanted to mention is that radiation detectors -- most of them have a strong energy response, and this is why it's important to calibrate these detectors at different energies. And what is usually done is it is calibrated at three points, at low energy, around -- between 60 and 300 kiloVolts with X-rays, the high energy cobalt, and then right in the center with cesium.

However, decades ago -- I'm talking 45, 50 years ago, it was established -- cesium was established as the reference energy. And there's a reason for this. I wouldn't have time to go through all of them, but mainly all detectors have a very flat response in the cesium region of energy. And this is why cesium was picked.

And I just show a spectrum of cesium. You see it has a nice, single line, which is ideal for calibration.

Next, please.

So I guess the question we want to pose, then, is: should a ruling be based on speculation that other forms of cesium will become available some day? Again, if there would be some other technology that would provide for instrument calibrations, energy -- around 600 keV -- this could be done.

But as of today, if we pick up the phone and call a manufacturer of irradiators, and say, "Can you build me an irradiator with another form of cesium?" or an X-ray manufacturer, "Can you build me a machine that produces an X-ray beam with a quite peaked spectrum, around 600, can you do that?" The answer is, no, I think we agree all on that.

There are speculations that -- from what we heard yesterday that this could be available in two, five, 10 years. The question is: should we be doing a ruling based on that? If that doesn't show up in five, 10 years, what do we do? How do we ensure the safety of all these users?

So I guess my view, and the view of NIST, is that only when other forms become available -- and a national standard for these other forms are developed -- then, only then, we can talk about phasing out cesium.

And one more slide at this time.

Otherwise, I'll quit here.

I just want to mention that there are lots of protocols and recommendations in standard documents that rely on the use of cesium. Most of them -- some of them, published by ANSI, for the use in homeland security, and they were published within the last six years or so. And there are other standards for radiation protection written by -- also by ANSI, by ISO, by NCRP.

Furthermore, there are several accreditation programs in the U.S. One is run by the Health Physics Society, another one by the Department of Energy called DOELAP, and NVLAP, and all these -- all these accreditation programs rely on the use of cesium for the reasons I mentioned before.

And, finally, NIST, as well as secondary labs in the U.S., which were shown in the map I showed before, performed blind tests with users to test millions of personal dosimeters. And this is used -- this is done specifically with cesium.

Thank you.

(Applause.)

MR. BENJAMIN: Richard Benjamin, American Red Cross. I just want to clarify something following Dr. Bianco's presentation.

American Blood Centers collect about half the blood supply in the U.S. The Red Cross collects about the other half. Dr. Steve Wagner yesterday presented during the discussion our experience with cesium sources, and I just want to repeat that.

The American Red Cross has 32 cesium-137 sources at 32 centers around the country. We also irradiate just under half a million blood components a year. So between American Blood Centers and the Red Cross we are irradiating about a million products.

You heard from Dr. Jed Gorlin yesterday that from the AABB, representing not only the blood centers but also the hospitals, that about 2.3 million blood components are irradiated in the country in both hospitals and blood centers.

Essentially, the hospitals, then, must be irradiating about 1.3 million products, the blood centers about one million products a year. Just give you an overall view of the blood irradiation in the U.S.

Thank you.

FACILITATOR RAKOVAN: Any additional opening statements from panel members? Please.

MS. RIBAUDO: Cathy Ribaudo, National Institutes of Health.

I speak this morning on behalf of our Department of Transfusion Medicine, who couldn't be here today. I have statements from Dr. Susan F. Leitman, the Chief of the Blood Services Section, and I will just read them for the record.

"In response to the possible phaseout of cesium chloride sources, I will tackle a couple of issues. Number 1, current security levels. NRC has done a stupendously, some would say onerously, good job of initiating security clearances for all campus employees requesting access to campus irradiators.

"The likelihood of a breach by persons who intend to harvest the cesium chloride out of one of these devices, and use the material in a bioterrorism activity, is wildly improbable on the NIH campus. It would take a considerable amount of unobserved time, probably involving more than two people, to dismantle one of these sealed irradiator sources to gain access to the encapsulated pellets.

"The security cameras, not to mention nearby personnel, are set up to detect this kind of sustained activity. It would have to be done by persons with inside knowledge, and the location and use patterns of these irradiators. Again, highly unlikely.

"The cost of decommissioning all NIH cesium chloride irradiators, having them removed, all 4,400 pounds each, disposing of the cesium chloride pellets according to NRC guidelines, and replacing them with an X-ray generating device, would cost tens of millions of dollars.

"It does make sense, given the level of concern, to interdict future purchases of sealed sources of cesium chloride. The self-contained, free-standing, X-ray-generating devices do provide the same function, though they have their own problems.

"The only non-cesium chloride alternative for a free-standing, self-contained, blood and research component irradiator is an X-ray-generating device. There is only one available on the market now, branded as the Raycell, and distributed by Nordion of Canada, now Best Theratronics.

"Nordion acquired the license to distribute this device from Rad Source in 2003, and is the sole distributor. It costs about $20,000 -- sorry, $200,000, not counting taxes and shipping fees."

(Laughter.)

"There are two X-ray tubes per machine, and they are covered by warranty for 2,000 hours of

service each, which equals 120,000 minutes each, 240,000 minutes total. It takes two to three minutes to warm up the machine from a cold start, and another five to six minutes to accomplish the irradiation. So nearly 10 minutes per cycle.

"In the Department of Transfusion Medicine, we irradiate 12,000 components per year, so we would eventually be replacing the X-ray tubes every two years at a cost of $20,000 per tube. In addition, there are yearly preventive maintenance costs and the cost of recommended twice-yearly dosimetry assessments.

"Compare this to the cesium chloride where there are no costs for upkeep of the device other than the yearly preventive maintenance and dosimetry, $6,000 per year. There is also the requirement for a source of running cold water and drain, since chilled water must run at 10 to 20 liters per minute to cool the X-ray tubes during the five minutes of operation of each cycle.

"I am told that mechanically the Raycell device has issues with frequent door closure failures. Right now, it takes 2.5 minutes from start to finish to perform an irradiation cycle on the blood bank's cesium chloride irradiator, whose canister holds as

many as six red cell and platelet bags. It would be markedly inconvenient, annoying, and disruptive, to change this to a five-minute irradiation cycle, especially for stat blood orders, in a canister which holds a maximum of two units of blood component.

"The Raycell is not as convenient and efficient to use as the cesium chloride irradiator, is wasteful of technologists' time, is more expensive due to biennial tube replacement, requires more upkeep, is more prone to breakdowns, and requires a proximal high flow, chilled water system.

"On balance, the cesium chloride irradiator markedly exceeds the Raycell X-irradiator in all elements of performance and maintenance. However, we would get rid of all the NRC security issues with the X-irradiator.

"Please do not let the cesium chloride irradiators at NIH go gently into that good night."

(Laughter, followed by applause.)

FACILITATOR RAKOVAN: Thank you for that very poetic statement.

(Laughter.)

Any further opening statements or presentations before we open for discussion?

(No response.)

Okay. Seeing none, anyone want to jump in with discussions on the first part -- or the first question, (a), (b), or (c)?

MR. BIANCO: Well, we had good discussion yesterday about the medical consequences. It would be tragic for patients that are immunosuppressed to receive a unit of blood that is not irradiated, leading actually to some extremes in cancer hospitals and others where they decide to irradiate all the units that they are going to transfuse, just to prevent a mistake that could be the introduction of one of those units into a patient that will later develop fatal graft-versus-host disease (GVHD).

So I -- I think that this makes irradiation an essential part of medical care today.

MR. BENJAMIN: And I'll just reiterate that graft-versus-host disease post-transfusion is a rare complication of transfusion. However, cesium sources allowed a relatively low-cost intervention that provided a high degree of safety against this. It may be rare, but it is fatal. It's 100 percent fatal with about a one- to two-week time period from transfusion to death.

So it has provided a very nice solution to a rare problem. I do not believe we can stop

irradiating or doing something to prevent GVHD. So that can't happen.

So if cesium sources were to be removed, we would need to move to another technology. I do believe that may cause some shifts in how things are done. Currently, I mentioned that more blood is irradiated in hospitals, because the technology is simple, easy, rapid, cheap, and hospitals can do that.

I think if irradiators were to -- needed to move to X-ray irradiators, we may see a move of irradiation out of the hospital and back to the blood centers, because we have more time and we can do that in preparation.

The problem is that there are a lot of stat orders for irradiated blood in hospitals. And so I don't see that hospitals can get completely out of the business, but I do see a shift of business to the blood centers. Certainly, we could move to 100 percent irradiation of platelet products, because irradiation has very little effect on platelet products.

Irradiation does have adverse effects on red cell products. There's a loss of potassium and some other consequences that require us to reduce the shelf life from six weeks down to three weeks after

irradiation. So we probably could not move to 100 percent irradiation within the blood centers for red cell products.

So I do see that a loss of the cesium sources could have some dynamic effects on how things are done and where things are done regarding irradiation. We are not going to stop preventing GVHD. I don't see that happening.

MR. CHARBONNEAU: Kevin Charbonneau from Yale University. The banning of cesium chloride irradiators is obviously a big issue for the university environment.

Dr. Ring yesterday kind of gave you the sentiment from his research -- researcher's perspective, and I have similarly heard exactly the same sentiment from our researchers, that the wide range of concerns about the elimination of cesium chloride and the impacts on their research, the impacts on their funding for the research that they are currently doing, I think from a university perspective we understand the concerns about cesium chloride and wholeheartedly agree that, you know, if there is another option, some -- the ability to be able to produce it in a different form that would produce the same results from a research perspective,

makes tremendous, you know, sense.

From a university perspective, the increased control programs that have been put in place, I agree that -- with some of the other panelists here that increased controls have played a significant role in increasing security, even at the -- in a university environment where it is known to be a very open and sharing environment. That's actually a good thing in some cases.

From a security perspective, we have seen a tremendous increase in the concern level from our researchers. Their understanding about increased controls and making sure that they are in compliance with these increased controls has been very compelling to them to make sure they are in compliance with it.

We agree that the hardening program, where you make the irradiators more difficult to -- you know, basically to be able to access the source, again, makes a tremendous amount of sense, slows somebody who might want to acquire the sources down, and allows our security programs to kind of kick in gear and mount a response. Those are things that we feel are very appropriate and do add another layer of security on top of that.

Thank you.

FACILITATOR RAKOVAN: Thank you.

Any additional discussion on this -- these particular questions? The crowd has been kind of quiet this morning. Charlie Miller?

MR. MILLER: Thank you. Charlie Miller, NRC. I'd like to pose a couple of additional questions to the panel, or any experts that are in the audience, for the NRC's benefit. As we go forth and ponder the results of this workshop and decide what, if any, regulatory action we would recommend, we don't want to do something that is going to inhibit medical care.

The NRC is a regulator; we're not necessarily medical experts, nor should we be. But, nevertheless, we do have to have a thorough understanding of medical technology to be able to make informed decisions. That said, Dr. Benjamin talked a little bit about the differences in shelf life. We've got some anecdotal evidence from talking to various people, but since we have such a group of experts here today, I am very interested in knowing, you know, any additional views concerning shelf life with regard to using cesium chloride versus X-ray technology.

Does that impact patient care? Does that impact the timing of treatment for patients in

environments where there is a high throughput? Is there any difference in the quality of the irradiated blood by one technique or the other with regard to the risk to patients, to some of the things that can happen, especially with patients who are receiving this because of immune deficiencies?

So any insights that we can get on that front from this group would be very beneficial to us as we formulate our views.

Thank you.

FACILITATOR RAKOVAN: I was just scrawling down Charlie's points.

MR. BENJAMIN: I am not aware of any differences between X-ray radiation and cesium irradiation on the quality of the product for transfusion. So I do not believe that is an issue from our point of view.

FACILITATOR RAKOVAN: Anyone else care to comment? Please.

MS. MARTIN: I have -- this is Melissa Martin representing ACR. On a personal experience -- and that's where I would come from -- having worked in facilities where at one time the Radiation Oncology Department was the one responsible for irradiating the blood products prior to obtaining one of the cesium

chloride irradiators, one point I'd like to make is it was a significant impact on patient care.

You heard the talk yesterday, the price of a linear accelerator starts at about $1.5 million and goes up from there. When those -- and those patients are normally booked, every slot is filled for radiation oncology treatments. Those would have to be stopped, because it was stat irradiations for the blood products. And so you would stop your linear accelerator, totally regear. You are losing basically one or two patient slot times for patient treatments due to the fact that you had to do the stat irradiation.

And so it wasn't a matter that we could wait. We had a very active bone marrow transplant program, and we had to provide the blood products as needed.

So I would just reiterate it is a stat problem. I think it would be a significant impact on the clinical environment if we lost our irradiators again.

FACILITATOR RAKOVAN: Real quick, and then I'm going to go to the microphones.

MR. BENJAMIN: Okay. I think I tried to point out earlier that a loss of the cesium sources

would change the way we do things. There is a shift right today happening already in the way radiation occurs. Irradiation was always -- has been something that the attending physician requested of a blood product because his patient needed it.

Many big hospitals are really concerned about that, because if the attending physician forgets, or the patient, who is immunocompromised, goes to a country hospital after a trauma, or is admitted to an emergency room, they may be transfused with unirradiated blood, because those attending physicians don't know of the need.

So many large hospitals have, in fact, moved to universal irradiation just to take that whole question off the table and add an extra layer of safety. So there has been a move towards more irradiation to cover a broader spectrum of eventualities.

Last year we saw a 10 percent increase in requests for irradiated blood. I do think that that does reflect the changing reality.

If we were to move to a less efficient system with X-ray irradiation, I would expect that we would be doing fewer stat requests and more first thing in the morning the blood bank would irradiate 50

products and have them on the shelf and use them as necessary. So we would change what we do in response to a less efficient irradiation system.

FACILITATOR RAKOVAN: Can we go to the second mic, and then to the first?

MR. GORLIN: Gorlin, AABB, where my pediatric hematologists had -- I would certainly point out that a disproportionate number of the cesium irradiators are located in large children's hospitals that take care of increasingly small neonates. With the advent of surfactin therapy, neonatologists are able to save infants down to 25 weeks and 500 grams.

The smaller the infant, the greater the risk of the potassium leak that Dr. Benjamin has pointed out and the greater the importance of not having extended times between the irradiation and the transfusion, because the potassium leak increases the potassium into the supernatant fluid as a time-dependent function over a number of weeks. And so having those irradiators onsite is important.

The relevance of this is there was a suggestion from an NRC inquirer about consolidation as a strategy to limit the number of cesium sources, and having those sources proximal to the site of transfusion is, in fact, functionally important.

X-ray, of course, there is no difference, however.

FACILITATOR RAKOVAN: Ms. Hamrick?

MS. HAMRICK: Hi. Barbara Hamrick with the State of California. Let me just pull that off of there.

I actually have a question. I don't know if this was maybe gone over yesterday, and this is mostly out of my own curiosity. It seems to me that there would also be a big reliability issue in terms of the dose that you are actually getting out of an X-ray producing machine.

And I'm just wondering -- because with cesium chloride you've got a 662 gamma out of there, and nothing is going to change that. That is always going to be what you get out of cesium.

But it seems to me there is a whole lot of variability that you would have with a machine -- you know, mechanical failures. Was that question addressed, and I just missed that, or have -- have we thought about that?

FACILITATOR RAKOVAN: I think we talked about that a little bit yesterday. If there's anyone in particular that wants to give just a brief summary of that, or talk with Ms. Hamrick during a break, that would be great.

MS. HAMRICK: I'd be glad to talk with somebody during the break.

FACILITATOR RAKOVAN: Okay.

MS. HAMRICK: That's fine. Thank you.

MR. SULEIMAN: Orhan Suleiman with FDA. I wanted to make a couple of points. One, to keep the playing field a little bit level -- LINACs in therapy units have been used. I don't think that has been brought up, but they are a possible alternative for irradiating. And it has been used in the past, and I assume it is used on a periodic ad hoc basis.

Shelf life is an issue. I think a day or two seems to be -- it could -- I don't think there is a definitive cutoff, but I think they want to use the blood as quickly as possible. After it is irradiated, I think somebody mentioned yesterday potassium does build up the longer it is stored after it has been irradiated, so there are some other issues.

The dose differences -- somebody asked about the differences between X-ray and gamma ray. I don't think it is a big issue in this application, but the guidelines -- FDA and the American Blood Bank recommend 15 to 50, but it seems like the consensus right now is 25 to 30 gray is the dose that everybody seems to be -- to be comfortable with.

I could not find any formal clinical trials that actually -- it seems to be a practice of medicine issue that has evolved, and they are really comfortable with the 25 to 30 gray delivered dose for the blood.

And I think the main issue, really, is -- is an economic practicality/reliability issue. I think the cesium -- the radioactive source is far more reliable and comfortable.

MR. KAMINSKI: Hi. Joe Kaminski. I just want to correct somebody. You know, I have worked in Radiation Oncology Department, and patients are scheduled typically maybe from 8:00 to 5:00. If we do need to do something stat, we just bump -- you move everything up a little bit. So we would not compromise patient care.

FACILITATOR RAKOVAN: And, actually, I was corrected. Ms. Hamrick, your topic was not fully discussed, so at some point, hopefully, for the record someone who is knowledgeable on your question -- and I might have you ask it again at some point -- will hopefully come forward and give us some information. And, if not, again, we'll get it out of the parking lot here during the break, and we'll -- and hopefully someone can take care of that for us.

Further discussion on the issues that are being tossed around?

MR. THOMAS: Jerry Thomas, Via Christi. I just need to, based on the last comment, share that community hospitals don't run 8:00 to 5:00. We're running 12 hours a day, and we're booked solid in our Therapy Department. So running on a LINAC in our facility would substantially impact health and patient care.

FACILITATOR RAKOVAN: Thank you.

MR. GORLIN: AABB, Jed Gorlin. AABB standards do require, for blood irradiation, documentation of adequacy of irradiation. Most of us use some sort of irradiation change sticker, so that, frankly, the X-ray irradiators -- it really doesn't matter if the dose is a little varied. We're toasting it enough that it's cooked.

MR. POWELL: I'm Brian Powell. I'm with Constellation Energy, representing nuclear power. I'd like to tag on with Dr. Minniti there from NIST.

One thing that has not been discussed to this point is conflict with other regulations. In the nuclear power business, we have a number of cornerstones that we have to meet in order to operate the nuclear powerplant safely. And one of the

cornerstones is the radiation safety cornerstone, which is based around our ability to measure dose and protect our workers that way. So we want to make sure that they receive as little dose as possible.

And in that cornerstone there are three subparts, three thresholds, that we need to make sure that we are on top of -- exposure to locked high-radiation areas, very high radiation areas. And the last one is a tricky one, it's any unintended exposure of 100 millirem or greater. And 100 millirem is a very low threshold.

In our ALARA program, low is a reasonably achievable program. We want to not expose any of our workers to dose, if it all possible. So the exposure to higher doses is not the norm, but exposure to lower doses is the norm.

Then, the question becomes, okay, well, what sources can we use to calibrate our instruments at these lower doses? We don't have a lot of room before we hit that 100 millirem. And we could use cobalt, but because our energies are so high, and they are not representative of what we're producing, the cesium, in the plants, then we would need more shielding.

And to make the adjustments with all that

shielding to calibrate the instruments at the lower dose is not as effective as an established program with a 600 keV source, which is more in line with what we're seeing. It is actually what we're producing in the plants. So I just wanted to point that out, that there is some potential conflict with some other regulations that we're required to meet, and that we want to meet.

And, again, we are all for the security measures, reinforcing security measures to making sure that these sources cannot come in contact with the wrong people. And I know where I work there are security forces that are just waiting for people to come walking up the road.

(Laughter.)

Grab hold of them.

Thank you.

MR. TAYLOR: Michael Taylor, AAPM. Two points when looking at alternate technologies. One is I think that it should be published for anywhere from two to five units what the dose homogeneity is going to be in these alternate technologies.

Cesium is pretty well established. They even put it in the brochures. And we know what the uniformity for dosing the platelets and the blood

units is.

Second, with the technologies, for example, maybe X-ray tubes need to look at how the beam quality changes over time. Are there hardening effects that happen as these beams are left on for many, many hours?

Thank you.

MR. LEWIS: Rob Lewis from NRC. One thing that I have heard several people kind of touch on, but I'd like to pull the string on if -- since we have a broad audience from around the country, people mentioned consolidating irradiation into the blood bank or the effect on rural hospitals potentially.

But are there any differences in the U.S. health care system regionally that would have a disproportionate affect of on one particular region if we were to phase out cesium chloride? The reason I ask, for example, as I understand, in the northeast there is a lot of irradiators in a lot of hospitals. And out west, as I understand the health care system, there is a lot of hospitals that are centers of excellence that you are sent to.

So I was wondering if there is a -- in terms of impacts of phaseout, regional issues in addition to the decentralizing in blood banks or rural

versus urban issues that could be explored a little bit?

MR. BENJAMIN: Certainly. It's our experience that the smaller rural hospitals don't have -- don't perform irradiation of blood. They rely on their blood centers to do that. The larger urban centers will -- transfusing more blood are more likely to have irradiators. So we, as the Red Cross, would be servicing the smaller hospitals.

MR. MORGAN: Yes. Tom Morgan from University of Rochester. There are areas in the country where there are centers of excellence, if you will, in metropolitan areas, where you do have hospitals that have irradiation facilities. But then, you have to drive 50 miles to the next country hospital, as you put it. If you wind up with a bad storm, bad weather, that closes the roads, then you run the risk of not being able to get blood products to where they need to go.

So I think that's something that -- to toss into the equation with regards to consolidations that -- you know, transportation time becomes an issue.

FACILITATOR RAKOVAN: Additional discussion on the issues on the table for this

particular question? Please.

MS. MARTIN: I would just reiterate what -- or one of the questions Rob was asking. My experience is limited to California, and, obviously, our -- most of ours are major medical centers out there, which are your centers of excellence that actually perform the bone marrow transplants. They are the ones that -- and other pediatric oncology or adult oncology, those are the centers that have their own blood banks, because they don't want to depend on, you know, getting them from the Red Cross or other blood banks.

Obviously, that is considered the back up. If for some reason the hospital did lose their irradiator, we totally depend on the back up of the blood banks or the Red Cross.

FACILITATOR RAKOVAN: Any further discussion on regional issues or the (a),(b), and (c) in terms of Q3.1-1?

(No response.)

All right. Let's go ahead and move to the second question. I'll read it again. 3.1-2(a), what would be the consequences if cesium chloride was to be banned for irradiators that are used for industrial and calibration purposes? (b), what is the impact on

existing ANSI standards and licensee conditions that require the use of cesium-137 for calibration purposes?

I think we have touched upon some of these issues in our discussions already. But if anybody wants to specifically address one of these two topics at this point? I'm not sure if I heard any discussion yet about the ANSI standards. Is there someone who is willing to make some comments about that?

MR. MINNITI: Yes. Just for the record, I guess I am Ronaldo Minniti again from NIST. And there are a few ANSI standards that were written recently for homeland security applications, and just to name a few those are ANSI N42.20, N42.32, N42.33, N42.34, and N42.49. And, again, these are specifically for just homeland security applications.

These were written and published between 2003 and to the present, and some are in development. All of these standards rely exclusively on cesium irradiators for testing these radiation detector instruments.

There are other ANSI standards that are written for radiation protection purposes, meaning that to ensure that these instruments read accurately and prevent people from being exposed unnecessarily --

and those are ANSI N42.17(a), ANSI N323(a), ANSI N323(b), and ANSI N13.11, which is this last one is for the testing of personal dosimeters.

FACILITATOR RAKOVAN: Okay. Anyone care to comment or start a discussion? Yes, sir. If you could identify yourself once you get to the mic.

