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NUCLEAR REGULATORY COMMISSION

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STAKEHOLDER WORKSHOP ON THE SECURITY AND CONTINUED USE OF CESIUM-137 CHLORIDE SOURCES

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MONDAY

SEPTEMBER 29, 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 8:45 a.m., Lance Rakovan, Facilitator, presiding.

PANELISTS:

PANEL 1:

ALBERT ALOY

DAVID COPPELL

MARK MAIELLO

BRAD PATTON

JOHN SCHRADER

LYNNE FAIROBENT

PANEL 1.2:
LEONARD CONNELL
JOHN FIKE
JOSEPH KAMINSKI
WILLIAM McBRIDE
JOSEPH RING
DAVID COPPELL
GRANT NIXON

PANEL 2:
BILL FITZGERALD
JED GORLI
MARK SVAJGER
RANDOL KIRK
DEBBIE GILLEY
ORHAN SULEIMAN
STEPHEN WAGNER
JOSEPH KAMINSKI
WILLIAM McBRIDE
JOSEPH RING
KEVIN NELSON
GRANT NIXON

ALSO PRESENT:

COMMISSIONER PETER B. LYONS
ROB LEWIS
KEVIN CROWLEY
JOHN JANKOVICH
CYNTHIA JONES
MICHELLE KILLIAN
CHARLIE MILLER
TOM MORGAN
BLAIR MENNA
LANCE RANKOVAN
MARY SHEPHERD
TOM WASIAK
ORHAN SULEIMAN
MOJI MOSHAASHAEE
JERRY THOMAS
LES JARDINE
BRIAN POWELL
ED GERSABECK
RONALDO MINNITI
PAUL MOSES
MIKE RYAN
GAMAL AKABANI
PETER ZIMMERMAN
JERRY THOMAS

STEVE ROGERS

STEVE FORASTE

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P R O C E E D I N G S

(8:45 a.m.)

MR. RAKOVAN: Good morning everyone. I got a little bit of reaction there. My name is Lance Rakovan. I am a communications specialist at the Nuclear Regulatory Commission and it's my pleasure to facilitate this two-day workshop on cesium chloride. The main focus of the meeting, of course, is to have some discussions about the issue at hand. But before we start those discussions, there's a few presentations that we'd like to have, just to give a little bit of background on the subject.

Please note that we've extended the comment period for written comments from September 30th to October 15th. The extension was published in the **Federal Register** last week. Copies of this **Federal Register** notice are also available outside on the registration table.

As I said, we're going to start the workshop with a few formal presentations. Following the presentations, we'll proceed to the roundtable discussions after a short break. We should be starting with the discussions around 10:15, 10:30, following Commission Lyons' address to the workshop.

Again, at the registration table we had copies of the **Federal Register** notice and the agenda. There was also some copies of other materials, and a feedback form that you can fill out for us on our public meetings, if you'll just take a moment and fill that out today, or you can do it afterwards and drop it in the mail. It'll get to us, there's no postage necessary, and that gives us an idea of how we can improve these workshops.

So if you could take a moment to do that, that would be a great help to us. If there's not copies of all the presentations that you'll be seeing today, we plan to post them on the Cesium Chloride Workshop Web site following the meeting, so that you'll be able to see them after the workshop.

I'll be back again before we start the panel discussions, just to go over some ground rules and such, but at this point, the agenda for the morning, like I said, has some presentations, so I'm going to turn things over to Rob Lewis. Rob.

MR. LEWIS: Good morning everybody. It's always nice to have a big neutral zone between the speaker and the audience. I'm Robert Lewis. I'm the NRC's Director of the Division of Material Safety and State Agreements. Together with the

Office of Nuclear Security and Incident Response, we're hosting this workshop. And welcome. It's NRC's Workshop on Security and Continued Use of Cesium Chloride Sources.

Now we do view those as two discrete topics as you'll see in the agenda, cause I think continued use or phaseout, or alternative technologies need to be considered, together with additional security measures that might be complementary or achieve the same end objective.

Thank you, first of all, from NRC, for preparing for this workshop and for your participation in this workshop, especially those roundtable participants and those that have traveled some distance, including international travelers.

We have collected here today, I think a wide-ranging set of expertise, and participants that can speak authoritatively on cesium chloride, its uses, and the impacts of any changes to its uses.

We have people from industry, the source-manufacturing industry, device manufacturing industry, the medical industry, including doctors and administrators of hospitals, research facilities, calibration licensees. We have representatives from government, from Federal

Government as well as state government. Several different agencies across the Federal Government are working on cesium chloride issues.

We have representatives form nongovernment organizations, and I particularly want to thank the National Academies for being here today. Much of what we're doing here today is resulting from recommendations they made in a report earlier this year.

And we have I think also some international participants. So thank you, again, for traveling so far, and for your interest in this topic, and congressional staff interest as well.

The participation reflects the importance of this subject. If not approached properly, I firmly believe that this activity has the potential to impact the lives of patients in hospitals, and also the way we do business in research, in calibration.

I would like to use my time to talk about NRC would like to accomplish from this two-day workshop, and also describe a little bit about how we got to this point.

In terms of what NRC would like to accomplish, this is a workshop, it's not a seminar or a conference where we just have speakers come, a procession of speakers, very informative maybe, but this is a workshop where we are depending upon active participation to get views.

I think, as I mentioned earlier, this audience is very unique, and probably never been assembled before--the expertise and knowledge of the uses of cesium chloride that is in this room right now. And your participation of course is essential in all of the topical areas. We want to specifically hear what you perceive to be the impacts of phasing our cesium and replacing it in the future, for future devices, but also phasing out cesium chloride and its use for existing devices and replacing those devices with alternatives, be they different sources, different types of source such as cobalt, different form, chemical forms of cesium or different technologies such as x-ray.

We also want to brainstorm alternatives on security of cesium chloride. We have increased security of these sources in their settings, quite a bit in the last several years, and we're at a point where we have a great deal of experience in what the security has done, and it's time to reflect, I think, upon how to improve that, perhaps as an alternative to replacing the existing sources.

It's also fair game to say that the security that we have is adequate. So if that's your opinion, let us hear that.

Now as the regulator, we don't have all the answers here. We have been charged, I think, with looking into alternatives as a regulatory action, but we don't have the experience in the use of the material or the experience as licensees, or even as members of the public, that is necessary to bear upon what would be the impacts of phasing out such long-standing successful devices that have real impacts upon people's health and safety, and research, and the value of research.

No one group has those answers. In preparing for this workshop, we've talked to many of you individually, and I guess I would characterize those discussions as everybody has their own little anecdotes about whether x-rays or cesium chloride is better, better in a business sense, better in a technological sense. You know, all kinds of anecdotes. Anecdotes about research that had been done several years ago to replace them, and whatever happened to that research.

What we need, though, for regulatory

decisions is not anecdotes but a collective consensus of the impacts. Regulatory impacts to safety, to security, and to cost, and to the environment.

Let me turn, briefly, now, to how we got to this point.

Cesium chloride is of course a salt. It's a powdery salt that is compressed and formed into sealed sources, and used in large-curie quantities, primarily in blood and research irradiators, also calibration irradiators throughout the world.

There is one manufacturer currently of cesium chloride in Russia, and it produces the world's supply, and then the sources are then sent, manufactured and sent to device manufacturers of various types.

There's three main vendors of the irradiators in the U.S., but again, it is used worldwide. Cesium chloride is a highly-dispersible salt and it's very soluble. So in a lot of ways, even putting security aside, it's not an ideal material to make sources from, and, in fact, there have been, over the years, many studies on replacing cesium chloride, especially after the incident in

Goaiana, Brazil, in the late '80s, when a cesium chloride source was taken apart by some local people and some very serious health effects occurred.

That really started the IAEA down the road of looking at source safety and security, and of course then we had the terrorism attacks of 2001, which put additional focus on the security aspect.

That all resulted in development of the Code of Conduct for sources, and the NRC has used the Code of Conduct with the rest of the U.S. Government to establish levels of security which need increased controls.

The increased controls orders were issued in 2005 to all the NRC licensees and to the Agreement State licensees around the country for large-curie quantities of cesium chloride. So blood irradiators and research irradiators essentially all got the increased controls requirements.

Those have substantially increased security of the material, looking mainly at the facility aspects and the personnel that use the material, and providing security features to ensure that the material is used properly and accounted for.