MR. RUSHTON: Robert Rushton, Hopewell Designs. We supply irradiators primarily for instrument calibration, and have been dealing with this issue for some time talking to a number of our customers, including DOELAP, the Army, a number of other laboratories around the world, including nuclear power.

We also do a good bit of work with the international community, and what we found is that cesium is the source that is used. We have looked at whether that could be changed, and from our perspective that cesium cannot be eliminated. Cesium chloride, in fact, could be eliminated, but only when other forms come into play.

We have seen that there would be a dramatic impact on the DOELAP program, on other calibration programs that, as Ronnie had mentioned, could be catastrophic to the community of instrument calibration.

What we then looked at is if, in fact, another form of cesium becomes available, what's the impact on our users and our customers? And what we've seen there is that the financial impact can be quite dramatic. The cost of the source itself is still in question, but assuming that that's somewhere in the same range it was -- what it might be for current costs, that's only one small part of it.

The transportation cost, the modifications to the irradiators, and then, of course, the disposal cost is another question. So all of those can have -- add up to, equal, or exceed what the cost of a new irradiator might be today.

Then, the issue came up as to what would happen as the timeline was established, and another form of cesium became available. What would happen in the interim? And what we looked at there is if someone were to purchase an irradiator today, five years from now, or whatever the timeframe might be, another form of cesium became available, do these irradiators now have to be phased out? And if that being the case, then what would we tell customers now who might be considering making a very substantial investment?

So it's a lot of issues that would have a

dramatic impact in the instrument calibration community that we see as being very dependent on what the timeline is, and if and when another form of cesium might become available.

MS. SHEPHERD: Mary Shepherd, Shepherd and Associates. I'd like to restate something on instrument calibration -- that all licensees, anybody that has a radioactive materials license worldwide has a responsibility and an obligation to provide radiation protection, and that includes having a calibrated instrument, dosimetry, emergency -- and emergency response capability, or that's provided by your local emergency response people.

To restate something even more obvious, if you are a regulator, the States, the NRC, you, too, have to have instrument calibration capability, because you have instruments, inspectors have instruments, they come out and inspect, those need to be calibrated.

I think also regulators also have dosimetry. This doesn't affect just the industrial; it affects everybody on a radiation protection scope. You have emergency responders. In the midwest -- I haven't heard anybody talk on this -- the midwest emergency responders are almost all volunteers on a --

you know, fire departments, any kind of emergency response, in the heart -- in heartland America is volunteers. The cost to them is astronomical to replace.

We have the homeland security issues, the port issues, that has been brought up. But I just wanted to restate something that was probably very obvious, and that was it.

FACILITATOR RAKOVAN: Thanks.

MR. MINNITI: Yes. Thank you, Mary. This is Ronnie Minniti again from NIST. I just want to add to what Mary Shepherd said. As I listed in one of my slides, there are lots of different types of users of these instruments, and I believe we should not overlook the importance of having an instrument calibrated.

This is not a scientific need like some people -- somebody mentioned yesterday, this is a critical need to ensure that people are safe, right? If -- again, as Mary Shepherd just mentioned, if an emergency responder has to walk into a radiological incident with an instrument that is non-calibrated, that -- he or she cannot prevent -- cannot assure that the people they are trying to protect are safe. So it is critical.

And, again, as I said before, about 40, 50 years ago, cesium was established as the reference energy for calibrating these instruments. And there is a reason for that. There are several reasons, actually, but one of them is because most of all these detectors have an energy dependence. And you need to calibrate detectors in an energy region where detectors have a flat response, a constant response.

And this happens around the energy of cesium. I don't want to get very specific about that, but, as was mentioned before also, most of these users -- some of these users have some radiation background, but some of these users are volunteers. And they really on this black box that is given to them, and that has a -- that measures correctly.

We actually -- at NIST, we did some testing a few years ago, and the work is published in the Health Physics Journal, and we tested a lot of different instruments using homeland security specifically. And what we did is we just purchased the instruments from the manufacturer, so we didn't get a special set, and we tested it. It's like a Consumer Reports thing.

And we have noticed that some of these instruments, the manufacturers of these radiation

detectors claim that the instruments would measure accurately within plus/minus five percent over a broad range of energies, right? And this is between 60 keV and 1.25 MeV, the core of energy.

This is the claim in their specifications. What we published in that journal, in that article, after testing all of these detectors, some detectors were off as -- by a factor of two, even three.

So what I'm trying to say is, even with the system as we have it established today, using cesium, and all this network of calibration facilities across the country that I showed in my presentation before, we still have large margin of errors, and we did put in that -- we did recommend in that article published in the Health Physics Journal that manufacturers do need to do a better job in characterizing these detectors.

So I guess what I'm trying to say is that cesium-137 -- the use of cesium-137 irradiators is critical in the nation for ensuring that radiation detector instruments measure correctly. If there is a -- if there would be a suitable replacement, another form of cesium that could give a spectrum -- a cesium spectrum, that would be okay. But from what we heard yesterday, there is not -- as of today, this is not

available.

And we heard all of these different issues that, well, maybe the technology would be available to address the solubility of cesium. However, we don't know if that would be enough to address the dispersibility of cesium.

So this poses another question. Do we really meet the risk requirement, if we get this other form of cesium? I mean, these are all open questions. So, in the meantime, based on all of these facts, should we -- should a ruling be made based on these things that do not exist? And if it's made, the impact, really, on at least the instrument calibration community would be negative, definitely.

So anyway, thank you.

MR. SVAJGER: Good morning. Mark Svajger from Fluke Biomedical. I'll put calibration aside for one second and hone in on the manufacturers of radiation detection equipment.

When a manufacturer is forced to make some design changes to the detector, they have to verify that it will respond appropriately, and that includes over a wide spectrum from, oh, let's say, M-40 X-ray technique to cobalt-60. So cesium-137 is -- it's very important in verifying that the detector has not -- or

the process to develop the detector has not changed.

That would be more important, for instance, in dose equivalent survey meters that -- perhaps if the plating operation changed by a -- I don't know -- a fraction of the thickness of the plating, that will have an adverse affect over the entire range of detection. So cesium-137 being a middle of the line is just as important as the X-rays in cobalt-60. So that's -- that's it.

MR. BIANCO: Just to remind people that we also in the -- Celso Bianco, in the irradiators for blood and medical irradiators, we also depend on calibration. We are part of your community, because if our machines are not well -- if detectors don't measure correctly, we are not going to be very good with our -- for our patients.

MR. BOHAN: Mike Bohan from Yale-New Haven Hospital. You know, when train my nuclear medicine residents, you know, I always talk to them about, you know, technetium-99m is like the perfect isotope for nuclear medicine purposes. It has got just the right energy, it has got a short half-life, it doesn't give off any secondary radiations that cause excess dose. It's a perfect imaging agent. You know, it's just a miracle that we have this particular isotope to do

what it does.

And it -- cesium-137 is one of those isotopes, too. It is the isotope that there is no substitute for. There is -- you know, we might look at cobalt-60, but because it's got a shorter half-life and a much higher energy, it brings with it its own issues. Cesium-137 is -- it's, you know, easily obtainable, because of the way that it is produced, you know, through fission.

And, you know, for all these variety of reasons this is the reason why cesium-137 is in the position that it is today. And for us to just change everything out of the blue, I just don't see that happening, you know.

So I think that one thing that we should do today is to make sure that the manufacturers and the vendors come away from this meeting with a realization that the problem is cesium chloride, the problem is not cesium, and that we really need to go to a different technology but still retain cesium as the primary source of calibration, because of all of the historical background between that source.

And, you know, I can't even recall ever buying an instrument that doesn't have a cesium calibration some place along the line. So it's just

everything is wedded to this. We just can't walk away from it.

FACILITATOR RAKOVAN: Thank you.

MR. SULEIMAN: Orhan Suleiman, FDA. I just have a question. Aside from asking the current manufacturers of cesium chloride whether they could come up with an alternative chemical form for it, has there been any active initiative to encourage research or to come up with -- because I see that two ways. We're not replacing cesium, I sense. I think the issue is cesium chloride sources.

So you can break that into two questions. Do we want to replace cesium, or do we want to replace the chloride form of the cesium? And I think the latter seems to be where -- at least, again, how I'm seeing -- what I'm hearing.

But has there been any active effort to encourage the promotion of that kind of a technology? And whether it's putting it in ceramic -- forget my epoxy suggestion yesterday, but --

(Laughter.)

I'm just -- I mean, has there been an active effort, or has it been passive? We just asked the current reprocessors, "What could you do?" and they say, "Well, we've got other things to do. We'll

look at it."

FACILITATOR RAKOVAN: Someone want to take 30 seconds to respond to that? Please.

MR. JARDINE: Les Jardine, consultant. I just will repeat -- the Russian representative can correct -- but Russia has been doing work for 20 years or so, looking at alternatives for cesium-137 for different applications. They have had a research program. As they summarized, it has not used active cesium-137. But they have two programs for one specific ceramic, one specific glass. That's an active program.

So Mayak, and its institutes, or national laboratory equivalence, are conducting that research on their own, and it's in progress. And the Russian people have to tell you what it is.

FACILITATOR RAKOVAN: Thanks.

MR. ALOY: Good morning. Albert Aloy from the Khlopin Radium Institute, St. Petersburg, Russia.

If you can open the proceeding of the international -- sorry. If you can open the proceeding of the international conference, name is Global '99, which was held in United States, Wyoming, Jackson Hole, I presented the paper about the new glass form for the encapsulation of high amount of

cesium oxide compared with the specific activity, very close to the cesium chloride.

But I only would like to say that in Russia we thought about the new technology and new form for cesium-137 many, many years ago. But, unfortunately, due to economical reason, we cannot develop this technology and implement in the Mayak site. Maybe from '99 we spent about 10 years, so maybe if we combine our efforts and they have intellectual knowledge, and economical basis for resources, and we can implement these new cesium alternative forms very fast.

But, nevertheless, we need to find some additional investment for this, because we need to provide additional testing for compatibility, for leachability, for dispersibility, and so on, in the -- to meet all requirements for safe -- safety analysis and safe implementation of these new sources.

Of course, we need to meet each other from one -- one point of view, the requirements of -- radiological requirements, radiation safety, and from other points of view, the technological availability to be in context of ALARA principles as long as available, which is -- is reasonably available from the point of cost of new technology and new materials.

This is -- maybe I am not very clear explaining to you, but I tried to explain the -- in Russia we thought about new alternative forms for cesium many, many years ago. But we also -- additionally, I would like to say that this technology to convert cesium nitrate into cesium chloride is not a good technology. It is very dirty technology, because we use hydrochloric acid in this process.

And the secondary waste produced during this is a very -- very great amount, and it's very corrosive gases produced during this technology. So because of that, we thought about the new alternative many, many times ago.

But if you have some questions, please, maybe it's more easy for me to answer for concrete questions than explaining in general form.

MR. RAKOVAN: Okay, thank you, sir. Any further discussion on the --

MR. LEW: I have something.

MR. RAKOVAN: Please.

MR. LEW: Bill Lew, University of California. This is just to go on the record to reiterate to the audience members from the Department of State that we should have perhaps financial incentives to link in with our Russian Colleague to

work towards improved forms of cesium. Thank you.

MR. RAKOVAN: Okay, can I focus back on the question on the board? Anyone have any further comments on this before we move on to the next two questions which involve economic consequences?

MR. MINNITI: I would just way one more word. Again, this is Ronnie Minniti from NIST. I just wanted to add to one of the comments of one of the manufacturers of Cesium-137 irradiators. Caldwell (phonetic). As he said, if there would be a ruling to ban cesium based on possible or alternative technologies, the -- I believe that until new technologies are not available, we think we should -- it probably is not a good idea to put incentives not to allow builders of irradiators to continue issuing -- supplying the demand of those who provide calibrations. Otherwise, these need to be upgraded and there will be calibration facilities in that period of time that need to upgrade their facilities and that needs to be there.

So again, I think I'm reiterating what I've said before. Until another form is not available and from what we've heard, that's not there today, we should wait until any ruling is done. Thank you.

MR. RAKOVAN: One more comment and then

we'll move on.

MR. McBRIDE: I'd just like to -- this is Bill McBride from UCLA and representing ASTRO. I'd like to go back just a little bit to question 2 primarily but to also ask other people in the audience a question about the issue of dose rate.

MR. RAKOVAN: I'm sorry, a point of clarification. This question 2 or a different question 2?

MR. McBRIDE: This question. The question before us, it's a more general kind of issue about dose rates and the issue really kind of comes from the point of view of trying to replace a cesium source with an x-ray machine and I think that there are large biomedical research interests which look at low dose exposures. I don't think this has been mentioned so far in any of the discussions. I think that this is a very important aspect of radiation exposure which really I think would be impacted very, very seriously if you had to go to an x-ray machine.

You can't treat animals, for example, with low dose rates. So you can't use that alternative source. It's totally impractical. So cesium irradiators are -- you can use for these purposes and cobalt as an alternative, but the idea of doing any

kind of low exposures over prolonged periods of time is just impossible with an x-ray machine.

MR. RAKOVAN: Okay, Michelle, if you could bring up the next two questions. 3.1-3 is "What would the economic consequences to users be to" -- I'm sorry, "What would be the economic consequences to users if cesium chloride was to be banned"? And similarly, 3.1-4, "What would be the economic consequences to vendors if cesium chloride was to be banned"?

Again, I think this issues have come up a little bit. Does anyone want to go a little bit more specifically into the economic issues, though?

MR. MINNITI: No, I just want -- of course, any change will take -- will require funding, right, and I think the last gentleman who made the comment said that and we should -- we should remember that, okay, anything is possible. We can probably come with a new technology but that's going to require a lot of research, effort and funds, right?

And I mean NIST has an institute that holds primary standards for radiation dose. Our job is not only to disseminate the standard across the US but we also -- you know, we're always looking into alternatives. So there have been in the past, efforts

to try to find other replacements, but again, we can talk about this and speculate and think out of the box, but all these things require time. And so far, we haven't found anything and from what we've heard yesterday, that's the case.

So anyway, I guess going back to the question, yes, this will require funding from someone to be able to pursue new alternative technologies.

MR. BIANCO: I just want to reiterate -- Celso Bianco, America's Blood Centers -- that the estimate that we did on the quick last few weeks is that it will cost for our system, over $20 million just to replace the current cesium irradiators with x-rays and I think that Ronaldo just mentioned time.

Time -- we'll need time not for new different sources, but just to have the other instruments available and all that. And that is a very complex issue that cannot be just done at snapping fingers. And time is money, too.

MR. McBRIDE: I would just like to mention the economic consequences for biomedical research.

MR. RAKOVAN: Could you please remind us who you are?

MR. McBRIDE: Sorry, Bill McBride, UCLA, ASTRO.

MR. RAKOVAN: Thank you.

MR. BROWN: Basically, if we do away with cesium, there is enormous amounts of historical radiobiological research which is based on cesium. That review would have to be redone. A lot of those kind of studies. That's an enormous economic cost. It will cost a lot with animals as well, which goes, of course, against the three Rs.

I think that there is additional costs which really come from trying to bring in new machinery, for example, x-rays. You know, it's actually a lot easier to replace in a blood bank than it is in biomedical research. In biomedical research, and radiobiology for example, we're interested in the response of the mouse brain to radiation, bits of animals, tissues and so on, and this is really kind of technically very demanding. In order to do this effectively, you really need a team of physicists and biologists to get together and rework whole systems.

This is not -- the cost of doing this really is probably five-fold what it is to replace a blood irradiator, just because of the additional issues with respect to homogeneity of the field, et cetera. So this is going to be an enormous consequence. It's going to effect the counter-

measures program and all of radiobiological research really adversely.

MR. BOYLE: I just wanted to comment. I mean, an unusual situation of sitting next to my colleague Dr. Bianco and being able to say at the cost to the Red Cross should be less on behalf to the ABC centers, we have 32 cesium sources. So we would expect our cost to be somewhere around at least $10 million to switch them out. However, Dr. Bianco's estimates may be an under-estimate. I heard yesterday that the decommissioning costs of a cesium source may be much higher than he estimated, as much as $100,000.00 a unit.

Also the cost, the continuing operating costs of an x-ray irradiator is much, much higher than a cesium source. To make the point that we get reimbursed by our client hospitals in user fees for the blood that we provide, and so any cost would be passed on to the hospitals who have no way of getting compensated for those extra costs.

CMS [Editor: Centers for Medicare and Medicaid Services] reimbursement can take many, many years to decades before it meets the new expenses of the sort. So the cost would be borne by the hospitals and I'm not sure they would be very delighted for that

to happen.

MR. RING: Joe Ring, Harvard. In addition to the cost for biomedical research that were identified, you will have to note that much of the biomedical research is supported by federal grants and contracts which require the use of a cesium irradiator in that research. And they would not be able to deliver on those grants and contracts that are already in effect.

MR. MAIELLO: Mark Maiello from Wyeth Research.

MR. RAKOVAN: If you could try to speak a little more into the microphone.

MR. MAIELLO: Sure, sorry about that. This is mainly directly towards you, Ronaldo, because you probably have the expertise in this. There may be, there may be a small group that is probably not represented here today and that might be the commercial calibration services. Now, I don't know that they have Category 2 or above sources. My gut feeling is they have less than that.

I presume then that, you know, should a ban go into effect, they would get to keep their sources. On the other hand, if it's across the board, they go out of business. They depend a lot on that

service. We, in fact, contract one out and have done so for years. The map you showed, I take it, were the government facilities.

MR. MINNITI: There were a couple that are in the private sector but most of them, you're right, yeah, they're federal facilities or state facilities.

MR. MAIELLO: May I ask a question? Do you charge for your services?

MR. MINNITI: NIST does charge for its services, yes.

MR. MAIELLO: It does charge for its services, to this would effect -- a ban, of course, would effect you and a changeover to a different form would effect you.

MR. MINNITI: Yes, it would. However, the main -- I should point out that the main mission of NIST is not to make a buck from calibrations.

MR. MAIELLO: Correct.

MR. MINNITI: It's to maintain the standards and while one is to maintain the standards for radiation dose, right, from gamma beams, and also the second one is to disseminate that standard. Of course, we couldn't calibrate all the instruments in the nation. So the way it works, is we just disseminate the standard via calibrations to secondary

labs, a few secondary labs and then they calibrate the instruments for other labs and so forth. And this way you get, you know, a network established across the country.

Of course we do have to charge because you need to maintain the standard, right, and the facilities so that's what the --

MR. MAIELLO: If a commercial calibration service buys a source, they get a traceability back to NIST.

MR. MINNITI: Yes.

MR. MAIELLO: Does that get in any way renewed every once in awhile or is it a one-time thing?

MR. MINNITI: No, they do have to renew their calibrators, after it decays a period of time.

MR. MAIELLO: So that's more a population of commercial vendors who are probably not here with any representation today would be effected in some way even --

MR. MINNITI: Yes.

MR. MAIELLO: -- though they may have less than Category 2.

MR. MINNITI: Yes, of course, yes.

MR. MAIELLO: I just wanted to get that on

the record.

MR. MOSHAASHAEE: Moji Moshaashaee, Schering Corporation. Just like other companies, we contract our basic meters to be calibrated by smaller companies. We're talking about economic, actually consequence, imagine how many smaller companies, maybe not represented here and what would be the consequences of banning cesium sources to all these companies, the economic crunch that we have a lot of businesses that are going to lose actually, their job.

MR. STRACCIA: Fred Straccia, Radiation Safety and Control Services. We do health physics consulting and we also have a commercial calibration laboratory in the State of New Hampshire. And we do have one Category 2 source, so just to mention that. We would be greatly effected by any type of ban on cesium chloride with our one -- we have a couple of -- one beam source and one box calibrator, both cesium chloride and we find it necessary for cesium. The ANSI standard for portable survey instruments, ANSI 323(a) does specify that calibrations be performed on the type and energy of the radiation to be measured and obviously, as has been stated many times yesterday and today and I'll just reiterate, we do need to use cesium. That is the one isotope that does provide

this type of calibration.

Cobalt 60 won't work, x-rays won't work. So just to reiterate, you know, we do use cesium. We do have a Category 2 source and we would be extremely adversely impacted should there be a ban on these sources. Thank you.

MR. THOMAS: Jerry Thomas of Via Chrisi, Wichita, Kansas. From a Midwest hospital where we've indicated that we might have differences in care delivery across the country, we looked critically at the cost or replacing our cesium with x-ray. Because of the concern about the reliability of the existing x-ray product, we would have to replace irradiators, two devices for one because we're the principal and sole provider of blood irradiation for a majority of the products with south central Kansas.

I think that's also going to be applicable to other centers of excellence throughout the Midwest. I can only, though, speak for what we have in Kansas.

MR. MORGAN: Tom Morgan, University of Rochester. Just doing a little bit of math here in my head the last few minutes, to decommission and dispose of our irradiators through an approved vendor and to purchase new equivalent irradiators assuming that our current ones could not be reloaded with some other

form of cesium chloride, would cost us between two and a half and $3 million at a minimum, and we could not replace one or two of those irradiators with x-ray irradiators because of the nature of the biomedical research that we do.

So that's just a single point of cost for one institution.

MR. RAKOVAN: A couple more comments?

MR. SULEIMAN: Orhan Suleiman. If you were to decide to phase out cesium chloride, wouldn't that -- but would allow a grandfather period for the existing sources, would that possibly have the unintended consequence of people getting as much cesium chloride before the ban took effect, and therefore, increasing the probability of more of the stuff out there? Has the been -- I mean, that probably would happen if -- it's got a 30-year half life so --

MR. RAKOVAN: Anybody want to touch that one, briefly?

MS. SHEPHERD: Mary Shepherd, Shepherd and Associates. I don't think anybody could gear up for the capital equipment costs that quickly. Cesium irradiators are expensive and people need to budget for it. On research cycles, it is congressionally,

you know, funded through NIH had whatnot, just as the off-site source recovery program is funded by Congress. Those are years in advance, so I don't think you'd see a lot of people hoarding on those applications at least.

MR. RAKOVAN: One last comment, and then we're going to move onto the final question.

MR. POWELL: Brian Powell, Constellation Energy, so representing nuclear power. I've been trying to think this through in my head and I did talk to our calibration specialist at length on the phone yesterday. The first point that he said is that in the replacement of the cesium chloride, to try to go to something else, by the time you add in all the costs of losing the knowledge of a program that's been based since the plan has been running, cesium chloride to try to go to something else, he estimated about a million dollars per unit.

But the bigger question to me goes back to that cornerstone and my ability to accurately tell people what dose it is that they're getting. We have -- as I mentioned before, a fresh load of 100 millirem of unintended occupational exposure. So we need to be able to measure energies at very low levels.

If we are unable to do that, and I was in

the position of having to go to the corporate headquarters and say, "I'm unable to tell you what your workers are getting at doses of low levels accurately", and the NRC came in to inspect our site and I had the same answer for them, I don't imagine that our plants would continue to run.

Then we're faced with other circumstances as well as you know, exactly what is it that we're going to do with all the plants not running? Can we still go out there and keep our workers safe while they're monitoring the site?

So it's not just nuclear power but I understand that you know, there's a significant economic impact to the blood bank. There's cleanup sites, there's medical sites. This is an all-encompassing but phasing out the cesium chloride is putting I'd say radiation protection departments in a position of having to make some recommendations that are unfavorable.

MR. RAKOVAN: Two quick questions, or two quick comments, please.

MR. BODNARUK: Ethan Bodnaruk, NNSA, National Nuclear Security Administration. While we're on the topic of consequences, I just wanted to mention briefly --

MR. RAKOVAN: Could you get a little closer?

MR. BODNARUK: Sure. I wanted to mention briefly that in addition to the security work we do on facility upgrades in irradiators, that NNSA just started a research and development program on alternatives recognizing that the only way to minimize the consequences, economic consequences, is to have alternatives that are viable and acceptable to users. So I just want to make that note.

MR. RAKOVAN: Closing comment and then we need to move on.

MR. RING: Joe Ring, Harvard. Just to give you a quick assessment of what we think it's going to cost if we switch from cesium to x-rays. Simply for the initial cost to switch irradiator systems, no other changes, we were looking at three and a half million dollars just for the university.

MR. RAKOVAN: Okay, Michelle, if you could go ahead and put the last question for this panel up, 3.1-5(a), "Should the NRC discontinue all new licensing and importation of these sources and devices? "(b), What is the regulatory basis and (c) who, NCR, DHS or jointly should conduct the risk analysis"? Anybody want to address any of these

issues?

MR. BIANCO: I would just say, no.

MR. RAKOVAN: Is that (a), (b), (c), all of it?

MR. BIANCO: Well, they all depend -- (b) and (c) depend directly on (a) so I think it goes for all of them.

MR. RAKOVAN: Anyone have a different opinion than no?

MR. MINNITI: I'll just say no also to (a).

MR. RAKOVAN: Okay, support for (a) is okay as well.

MALE PARTICIPANT: I certainly would go with no.

MR. RAKOVAN: Rob, do you want to say something? Please, while Rob's going to the mike.

MS. GILLEY: Well, ACR was also on the record as saying no.

MR. RAKOVAN: Okay, I wasn't trying to take a vote, but -- Rob?

MR. LEWIS: Rob Lewis from NRC. Let me -- you know, we didn't come up with this question. This is a direct recommendation to NRC in the NAS report, now, we are in a position of needed to act upon. So

while no is a perfectly reasonable answer for you to say, I'm not in a position that I can say no without saying how and why and it's what the BNC are about. Even if we say no, we need a regulatory basis to say no and yes, we disagree with you or we agree with you or we agree with you in part.

So we really need your help in flushing out no, but why.

MR. RAKOVAN: Thanks for the clarification. I'm going to go to the mikes first. Back, please.

MR. MILLS: Grant Mills with North Carolina Radiation Protection Section. I believe early on I heard most of the panelists indicate that implementation of the IC's was successful and that there were benefits from that. And I was wondering what was the basis for that successful determination? Was it regulatory inspections or was it internal security evaluations or I guess, what is your basis for determining that implementation has been successful to this point?

MR. RAKOVAN: I'm sorry, I missed who that question was focused on.

MR. MILLS: I'm sorry?

MR. RAKOVAN: Who was that question

focused at, please?

MR. MILLS: The panel in general.

MR. RAKOVAN: Okay, anybody want to address that? Please.

MS. MARTIN: I would only address it as having the personal experience and we had an unannounced inspection and it was very effective to have -- basically, the inspectors stopped at the door. So that was our justification for saying that, yes, we had implemented the proper controls. The person that we had committed to using personnel for those -- for that compliance, and it worked.

MR. CHARBONNEAU: Kevin Charbonneau from Yale University. To, you know, stop licensing potential applications for cesium irradiators could have a significant impact on the university environment. Researchers, that's what their whole process is, is trying to develop new experiments, new research to develop cures for certain diseases in certain things.

If we limit their ability to have access to these things while this process is underway and trying to develop a new form of cesium chloride, we could, you know, definitely hamper some of the research that, you know, could impact us from today

on.

MR. RAKOVAN: Front mike and then back mike, please.

MR. TOOHEY: Good morning, I'm Dick Toohey. I'm President of the Health Physics Society. If anyone doesn't know what the Health Physics Society it, we are the US national professional society for radiation safety specialists. We have about 5500 members.

Generally, we do not advocate any particular use of radiation or radioactive materials. We are advocates for radiation safety. However, the basic principle, one of the basic principles of radiation safety is that of justification and that is any use of radiation, radioactive materials should have a net benefit which is greater than the net risk of that use.

And in that context, I'd like to help the NRC answer no. We think that cesium chloride sources should be subject, through the normal licensing process both for new licenses and renewals, to evaluation of justification of that source, and that it be incumbent upon the licensee to demonstrate in the license application that the net benefit of the new or continuing use of a cesium source outweigh the

risk in detriment.

The risk equation has changed since 2001 and that is really what justified this and that needs to be looked at, of course, but we would suggest that license applications investigate alternate technologies and determine the licensee's or I should say document the licensee's determination that no suitable alternative exist on whatever basis, whether economic, availability to do the required job or whatever.

And the NRC should develop guidelines for determining that sort of thing as part of the licensing process. The decision to discontinue or replace a source should be made on a source by source basis unless considering the specifics of the source use and location. As we've already heard, security requirements for a cesium calibration source at a nuclear power plant or a military base, where there are armed guards with no sense of humor, could be very different from the security requirements or provisions at a blood bank or a hospital for example.

And we have submitted our comments in written form and I'm not going to read the whole thing in, in the interest of time. But the discussion of the regulatory basis does trace to the basic principle

of justification. And the big question now, is who should conduct the risk analysis. Well, we think everybody who has a dog in the fight should be involved in the risk analysis which is both radiation safety professionals, users, manufacturers and so on and also involving people with specific expertise in the new risk environment that would include Homeland Security, the FBI and the National Nuclear Security Administration.

A generic analysis is necessary for identifying and high risk sources and providing guidance for risk analysis to be provided and we also think this sort of risk analysis and guidance needs to be updated periodically, say every five to 10 years as technology changes both for the use of the source and ways of protecting these sources. And I'll stop there and we'll have more comments on other questions later on. Thank you.

MR. RAKOVAN: Thank you. The back mike.

MS. SALAME-ALFIE: Hi, I'm Adela Salame-Alfie. I'm representing the Conference of Radiation Control Program Directors. Essentially every state radiation control program is represented. We sent out a quick survey and though we didn't get 100 percent response, it was a resounding 100 percent no to

question (a) from the program directors that responded.

I would like to read two quick statements on Parts (b) and (c) and we plan to submit written comments which will elaborate on these issues. On Part (b), we're saying that prior to taking any action to discontinue licensing these sources, the Federal Government should evaluate the risk of radioactive materials in relationship to the risk of other hazardous materials. Increased controls and security improvements in the industry have made the radioactive sources safer and the vulnerability to these devices should be reduced.

On Part (c) as to who should conduct the risk analysis, the membership feedback was that the analysis should be performed by independent institutions or national labs that are not looking to promote additional activities or training. Any action to discontinue or replace radionuclide radiation sources that meet the fundamental radiation protection principle of justification that is, that the net benefit versus risk of using this source is positive, must comply with the recommendation of the National Academy of Sciences, National Research Council.

That replacement of the source should be

done with caution insuring that the essential functions that the radionuclide radiation source performs are preserved. Thank you.

MR. RAKOVAN: Thank you. Any further discussion on any of the questions or issues under 3.1 Potential Rulemaking Issues and Justification for Regulatory Change? It looks like we have some, please, at the back light.

MS. WHITWORTH: Yes, I'm Julia Whitworth with the Offsite Source Recovery Project at Los Alamos National Laboratory. I just wanted to say on both this question and the previous one, agreeing with several of the previous commentors that it does greatly depend on the --

MR. RAKOVAN: Go ahead and bring the mike down. That's okay. Yeah, there you go.

MS. WHITWORTH: Okay there we go. The answers to those two questions do greatly depend on the existence of replacement technology and I think the example that we've been through in the last five years or so with cessation of US sales of americium is instructive since that occurred in about 2003, I believe. There is now only one supplier of americium -- well, there are starting to be others but the price of americium has increased five-fold. So it does --

the economic consequences do greatly depend on availability and wide quantity of the replacement technology and also of course, on the disposition cost.

There's a lot of uncertainty right now about what the disposition pathway for these types of sealed sources would be and that uncertainty creates a huge uncertainty in the economic consequence calculation. That's what I wanted to say. Thank you.

MR. GERSABECK: Yeah, Edward Gersabeck with U.S. Department of Agriculture. Yesterday we heard sort of the story of an accident in a developing country and it seems as if this panic response to ban of use of sodium chloride is a response to that event. But the US is different and in the nine Husman irradiators that we operate, those machines have an inch shell of steel and the cesium chloride is welded in place by a plug that becomes an integral part of that machine and should someone get by our armed guards, should someone get into the room, someone get by all the monitoring, things we have to safeguard those machines, I don't see how they would easily get this sodium chloride or cesium chloride out of those machines in any easy obtainable fashion.

The other thing I would say is that as the

US Government is the owner or co-owner of these machines, we are certainly aware and cooperating with the NRC and all the guidelines for safety and safeguarding and I think we've had good stewardship of these machines. So I think the risk analysis has to go beyond just saying cesium chloride is soluble. You have to look at where these machines are, what kind of machines they are installed in and who actually is responsible for safeguarding these machines. Thank you. Because I doubt that our machines would ever end up in a landfill or a metal recycling. I just don't see that happening, you know, with the US Government being co-owners of, like I say, these Husman irradiators. Thank you.

MR. RAKOVAN: One more comment and then I'd like to let you guys go before the food goes away. No pressure.

MR. HEINIG: I'm Steve Heinig. I'm with the Association of American Medical Colleges and I think this question would be of real interest to members of Congress also. I think there will be many of them that would wonder why they wouldn't want to discontinue new licenses.

Given what's been said earlier, that it would be really beneficial to have an alternative form

of the cesium isotope, ceramic or glass or what. I have two views, two possible impacts of a moratorium or a discontinuing of new licensing. One is that it would encourage development for a new form of the cesium. Another is that it would have a chilling effect and it would just get developers, vendors, whatever, out of the business all together. And I guess I'm putting it to the panel or to other people in the room, if they think there would be an impact either way.

MR. MOSES: Paul Moses, Best Theratronics. If you were today to say no more cesium units out there, of course, we've heard the science community indicating the impact on the millions of dollars that would be required to look at how they are going to do it. But the other things is, is if you look at blood banks for example, if they have a high volume throughput requirements, typically, they would order what's called a GammaCell 3000 Model 2. The processing capability on that unit, you can have four blood bags to five blood bags in the canister and it would take you two and a half minutes.

The x-ray unit required right now that's available on the market right now that we also sell, it would hold two blood bags at a time and its

processing time is five minutes. So you'd have to buy two x-ray irradiators to replace the one. So there would be a big financial impact but then if you start looking at a supplier, we have cesium, if course, and what are we going to do with it?

So we'd be looking at other countries to ship it to pretty quickly, I guess in terms of products, but that deals with another problem at another time, I guess, in the discussions. But I just -- I don't look at that as being a feasible way to just cut this right out, right now.

MR. RAKOVAN: Okay, two closing comments and then we'll move to the break.

MR. BOYLE: Can I just comment on that last one?

MR. RAKOVAN: Okay, go ahead, quickly, please.

MR. BOYLE: I want to point out that in the American Red Cross system we have below capacity with the current gamma cells that we use and we're probably running at 25 capacity usage one shift a day. So I'm not sure that the two for one argument directly applies.

MR. KAMINSKI: Just Joe Kaminski, Radiation Oncologist. It's certainly too premature to

answer yes to this question at this point, but with all technologies, there is resistance to new technology and we saw similar debates, although I wasn't present 20 or 25 years ago with moving from cobalt gamma sources in treatment of patients over to LINACs about problems with the fidelity of the machine, whether it will break down and so forth.

So the point is now LINACs are commonly used. We don't use radionuclides as therapeutic sources for teletherapy any more except in gamma knife but even that's probably over time going to be phased out just because of LINACs and better capabilities for stereotactic radiosurgery and so forth was a standard LINACs.

MR. RAKOVAN: One last comment before we take a break.

MR. TAYLOR: Mike Taylor, AAPM. Just is there anybody in the group that can approach a group that hasn't really talked and that is the big industrial irradiators and how about non-destructive testing or talk about risk analysis? I think those old cameras sometimes disappear.

MR. RAKOVAN: Anybody want to address that real quick? All right, seeing no hands, let's take a half an hour break. We'll start back a little after

10 after.

(A brief recess was taken.)

MR. RAKOVAN: Okay, let's go ahead and get started. Just a few quick reminders; for those of you who parked in the parking lot over here, they do have these vouchers at the registration table. I was told a few people either didn't hear about them or didn't collect them yesterday. So if you parked over there, please take some time to pick one of these up so you won't have to pay for parking.

If you have a business card and you've made a statement, the transcriber has asked that you could drop one off for him, that way you can make sure that he has your name and affiliation properly spelled and properly represented in the transcript. That would be a great help. You can go ahead and just drop them anywhere on the table over here or if you want to put them on the corner of the panel table, that will work as well and we'll collect them.

Just to remind you, as we're kind of going along in the second day, we've had a lot of discussion, we've covered a lot of ground. All of it has been taken down into the transcript for the meeting. So if you want to just refer back to a point that's already been made, when you make a point, that

would be appreciated to try to keep the conversations focused primarily on the discussion topic at hand.

And before we get started with the panel, there were a few questions that we kind of threw into a parking lot and I think, Cyndi, are you going to address those, or John? You'll both address them. Okay. Why don't you guys come and take the microphone then?

MS. JONES: Cyndi Jones with the NRC. I think, Barbara, your question regarding x-rays and QA/QC was discussed a little bit more yesterday and I would offer that we could take a look at the transcript with it's published and see if it's answered the question, but there clearly was a lot more QA/QC that needed to be done in order to make sure that the beam was hardened for the right energy that is needed for the application that it's being used at. And that's kind of the general answer for that.

And I think John will answer the large industrial radiator question that we had at the end but suffice it to say that those devices in this country at least, are cobalt-60 and they're outside the scope of this workshop. Thank you.

MR. JANKOVICH: We did look at the

question of large scale panoramic irradiators and most of those use cobalt sources and we only just found one facility at the University who is using cesium sources. And those -- that university, that facility, is under increased controls.

MR. RAKOVAN: Okay, let's go ahead and move onto our panel for Issue 3.2, Transportation and Storage Issues Associated with Removal of Cesium Chloride Sources from Licensee Facilities. There's three questions to address in this particular issue. Michelle, I'm going to unveil and hope that you -- all right, very good.

Question 3.2-1(a), "Are there transportation packages available for transportation and the second (a), which I guess should be (b), who should bear the transportation costs. Q3.2-2 (a) how could the current cesium chloride sources be disposed given that cesium chloride is defined as a greater than Class C source and currently has no disposal mechanism in the US. And (b), if disposal was made available by DOE what would be the cost of disposal, and finally, Q3.2-3(a) where could the decommissioned sources be stored and (b) what disposition options are needed in the United States?

If we could go ahead and start with our

panelists introducing themselves, please. Ms. Gilley, if you'd like to go first?

MS. GILLEY: Good morning. Debbie Gilley, representing the Advisory Committee on the Medical Use of Isotopes.

MR. MENNA: Good morning, I'm Blair Menna from Best Theratronics.

MS. ROSSER: Good morning, Constance Rosser, Food and Drug Administration, Center for Food and Applied Nutrition.

MR. RAKOVAN: And I'd ask the panelists to not be afraid to get close to your microphones so that everyone can hear you. You've got your own, so go ahead and make yourself comfortable. Do any of you have opening statements or presentations that you'd like to give?

MR. MENNA: I have a presentation to answer the first question. So I'm Blair Menna from Best Theratronics. We manufacture both x-ray and cesium chloride irradiators. The first question is, are there transport packages available? The short answer is, yes, there are. Next slide, please.

We started a program 10 years ago to design, test, analyze and have certified a fleet of transport packages. The ones shown here are for our

cesium chloride irradiators. I'll quote the models just for the record. On the left is our F-430 transport package. It was designed to ship our GammaCell 40 research irradiator.

On the right in this photo is our F-431 transport package which was designed to ship our gamma cells 1000 and 3000 blood irradiators. Next slide, please. So those two first the smaller one, the F-431, it has a payload of about 2700 pounds which corresponds essentially to our blood irradiators plus the internal bracing. Both of these packages were -- the safety analysis reports were submitted to the NRC. The F-431 has a C of C Certificate Number 9310. The F-430 also has a C of C Number 9290 and it has -- it's a larger, physically larger and heavier container.

It has a payload of approximately 4500 pounds. That F-430 turns out to be our workhorse. There's a lot of the devices that we've been talking about over the last day or so that fit into that category and work -- fit very nicely in this over-pack. For commercial reasons we have not certified competitors' units through the NRC but through the Canadian Nuclear Safety Commission. We have submitted safety analysis reports and we do transport some of our competitors' models. Next slide, please.

Then the largest of our self-contained irradiator over-packs is the F-423. This was designed to ship large cobalt-60 irradiators. It has a payload of about 10,000 pounds and was also certified by the US NRC, C of C 9299. That's it for our self-contained irradiator transport packages. We also have the ability to ship other products. Next slide, please. We ship bulk sources. We have our flask Model F-127 which is a self-shielded. It's a lead shielded container, has a maximum authorized content of 60,000 curies of cobalt-60 and we also have a fleet of teletherapy source changers.

Generally, they ship today only cobalt-60 but they are certified for cesium-137. Our F-147 round drawer source changer is certified for up to 8,000 caries of cesium. Thank you.

MR. RAKOVAN: Please.

MS. ROSSER: As a consumer and a private citizen, I think it's important to start rethinking the cost of doing business with the cesium Category 1 and 2 sources. If you're familiar with Department of Defense base realignment and closures, we do have a facility moving into my community that has a lot of calibrators. So we're going to be increasing the number of calibrators at Aberdeen Proving Grounds and

yet as community, we are not being informed of these issues and how they're going to be transported, if they're going to be consolidated with those that are already there in existence.

When you start taking into the public interest I know one person here yesterday said they were representing themselves as a private citizen, we're stakeholders and we haven't addressed the issues for the private citizen living in these communities. What if you become an interim storage facility, are you prepared to address the public with some of the issues that may be resolved that you would have to have increased security. You may not be able to access different areas.

So I think as a stakeholder, we do need to look at the public interest and dense populations where we may be having interim storage or even transporting them.

MR. RAKOVAN: Further discussion on transportation and storage issues? Please.

MS. SHEPHERD: Mary Shepherd, Shepherd and Associates. I have a question for Blair. Is your -- are your packages for -- approved for domestic US use at this time or are they import/export only?

MR. MENNA: The -- we are approved for

domestic use in the United States to transport our -- the irradiators that we have designed so we have not -- when we design these packages, Mary, we -- we're mainly interested in global transport, international transport because we sell our devices all around the world. But we do have a large installed base in the United States and we have customers that often request to have their devices moved and so for that reason, we had the original application our models certified by the US NRC so that allows us to do domestic transport.

Assist irradiators, for example, the IBL-637 and the model 437, we are only allowed to export because what we have is a CNSC certificate that was endorsed by the DOT.

MS. SHEPHERD: Okay, thank you.

MR. MENNA: I guess, to just elaborate a bit on that, we could, of course, submit to the NRC for -- to have that C of C expanded. We just haven't had a commercial need to do it at this point.

MR. SULEIMAN: Orhan Suleiman. I haven't stayed on top of some of this stuff but where are you transporting these for storage? I mean, I understand you can manufacture them. I understand you can ship them to and from, but I understand there's a storage or a waste disposal -- I hear this in the paper all

the time and I hear that the hospitals can't get rid of their waste now, so where would these sources be disposed of?

MR. MENNA: That's an important question, because I think the word, "disposal", has a different meaning for a lot of different people and it's probably important to get the semantics correct here. We have a relationship with Atomic Energy of Canada, Limited, where they will take our disused cesium sources from us. We generally tend to call that disposal but it's an inaccurate use of the term. It is essentially long-term storage.

So we do not have a Canadian solution to the problem. My understanding is, in the United States there is not a permanent solution to the problem either. So the question is up for discussion and unfortunately there isn't a simple answer.

MR. RAKOVAN: Anyone want to elaborate on that? Yes, sir, please.

MR. RUSHTON: Just to address the issue --

MR. RAKOVAN: I'm sorry, could you please identify yourself?

MR. RUSHTON: Robert Rushton, Hopewell Designs. Currently, there are a number of shipping packages that have been retired and, of course, as of

tomorrow, the 20 FC along with a number of over-packs will no longer be able to be used. So until new packs, new casks are approved by the NRC, which is going to take some time, there will be a pretty severe shortage of shipping casks, both domestic within the United States as well as international shipments.

MR. RAKOVAN: I think someone is irradiating an elephant.

(Laughter)

John, you had a -- do you want to go to the podium?

MR. JANKOVICH: John Jankovich, NRC. It was good to hear Blair Menna's presentation that Best Theratronics has a number of packages which are C of C approved. However, we have to look at the number of packages they have. They are one manufacturer, distributor of new products and they have the packages to deliver their own product. And that's what their number of packages are designed.

However, if we talk about the ban or collecting the irradiators what we have all over the country, we will need a large number of packages in case we want to do that in an acceptable time frame. For example, even one shipment going there with one package removed the irradiator from its physical

location, packing it, transporting to disposal site is a minimum of two weeks.

In our working group, we discussed this transportation cycle. And if there is let's say five or 10 packages available, we just have few transportation shipments a year and we talk about hundreds and thousands of units to be moved. So we need a large number of transportation packages and that must be kept in mind.

MR. RAKOVAN: Further discussion on this issue or also see if we can -- sorry, Ms. Gilley?

MS. GILLEY: Yes, I think the medical community would like to see this workshop as we look at going to alternatives to cesium chloride, parallel processes, we must address long-term storage and disposal issues. They must work simultaneously. Having an alternative to cesium chloride and not having a disposal option for the existing units that we have, doesn't gain us a whole lot. Thank you.

MR. JARDINE: Les Jardine, consultant. A question, could someone elaborate how the cesium sources are removed from the Mayak Ozersk site to some place in the US? What path does it take when it leaves Russia and eventually it ends up an irradiator. I don't have a -- I'm just not aware of that.

MR. RAKOVAN: Does someone else want to take a 30-minute shot at that?

MR. COPPELL: Dave Coppell from REVISS Services. We move them in transport containers. These are BU-approved containers. I don't think there's a whole lot of point in discussing the precise route so I'm not going to do that, but they go through the UK. They're then transferred to the equipment manufacturer, wherever that may be. There's not much more to say about it. It's an approved process.

MS. SHEPHERD: Mary Shepherd, Shepherd and Associates. To elaborate on Dave's comment, it's also an extremely regulated process with very many approvals for domestic and international including the NRC import/export permit and then you have all kinds of domestic issues and permits and there's security issues that you can't talk about at this meeting or any where but it's highly, highly regulated.

MR. RAKOVAN: Additional discussion on this question specifically. I don't know if we've attacked Part (b) here, who should bear the transportation costs. Any opinions on that? No opinions on who's going to pay for something?

MS. ROSSER: I think when we start looking at life cycle management, one of the things we have to

begin adding in to our budget is the cost of transportation, whether it's a replacement of cobalt-60 or if we continue with the cesium, is did we consider the disposal cost or the transportation? So we share part of that as a user but then we're looking for the government to come and help us out in some of these new requirements that we had not foreseen previously.

MS. GILLEY: I suggest that the medical community doesn't have the funding for the transportation costs if they are significant.

MR. LEW: As a stakeholder, the Federal Government should bear the transportation costs similar to the transportation costs for the offsite recovery program.

MS. FAIROBENT: Lynne Fairobent, from AAPM's perspective when we look at costs that may be incurred simply because of a perceived risk to remove the sources from use, that may be security-driven. We believe that there should be incentives and this also though touching into Issue 3.3. We believe that the incentives should be established so that the full cost of the removal and disposal is borne by the Federal Government if this is driven simply because of perceived security concerns.

MR. RAKOVAN: Okay, I'm sure we'll get into more of that after lunch. Any further discussion on transportation issues before we move to the next question? Nancy, if you could introduce yourself, please.

MS. OSGOOD: I'm Nancy Osgood, and I work in the NRC's Division of Spent Fuel Storage and Transportation. And I guess I would like to, after it appears that everybody else has finished their discussion about the first part of this question, which is the transportation packages available and I think Dr. Jankovich also eluded to the fact that we're -- with respect to replacing a lot of sources, we are talking about a different level of transportation activity than we have seen in the past.

And there are a large number of transportation packages that are being retired. As a matter of fact, tomorrow is the last day that they can be used. These are packages that are very dol designs that were originally certified against regulatory standards that were developed by IAEA in 1967 and IAEA terminated use of these earlier designs in their regulations dated 1996 which were implemented in 2000.

NRC followed suit through a participatory rule-making process where we gathered input from

stakeholders in developing our regulations for transportation. And in 2004, we issued our final rule where we would eliminate or terminate the use under general license of these older designs. There are about 39 designs that are being terminated. Not all of them are for spent -- for high activity cesium sources but there are a number of packages that are being terminated.

We're relying on the public sector to develop new package designs. We have some replacement designs that have been developed and have been certified and others have been -- are in the pipeline but I think it is important that people understand that there is a potential shortage of transportation packages that can accommodate these sources. I think Nordia or Best Theratronics has been very pro-active in anticipating these regulatory changes and so they have pursued vigorously certification of designs to accommodate their products. But I think in general, you can say that there are very limited supplies of transportation packages and the phase-out of these very, very old designs I think, could exacerbate that problem and we are counting on the private sector to develop and fabricate new transportation packages.

MS. WHITWORTH: Julia Whitworth, again,

with the Offsite Source Recovery Project at Los Alamos and I thank Nancy for her comments. Nancy is exactly right, there are specification packaging that are about to expire. One that we commonly use is the 20 DLC that is expiring tomorrow. We do have -- I don't like to, you know, whine about this problem because we've all known that this was coming. So we should be ready, right?

But I did want to say industry certainly is designing containers to be able to -- or already has containers certified to move devices that they designed and that they buy and sell or have designed in the past in some cases. But there are lots of containers out there, old ACL and Oak Ridge designs and various others that are no longer sold. Many of the manufacturers are out of business.

There are not many things on the horizon that have a wide enough application to be able to over-pack all of these different designs and that's one of the main problems that we foresee. I also wanted to say in terms of who should bear the costs of the transportation, a lot of what we've recovered have been at old places like high schools, old gamma meter irradiators that were distributed back in the `60s and `70s from high schools for irradiation experiments in

high schools and things like that are at small public hospitals that don't have a lot of financial resource. Those are really problematic and who's going to bear the cost of transporting those and doing something about them?

We're trying to do as much as we can to help solve that problem but it's a larger question for the federal community and Congress.

MR. RAKOVAN: Further discussion on the transportation issue? Cyndi? Yeah, please.

MS. JONES: Cyndi Jones, NRC. As long as we're on the transportation issue, if there is an individual in the audience that can answer the question regarding cost of transportation using the available casks for cesium chloride sources, we've gotten a wide range of estimates for rental of these transportation casks and if there's anyone that has that information, that would be helpful to us. Thanks.

MR. MENNA: I can take a bit of a stab at it. I don't want to get into very specific numbers but the NAS report quoted in the order of $50,000.00 for a single shipment. Bear in mind that was with the old spec packages. So I said that we'd just -- well, we ran a program for about five years, started about

10 years ago. We literally invested millions into this whole venture, if I can call it that.

So I would suggest in answer to your question, that the $50,000.00 number is no longer applicable. It's going to be a lot higher than that.

MS. SHEPHERD: Mary Shepherd, Shepherd and Associates. I have to agree with Blair. It is going to go up significantly. Using the spec packages that are going out of service, depending on the activity, it could be anywhere from 12,000 to probably 24,000. That goes away tomorrow. If there's a special permit granted, there -- it will again go up because of the restrictions placed on special permits until our packages are approved. And we have been -- we are in testing for our new transportation packages as we speak right now, but there's still the modeling and the application permit process to NRC to go on for domestic and then we'll go to international as well.

MR. RAKOVAN: Any further discussion before we move on? One more?

MR. BOYLE: Thank you. I'm Rick Boyle with the Department of Transportation. So I'm trying to listen and I'll be here all day if you would like to talk about spec packages, but I think we need to be a little clearer that these packages actually went out

of service in `95 when the IAEA took them out and they went out of service internationally when we stopped issuing certificates for them, around 2000. So an international issue is not really applicable. You haven't used specification packages or Type B for end packages since around the turn of the century.

(Laughter)

About five years ago, we did put out a rule-making that said the specification packages and B(packages were going out of service in five years. And at that time in the rule-making, everyone accepted that. We didn't receive significant comment to say five years wasn't enough time. And over the past year, we found out or people have brought it to our attention, they did need more time and as I think Mary eluded to, Ms. Shepherd, excuse me, we have a permitting program to continue the use for those that have shown a good-faith effort and have put a design to paper and actually built it and tried it, test it, or have it through the NRC. We have a permitting process for the domestic transport and maybe its specification packages exactly. Some of them are their own packages.

And I think -- I don't want to speak for the NRC, but they have a similar program for B(

packages to carry you through that maybe you thought five years was enough time but it didn't turn out to be true. So on a case-by-case example, basis, we've extended that and that would also include the off-site source recovery if they're recovering in this country.

When they go overseas, of course, we haven't used spec packages since 2000. So I'm not sure what they'd by using to recover them overseas. And I think it is fair, you would say it was Best Theratronics that much more proactive than everyone else? No, they were NDS Nordion in Canada and Canada took these regulations to heart more in the `95 time frame and said, "No more spec packages" and pushed Nordion to develop these types of over-packs and types of packaging so they're somewhat ahead of the time because Canada looked at it as an international IAEA issue. So I know -- I apologize transportation was on the agenda today. I heard it was talked quite a bit yesterday. I'll be here the rest of today if you'd like to talk over lunch, at a break. I didn't mean to dominate the floor. Thank you.

MR. RAKOVAN: Thank you. Okay, let's go ahead and move onto the next question, 3.2-2. "How could the current cesium chloride sources be disposed given that cesium chloride is defined as a greater

than Class C source and currently has not disposal mechanism in the US and also if disposal was made available by DOE, what would be the cost of disposal? Anybody want to address either of these questions? Are you guys ready for lunch already?

MR. RATLIFF: Richard Ratliff, Texas Department of State Health Services and representing the Organization of Agreement States. I think we're all waiting with bated breath for a DOE greater than Class C waste site, and I think that's the big issue of the day with multiple things even besides the cesium sources where we have licensees with greater than Class C wastes that are having to store them and so I'm hoping that DOE has plans that are going forward with a storage and disposal site.

MR. RAKOVAN: Okay.

MR. RYAN: Just to help the record a bit the --

MR. RAKOVAN: If you could introduce yourself, please?

MR. RYAN: I'm sorry, Mike Ryan, ACRS. Cesium chloride is not defined as a greater than Class C source. Anything that contains cesium greater than 4600 curies per cubic meter is a Class C source. So it's not cesium chloride that makes it Class C, it's

the concentration.

MR. RAKOVAN: Thank you for the clarification.

MR. JOYCE: Hi, my name is Jamie Joyce. I'm with the Department of Energy and I work on the greater than Class C disposal project. And I'd like to update you on our process. We formally kicked off the process in July 2007 with what's called a notice of intent to prepare Environmental Impact Statement and we conducted public scoping meetings across the United States on the disposal alternatives that we've identified.

Where we're at right now, the focus is on preparing the required Environmental Impact Statement. We're working on that now. We plan to issue a draft Environmental Impact Statement in 2009 and then that will be followed by another public comment process and then a final Environmental Impact Statement in 2010.

And once that's done, there's a requirement under the Energy Policy Act, that we submit a report to Congress on the disposal alternatives that are being considered and then we await congressional action and so we plan to submit that report at about the same time, shortly after the final Environmental Impact Statement is issued in

2010.

And then once we receive congressional action, then we'll issue what's called a record of decision that you know, that identifies the preferred alternatives. So as you can see, there's a series of steps that we need to go through just to identify and select a disposal facility or facilities. And then, of course, once you make that decision, depending on the alternative, if it's an existing facility, there could be legislation required. There's licensing requirements.

If it's a new facility, you're looking at construction and so you know, then that begins the implementation phase and so you know, there is somewhat uncertainty as to when the facility would actually be available but assuming that you haven a -- you complete the Environmental Impact Statement process, and you make a decision in 2010, 2011, you could be looking at perhaps depending on the alternative, five to 10 years beyond that for disposal capability depending on the alternative. Thank you.

MR. RAKOVAN: Further discussion on this issue? Okay, let's go ahead and move onto to the final question before lunch, 3.2-3; "Where could the decommissioned sources be stored and also what

disposition options are needed in the United States"? Anyone want to make a comment on these particular questions or any of the questions in the particular panel of transportation and storage issues associated with removal of cesium chloride sources from licensee facilities? Please, if you could introduce yourself again.

MR. JULIE: Dick Julie, Health Physics Society. Our comments on this question, not just the last one, are that really, as we all know, there is no current disposition option.

MR. RAKOVAN: Sir, if you could move the microphone just a little bit closer.

MR. JULIE: I'm sorry. As we all know, there currently is not option for disposal and this will clearly require congressional option and, in fact, we feel the overall radioactive waste disposal system in this country needs a complete overhaul. We do have a position statement on that and background information which has already been submitted as part of our comments.

The only feasible short-term option for decommissioned sources is that custody of them be taken by the Federal Government, quite possibly the National Nuclear Security Agency for storage or

possible disposal. However, the one thing we do recommend in terms of the licensing of these sources and let me also clarify on our previous comments, make sure it's in the record. We are talking not just new licenses for new sources but also renewal of existing licenses for sources already in place, that we request the NRC require that in the licensing process any owner of a Class 1, 2 or 3 source provide financial surety for disposal of the sources in the licensing requirement. Now granted, that doesn't solve the current problem, but in case of future use of this source it will help defer some of the public cost of this option. Thank you.

MS. CUTHBERTSON: Abby Cuthbertson with the National Nuclear Security Administration, Offsite Source Recovery Project. And I just wanted to point out that right now, under the Atomic Energy Act we have authorization to recover cesium sources, as well as other sources, that present a public health, safety or security risk. So we are recovering sources in that context.

MS. SHEPHERD: Mary Shepherd, Shepherd and Associates. In regards to financial surety, I believe that's already been implemented with all licensees, NRC and agreement states from what I understand

because I get lots of quotes for decommissioning for financial surety.

As a disposal option, most of the manufacturers will take back their sources and we will take back defunct manufacturers' sources that -- especially cesium. That option will be closed if we're -- as a licensee, we're no longer allowed to receive cesium sources. So that method of disposal would be closed to us and everything would have to go to some sort of federal repository but most of the manufacturers have had -- it does cost money, it's not a free service. But we do accept back our sources and our company, in particular, will take back other sources as well, as long as they meet our license conditions. We're not Barnwell West by any means.

MR. RAKOVAN: I'm sorry, what was that?

MS. SHEPHERD: The question was asked, what do we do with them. They go into our particular inventory at various sites, just not at our facility. It depends on what they are. They stay in inventory until they can be -- for cesium, we do not cut open cesium sources and recombine them. We are licensed for re-encapsulation and we will combine used sources into new source capsules and provide a recycling per se. That doesn't mean there's always an immediate

industrial application for them and you know, it's not a two-day turnaround by any means, but if a source meets a condition of our license, we will accept -- you know, we'll take it back.

MR. RAKOVAN: Thanks. Sir?

MR. POWELL: Brian Powell, Constellation Energy representing nuclear power. In our industry with the closure of Barnwell, we've had to look at our options for handling the Class C waste. We don't have a place to put it, so we're looking at on-site storage. And I didn't hear that mentioned with everyone that's using these cesium sources, that they maybe forced to take an on-site storage route until there is a disposal path available.

In our case, we produce cesium. It goes into our resin. It's not considered a radioisotope of concern in that regard because of how it's dispersed throughout the resin but curie contents are certainly there that we need to maintain. So this, from our perspective, puts us right back into the safety and security requirements for the Category 1 and Category 2 sources. We have these sources. We're going to be storing them at our facility until there's a place to put them and we've taken the steps necessary to meet all the regulations as far as what's needed to make

sure that no one could get access to them, and that may be something that all of us are considering or we'd need to consider is, you know, what kind of resources are we going to need to devote just to have somebody there or something there that can watch something that's not being used.

MR. RAKOVAN: Any further discussion on issues of 3.2 before we break for lunch? Please.

MS. SHEPHERD: Mary Shepherd, Shepherd and Associates; one more comment. What we are seeing what's happening with the economy, today is some companies are going bankrupt so that they are going out of business and we're having to tell them, "You're going to have to put your source into storage in a facility that is not staffed." They'll have to maintain staffing in a biomedical research park in their -- not a university per se, but the private small biomedical companies are taking a big hit now. Those sources, if there's no transport, need to stay in secure storage until there's a transport requirement. If they cannot wait for LANL to pick them up, we're one of their resources of choice at least to help facilitate getting the sources to LANL, if they can afford the transport costs to recycle to us, but that will probably pick up considerably as the

economy keeps going downhill.

MS. GILLEY: This is Debbie Gilley and I'm going to speak on behalf of the State of Florida. When companies go into bankruptcy, the orphan sources or the sources that they leave become the responsibility of the states. We too, don't have an option for disposal of these things, so we talk a lot about federal assets but now we're also including state assets that were going to have to be used to maintain the secure storage of these locations or find some other options.

It's an additional cost that should be considered. When we talk about financial assurance, a lot of the financial assurance, the bonds that we charge licensees to assure that there is a disposal option, are difficult now for us to evaluate since we don't have a fixed fee for disposal or a fixed fee for transfer back to an organization like Mary Shepherd, Shepherds and Associates.

So those numbers become difficult for us to get our arms around and we spend a lot of time trying to do what is adequate to the license community, the regulatory community, but also as a safety and secure issue for the states to make sure that they are not -- don't have the burden of trying

to find an alternative for the source in the case of bankruptcy.

MR. MOSHAASHAEE: Moji Moshaashaee, Schering Corporation. Help me understand, you know. We're trying to get sources away from licensees. Now, I hear licensees should actually store it in their -- actually the facility? You know, we're defeating the purpose. So why are we getting rid of it in the first place? So you still have control over it going back to the basic security? So we still have to have security.

MR. RAKOVAN: Further discussion? Please.

MS. ROSSER: It's a question for a vendor, maybe Mary Shepherd could answer it. Constance Rosser, FDA. For a pathway moving forward on returning to vendors, would that include also giving them a certified package to transport the particular item in if you have approved containers? Would you be providing that as part of that pathway for returning to vendor?

MS. SHEPHERD: That's -- Mary Shepherd -- a two-fold question. As a manufacturer, yes, we would have a package for that pathway, once it's approved or we get a special permit to continue using our existing packages. However, as a licensee, if the

distribution and use of cesium chloride is banned, that pathway for return to the manufacturers would be forbidden and there would be no pathway. The current pathways that exist right now, would be gone.

FEMALE PARTICIPANT: So are you stuck?

MR. ZIMMERMAN: Peter Zimmerman, King's College, London. I don't understand that last comment. Simply banning the use and transport of cesium chloride which is a good thing to do, can certainly be enacted in such a way that the return pathway remains open while the sources are brought back. Don't you think that's possible?

MS. MARTIN: Melissa Martin speaking for the ACR. I'm certainly not going to answer the last question but I would reiterate, I would come back to the point, most medical facilities are certainly not set up to store a cesium chloride irradiator if it's taken out of the secure area that we've gone to great lengths to set up now to have security pathways approved for. The last thing I would think we would want to do is move it out to what we call the storage area.

(Laughter)

MR. RAKOVAN: Any further points before we wrap up? One more?

MS. SHEPHERD: Mary Shepherd again. Manufacturers are licensees as well. We don't enjoy a certain different status because we are a manufacturer or a distributor. We also have our own radioactive materials licenses and we have to comply with all our state and federal regulations and as a licensee, any kind of anticipated rule-making would directly effect the manufacturers just because we are licensees. There's no special status and it would be a general across the board rule-making and you know, all the manufacturers in the US would be effected by that.

MR. RAKOVAN: Okay, I think now would be a good time to break for lunch. If those on panel 3.3 could come to the panel to begin with. If you've got business cards, please leave them over here for the transcriber and we'll start promptly at 1:00.

(Whereupon at 12:00 p.m. a luncheon recess was taken.)

ISSUE NO. 3.3: CONSIDERATION OF GOVERNMENT INCENTIVES AND VOLUNTARY ACTIONS BY INDUSTRY AND MANUFACTURERS

MR. RAKOVAN: I'm not sure if the dwindling numbers in the room reflects that people are still at lunch or whether they are just not coming back. So we'll see how that progresses.

Starting off in the afternoon we are going

to be discussing Issue 3.3: Consideration of Government Incentives and Voluntary Actions by Industry and Manufacturers.

If we could start off by having our panel members introduce themselves please.

MR. MOSES: Paul Moses, I'm the director of sales and marketing for Best Airtronics.

MR. PHILLIPS: Robert Phillips, Food & Drug Administration, Center for Devices and Radiological Health.

MS. SHEPHERD: Mary Shepherd, Vice President, JL Shepherd and Associates.

MS. SYLVESTER: Ruth Sylvester, director of regulatory affairs with America's blood centers.

MR. TAYLOR: Michael Taylor representing AAPM.

MR. RAKOVAN: Okay, to start out with I'll go ahead and read the questions that we'll be discussion in this particular session.

Question 3.3.1: Should the federal government issue incentives to implement replacements?

3.3.2: Are there feasible incentives to shift users away from radioactive cesium chloride for users and also manufacturers?

3.3.3: What incentives should the federal

government provide to licensees to decommission their existing sources or devices because the devices still have use value; and also for licensees that are defined as not for profit, e.g. Hospitals, what type of incentives could be made available to change technologies?

And finally 3.3.4: How can the federal government compensate licensees when they are forced to decommission these sources? Should compensation include the cost of replacement technology and decommissioning?

I'd like to start out as usual to see if any of the panel members have presentations or statements they'd like to make?

(No response.)

MR. TAYLOR: Next please. There it is. End of story. Next please.

The federal government should provide necessary financial support for the conversion to alternate sources where the change is necessitated by national security needs. That's what is defined.

However, decisions should be substantiated by detailed cost-benefit risk analysis that includes demonstration of patient care and research are not negatively impacted. Next please.

There will be an impact on ongoing research in clinical trials involving the cesium chloride irradiations if sources are described. The sponsors of the trials whether for drugs, medical devices, biological products, will have to consider what is the impact of the change of the radiation source, its changed on the protocol for the trial, and depending on the analysis of the impact of the different types of radiation providing justification and submission to the FDA to substantiate the validity and comparability of data obtained from different sources.

If this validity cannot be demonstrated with the appropriate data the clinical trials might have to be significantly revised or extended.

Financial and logistical help, both of those have to be considered with what we were discussing earlier, the logistical as well, with the source disposal, and all aspects of disposable and replacement is critical.

In both clinical and research facilities the major expenditures will be the procurement of the new equipment; removal of the old source; packaging of the old source; safe transit and disposal of the old radioactive source; the formal decommissioning of that

facility which is not insignificant; partial demolition and reconstruction may have to happen to that room that this device is in to be accommodated to removal of the source mentioned above. Next please.

It's necessary to have significant financial incentives for the replacement of the old sources or if greater risks are perceived or if the government wants to phase the removal quicker. Next please.

In summary future units may be able to meet our research requirements, but at this point we must move carefully and slowly. Consideration must be given to the cost-benefit analysis of our actions, even if money is available to procure the newer units.

Not using cesium chloride, it's unclear if they'd be able to meet the current requirements of research. Next, please.

And that is who I am and if you need to contact us. Thank you.

MS. SYLVESTER: Good afternoon. I'm Ruth Sylvester with America's blood centers. Next slide, please.

Dr. Bianco earlier today showed you this slide of what America's Blood Centers is, and who we represent, and the one point I wanted to drive home is

that we have a number of members out there that are all nonprofits and they range from collections of 10,000, which means they are very small centers, to our largest member who collects over 800,000.

Next slide, please. This is the summary data that he showed you from the survey we had done. One of the comments that has been made throughout the meeting in the last day and a half is about being able to provide a backup should you be down. And our members provide backup to 188 other facilities that do irradiation. Next slide, please.

The membership currently has 65 cesium irradiators out there that have an average purchased year of 1996. These irradiators have a shelf life, or a lifespan of 25 years. They have significant value remaining in the irradiators that are in our facilities. And we estimated that value to be over $3 million.

When we look at decommissioning a comment that was made earlier has been the cost of decommissioning. On our survey we asked that question, and we got an average of $12,000. But you can see from the slide that the high was $30,000. Then we had two members that were able to get the funding to decommission it, one from DOE, and one from

Los Alamos NNSA. So the centers that were able to procure grant funding to remove these irradiators, it was much easier on them to get the irradiators out of there.

This is the total phaseout cost. As Dr. Bianco had showed earlier. We want to drive home for our membership, we are looking at over $21 million to decommission and switch out all the irradiators. Next slide please.

The obstacles that he mentioned this morning remain the same, and these have been gone over repeatedly. One more slide, please.

The question is how do we overcome these obstacles. Unlike what I've heard in the research arena, the blood banks could convert over to X-ray technology to irradiate blood. But then what are some fo the challenges that our industry fac3es in doing that? And some of these are listed here.

Some of it is education of the users, as we were planning for this there is a questions and belief as to the validity and how good the X-ray irradiators are, and that's something that needs to be overcome in the industry.

And a precise assessment of the availability of new instruments and comparison for

effectiveness. I doubt very seriously that JL Shepherd and Best Theratronics could turn around tomorrow and ship me 65 irradiators. So that is not something that can happen very very quickly. It has to be planned out, and thought has to be given to that.

Facilitate decommissioning. As we just heard in the last session, I believe this is probably one of the biggest challenge our industry faces at getting rid of our old irradiators is, how do we transport it, where do we transport it, and how do we get rid of the cesium?

Promote the availability of new instruments, again, synchronizing the ability to get rid of them as well as the availability fo new ones.

And then funds for conversion. As I mentioned in the beginning of my briefing, I have very small members that are nonprofits. They just don't have $100,000 sitting around in a coffer that they can unscheduled and go out and buy a new irradiator. I did like the Red Cross' attempt yesterday to solicit funds. We are nonprofits, and we do have a foundation. So if y'all would like to help us, we will take those funds also.

Then the biggest thing we could ask, since

we could, our industry could switch over to X-ray, it has got to be done in an orderly - give us enough time to do it. And I would imagine that 10 years is probably required to accomplish this for our industry.

And I think that is the last slide I have. Thank you very much.

MR. RAKOVAN: Do any additional panelists have statements they'd like to make?

Okay, seeing none, Michelle, if you could bring up the first question again and throw it out for discussion.

STATEMENT & ROUND TABLE DISCUSSION

MR. RAKOVAN: Any of the panelists or any of the audience want to expand upon any of the topics that were mentioned in the presentation or start something new?

Okay, sir, if you could introduce yourself please?

MR. TAYLOR: Michael Taylor, I'm a private citizen now, taking my other hat off. I just want to give a little story of what happened at my institution when the security measures came in.

They came in as an unfunded variance. I spent $80,000 hardening, quote unquote, my system. And when those numbers came through, we had to make a

budget decision to actually go from three irradiation sites to two irradiation sites, so we effectively had to close down one to pay for this.

If we continue with having to have these unplanned unprogrammed changes of the magnitude of this or greater, already there are thoughts that we may go down to one facility.

Now from a security minded person that may be great; we are reducing this number. However, with - I'm in a big medical system that takes care of all of Northern Virginia, part of Maryland, and part of D.C. If you got yourself or your loved one needed an irradiated unit dose, and we have to get it from our one left facility, and get on this nation's highways are rush hour, you are going to have a mess.

So we want to try and keep as many facilities so we can keep distributed, so we can get the stat blood units to the place that they are needed in a reasonable amount of time.

Thank you.

MR. RAKOVAN: Any discussion on incentives, voluntary actions? Is everybody digesting from lunch?

Please.

MR. PHILLIPS: Robert Phillips. It strikes me that the talk of incentives except for some

specific areas such as the blood irradiation area, might be premature. My take from the discussions yesterday and this morning - my take from the discussions yesterday and this morning is that for many uses there really is not yet alternatives to the cesium chloride approach and that rather than talk about incentives to users, you ought to be talking about incentives to researchers and industry so that they can establish that alternatives are feasible and commercially viable.

MS. SHEPHERD: Mary Shepherd. I think the manufacturers have been working with the Department of Homeland Security on various issues voluntarily. Again, it's too premature because we don't know what is going to happen to comment on incentives, but I would like to ask that after we've decided on dispersability, feasibility or additional security measures are in place, that perhaps a - if we go to additional security measures on top of what we already have, that that would be a straight tax deductible expense for most institutions.

MR. LEWIS: Rob Lewis. Just to follow up on Dr. Phillips' comment about is this question premature. And I think what we meant by this question when we asked it in the Federal Register Notice, the

NAS report included a recommendation to develop push-pull incentives for some users that might either be considering replacing at the end of their 25-year life of an irradiator that they have, replacing it either with a new irradiator or with an X-ray, or somebody that's just getting into the business, or opening a new center, can the federal government do something so that it's more attractive to them to buy an X-ray device versus a cesium chloride irradiator?

Because we do know that X-ray blood irradiation does occur, so there are facilities that can go do it, in a linear accelerator. And it may be more expensive, so to overcome those expenses, is there a way the federal government can get involved to tip the scales towards better security?

And notice that those may not be questions for the regulator, and we posed the question, should the federal government do something? As the regulator, I think we are just evaluating a license application against the regulations, and not, did you consider an alternative technology or not.

But the federal government could certainly try to do something to minimize its posture if we are to pay the decommissioning eventually, you know, we shouldn't be contributing to our own costs down the

line as well.

MR. BIANCO: Celso Bianco, with America's Blood Centers. I think that I'd like to see this concept of incentives spread over the entire set of issues that we're discussing. Irradiators at blood centers or irradiators at blood banks in hospitals, my impression from this meeting is that they constitute a small fraction of all the cesium chloride irradiators. So you need the incentives to stimulate the manufacturers or the researchers to work on alternative forms of cesium. You need incentives for better disposal of the materials. You need incentives to facilitate for the research arm to do the comparative studies that they may need to use other forms and other things.

So otherwise there is the only incentive that people will have here is to withdraw, because we are not encouraging the manufacturers to do much if they are very concerned today, as I feel in the air, if this field is going to survive. And I think that is very concerning.

So I hope we incentivize everything.

MR. MOSES: I would agree with that, in terms of what I've heard over the last day and a half has been, you have to look right at the beginning, the

source manufacturing of it is clearly going to have to change so that it's not that dispersable, that's primary.

Then after that you have to look at the unit. So the cesium supplier, and actually the supplier of the units, will have to work very closely. And that's going to take a lot of money.

If you start looking at the change of the design itself, where the design actually gets bigger, which is very possible, then you look at the over-pack that it has to go in to be a legal shipment, then that over-pack has to go through a drop test, fire test, immersion test, and we destroy millions of dollars of product just so that we can get a license.

So there's a big economic impact all along the way, long it gets to the blood bank. And in order for us to really have an appetite or a fire in our belly to do it, there is one thing, there is regulatory pressure, and Homeland Security pressure. But then we are business people too; do we really want to do this?

So the incentive I believe starts there. And then you have to look at the blood bankers who do really good work. And I've had the privilege of working and rubbing shoulders with the blood bank

community and research community for over 30 years, and they are hard working people, and they do a lot of good stuff. And you know, it's - where does - the other thing is, when you start looking at the requirements by the US NRC in terms of what Homeland Security has asked for, will we get credits? Will the blood bankers get credits so that they do not have to have a more secure facility? Will that diminish?

Not likely, but would it? These are all things that impact costs, operating costs. That's a huge thing. And almost another committee could be designed just to look at this.

MR. LEW: Yes, I'd like to see the federal government issue incentives, perhaps through a national lab, and really hit on a good product and perhaps make something very viable to the blood bank industry. And perhaps that becomes a lesson learned, to try the machine irradiation sources into the research arena.

So definitely again if Homeland Security is here, and if they could perhaps put some of that money into the process. Yes, very much financial incentive.

Thank you.

MR. RAKOVAN: Further discussion on these

two questions?

MR. POWELL: I'm Brian Powell, Constellation Energy, representing nuclear power. And I just wanted to restate again something that I brought up yesterday about voluntary actions by industry or manufacturers.

Clearly in our case with the removal of cesium chloride for our calibrations it has the potential to effectively shut down our ability to generate power and help the U.S. in that manner.

Taking that into consideration, we have gone the opposite way and made our security of these sources formidable to say the least.

In our current state what we are doing is looking at the other IAEA sources, and what we can do about them, and their cost to things like radiography business, which is a big part of our business as well, to get these IAEA sources to our facilities to measure the pipes and other things that we look at, has impacted our cost as well. So they have increased costs, and as a result we have increased costs to bring them in.

We are looking at how to deal with the other IAEA sources. In one specific case we are looking at pulsed X-ray as a form of doing

radiography.

So I just wanted to make the statement that we are in the nuclear power industry looking at the whole picture, and what we can do about it while we are waiting for glass or ceramic cesium source to become available.

Thank you.

MR. RAKOVAN: Michelle, why don't you go ahead and put the next question up.

Question 3.3: What incentives should the federal government provide to licensees to decommission their existing sources or devices because the devices still have use value. And also for licensees that are defined as not for profit, what type of incentives could be made available to change technologies?

Please.

MS. SYLVESTER: As I mentioned in my opening statement for the blood bank industry and the not for profit industry, we certainly would need financial incentives from the federal government to be able to replace technology, to buy out the remaining value that still exists in a very reliable system, as well as assistance to decommission the sources. As you say from one of the slides, two of our centers out

of 12 who have decommissioned were able to get grants to cover that cost to a significant savings, and which gave them the incentives to do that.

I know, I was involved in a conversation with one of our members who were evaluating the two different technologies, and actually went with the cesium just because of the significant increased costs of the tubes and stuff over cesium. And that purchase occurred just last year.

If someone has a 25-year irradiator that you would now want them to change over, that would be a significant loss if not compensated.

MR. RAKOVAN: Further discussion on these issues?

Please.

MR. MOSES: To your point, if you look at a logical way of taking units out of the field, and you are going to install X-ray units, the most logical way to do it would be to look at the old units, the ones that are 22, to 25 years old, 30 years old. Just due to the fact that they have gone pretty close to a half life.

And to their ability to irradiate blood in a timely fashion has diminished. So if you started with those, then the actual impact on the blood bank

itself would be minimized because the timeline would probably be improved with an X-ray unit. As you know it's five minutes to be in compliance with the AABA and FDA. And instead of having that seven or eight minutes, there is an improvement there.

Now for someone that has a unit that's even five to 10 years old, the throughput capability on a cesium unit is much higher. So there would be a bit of pain in a couple of ways: the payment of the new unit, but also their processing time would drop also.

MS. SYLVESTER: One of the questions we did ask on our survey but I didn't show the data was the actual cycle time on the irradiators, and he is correct. We had as low as three minutes to as high as 11 minutes, and the cycle time was directly related to how old the unit was.

So that type of an approach would certainly make sense, because the older units are taking longer, so you would reduce almost by half the amount of processing time, cycle time, it would take for a run.

MR. RAKOVAN: Does anyone want to address the second part of the question specifically involving not for profit organizations?

MS. MARTIN: Melissa Martin, speaking for ACR. Speaking on behalf of most of the medical facilities, which I would assume this question is aimed more for hospitals, the main incentive I would think is going to be financial. But it's also going to have to be assistance with the disposal. Those are the two primary things that most hospitals are not set up for, at least in tight budgets, is to absorb the disposal costs, and then any kind of financial incentive to replace an operating unit would be a great incentive.

MR. RAKOVAN: Please.

MR. BOHAN: Mike Bohan from Yale New Haven Hospital. Most free-standing hospitals, and Yale New Haven Hospital, though we are affiliated with Yale University, we basically have our own license, so we are just really a medical operation, not a university operation. But I just wanted to point out that most hospitals do not normally do waste disposal, because almost all the sources that we do use are short half-life we hold for decay. And I think it's an important thing for people to understand is that if hospitals are all of a sudden going to be thrown into having to decommission their cesium irradiators, you are going to have a lot of people who don't have much experience

in handling waste disposal trying to do that.

Then again, I'm in a not for profit institution, even though the NRC still sends us a bill every year for our licensing fees. But at the end of the year when the hospital buttons up its budget, we are an operation that probably cycles hundreds of thousands of dollars through the institution and costs and services. They tell us that our profit at the end of the year is only a million or two dollars, so we're really not operating on much margin.

MS. SHEPHERD: Mary Shepherd. I think when this question was proposed, not for profit was looking at hospitals, Red Cross. But the universities are also included in this. Universities are not run for profit, and I think the majority of the research irradiators using cesium chloride are at university facilities, and should be included in this conversation, and the costs would be significant for them.

MR. FAIROBENT: Lynne Fairobent with AAPM. Two points. One is, I'm not so sure in the current economic situation that we are in today, I'm not sure the incentives vary that much whether you're a for profit industry or a not for profit industry. I think the purse strings are equally as tight.

But secondly just to expand a little bit about Mary's point about academic institutions doing research, or even private institutions doing research, I'm not sure that the NIH or other funding organizations such as the National Science Foundation, any of them really choose to have a large percentage of their grant funds for research going to disposal of waste material, or no longer seen as viable use material.

And I think that that implication as to decisions made on grants, if one is putting in a grant, and one has to have a disposal cost option in there for radioactive material versus somebody who may be coming gin for a grant that does not utilize this material, I'm not sure how that would be viewed or analyzed. But I do think that when we get to the cost-benefit risk analysis in five, I think that this is a variable that we are not used to dealing or factoring into the equation.

MR. RAKOVAN: Sir, if you could introduce yourself, please.

MR. RING: Joe Ring, Harvard. And that's exactly one of the points that I was going to bring up. Most of the research that is done in basic science is actually funded by the federal government.

And the cost for disposal and management of these types of materials is not included. So there would be significant expenses in addition to the research correlation studies that would have to be done.

So those would not be supported by the federal grants that are out there right now, and that would leave the researchers at a severe disadvantage and probably hamstring research.

Thank you.

MR. SULEIMAN: Orhan Suleiman, speaking for myself again. The money that you would be using for incentives would be better spent targeting some of the earlier issues and solving the problem technologically in terms of hardening the source. The FAA didn't call a meeting to ban airplane flights. They hardened the security and the other issues.

So I think continuing to play this out when it's obviously that cesium is a viable, unique source of radioactvity. This is an interesting exercise, this later part. But I think the consensus is not to eliminate it but solve some of the problems otherwise.

MR. RAKOVAN: Could you identify yourself?

MR. ERTEL: John Ertel, from the United States Naval Academy.

MR. RAKOVAN: Could you say that again, please?

MR. ERTEL: John Ertel. I'm from the United States Naval Academy. And I'm sort of a cold blooded numbers kind of guy. And I look at cesium 137 and I look at it as a 30-year and a little change half life isotope, and I'm thinking, you know, when you bought these things you had to expect that in 30 years you'd still have half of it left. And you were expecting that in another 30 years that you would do something with it. You weren't just going to put it in the trash can or down the drain. I have to believe everyone has considered an exit strategy after 30 years of use. You must have planned on something to do with them.

How come we are worried so much now about the cost of getting rid of these irradiators at the end of the first 30 years of their half life? Surely we considered that to begin with.

MS. SYLVESTER: This is Ruth Sylvester with America's Blood Centers. To be honest with you, I don't know that my membership actually considered that. This has been a very very reliable machine. It has very few moving parts. The cylinder rotates, exposes it, and it rotates back. And when you have

machines out there that are 20, 25, and approaching 30 years old, and they are still a work horse, the membership I don't think sees it as an imminent need to be replaced, and so it's just a very stable entity.

And one of the comments that was made earlier about not having much experience with decommissioning, that's true. Out of my 77 members only 12 have decommissioned irradiators, and some of the general comments that they sent to us were like headache, and some things that weren't repeatable as to what you had to go through to actually decommission an irradiator.

MR. BIANCO: Celso Bianco from the America's Blood Centers. I just want to add to what Ruth said, the only thing that we do as time goes by is to have it recalibrated, and we increase the time of radiation, and that has been the routine, and the way we operate.

MR. BOHAN: Mike Bohan from Yale New Haven Hospital. You know if I think back 30 years ago, or well, not that long, but we put in our first cesium irradiator about 20 years ago or so, the cost of disposal was much different than what it would be today, which was not anticipated when we first installed them.

So while we may have planned that we would be paying the piper someday for its disposal, no one could have foreseen a situation where we are today with respect to what it would cost to dispose of it as opposed to when they were purchased.

MR. FAIROBENT: Lynne Fairobent, AAPM. Thirty years ago we had disposal options. Today we do not have disposal options, and I think that changes the equation of what we are dealing with also today. It's not a question that these irradiators are no longer useful or have viability. It's a question that they are being perhaps taken out of service for some other extenuating factors that were not envisioned 30 years ago when these were purchased, or even as recently as two years ago when they were purchased.

So I don't think that it's the same equation that one went into when making the decision initially to purchase these.

MR. RAKOVAN: Michelle, why don't you go ahead and put up the final question to wrap up this panel. How the federal government compensate licensees when they are forced to decommission these sources? Should compensation include the cost of the replacement technology and decommissioning?

Please.

MS. SYLVESTER: Ruth Sylvester America's Blood Centers. Yes to both.

MR. RAKOVAN: Would you like to give some reasoning behind that?

MS. SYLVESTER: I think I said it in my opening statement, and as we've discussed here. The reality is, these have - these are very reliable machines that have life left in them. We are not for profits. We do not get reimbursed, or hospitals don't get reimbursed from the federal government from Medicare for the amount that it actually costs to create a unit of blood.

And so we're in this cycle where we are always chasing and trying to catch up and having to implement new testing strategies, new technology, without getting remuneration that should come along with it, and we can't pass that cost on. This would be another cost that the membership would incur that it had not planned on; would be forced to do so because of a change in regulations.

MR. THOMAS: Jerry Thomas from Wichita, Kansas. I need to second that from the not for profit hospital standpoint as well. And that is, we have a perfectly good functioning piece of equipment now that has proven reliability. Consequently if it's to be

replaced because of a homeland security issue that is of national importance, then that should become a federal initiative to both replace the equipment and decommission it, as well as provide the appropriate replacement technology that is being removed based on a federal mandate as opposed to any other reason for replacement or removal.

MR. TAYLOR: Mike Taylor, AAPM. I find it for those of you that have done business analysis on lifecycle replacement of equipment, there are just too many variables right now. There is no way that we can identify what the lifecycle replacement of these devices is. I resource my unit, so it's infinity maybe. I have no idea what disposal costs are. I have no idea about the whole thing. So it'd be very hard for me to go to my administration with a business case and say, here is what I'm going to need to replace this unit. Because there are just too many variables at this time.

MS. SHEPHERD: Mary Shepherd. I have had people calling us as late as last week. We don't like the increased controls. We would like to get rid of our source. Can you come get it tomorrow?

(Laughter.)

MS. SHEPHERD: And with the situation, with

transport, with the uncertainty, especially with transportation right now and the uncertainty as to what is going on, I can give a range from a couple of hundred thousand dollars to close to a million dollars just for decommissioning if you don't want to wait for the offsite source recovery LANL project. And it's still up in the air because the containers that are available, the contracts on them are filling up quickly, and as they fill up the costs do increase, the ones that I can rent.

So right now the whole dynamic has totally changed. We are almost in a perfect storm, and for even a manufacturer like me to give a quote just to recover back to my place, like I say can run anywhere from a hundred thousand dollars to close to a mil depending on what the dynamics are. And it will continue to get worse.

MR. RAKOVAN: Closing comments on incentives and voluntary actions?

(No response.)

ISSUE NO. 3.4: IMPACT OF POTENTIAL U.S. CHANGES TO REGULATING CsCl ON THE INTERNATIONAL COMMUNITY

MR. RAKOVAN: Okay, we are going to go ahead and push through to the next panel, which is issue 3.4, impact of potential U.S. changes to

regulating cesium chloride on the international community.

If those if you on the panel could please come up to the table.

While they are doing that I might as well use the time to read the three questions that we'll be addressing in this panel.

Question 3.4.1: How can the U.S. prevent recovered sources from decommissioned devices or the devices themselves from being sold outside the U.S.?

3.4.2: If the U.S. decides to ban the use of cesium chloride sources, should the U.S. have a position in denying or eliminating after-market sales of cesium chloride irradiators outside the U.S.? And also would this be potentially denying medical care to developing countries?

And finally 3.4.3: What should the role of the International Atomic Energy Agency be in assisting the U.S. in assuring the safe and secure use of cesium chloride sources and devices?

We'll just pause for a second as our panelists take their seats.

(Pause.)

MR. RAKOVAN: All right, if our panelists are situated, if everybody could take a moment to

introduce themselves, please.

MR. MINNITI: I'm Ronaldo Minniti from NIST.

MS. MURTHY: Kavita Murthy from the Canadian Nuclear Safety Commission.

MR. TOOHEY: Dick Toohey, Health Physics Society.

MR. ZIMMERMAN: Peter Zimmerman, King's College, London.

MR. COPPELL: I am David Coppell from REVISS Services.

MR. RAKOVAN: Are there any panelists who have a statement or presentation that they would like to start out with?

Okay, we'll start out with Mr. Zimmerman, please.

MR. ZIMMERMAN: How do I advance the slides, or do you take care of it?

Thank you very much for having me here. Thank you very much for having this interesting meeting, and for all of you who are attending for the questions I'm sure I'm going to get.

I simply want to remind the Commission and those who scheduled this meeting that this is Rosh Hoshanah. It is the Jewish New Year. And frankly,

because this meeting is important I am making an exception to my normal practices of going to services and not working today.

Let me say that this scheduling of Rosh Hoshanah has been on the books for a long time, and I'm very disappointed that a number of people who would have liked to have been here were unwilling to make the compromises that I did. And I think that that should be entered into the record and taken into account for the future.

I want to make two points before we go to the next slide - well, we've gone to the next slide, but I'm still going to make the two points before we go any further. The only radiological dispersion devices scenarios that I'm aware of, and I have been writing on this since about 2001, the only RDD scenarios that can kill in excess of 1,000 people at a crack exploit the physical properties of cesium chloride. And they are sufficiently dangerous that, those scenarios, that I think we should be putting that high on our list of criteria.

Second, if you do a study of the economic impact of a major dirty bomb using cesium chloride, as Cheryl Loeb and I did for the National Defense University some years back, we found that an attack in

lower Manhattan on the 10th of September, 2001 could have caused just about as much property damage and economic loss, all told, as the terrorist attack the following day.

Again, we were exploiting the physical properties -

MR. RIVERS: Excuse me, if we could make sure we don't get into any specifics in the use, it would be very helpful.

MR. ZIMMERMAN: I'm sorry?

MR. RIVERS: If we could make sure - I'm Joe Rivers from the Office of Nuclear Security and Response.

MR. ZIMMERMAN: Who and what?

MR. RIVERS: I'm Joe Rivers from the Office of Nuclear Security Incidents and Response. We just want to make sure that this is something that's public, essentially something for the public.

MR. ZIMMERMAN: I'm going into no specifics whatsoever. Okay?

MR. RAKOVAN: And sir, we are just trying to make sure we are covered, okay?

MR. ZIMMERMAN: Thank you for that pleasant intervention. Let me go on to the next slide, please. United States doesn't produce very much in the

way of radioisotopes but it consumes a lot as we have heard today. U.S. leadership will be very important to any kind of global attempt to reduce the threat from RDDs.

What we do matters. It matters enormously internationally. If we are able to move away from our dependence on powdered cesium chloride other countries will too. Next slide.

How can the U.S. prevent recovered sources from getting out on the international black market or elsewhere? Simple. We take the sources back. Ultimately we will have to have legislation that allows the Department of Energy to take charge of all sources that cannot be recycled into some other chemical and physical form than cesium chloride.

Such sources can be disposed of in WIPP. It takes legislation. It will take a bribe to the state of New Mexico. But technically WIPP is capable of handling all the high level waste in the world. Next.

Should we discourage such sales? Well, of course we should. Will it reduce medical care? Well, yes, we may have to provide a subsidy for blood irradiators elsewhere in the world. We may have to tolerate that blood irradiators elsewhere in the world

use cesium chloride powder a bit longer than we do.

If we are talking in terms of teletherapy, cobalt 60 is a proven irradiator, and it doesn't come in a white powder.

We've been talking a great deal about what happens if we lose the particular properties of cesium chloride. Well, the answer is, more accurately, the particular properties of cesium-137. I don't believe that any of us who are in the abolitionist camp would urge taking cesium-137 away. What we'd like to do is to find alternative physical forms in which it can be delivered. Perhaps the physical density of cesium atoms per cubic centimeter will decline in a vitrified form. We'll find out.

In that case, yes, sources will have to be modified. Or we will tolerate working with 10 or 20 percent lower source strength, and consequently, somewhat longer irradiation times. Next slide.

The role of the IAEA - I'm not quite sure why that slipped into this particular set of questions. But I think it's pretty clear, the IAEA will do what it has done forever. It will encourage appropriate nuclear technologies. It will attempt to set international standards that are adhered to. And it will handle such things as recordkeeping and the

recovery of sources from countries that are unable to handle their own recovery.

I think that is the last question. I think that completes the presentation that I had. Thank you very much for listening.

MS. MURTHY: I'm Kavita Murthy, Canadian Nuclear Safety Commission.

MR. RAKOVAN: Please bring it very close.

MS. MURTHY: Kavita Murthy, Canadian Nuclear Safety Commission. Thank you for this invitation to participate in this public meeting. It has been an illuminating experience.

My division is one of three at the Canadian Nuclear Safety Commission that is responsible for the regulation of the types of devices that we have been talking about in this meeting.

Please note that my perspective is purely from the regulatory standpoint, not from the end users' standpoint.

The system of controls in place in Canada for Category 1 and 2 sources is based upon the recommendations contained in the IAEA code of conduct on the safety and security of radioactive sources of which Canada is a signatory.

In accordance with the code of conduct

recommendations, in 2006 Canada established a National C Sources Registry, and implemented a C source tracking system for tracking high risk sources. This cradle-to-grave system for source accounting allows us to track individual radioactive sources from the time of their entry into the regulatory stream to ultimate disposal.

At present there are 138 Category 1 and 2 cesium-137 sources under CNSE license in Canada. Most of these sources are in devices originally manufactured by NDS Nordion, now Best Theratronics, or JL Shepherd. Important export of Category 1 and 2 sources into and out of Canada are also based on provisions of the code of conduct. Additionally in accordance with other guidance issued by IAEA we have put into place security requirements for Category 1 and 2 sources.

In summary, the CNSC over the last eight years has made significant advances in its efforts to assure that high risk sources are secure and accounted for.

Onto the subject of this panel: the impact of potential U.S. changes to regulating cesium chloride on the international community.

From a Canadian regulator's perspective,

the impact of your decision on this matter will be most significant on companies based on the U.S. doing business in Canada or elsewhere who will be subject to the restrictions you may place on them.

The IAEA code of conduct calls on its member states to use the guide, and I quote, for the development and harmonization of policies, laws and regulations on the safety and security of radioactive sources.

The code further calls upon states to encourage the reuse and recycling of radioactive sources, and where allowed by national law, to allow for the reentry into its territory of disused radioactive sources so they can be returned to the manufacturer.

Since some of the major manufacturers of these devices are based in the USA, it follows that any regulatory action taken by the NRC will have implications internationally. This avenue especially for returning sources to the manufacturer if closed off could result in a stockpile of disused devices still containing significant quantities of cesium chloride in countries that do not have adequate disposal or storage facilities. This is a potentially risky scenario, given that cesium chloride is

extensively used in the developing world with weak regulatory controls.

Provisions for the use, storage, and/or disposal of these devices worldwide are imperative if one is to address the issue of threat elimination from cesium chloride Category 1 and 2 sources in its entirety. Therefore it is necessary to take a harmonizing approach that applies worldwide rather than to undertake any actions in isolation.

In other words one should be careful that in trying to address it at home, one does not create a greater threat worldwide.

Thank you.

MR. TOOHEY: Dick Toohey, Health Physics Society. I can brief, because we agree with almost everything Dr. Zimmerman said.

Basically we think the NRC should make it a license condition that sources be dispositioned, either by the appropriate federal agency or an appropriate disposal facility.

We do believe that if the U.S. bans cesium chloride sources or works for their eventual elimination, we should also do the same on after-market sales and export. We live in a very flat world, and doing something in isolation is probably

not going to solve our security problems, although ensuring high quality medical care in developing countries is extremely important. The potential risk to U.S. security must also be considered.

And finally we feel the U.S. should continue to work with the IAEA in implementing the code of conduct for import or export of cesium sources, and ensuring through our regulatory initiatives in the U.S. that the provisions for safety and security of these sources throughout the world be at least as stringent as U.S. regulations, and the IAEA guidelines.

Thank you.

MR. RAKOVAN: Any additional opening statements?

Okay, please.

MR. MINNITI: Good afternoon, this is Ronnie Minniti from NIST. I'm just going to pull up one of the slides I showed this morning.

Again, this is a map of the U.S. with a partial list of the calibration facilities that owns cesium calibrators. And what I said this morning is that all these facilities are traceable - or all the measurements of these facilities are traceable through a national standard which is held at NIST here in

Maryland.

Now the reason I'm showing this is just to give you a little bit of perspective, since this is an international session. Every country has a similar network. So they have a primary lab, and a lot of secondary facilities. And what we do, NIST as a primary lab interacts with all the primary labs, in the rest of the world. And in the UK it's MPL, in Germany it's PTB, and so forth.

What we do by interaction I mean we routinely compare and make sure that we all are on the same page, and our measurements agree within a given tolerance.

Now above all these primary labs in the world, there is one that basically coordinates all of them, which is - it's in France, and it's IBPM, the International Bureau of Weights and Measures.

So anyway I just wanted to give you a perspective of the impact of making any ruling in the U.S. Of course all these other countries have cesium irradiators, so one of the things that could happen, and I don't want to start speculating, but if cesium is removed from the U.S. some of these facilities could look for traceability elsewhere.

Thank you.

MR. RAKOVAN: Okay. I think we've had - we've got one panelist who hasn't made one, so I'm going to offer it to him.

MR. COPPELL: I was just going to comment on the questions as they come up.

MR. RAKOVAN: Fair enough. Let's go ahead and open it up for discussion then.

STATEMENTS AND ROUND TABLE DISCUSSION

MR. RAKOVAN: Question 3.4.1: Do you want to start out the discussion on this one?

MR. COPPELL: Yes, Dave Coppell from REVISS Services.

I guess it's a bit more general comment than just on this one question. But it seems to me everybody has to understand this is a global issue; it's not just an issue for the United States.

I don't know what proportion of the planet cesium chloride exists in the U.S. versus the rest of the world, but I guess you've got to be confident that there is a lot of cesium chloride outside the United States.

And it seems to me that any solution which is intended to address an improvement to security here in the U.S. needs to take account of what the availability of that material is for terrorist

activities overseas. So it needs to take accountability of how you address that problem too.

Well, that's my perspective on this issue of international effect.

I think that some of the foreign regulatory agencies involved are probably watching what the U.S. NRC decides to do or the U.S. Government decides to do, and track record has it that a lot will follow suit in due course. But some won't; some can't afford it; some regulatory infrastructures are not well enough developed to follow suit.

So I guess in conclusion it seems to me that a solution which encourages the whole world's community of users of cesium to change to a technology which is safer for all of us is the right conclusion.

MR. RAKOVAN: Further discussion on international impacts?

MS. DANIELS: Hi, Sameera Daniels, Ramsey Decision Theoretics. I think what's important in the global context has also to do with how we frame this debate, you know, commonsense things like tone and so forth.

And in this regard the State Department and other organizations including the United Nations have a lot that they can offer, because one of the

problems that has been occurring is that there is a kind of a lecture quality to our concerns about terrorism and so forth. And while that is understandable, I think there is something to providing a conversation which can promote cooperation.

MS. SHEPHERD: Mary Shepherd again. I'm speaking on the international community, the international community in regards to nuclear power internationally, their calibrated on an international standard. We sold most of the cesium calibrators to power plants across the world.

Military applications: anybody with the nuclear Navy for personnel, health and safety radiation protection, still has the same issues. Canada, Britain, France, Israel, Russia, everybody has the same concerns that we have for radiation protection, and that is international in scope.

One thing that hasn't been brought up is I believe, since we've been doing this for over 40 years, and Nordion has been doing this for over 40 years too, the majority of the chloride sources out there to this day are still U.S.-made chloride sources; they have not been decommissioned just because of the longevity. Those radiators go for 30 -

40 years. We have irradiators out there for 40 years.

And so I would say, since DOE was the primary manufacturer for years and years and years, that this is probably a U.S. problem more so than a Russian problem globally for the recovery of most of these sources.

And that's it for right now.

MR. MOSES: Paul Moses, Best Theratronics. If you look at the cesium units that would be out of North America, it probably would be the same number that would be installed within the United States and Canada; so they are significant.

The other issue is, I'm sure everybody in this room agrees that the rest of the world deserves good health care too. And I keep on telling my 4 year old, who is a little egocentric, it's not always about me. And the thing is that safety is critical. And if you start looking at where these sources come from and where these new units come from, once again to REVISS' point, you start with a new type of source configuration, it goes in a different type of unit, but that doesn't take the problem away. You've got an awful lot of cesium units out there that have to either one, come home, but more important, education.

When you talk - when I talk, because I

travel a fair bit, when I talk to different doctors - and I've been in India, Pakistan, China, Japan - they don't see this as a security issue. They don't even have the kind of security you're talking about in your blood banks. Nowhere close to it. So there is an education component that Homeland Security will have to take around the world.

And then so this is a big picture, because if you really look at the potential of having an old cesium unit come in a container into the United States from somewhere else in the world and take it somewhere, that is a problem. That would be easier to me than trying to get it into one of your blood banks right now.

So I think you have to put things into perspective on the education end of it. Then there is the actual impact you are going to have on health care which is significant. Because the other thing is, you can't sell these people in third world countries X-ray radiators. They don't have the infrastructure that can facilitate consistent energy power. That's why they don't sell LINACs in India very well. They have cobalt units there.

In South America they have cobalt units. They don't have LINACs, because LINACs cost $3 million

and another couple of million dollars every other year to make them work. So it's a different world.

And once again you got to think of the world, too. Because that is going to buy you an awful lot of credit as Americans around the world, too, how you treat your neighbors.

MR. KAMINSKI: Joe Kaminski. I don't think anybody disputes that. I think the form of cesium-137, so -

MR. ZIMMERMAN: Excuse me, I missed that.

MR. RAKOVAN: Can you say that again, please?

MR. KAMINSKI: I said it's the form of cesium, cesium-137 chloride, that is a concern.

MR. RAKOVAN: I think some of the previous speakers' statements fed directly into the next question that we have, so Michelle, if you could bring it up.

If the U.S. decides to ban the use of cesium chloride sources, should the U.S. have a position in denying or eliminating after-market sales fo cesium chloride irradiators outside the U.S., and specifically, would this be potentially denying medical care to developing countries?

Does anyone want to address one of these?

Please.

MR. COPPELL: Yes, David Coppell here from REVISS again.

I understand the question, but it seems to me to be approaching it from the wrong direction. This isn't about denying the supply of future cesium chloride sources to the rest of the world. There are plenty out there already.

What we need to do, is if we are worried about security, we need to facilitate the replacement of those sources with something that we consider is a better security risk.

Denial is really hardly going to touch the problem.

MR. RAKOVAN: Does anyone want to expand upon that? Please.

MR. ZIMMERMAN: I actually wanted to expand more upon the next to last statement from the rear mike. You were discussing teletherapy units in the third world using cobalt-60. I think that is not really germane to the question we have before us, is it?

MR. RAKOVAN: If it's not germane, then I suggest we don't consider on the conversation. Do you want to say something briefly? Let's try to stay on

focus.

MR. MOSES: A cobalt unit, it uses cobalt-60 to deliver the dose. A teletherapy unit uses a lot of electrical power. So the electrical power, I was using the analogy that electrical power for an accelerator and an X-ray unit are very similar.

MR. ZIMMERMAN: Cobalt-60 used outside the body is teletherapy and all you really need is rotating the source can the same as you would with anything else.

MR. MOSES: I think you are going to have some people address that for you.

MR. RAKOVAN: Okay, I'm going to try to bring us back to the topic at hand in terms of the international impacts of cesium chloride.

Does anyone want to continue discussions on that issue?

Michelle, why don't you go ahead and put the third topic up, third question. And this is specific to what role the IAEA should have in assisting the U.S.

Any discussions on the international impacts of U.S. changes to cesium chloride?

Everybody is ready for a break? Please.

MR. COPPELL: It's David Coppell here from

REVISS. I guess that it's easy to be cynical about the IAEA's role. But it seems to me that if we are concerned about the use of some of these materials in developing economies, the IAEA does have some degree of influence there, perhaps more than other organizations, and perhaps we in this room have got some opportunity to influence the IAEA.

So maybe it's a viable and valid route to try to spread this message to some of the overseas locations where we may have more concern about the security and safety of cesium irradiators.

MR. POWELL: The question is, what should the role of the IAEA be in assisting the U.S. in assuring the safe and secure use of cesium chloride sources? I'm Brian Powell representing nuclear power.

And I'm not sure if this is the right agency or not, but it seems after listening for two days that the problem is again, as Mr. Kaminsky pointed out, it's not the use of cesium, it's the form that the cesium is in.

And at least in my business, when we run into a problem we throw resources at it. We throw money towards it, and we throw people towards it to try to address the issue.

And it seems that we have an opportunity

to work with our counterparts in Russia to apply resources to help the development process along to change the nature of the cesium that we are using.

And I haven't heard in two days how exactly we are doing that or plans to do that.

MS. CUTHBERTSON: Abbie Cuthbertson with the NNSA office of global threat reduction. One of our projects, as I referenced earlier today, is the outside source recovery project, which recovers sources both domestically and internationally. But beyond that we coordinate with the IAEA closely and with partner regulators in over 100 countries around the world providing physical protection upgrades as well as recovery as well as support for other security related projects.

So I just wanted to reference that we are engaging countries around the world. We are raising awareness of the concerns with cesium chloride as well as other sources. And we are coordinating closely with the IAEA and with the State Department in these projects.

MR. ROGERS: Steve Rogers, U.S. Army Primary Standards Laboratory. The question regards safe and secure use of cesium chloride sources and devices. It seems like not that long ago we were

talking about banning cesium chloride.

MR. ERTEL: John Ertel, United States Naval Academy. It seems to me this question would be best handled by slightly rephrasing it and in that way say, what should be the role of the International Atomic Energy Agency in assisting the U.S. to ensure the safe and secure use of cesium chloride sources by removing them and replacing them with an alternative cesium form, the best suited to match medical applications in the one area, and commercial production applications in another area.

There is simply no reason that I can think of that we need to have cesium-137 available in the most easily dispersible and weaponizable form as the standard in the United States.

MR. KAMINSKI: Joe Kaminski. I just want to echo that. It makes absolutely no sense not to move - it makes no sense not to move forward with what he proposed just because - I mean it's silly not to.

MR. ERTEL: Without addressing any significant security issues, I'll just say that it's not been too long ago that we worried about how in the world could someone find a methodology in their back yard or in their garage to weaponize anthrax. Why not move ahead to another form?

MR. RAKOVAN: Any final comments involving specific international issues?

(No response.)

MR. RAKOVAN: Okay, let's go ahead and take a half an hour break. We'll start up again with the panel for issue number four at five minutes of 3:00 promptly.

(Whereupon at 2:20 p.m. the proceeding in the above-entitled matter went off the record and resumed at 2:56 p.m.)

ISSUE NO. 4: ADDITIONAL REQUIREMENTS FOR ENHANCED SECURITY OF CSCL SOURCES

FACILITATOR RAKOVAN: Why don't we go ahead and start the panel. Let's have them introduce themselves, starting here to my left.

MR. MILLS: I am Grant Mills. I work for North Carolina. I am here representing the Organization of Agreement States. And next to my name is also the Gamma Industry Processing Alliance. I am not sure who they are, but I will take a check if they are here.

(Laughter.)

MR. RATLIFF: Richard Ratliff with the Texas Department of Safety and Health Services representing the Organization of agreement states.

MS. SALAME-ALFIE: Adela Salame-Alfie with the New York State Department of Health. And I am here representing the Conference of Radiation Control Program Directors, a.k.a. CRCPD.

MR. THOMAS: Jerry Thomas, Via Christi Regional Medical Center in Wichita, Kansas. I'm representing the largest health care organization, State of Kansas.

MR. TOOHEY: Dick Toohey, Health Physics Society.

MR. RING: Joe Ring, Harvard.

FACILITATOR RAKOVAN: Okay. The issue that we will be discussing for this panel is additional requirements for enhanced security of cesium chloride sources.

Just to remind everyone, please note that this is a public meeting. So we will be discussing only publicly available information. Participants should not discuss specific security-related information about their licensed facilities, nor should there be discussions on the specific scenarios or additional security measures that should be added to a certain device type. This type of discussion could potentially cross into safeguards or classified information and are not appropriate for a public

workshop.

I will take a moment to read the three questions that we will be addressing in this panel. The first one is, should the NRC and agreement states require more stringent security measures than those currently mandated?

Question 4.2, should the NRC and agreement states require more stringent security measures for lower than category 2 cesium chloride sources and devices?

And question 4.3, would additional security requirements for cesium chloride create a disincentive for owning them?

As we usually start out, I would like to see if any of our panelists have presentations or statements that they would like to give. Please?

MS. SALAME-ALFIE: Thank you.

STATEMENTS & ROUND TABLE DISCUSSION

MS. SALAME-ALFIE: I will be presenting some comments that were compiled from our membership. We sent a survey a few weeks ago. We didn't get 100 percent response, but we have about 40 percent. And these comments will reflect those opinions.

These comments -- next, please -- are based on official petition statements of CRCPD in

input to a recent survey. The regulatory community and its federal partners have explored security-related alternatives and have implemented many of these options to assure the safe and secure uses of cesium chloride in institutions throughout the country.

Next, please. Until a vulnerability assessment and comparison to other hazardous materials is performed that demonstrates that there is significant risk, the possession and use of the devices should continue.

Current emphasis on security of the sources as well as increased regulatory inspection by most agreement states is more than adequate to address a perceived risk of category 3 sources.

While the IAEA Code of Conduct indicates that one may consider looking at other risks, it does not consider category 3 sources a security risk. The basic health and safety standards concerning the storage and use of the lower category sources provide an adequate level of security protection commensurate with the level of risk.

Prior to taking any action to discontinue licensing these sources, the federal government should evaluate the risk of radioactive materials in

relationship to the risk of other hazardous materials. Rather than require disposition of current sources in use, it is better to make the current sources safer.

I have a couple of more general comments. Many companies have spent a lot of money over the last few years to meet the NRC's mandated redundant security requirements. After all the effort and expense for improved security, requiring disposal of them and the commissioning of the facilities would be devastating.

It's not in the slides, but the states have invested a lot of time and effort also getting our inspectors up to speed to evaluate those security inspections.

The cost of storage or disposal is astronomical, as was discussed before, and increases every day. There is currently no true disposal pathway for these sources, only long-term storage.

If alternative technologies are required and the sources must be disposed of, federal incentives should be provided to encourage licensees to replace and dispose of these sources.

I just have a couple of slides with some of the survey results that we thought were pertinent to this and the next panel.

Next, please. On the question of what regulatory issues are involved with changing to other forms of cesium-137, mostly with licenses sourced and device registration, transportation-type certificates, et cetera.

Other comments we have received are if we record all sources, then we have a labor-intensive action to take. We would have to issue new SS&D sheets covering the new source.

And one comment that I felt I should include is if anything is done, it is imperative that it be done through normal rulemaking and not through orders.

Would there be an impact due to the more frequent change-out requirements in cobalt-60 devices, required if you use cobalt-60? Ninety-four percent say yes. And a lot of it has been discussed in the last day and a half.

Are regulations and licensing inspection procedures in place in your state that would adequately address X-ray or accelerator technologies that we use in place of cesium-137 or cobalt-60 irradiators? Eighty-seven percent say yes.

As most of you know, we regulate X-ray as well as radioactive materials. So we do have some

expertise in that area.

What other regulatory issues are involved in converting to alternative technologies, such as staff knowledge and training? Some of the responses included staff training to be able to inspect and regulate alternative technologies, development of new regulations, and acceptance of new regulations by the regulator community, lack of available training sponsored by FDA or other federal agencies for X-ray or accelerator system licensing and inspections.

Do you think that current suggested state regulations cover the X-ray and accelerator technologies that are capable of replacing category 1 and 2 sources? Sixty-two percent say no.

For those of you who are not familiar with CRCPD, we developed suggested state regulations to help state programs that have to implement regulations and they don't have staff dedicated to writing regulations. So we still need to do some work in that area according to the survey.

Should NRC discontinue all new licensing and importation of the sources and devices at this time? Ninety-four percent say no.

Should the federal government issue incentives to implement replacements provided that --

the answer is yes, 92 percent.

Should NRC and agreement states require more stringent security measures than those currently mandated for category 1 and 2 sources? Seventy-five percent said no.

Should NRC and agreement states require more stringent security measures for lower than category 2 cesium chloride sources? Sixty-nine percent say no. And, again, we didn't get everybody to respond.

And the last question was, do you feel that the recent additional security measures required by NRC and agreement states are adequate and should be taken into consideration when deciding on further actions? I have to say everybody agreed on that one. It is a yes.

Thank you.

FACILITATOR RAKOVAN: Additional opening statements or presentations? Richard?

MR. RATLIFF: Yes. In Texas, we had 260 licensees that came under increased controls. As you know, with a lot of oil and gas industry, we have a lot of industrial radiographers. And we found that they had the biggest problem because many of them, even though they received the binding license

conditions, were waiting for an inspector to come. And they didn't do anything.

But once they came in -- and we took a different approach in NRC. We made the violation severity level one, two, and three. And so many of them had to pay administrative penalties. And it seemed that that kind of incentive really spread across and we saw the improvements continuing.

We had several blood irradiator facilities come in. They basically had the feeling that there was no threat from these devices, that no one could get into them. And we explained things we could explain to them, and they paid their penalties. They basically showed real good reinspection.

What we found that was I think of note was that many of the facilities, especially in medical and educational, failed when they were doing their trustworthy and reliability and their fingerprinting to check their IT staff because who has access to all of the card systems to get in or to control the motion detectors.

And so we really started making sure that they looked at their IT. If they had direct control over their security measures, fine, but many of them, especially in hospitals and blood banks, their IT

person was the person that controlled that system. So they needed to be determined to be trustworthy and reliable. And we recorded them to have fingerprinting.

Then we found I think the biggest issue, industrial and somewhat medical, is what we call care and feeding. They get everything fixed and it's working fine, but they need to make sure, especially where they are using a lot of chemicals, like industrial radiography, the switches all of a sudden get corroded and don't work. So you really do have to have an ongoing quality assurance program to make sure.

If those all work, the security is really good. It's a new world for a lot of them. But they really have taken on the challenge once they realize the issue. And with the inspections and the repeat inspections, we are seeing almost no violations on repeat inspections.

FACILITATOR RAKOVAN: We've had a new panelist join us. If you could just introduce yourself real quick?

MR. ZABKO: John Zabko. I'm the Deputy Assistant Director of the Architecture Office of the Domestic Nuclear Detection Office of DHS.

FACILITATOR RAKOVAN: And if any of the other panelists have opening remarks or presentations that they would like to give? Please?

MR. TOOHEY: Yes, on this item. And, actually, it's more in response to 4.2. Health Physics Society actually does believe that category 3 sources have the potential for severe health effects to individuals if mishandled, lost.

And, consequently, we think that in the licensing process for these sources, attention should be paid to use of alternative technologies. But the detail and depth of that analysis should be proportional to the risk involved, which is, of course, a function of the source activity.

Clearly the evaluation and imposition of additional security requirements and replacement with alternative technology priority must be given to category 1 and 2 sources. And the question of what to do with category 3 sources can be deferred until the higher hazard sources are squared away.

MR. ZABKO: From DNDO's aspect, we are trying to promote the enhanced hardening for the irradiator program to allow time for the items that you have been discussing over the last two days to come to more fruition, such as the evaluation of

phasing out alternate technologies.

We believe in conjunction with the DOE program for the irradiator hardening and the security upgrades, this buys the U.S. government and the licensees and manufacturers the time to make qualified, educated decisions in a timely manner to both promote security but also not limit the use of these sources in the medical or industrial community.

FACILITATOR RAKOVAN: Anyone else on the panel like to make an opening statement? Please?

MR. RING: Joe Ring, Harvard. I think if we do make any additional changes to the security, they should be based on risk considerations. Significant changes have already been made. And those aren't really considered in much of the work that we have talked about today.

FACILITATOR RAKOVAN: Okay. Let's open this up for discussion. Anyone want to add to the discussion so far? Okay. Please?

MR. THOMAS: Yes. I would like to just comment on each of the questions as we come to them. Our first question, should we have more stringent security? I don't believe that we should, but in discussions that I have had with medical treatment facilities across the nation, I find that the

implementation of the increased security controls don't appear to be consistent, either as directed by the state or directed by NRC regulators who are overseeing that process.

I think with more uniform guidance as to what would be expected in terms of the controls -- and I'm specifically thinking of health care facilities only, which would be at this point class 2 source devices -- there is a general trend in medicine that hospitals are open and that they are not secured vaults or secured areas and consequently is something that is widely open to public access. Increased controls are a foreign concept to people that are trained and working in a medical treatment facility.

Again, I want to emphasize from what I have heard from others as well as from what we have seen in our organization and other organizations. I think for today, the increased controls are adequate.

I learned yesterday and had my eyes opened when we had the discussion from Sandia, Len, I believe. That will also influence some of my comments a little bit later.

MR. MOSHAASHAEE: Moji Moshaashaee, Schering-Plough Radiation Safety Officer. Personally my company actually doesn't have any problem with

hardening if you call that requirement hardening. So I think it is a good way to secure the source. So this could be a requirement: Hardening the source. I am for it.

MR. LEW: Bill Lew. With respect to issue 4, as an RSO and representing other RSOs in my system, should additional IC requirements be brought forward, particularly with outcomes on future reports?

We would like to have the NRC continue your stakeholder meetings out there in the regional offices or nearby regional offices to give stakeholders easy access to your meetings.

With regard to cesium chloride, should the future reports indicate that there is a particular index of risk? Perhaps the index risk for a non-cesium chloride source, there would be some kind of a process to perhaps bring them into equivalent protection so that the IC process, so we as users can believe that we have achieved adequate IC.

MR. MORGAN: Tom Morgan, University of Rochester. I would say that what we have done to date has been an 80 percent or an 85 percent solution. Going a little bit farther is not going to buy us that much more safety, frankly, because I believe the greatest risk is people. And we have gone about as

far as we can go with doing trustworthiness and reliability determinations with the background checks and the fingerprinting and that kind of stuff.

Any more physical security measures short of locking everything up behind a door, putting an armed guard there, still you've got people involved. And when you have people involved, you are going to have risk. And I just don't see what else we could do personally to reduce our risk any farther.

FACILITATOR RAKOVAN: Go to the table and then to a comment from the floor.

MR. MILLS: Grant Mills, OAS. I agree with that totally. And also, reiterating what I have heard up here, what we are seeing in the field is the existing ICs are adequate. However, there is still a lot of ground to be covered in enhancing the security culture.

And it may be just a matter of time, but for a long time, we have told folks that specifically blood irradiators, the only way it can hurt you is if it falls on you.

(Laughter.)

MR. MILLS: And now we are shifting gears on folks. And it is going to take a little bit of time to institute that culture of security, which is a

foreign discipline to a lot of folks.

MR. RYAN: One of the things I think that is important to think about when you think about risk is it is not just about the consequence.

A lot of times we have talked in the last couple of days about consequence. There are three elements of risk that I always think about as the risk triplet, first published by Kaplan and Garrick in 1981. What can go wrong? How likely is it? And what are the consequences? So those three elements in anything come together to really help you define the risk. It's not just about what are the consequences. It's about how likely is it and what can go wrong.

There is a probability the Earth could be cleaved in half by a meteor. It's a very low probability. So it is not something we spend a lot of time worrying about.

But I think in the context of cesium chloride or irradiators or any other radioactive material or even reactors, which is a very common way we assess those, we use probabilistic risk assessment. What can go wrong? How likely is it? And what are the consequences? And I hope we hold those thoughts about risk as a whole concept.

FACILITATOR RAKOVAN: Sir, could you

remind us who you are, please?

MR. RYAN: Sure. I am Mike Ryan from the ACRS.

FACILITATOR RAKOVAN: Thanks.

Mr. Ratliff?

MR. RATLIFF: One thing I think we have found that has helped, initially a lot of the local law enforcement was not cooperative. And I think once they touched base with their governor's homeland security person and they described what money was coming down and what was not coming down if they didn't work, they have actually interacted well with the licensees.

(Laughter.)

MR. RATLIFF: So I think now basically you have done trustworthy and the reliableness of the workers. You have done the hardening. So you have advanced warning if someone breaks in. And now with local law enforcement knowing what is there, I think that has been a real benefit because they actually now come to the sites. They will actually interact with licensee groups.

And, if nothing else, if there is an attempt at theft, you have a much quicker response and ability to stop the people from getting away with the

sources.

MR. ZABKO: Along the same lines about education and cooperation between local law enforcement, irradiation health, and just bolstering the security culture of licensees and local law enforcement, New York City is a good example of one of the areas that that has really taken root in.

There is a combined effort up there with the NRC, the agreement state of New York, DOE, and ourselves at DNDO DHS to pull that area together and promote these exact best practices that you are hearing: One, the irradiation health and the local law enforcement going on the IC inspections in tandem so they can both teach safety and security at the same time as well as doing the inspection for compliance; involving local law enforcement in facility tours specific to the cesium chloride irradiators or whatever their source of risk is there in the hospital; working together to standardize the application, although the ICs are very, very good for what they are intended to do but to standardize them across all the licensees in the New York City area. They have done a very good job at sharing best practices to not only meet the ICs but make sure that all of the licensees are at the same par throughout

the city.

There is a coordinated effort between the groups that I just spoke of to produce a best practices report and to spread that across the United States so that this will be kind of a standard security culture awareness and a rise in security culture across the United States.

MS. FAIROBENT: Lynne Fairobent with AAPM. Just a couple of points. I am assuming that this question is truly just limited to increased controls being added to cesium chloride sources below category 1 and 2. AAPM is on record, actually, that we do not believe there is a need to across the board expand increased controls below category 1 and 2.

Just to follow up on a couple of the comments that were made on addressing and educating to shift and change security culture to be a mode of operandi in the medical community, category 1 and 2 sources, in particular category 2 sources, at hospitals are a very small, finite set of licensees and facilities. If one, even with the cesium chloride sources, were to expand, both in industrial and medical use, below category 2, you're bringing in another whole universe of licensees that perhaps have not been as focused or aware of the issues that we all

have dealt with for the past seven years.

I think that there is a huge education and outreach potential that needs to be done, not only by the regulated community but the user community and the professional societies, on this before and which this question could be adequately answered to determine the true impact if one went below category 2 sources.

Many of the licensees who have not had category 1 and 2 sources I would tend to say are not even aware that this effort has been going on. They are not part of the universe that has tracked and followed Federal Register notices, either at the national or a state-specific level. They have not received the communications that have gone out on this. They are not party to the discussion.

We still have a huge education effort ongoing with category 1 and 2 licensees that once you open that universe up below category 2, I don't think we have a clue what the potential impact, both monetarily or education-wise, would be to do that.

FACILITATOR RAKOVAN: Michelle, why don't you go ahead and put 4.2 up there? Essentially it's the same question as the first one except it's expanding to category 3 sources, as Lynne was discussing.

Mr. Ratliff?

MR. RATLIFF: I think one of the issues we see is our resources, not only the NRC and the state regulators and doing routine and consistent inspections but, like I said before, the local law enforcement.

If they start to see where we're looking at more what I would consider trivial sources that you have to do more to have a real health threat, you weaken the whole issue of really protecting the category 1 and 2 sources and weaken the regulatory oversight of those programs.

MR. THOMAS: Category 3 sources have varying levels of security currently within medical treatment facilities. And if we look at the three elements of risk that were previously stated, I think it's clear that what can go wrong is that somebody can get access to them.

Most facilities have been 500 millicuries to 5 curies of those source materials and, additionally, sometimes instrument calibrators, which could put them up to potentially 10 curies within their facility.

How likely is it for somebody to break in and steal the sources? It really depends on the

existing security and knowledge of where the equipment is.

I look at the consequences of an individual or a group of individuals going to multiple hospitals within a region and collecting the sources. Now we have a collection of source material that is indeed in a category 2 category.

Because of that, what is the risk and the plausibility of that? I leave that to people that are more trained in risk analysis than myself. But I would say that it makes some sense if we are going to control higher levels, category 2 within increased controls, that if they are in place already, it makes some sense to put those same controls on category 3 sources that you will find primarily in your large medical treatment facilities.

MR. LEWIS: I am Rob Lewis from NRC. Just a point of clarification. I think maybe some of the vendors or maybe calibration licensees could help me. It is my impression that most of the category 3 cesium sources are ceramic or glass and cesium chloride is only used for category 1 and 2, much higher activity, much above 20 curies.

So in asking this question, it is not written in the question, but we are kind of drawing

out for the regulatory decision-making process the category 2, being cesium chloride, and category 3, being cesium ceramic or glass, that there can be a distinction made.

MR. THOMAS: Can I modify --

MR. LEWIS: I am not 100 percent -- sorry.

FACILITATOR RAKOVAN: Hold on. Please?

MR. LEWIS: Go ahead.

MR. THOMAS: I did not know that. So based upon that, I have to reverse what I have said, and that is that there is no reason because of the risk, the lower risk, that the material is not cesium chloride.

Now, if you already have the increased controls in place for your category 2 sources, I still stand behind my statement that it makes sense if you have got those controls in one location, to have them in another.

And I have worked in facilities that had essentially no control, just a padlock, to triple-lock controls and keypads on the same levels of category 3 sources. So it really depends broadly on where you are working.

In my comments, I did not realize that the lower-activity sources were not cesium chloride.

MR. KAMINSKI: Again Joe Kaminski, radiation oncologist, just speaking for myself. I am not 100 percent sure, but I am pretty close, that the cesium-137 they use in brachytherapy for gynecological malignancies is cesium chloride. And we have pretty easy access to that material. Again, it's in tens of millicuries, but still it's still potentially harmful. It is harmful.

MS. FAIROBENT: Lynne Fairobent with AAPM. The cesium sources used in brachytherapy are in a ceramic form, not in a cesium chloride powder form.

In addition, Jerry, I would respectfully disagree with your comment. If you have increased controls in place for category 2 sources, adding category 3 under them is not trivial. Remember, the number of individuals that would have to be fingerprinted, have unescorted access to category 3 sources is much greater in many medical facilities and academic research facilities than those that have unescorted access to category 2 sources. So the cost factor and the fingerprinting in the areas that increased controls may have to be applied are not necessarily the same as just bringing them in under the existing control parameters that are in place.

The other, I believe, is that the

additional educational costs to the employees that would then be involved also go up as far as training and as I think Richard used the term "care and feeding" of the culture aspect that is a new approach or a new direction for many of the materials licensees. That is different than what we grew up with in the reactor world, which is where I had started.

MR. RATLIFF: Richard Ratliff, OAS. I think maybe people lose sight, too, that if you have category 3 sources co-located to the amount that they reach that level, they do come under all the increased controls. So it's just only when you would have individual category 3 sources.

And we have worked in Texas with the petrochemical industry. They may have 1,000 or more cesium gauges on different plants. And so we have devised a way that they are not co-located because they have other security. But when they take them down and put them in one location and they are co-located, every increased control requirement takes effect.

MR. THOMAS: My point was not based upon co-location but someone other than the person that owns the source being involved in co-locating source

material.

I think that Lynne is exactly right. It depends on the facility that you are in in terms of the number of individuals that would be affected by the comment that I made. In some facilities, that would be a small number; other facilities, that would be a substantial number.

But, again, the discussions that we have had just over the last two days, quite frankly, I have changed two or three of my positions in terms of what I perceive as risks to be less laissez-faire and more restricted on access to and use of some of the source materials that might actually be used in a non-conventional manner is the best way to say it.

MR. MOSHAASHAEE: Again, Moji Moshaashaee, Radiation Safety Officer, Schering Corporation. Anybody can make a mistake. I wasn't there when we were talking about at first, you know, category 3. Yes, I am glad, you know. I have to retract what I said, even for hardening. So I just want to try and say, you know, I was wrong about that.

FACILITATOR RAKOVAN: Okay.

MR. POWELL: Brian Powell, Constellation Energy, representing Nuclear Power. I am a very practical kind of a person. And we have taken some

steps to secure category 1 and category 2 sources, not just cesium chloride but all of them. And these sources have been determined by the IAEA to represent some substantial health risks, either immediate or within close proximity.

And we are responding as a nation based off of a threat, threat from a terrorist. I would offer that terrorists operate in different ways. And reacting to something that someone is asking for and getting us to react is one way of accomplishing something.

You know, I just gave a class recently in which I talked about a speech that Osama bin Laden made where he was using another form of terrorism. His method of operation was called "bleed until bankrupt." He said, "I've just got to run to one side of the desert and wave a flag that says, 'al-Qaeda' and I can get the United States to chase me all the way across the desert. And I can put two more people on the other side of the desert and have them raise a flag with 'al-Qaeda' written on it. And they will run all the way across the other side of the desert." And for a few pennies, we are spending a tremendous amount of resources.

If someone were to get a category 1,

category 2, category 3 source and attach it to some method to detonate it, in the public's eyes, they don't know when we put in the paper "Oh, this was a category 3 source." It's not going to make a difference to them. They are just going to know that something got set off by somebody.

I would just offer this, that there is a point where we overreact and the resources that we put towards some efforts are no longer worth the risk.

Thank you.

MS. SHEPHERD: Mary Shepherd, Shepherd and Associates. In regards to Rob Lewis' question, there are some small source manufacturers who are not represented here today: Global QSA, Eckert and Ziegler. There are probably some other ones. There are a lot of historical source manufacturers that are no longer in business for the category 3 sources.

There is a wide variety, a very wide variety, of chloride or ceramic in category 3 sources. The sealed source and device sheets, we were never required to list the isotopic form. So it would be hard to cull that from the archives.

There may have been Department of Transportation special form certificates. Again, you would have to cull the DOT archives for the form of

the cesium. We've got some historical records, but we are by no means complete. We have a good library but not complete on every source historically that has been out there.

And some of those go back to AEC. So you would have to go back to the AEC archives if there are some still out there. They are now a category 3. So it's a hard question to answer unless you got the current manufacturers, but the old sources, it's all across the board.

FACILITATOR RAKOVAN: Okay. I am going to ask Michelle to go ahead and bring up the third question here, would additional security requirements for cesium chloride create a disincentive for owning them?

And I am going to ask if you come with a one-word answer, that you give some justification for it because I have a feeling what word I am about to hear. Please?

MR. THOMAS: I am going to have to choose my words carefully. The answer is possibly, depending on the perception of the user as to the impact of the increased control on their clinical or research operation.

Historically I have seen many researchers

in medicine and biomedicine choose alternative research methods and approaches because they found that the licensing and the oversight for dealing and working with radioactive materials they felt were onerous. If the increased controls are perceived by the end user as being onerous, I think exactly that is going to become a disincentive for owning them.

So if we want to reduce the use, we could make the increased controls onerous and people will certainly find alternative pathways for accomplishing the goals that they want.

It is clearly not the intent of anybody, I think, to do that, but that could be an unintended consequence of increased controls depending on the education processes of the end users as well as the end user's perception as to what those increased controls are going to cause on their impact to their organization.

If there were a new facility starting out today, my guess is the advice would be not to use isotopes for an application if an alternative could be found simply because of the increased control requirements as well as the concern about the risk of that isotope if we are dealing with a cesium chloride isotope.

MR. ZABKO: From the Department of Homeland Security's perspective, we are trying to keep these fixes for security implementation for cesium chloride irradiators at the minimal cost of the -- actually, the first program, the hardening, is at zero cost to the licensee besides the time and effort to participate.

The future programs that we may combine efforts with DOE and NRC and the agreement states, we're trying to minimally impact the licensee and the manufacturing community for the use of these sources. We understand that unfunded mandates are not the way to go. And overpriced security solutions are not the way to go.

So I just want to make sure that the audience understands that we do take this into consideration.

MR. BOHAN: Mike Bohan from Yale-New Haven Hospital. I just wanted to point out that we already have evidence that this happens. You know, 10-15 years ago, we used to practice radioimmunoassay in this country. At that time, fluorescent antibody technology came out, which I don't know if it was as good or better than radioimmunoassay, but our users basically wanted to get rid of radioimmunoassay just

because of the cost involved with waste disposal.

You know, $5,000 for a 70 and a half cubic foot of waste is a lot more expensive than whatever it would cost to get rid of fluorescent antibody waste. So basically just for a mild economic reason, they changed technologies.

You know, when you put in additional security requirements, you have changed the equation where people balance it. We may all say from the standpoint of safety that we are better, but we also have the unintended consequence that if people changed alternative technologies, we may miss something that we might have had that we may not realize right now that we lost because we changed technologies.

MR. MOSES: Paul Moses, Best Theratronics. When you start increasing the security requirements, it's been quite apparent to me, being in sales and marketing, that there were more people taking a hard look, of course, at the X-ray technology. So that is obvious.

The other thing that I was a little surprised at -- and, in fact, homeland security becomes part of the factor here, too -- because some people are hedging their bets a little bit and what they would do is call me up and say, "I want to use

one of your containers to sell my unit to" somewhere off shore. And that is due to the increased security requirements.

So, of course, I go through the series of questions where is it going, who are these people. We are allowed to do that, but let me tell you we just don't for good reasons, especially if we don't know where it is going.

So one of the things when you look at increased requirements and increased security, the licensees, you may want to ask them or stipulate that if they do plan to sell the units, there should be protocols that they have to follow to do that.

MR. ZABKO: I would like to address the international question. We are taking that into consideration. We have initiated talks with the European Union, IAEA, and EUROPOL to start the kind of grass roots movement that we have now in the United States with irradiator hardening efforts and the education and security in the European countries because we know that eventually these if they are going to be sold outside of the United States could become just the reverse problem for us coming in across our borders again. Although this is in a very, very early stage, we are taking this into

consideration.

We are also working as part of the irradiator hardening program with the manufacturers. We haven't quite worked out the details but to make sure that there is consideration for sales overseas, that these machines will be hardened as well as when they go over.

I know that is a kind of a secondary function of the program right now, but we are seeking that angle.

MS. FAIROBENT: Lynne Fairobent with AAPM. I think perhaps additional security requirements could create a disincentive for owning them if there were an alternative form of cesium or another source that could be used across the board for many of these applications.

We have heard a great deal over the past two days that there is not currently an alternative for these sources. So I think it is hard to say if you have no other option and you need to use the material to continue your application and use, be it in research or clinical practice or industrial application, you probably are going to bite the bullet and put the increased controls in and continue using the sources until there is an alternative.

I think a good example, though, one could look at if one wanted to get a feeling for where there are alternatives, in the medical community, there are two analogous machines. One is a gamma knife that uses a radioactive material source. And then the other is a cyber knife that does not. It uses an X-ray source.

One could probably take a look at the statistics of perhaps the increased sales for cyber knife since the increased controls were put in place for category 2 gamma knives and get some sort of correlation or data analysis at least to see when there is an equivalent alternative.

Now, one could ask many of the physicians who are gamma knife users versus cyber knife users. And you do get into some personal preference over who likes what device better and for what purposes, but they are analogous machines.

The other that we could take a look at downstream if increased controls are expanded down to category 3 is in some of the electronic brachytherapy now, the new ZAF system that is out versus using brachytherapy with radioactive material sources.

If you read some of the ZAF literature, they believe that with the increased controls and

perhaps the tracking and radioactive material and the concerns that are out there, that they believe that is going to help their market share now that their device has been FDA-approved.

MR. THOMAS: Another comment on increased controls and what impact it might have. And that would be in the research environment. Joe, I would appreciate your thoughts as well.

From the research world that I came from three years ago, I would say that many of our researchers would choose an alternate subject to study or change the course and path of the research program if they felt that the increased controls became too restrictive.

I know that many facilities now -- and you described yesterday the fact that some of your researchers now have to go through two or three levels of security to get access to the source.

I would expect that many researchers would choose not to go into a particular area of research or change their research focus based upon increased controls. Is that a valid perception on my part?

MR. RING: Thanks for bringing that up, Jerry. You are starting to see some of those reactions by researchers. On the other side, though,

the academic research complex has seen so many different areas of concern identified with materials that they are using of such a wide variety that the normally open, collaborative type environment is getting an awful lot of pressure on security. So this has become a very complex subject for researchers.

They are getting battered by different security requirements from so many different sides, chemical, radiological and biological, that they are starting to become numb to it.

On the subject of whether the incentives or the ability to replace it in the disincentives, there becomes a limit at which you can't replace it. Some of the scientists are saying that they need the cesium.

While you may find an alternative for some of the research components, there are still going to be some that, even after a while, they can't change. And if you have an opportunity to buy one piece of equipment to satisfy everyone's needs, you are going to have to go in the direction right now of the cesium irradiators.

We are currently looking at that for one of our new buildings. And so far we have been pushing X-ray technology. They have been coming back with for

some of the research projects, we could use X-ray, but for many of them and most of them, we cannot.

And so you wind up with the only incentive that you can get is not to do the research.

MS. GILLEY: Debbie Gilley, ACMUI. I would like to bring it to the attention that, even with the increased security requirements, we still don't have a disposal option. So if there are increased requirements put on these licensees, they will have to be compliant with that because they have no other option for getting rid of the sources.

FACILITATOR RAKOVAN: Last comment before we move on?

MS. DANIELS: Sameera Daniels. I think what is bothering me about the control like a security requirement and then, in the alternative, phasing out the cesium chlorides, whatever alternative there is will have its own worst case scenarios as well, I mean, that they themselves will engender some of the similar and different security environments. So I wondered. I mean, I am trying to get a handle on that. And if any of you have any comment on that?

MR. ZABKO: First of all, we're not favoring phasing out cesium chloride by any means. I do understand what the discussions have been for the

last two days. We are on the same line: Slow where it fits, if at all.

If you do go to other alternative technologies, such as X-ray, there really isn't a worst case scenario that you could do an X-ray to that you couldn't do with cesium chloride. So there are some alternatives. I know there are some problems with X-ray.

I mean, there aren't the same risks for a terrorist act, but if that is what you are focusing on with some of these alternatives, if you're going to go to cobalt, you've got a less dispersable piece of metal there, as opposed to a cesium chloride salt.

So each one you're right. And you're right in your concept of saying each has its own risk. But then the risk can be diminished by choosing the right alternate path or combinations of the right path.

So I think that is somewhat answering your point. It is not just going to another isotope necessarily. It could be a whole other technology.

5: ROLE OF RISK ANALYSIS IN POTENTIAL FUTURE CsCl REQUIREMENTS

FACILITATOR RAKOVAN: Okay. Let's go ahead and move on to our final panel. As the

panelists come up, I would like to thank everyone for keeping your facilitator's heart rate down and blood pressure down during those discussions.

(Laughter.)

FACILITATOR RAKOVAN: Issue number 5 is the role of risk analysis in potential future cesium chloride requirements. We will just pause for a moment while we switch over our panels.

(Pause.)

FACILITATOR RAKOVAN: Okay. I will go ahead and read the question. And there is only one question, Q5.1. How should the NRC determine the economic and social disruptions/impacts to the public, licensees, and the environment? (b) How should these factors be measured in decision-making? And this is, again, on the role of risk analysis in potential future cesium chloride requirements.

If we could go ahead and go around the table and have everyone introduce themselves?

MR. CONNELL: I am Len Connell from Sandia Labs. I do radiological and nuclear terrorism system studies.

MS. DANIELS: I am Sameera Daniels, Ramsey Decision Theoretics. And I am a citizen observer of the national security arena.

MS. SALAME-ALFIE: Adela Salame-Alfie, New York State Department of Health and representing Conference of Radiation Control Program Directors.

MR. ERTEL: John Ertel, United States Naval Academy. I'm an old nuke. I'm primarily an acoustician now, but I was asked to come to the panel.

MR. TOOHEY: I am still Dick Toohey, Health Physics Society.

MS. FAIROBENT: I am Lynne Fairobent with the American Association of Physicists in Medicine.

FACILITATOR RAKOVAN: Okay. Any of the panelists have an initial statement or presentation that they would like to give? Please?

STATEMENTS AND ROUND TABLE DISCUSSION

MR. CONNELL: I have one chart to show there. Connell. Let's see. I've been doing these nuclear terrorism studies for at least a decade. And this issue of risk came up in a series of Defense Science Board studies that I was involved in back in the late '90s. And one of the things that was obvious in these committee meetings was each of the committee members had their own favorite scenario of how a radiological terrorism attack would occur.

But there was really no context. And so the way we got started using the concept of risk at

Sandia on this was in a qualitative manner, really to just kind of organize our thinking and get our arms around the problem. And what resulted was this chart. So let me just try to walk you through it and explain it.

As others have mentioned, risk involves two basic factors: the probability and the consequences. So if you look at an RDD, a dirty bomb attack, you know, what does it take for a terrorist to pull this off? Well, first of all, let's look at the probability side. Those are all the yellow boxes. And so we can kind of break it down into its fundamental building blocks.

Well, first of all, you have to have a terrorist group that is motivated. And I can't talk a lot about what we know from the intelligence community, but what has been publicly released is that we know that al-Qaeda is interested in radiological terrorism. We've got a lot of evidence of that. So it would be irresponsible for the government to ignore that and to not look at these risks. We know that our adversaries are interested in using radioactive material against us.

So the next thing, given that we have got a terrorist group or an organization interested in

doing it, what do they have to do? Well, they have got to get the material. That is the next step: find some radioactive material. Learn how to disperse it and get your material and your dispersal mechanism to a target and go ahead and disperse the material. And if you do that, then you get the consequences, which are the three elements there in the blue boxes.

Now, one of the things that makes radiological terrorism unique is the psychosocial aspects of it. If you look at the public's perception of risk, it is often a lot different than the way you would actually calculate it. And it really hits all their hot buttons when you look at radioactive material in terms of the public's understanding of the risk, the fact that it is not seen.

The scientific community can't seem to agree on whether a millirem is a threat or a risk for cancer or not. I mean, we assume that it is a zero threshold, so the fact that we can't really agree on that.

The public's trust in the government associated, all of these different risk factors, the equitability of it, you know, infants and pregnant mothers are more at risk than others. All of those factors tend to make radioactive material an

attractive target for terrorists, just knowing the kind of consequence it is going to produce in the public perception.

At the other end of the spectrum is the health effect. And I think we have reached pretty much consensus in the government community that it is really, really difficult to create a serious health effect over a large number of people with an RDD. It's not impossible, but you really, really have to work hard at it.

And there are lots of other easier ways to kill people than using radioactive material: poisons, guns, explosives, you name it. So what really makes it unique is another part of it is the middle part. There are many credible scenarios with radioactive materials that are out there where you can create a very serious economic problem where you have contaminated the ground and you have a very, very difficult time cleaning it up.

That's different than a chemical spill or a chemical device, where you can neutralize the chemical, a biological species can be killed. You can't kill this material. You cant neutralize it. You've got to pick it up.

So that is what we call area of denial or

denial of access. And the consequences of that are what we find to be the dominant consequence, we think or I think, for the RDD.

Now, you can go back to each one of those boxes and look at there are things that governments can do to try to provide countermeasures, to inject negative probability or to mitigate the consequences.

You can try to de-motivate the terrorists by various mechanisms. We can talk through each one of those. But the one that we should focus on is the source material because that is obviously what we are talking about here.

So it's critical that we look at the different source materials and prioritize them and assign security levels that are commensurate with the risk. And what we have got now is NRC stepped up with the agreement states and has applied increased controls.

One of the things we noted in the National Academies study was that perhaps we could go back and re-look at things based on the consequence that that particular device or radioactive material has in terms of creating economic consequences.

And, you know, you brought these sources last time. I just want to mention that the increased

controls are based on the IAEA Code of Conduct and category 1 and 2.

This little cobalt slug is a category 1 source, 1,000 curies about. This cesium chloride, about 1,000 curies, is category 2. But which of these two actually has a greater risk of being used in creating this area of denial situation? It doesn't take a lot to see that there is a significant difference in which has a greater potential, which has a greater risk of being used effectively in area of denial.

So I will leave it at that, but that is where one of the National Academies' recommendation was to go back and rethink things based on the area of denial consequences of these materials. And that perhaps may lead to a different graded security regime for cesium chloride versus the other ones.

Thanks.

FACILITATOR RAKOVAN: Additional statements?

MS. DANIELS: I am Sameera Daniels, Ramsey Decision Theoretics.

Thank you. I come from a perspective of a citizen observer of the national security arena, as I mentioned. This role allows me to be an informed

citizen and serve the U.S. government in an independent capacity.

I wanted to preface my observations with an historical anecdote, which is that the first time I heard about a radiological device was when I was about 12 years old at a Union of Concerned Scientists meeting, which was held, I think, at that time in New Haven or in Boston. For the next five or six years, I had recurrent nightmares about it.

I raise this anecdote because it speaks to the issue of the fact that each of us perceives risks differently and perceives threats differently because of our experiences. And because of this, I strongly believe that we have to think harder about the kind of risk analysis and cost-benefit analysis that we do.

In looking at the reports, particularly the National Research Council report, and really having studied the various kinds of various modes of risk analysis and the cost-benefit analysis, I'm not so convinced that the one that we use is appropriate to this particular task and issue before us. And I don't have time to go into what that would entail, but I think that it would incorporate an approach which has a wider lens than is offered in some of the remarks today.

It would take full account. It would be an inter-disciplinary approach and take full account of social and psychological constraints which impede good policy-making and setting of priorities, drawing on perspectives from the media, social sciences, polity, and law because these domains have an enormous influence in shaping perceptions of risks and threats and, thus, they can frame the questions about and criteria for cost-benefit analysis.

And I favor specifically a cost-benefit analysis which just doesn't simply go to the aggregation of costs and benefits but also really explores who is being hurt and who is being helped.

Second, we have been hard-pressed to admit that economic and social disruptions to the public government have occurred because we have excluded or constrained rational and unpopular perspectives and have preferred perspectives and information which confirm our exiting biases.

Therefore, I am here to advocate for institutional safeguards which ensure that minority and unpopular policy perspectives are given public and confidential hearings, particularly when these perspectives can foster rational and informed responses, reduce the potential for defective

decision-making, reduce costs, protect civil liberties, and dispel baseless arguments, fears, and risk panics.

This is particularly important, given the fact that we are involved abroad in exporting our values and stuff. And in this country, to know that dissent might be perceived as aiding the enemy is something that we need to dispel also.

Third, as a consequences of conflicting threat assessment and media depictions of threats, we have become even more polarized over the nature and severity of national security threats to the United States and fundamentally disagree about how to frame and negotiate these threats.

These trends can distort perceptions and shape and distort, disproportionately shape our policy choices and specifically about the issue before us today.

Therefore, especially in cases where alarmist predictions are not backed by good evidence, we should strive to ask the right questions to the extent that that is possible.

We should ask for a comprehensive evaluation of sources and exculpatory evidence for these predictions, which will help us determine the

appropriate variables for informed cost-benefit analysis and sustained high-quality reasoning about the security and safety challenges of our time.

Thank you.

MS. FAIROBENT: Just a couple of quick slides just to put some things on the table from our perspective at AAPM.

Next slide, Michelle. For those who weren't here yesterday, this is just simply a statement of the mission of AAPM.

Next slide. This is just a compilation of the question.

You can go to the next slide, Michelle. The next two slides are simply examples of elements that I believe should be included in any cost-benefit analysis that is to be done or risk assessment. Since the increased controls were implemented under orders, the opportunity which a cost-benefit or regulatory analysis, environmental impact statement accompany the rulemaking was not provided the community the opportunity to review and provide comments on and as the Commission moves forward moving away from orders into rulemaking in these areas and spaces, these are some of the things that we feel need to be considered in doing the regulatory analysis.

Many of these have been items that we have mentioned over the past couple of days. And I am not going to belabor them because time is getting short, but I did want to get them on the record.

Next slide is a continuation of the list of some of the items to be considered.

And then the next slide, Michelle. In conclusion, however, AAPM believes that a generic risk analysis should be conducted by the NRC with input from its federal partners and the stakeholder community which focuses on the specific application of use.

I do not think that a cost-benefit analysis for the use of cesium chloride irradiators perhaps and blood banks or an irradiation or blood is the same cost-benefit analysis that should be done in the use of cesium chloride irradiators for research purposes.

I think they are not necessarily an apple-apple comparison. I am not totally convinced, though, it's an apple-orange comparison, but it is different. And I think each application has its own unique set of criteria that should be analyzed.

However, if the generic analysis, risk analysis, is done properly, I do not and AAPM does not

believe that there should not be a need for a specific licensee to conduct an analysis, any further risk analysis, for the use of the sources as long as they're used within the appropriate regulatory framework that the generic analysis assessed.

Thank you.

FACILITATOR RAKOVAN: Further opening statements?

MS. SALAME-ALFIE: I just have a couple of remarks from our membership. Regarding this topic, any decisions should also weigh their focus on security of radioactive materials versus the easier-to-obtain chemical and biological materials.

Current and prospective technologies, such as X-ray and security for radioactive materials, need to be reviewed and evaluated. Impact of the removal of cesium chloride should be solicited for those licensees who have devices. In addition, methods to control return sources to lessen the probability of environmental disposal should be reviewed.

I would like to add a personal comment, not from CRCPD. We have done a lot of work in security and hardening sources. We are moving in that direction. I will feel strongly that when we do the risk assessments, we take those additions into

consideration and don't do the risk assessment like we haven't done anything to increase security.

Thank you.

MR. TOOHEY: Okay. The Health Physics Society in general believes the risk-benefit analysis is initially best accomplished by expert panels and should be as quantitative as possible and take full account of the uncertainty in both the risk and benefit analyses, particularly in the risk coefficients.

Having said that, on a personal note, I would like to say I agree very much with Ms. Daniels' opinion that we have to have community involvement and take in the things that we as scientists normally ignore, which are the way people make decisions and value judgments and the rest of that if we are going to be at all effective in providing the benefits of these technologies with proper balance against risk and security requirements.

Thank you.

FACILITATOR RAKOVAN: Further discussion on risk analysis? Everybody is ready to hit the road? Please?

MR. STRACCIA: Fred Straccia, Radiation Safety Control Services. I would just like to hope

that NRC would consider, in addition to the risks associated with a radiological dispersal device and also the risks associated with eliminating the rest of the cesium chloride sources, that they weigh the comparative risks against the biological and chemical type of hazards that exist out there.

So before we spend millions and millions of dollars trying to recall all of these cesium chloride sources, we really make sure that it's a smart decision in terms of our limited resources for homeland security and that we're doing the right thing here.

Thank you.

MS. DANIELS: Also I had prepared a 30-minute speech because I didn't realize that it was a 3. I thought it was a 30.

(Laughter.)

MS. DANIELS: So I have a lot to say, but I just wanted to also point to one other thing. Each of us comes with a different knowledge about how to go about doing risk analysis and cost-benefit. I think that we are almost always never, we are ubiquitously never, on the same page; that is, the public, even among the experts.

I was mentioning to Dr. Malinowski that

some of us, you know, this is a culture thing, too, risk threats. This is a cultural issue, too. I mean, for some ethnic groups here, the salience of a catastrophic attack is greater than it is for some others. Age is another factor.

I think that more has to be done in the way of public education of bringing communities along and getting them on the same page and help to understand what risk analysis entails on some sort of basic level. So that was one of the things.

FACILITATOR RAKOVAN: Further discussion? Please?

MS. SHEPHERD: Mary Shepherd. And this time I'm speaking as myself.

(Laughter.)

MS. SHEPHERD: There are some stakeholders here that are not here, biotech companies. We haven't talked about the various kinds of research that have been particularly done with cesium that can only be done with cesium, the medical advances and the potential medical advances, stuff that is on the table now.

There was an article in Nature, "Cell Work," two weeks ago. The manipulation of regular cells into pancreatic insulin-producing stem cells is

on the table. That is a cure for diabetes or potential cure. The cost to the American public for something like that through Medicare and for medical applications is astronomical.

I don't think a lot of the research people unless they publish are going to talk publicly about their actual applications. And maybe that is something that the Commission could look at and ask different firms because a lot of that is very proprietary information where the research is going and what the future applications are for. You know, there is a lot of really neat, neat research being done that has incredible implications.

And this is just from me personally because I talk to a lot of the people. I am not a radiobiologist. But I don't think that is something that can be ignored, the potential for what is going on and where medicine could go.

MR. ZABKO: John Zabko, DNDO DHS. I just wanted to make sure that you were aware that the federal government, DHS, is looking at all threats, not only cesium chloride, not only radioactivity. But we are looking at the biologics, the chemical.

So in this forum, we are here to talk about radiological sources. That is why you are not

hearing the discussions about what we are doing in those other avenues.

I would also like to take it to even a broader perspective when you look at the analogy. We don't try to limit our research into aviation safety because more people are killed in their houses by falling in their bathtubs. They are mutually exclusive. You can't say just because there is a better bioterror threat out there, you're going to avoid looking at radioactive sources. You have to do it holistically.

Both are important. We are looking at them holistically. It's just that in these kind of forums where we all come together, we're talking about radioactive security.

So that is why you hear the focus here. I am not here to talk about DHS' biological safety program. So I just wanted to bring that out.

MR. GERSABECK: Edward Gersabeck with the Department of Agriculture. We have spent hundreds of millions of dollars to eradicate certain pests in the U.S. and to push them farther away from our shores. We have done that using cesium chloride and irradiators, which have a distinctive advantage that the input side of the machines you can put fertile

material in, but the operator does not have access to that fertile material. That operator only sees the irradiator material coming out.

When you go to the cobalt-based machines, you would reduce the risk of cesium chloride. The operator now has access to both fertile material and sterilized material. And there is a very real risk in our industry where a disgruntled employee could mix those samples and redistribute fertile material, causing a biological situation which was virtually impossible with a cesium machine.

So I would just ask folks to look at the consequences and the risk analysis, but also if we decide to go in that direction of removing cesium chloride, that he industry be given a break to maybe redesign some of the cobalt machines and the licensing of those new machines so we can reestablish that biological level of security in a limited input access door to distraction door in these machines, rather than having a single chamber type of access for both fertile material and sterilized material coming out of these machines.

Thank you.

MS. DANIELS: Sameera Daniels. I am so glad you raised this point because I think it was on

the first day someone mentioned that there should be some kind of a comparative analysis. I think I was kind of pointing to that same issue that there are security risks associated with the alternatives, too, and that it would be very helpful just as a way of organizing the thoughts to have that kind of analysis included there.

FACILITATOR RAKOVAN: One or two more comments before we finish for the day? Please?

MR. CONNELL: Let me try to actually address this economic issue. I know that after we briefed the National Academies study to the NRC, the main question was, how do we really account for the economic consequences?

That is a really difficult thing to do. There are many variabilities involved with calculating the economics. Instead of doing that, perhaps what we could do, instead, is take a look at each of the radionuclides and the decides and determine the maximum amount of area that it could cover to a denial situation.

And we could use as a basis of that the EPA's Relocation Protective Action Guide, which is creating a ground contamination level that reaches two rem in a year to the population.

Each of these nuclides, you can actually go to your health physics handbook or your nuclear engineering text and calculate how many curies you have to spread on a square kilometer to get two rem in a year.

For your alpha emitters, a pathway involving a resuspension inhalation, that can get you the two rem. And for the gammas, it's a ground shine. But it's not a hard thing to calculate. It's typically tens of curies on a square kilometer. There is some variability, a factor of two or four, between these materials. But it is fairly straightforward.

Then we know that in populated areas, urban areas, the population density is generally tens of thousands of people per square kilometers. So you could actually calculate how many people would be impacted, would have to be relocated.

Rather than going into all of the detail, you know, if you get the economists involved in this, they are going to take it and try to propagate the effect through the system. And it is just there are so many purple knobs that you got to turn that it just gets a little crazy. And I have seen numbers that represent several orders of magnitude in terms of the economic consequence. So, rather than doing that, we

could just do a simple analysis and figure out what is the maximum area.

Then the other fact you need to consider is, again, how much time, what kind of tools, what kind of knowledge is required to take these different materials and create that kind of an area denial. That's what part is missing right now in the analysis.

And that's where you have to start thinking about the different ways. And this is the classified part that we can't talk about, the different ways of actually weaponizing the material, weaponization potential.

With those two factors, understanding the attractiveness of the weaponization potential of the material, and what the maximum area could cover, that could be the basis for starting to think about how to grade the security different for these different nuclides.

MS. FAIROBENT: Lynne Fairobent. And I'm going to speak for myself since everybody else is taking hats on and off.

(Laughter.)

MS. FAIROBENT: I just want to follow up on two points that were made. One, Adela mentioned it from the states' perspective of needing not to do a

risk-benefit analysis with radioactive materials in isolation of the other risks involved. And Mary touched upon it also.

It's very difficult given regulatory authority and roles and mission as to how much perhaps NRC can do in a total all-hazards analysis. Department of Homeland Security, DNDO, DOE certainly can do an all-hazards analysis.

And typically in past lives, I was the science adviser to the Assistant Secretary for Environment Safety and Health at DOE. We certainly in our NEPA documents when I was at DOE and still today, they do look at all-hazard analysis. And they do look at all-hazard analysis from an emergency preparedness and planning perspective.

Mary touched upon, Mary Shepherd touched upon, something that is not easy to quantify. And that gets to the issue of incentives and costs and how do we equate what the true cost is going to be.

We can certainly run economic models for any scenario we want. We have the tools. We have the capabilities in this country to do that. We have the expertise. And we have the ability to get all of the experts in one room and to get on some equal playing field to run these economic models.

What we can't cost is the benefits of what we don't know and what we don't accrue. For example, of we remove cesium chloride sources used in research today and there is not an equivalent alternative source, I cannot easily quantify for you what that cost is going to mean to the medical development downstream to save the life of X number of individuals or even if you are that single individual, that medical development that is put in place that saves your life or improves your quality of living is not quantifiable if, in fact, that medical development never occurs.

What we can do in that scenario, however, is to tell you what the cost to have moved forward should we have had, say, cesium chloride and could have done that or what it costs to take a drug to market, then the risks and the benefits of the drug are not there. But we cannot easily provide a quantifiable model in the medical community or in any other field for some development that is unique and takes us to perhaps the next generation of something such as air flight pad in the early 1900s.

We can't put a price on that because we never will know what that benefit truly is.

FACILITATOR RAKOVAN: Time for one or two

quick more comments.

MR. SULEIMAN: Orhan Suleiman. I think the best you will ever get is an estimate. And I think sometimes we address the numbers over and over again. It doesn't I think improve the reliability of the confidence.

I think I spent my entire career communicating risk. Whether it's a chest x-ray or a human research subject who is going to get an oncology drug or radiation or you're dealing with probabilities, which I think a colleague recently has been deal or no deal, too, you know, the universe of winning a lottery ticket. It just doesn't make sense.

Recently in the D.C. area, they picked up trace elements of drugs in the drinking water, one in a billion or one in a trillion. The public went berserk.

What bothers me scientifically is an article gets published, one article, and the press extrapolates it and says, "This is going to cure cancer" and it contributes to the background noise. It's way, way, way early on the curve. So we amplify disproportionately potential benefits. We amplify disproportionately risks. And we really have a hard time dealing with that.

The lay public is not stupid. They are extremely smart, sometimes much smarter than a lot of the educated professionals. Some of them can communicate well. Some of them can't.

So the only thing I could say is up to a point, you go through these exercises. But unless you predict the model and it actually happens, then you can say, "I was right" or "I was wrong," but you're never going to be able to validate all of these estimates because you are dealing with probabilities which most of the time were never going to occur.

So I think you have to have all of the things on the table -- and I think we have brought a lot of them to the surface -- and just sort of give a real educated, credible effort at addressing those. But I wouldn't expend a whole lot of energy and excessive analysis.

FACILITATOR RAKOVAN: Last comment?

MS. DANIELS: Sameera Daniels, Ramsey Decisions. I think that what is really just heartbreaking is that the scientific community does a great job in presenting the case. And it gets undermined by the media, you know.

So this is what I mean. You have got these conflicting, you know, these tensions going on

in trying to educate the public. And I wish that there was more that the community can do to educate the journalists in comparative risk analysis and stuff.

FACILITATOR RAKOVAN: Okay. I think we are going to end the panel. I think Rob Lewis was going to come up and kind of give a quick overview. If you panelists want to escape into the audience real quick, certainly make a run for it.

(Laughter.)

FACILITATOR RAKOVAN: While they are doing that, I would like to thank everyone for your participation. Please remember to fill out and either drop off or drop in the mail your public meeting feedback forms.

And I am going to hand it over to Rob, who is going to give a quick overview and summary of the workshop. Rob?

SUMMARY AND WRAP-UP

MR. LEWIS: I'll close this out. Then I'll try to be brief. Before I start, I wanted to personally thank Cyndi, John, Michelle, and the court reporter, Lance, and the people outside, Linda, Andrea, Maria, that have really put this conference together. They have done a really good job, a great

job.

(Applause.)

MR. LEWIS: Thank you all for the last two days. When you work at NRC, you get involved in many different meetings of this type. I have to say that this meeting, in particular, has really set the bar in terms of level of participation and the expertise we brought to bear on the issues.

I really appreciate in a much better way the complexity and the multiple dimensions of the issues that we have before us. We could have only described those issues in a collective form such as this. And it would have never worked if we tried to talk to each of you individually.

You have made over the course of the last couple of days many, many compelling and very articulate points on both sides of the questions that we have asked regarding the ability to replace cesium chloride, both in the near term and in the long term, for existing devices and for future devices; the cost, a big subject of the last couple of days; and the broad range of uses. This is an area in particular where my appreciation has been greatly increased. I thought I came into this knowing a little bit about the subject, but I was naive in my ignorance.

As a regulator together with our agreement state co-regulators, we now need to take back what we have heard and provide options to the Commission.

We will be taking comments, in addition, until October 15th, as has been mentioned several times. So please do follow up with any written material, especially if your comments were abbreviated in terms of what you said in here, and share with your colleagues.

In particular, we do realize that this is a holiday. We did know that coming into the meeting and considered changing the date, but because of the federal fiscal year and our need to get information up to the Commission, we had to stick with this date. That was a decision we made. And we made it clear that this isn't the only opportunity to participate.

So I do apologize for any inconvenience that might have caused. It was unintentional at first. And we did try to be fair and consider the comments that we got to change the date, but we just couldn't make it happen.

I can commit to you that what you have said today will be heard by the Commission. We will take back what we have heard with the transcripts. We will scour the transcripts and any written material we

get and present those to the Commission in our options paper, which will be framed in terms of our NRC submission for safety, security, and effectiveness, realism. And we will present a suite of options, not just on any particular question, "This was the answer," but a suite of options for the Commission to consider that are policy issues on what to do about cesium chloride going forward.

I will commit that any actions that we will take as NRC, as a regulatory agency, this will not be the only opportunity to provide comment, nor will the written comments that are a part of this process be the opportunity. Any regulatory actions we do take would be doing through rulemaking moving forward.

There are active rulemakings ongoing on materials security that we heard a lot about this afternoon. There could potentially additionally be rulemakings on cesium chloride down, much further down, the line depending on what the Commission decides.

We will continue as well to work closely with the other federal and state partners such that we have a coordinated federal and state government suite of regulatory and voluntary security enhancement

activities.

We need to look at this issue, I think, holistically. We have made a lot of progress on that front in the last year, that on large source security, the federal agencies at this point are working very cooperatively. And we want to continue that.

So a Commission paper is due in the next two months or so. It will go up to the Commission. The options will be presented to the Commission. And they from those options will direct the staff to take whatever action they decide is the policy. Then there will be opportunities for further engagement.

Now, all of that said, we need to appreciate going forward from this workshop that cesium chloride security is getting and continues to get increasing attention and increasing expectations from many different federal agencies at the most senior levels, from Congress itself, from the public, and from the media. Sometimes those expectations aren't necessarily aligned with science or risk.

The regulatory actions we need need to be in the context of our mission. And risk-informed regulation is part of that mission. But external drivers will continue to exist. This workshop I think will go a long way towards being responsive to those

external drivers in formulating good public policy.

So, once again, just before we all go, thank you very much. I was floored by the level of preparation of all of our panelists. And this could not have been more valuable for me personally as we move forward on this issue. So thank you very much and have a safe trip home.

(Applause.)

(Whereupon, the foregoing matter was concluded at 4:34 P.M.)