Cesium chloride is, as I said, a part of the Code of Conduct and it's one of the many nuclides listed in the Code of Conduct. The Code of Conduct and source security measures were developed using a public health and safety perspective from the point of view of avoiding prompt fatalities from radiation injury.

So cesium chloride, in a way, is treated like all other nuclides on that framework. There are those who believe that cesium chloride, because of its dispersibility and solubility, deserve additional treatment, additional treatment from a security perspective, not necessarily because a certain curie amount could result in some kind of fatalities from radiation industry but from costs of cleanup, or contamination spreading. And socio-economic issues associated with any terrorist using cesium chloride.

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

So that's kind of why we're here today, asking whether the increased controls which do provide security in the frame of reference of safety, health and safety and prompt fatalities, also provide adequate security from the dispersibility aspect.

And the Energy Policy Act of 2005 established several activities to look at that very issue. The first is the task force. It's called the Energy Policy Act Task Force, which we'll hear about. One of the co-chairs of a working group of that task force, John Jankovich, is going to do a presentation on their study.

Basically the task force owed a report to Congress in 2006, produced that report which said, essentially, that cesium chloride needs an additional look.

The National Research Council of the National Academies was also chartered by the 2005 Energy Policy Act to produce a study on alternative technologies to radiation sources. They did produce that study earlier this year, and Dr. Kevin Crowley from the National Academies is here, and is the next speaker, actually, to talk about what they found.

In their study, they zeroed in a lot on cesium chloride, and in a lot of ways, their recommendations in their study is consistent with the findings of the Energy Policy Act Task Force, which I neglected to mention, the Energy Policy Act Task Force is made up of 14 different federal agencies, plus two state organizations.

More recently, in the last year, the Department of Energy, and the Department of Homeland Security, in cooperation with the NRC, has started a project to look at a hardening existing cesium chloride irradiators around the country. We issued a regulatory information summary, announcing that project. We have members of the National Nuclear Security Administration which is part of DOE here today, and also the Domestic Nuclear Detection Office, which is part of DHS, here today, to talk about those studies.

If anybody's interested, I can identify the contacts to you. Those studies, as I said, the increased controls are focused more on the facility and the users. The hardening efforts by those two agencies are focused on hardening the actual devices to prevent a delay in the amount of time it takes to remove the sources from those devices.

And we are all working together as a federal agency, in the last year, more so than ever.

Let me conclude by quickly mentioning how we're going to go about moving forward.

We have taken several actions at NRC. We have accelerated our inspections of the cesium chloride blood irradiators at hospitals. We expect to conclude all of our initial increased controls inspections at our licensees this month.

We have visited all the vendors at their sites and talked to them about how they have considered, in the past, alternatives to cesium chloride sources, whether it's a ceramic form or glass form, and if a source was produced, would it fit, would it physically fit in their device? Could it easily be replaced? Those kinds of questions.

Those vendors are here today, so we've kind of seeded the ideas with them of what we're looking for in the workshop, and I hope they'll participate in the workshop today.

The Energy Policy Act Task Force, Cesium Chloride Working Group, is delivering their product to the task force this week, and the task force will then take that product and the task force owes a report to Congress in 2010, but having the Working Group product, if the task force were to endorse it, the NRC would take the recommendations from that Task Force Working Group and bring those up to the Commission where any policy issues were highlighted.

The irradiator-hardening effort started in ernest in the last month or so, and we'll be working together with NMSA and DNDO to go out to the sites and to implement hardening efforts on the irradiators. In conjunction with those hardening of irradiators, which is no cost to the industry, by the way, it's all paid by the Government--in addition to the hardening efforts, while the NMSA and DNDO people are on site, they are offering security-assist visits, where some security experts can provide advice on how to improve security. Many, many different angles.

One thing about this materials industry that's different from maybe the reactor industry is the amount of communication between licensees is very limited.

So the reactor industry, I think they all line up behind how to do security, and materials industry, it's not conducive to that, first of all, because of the disparate types of activities that occur.

But even among hospitals in a particular city, it may not be communicating how to do radioactive material security. Maybe they communicate neonatal security, or something. But we have to do some international outreach, going forward, as well. As I said, there's one producer of this material for the Free World, and that producer, any impacts, anything that we do in the U.S.--we have a session about this tomorrow--we certainly don't want to inadvertently cause security to be decreased by--for example, when teletherapy units in the U.S. became no longer economical to use in the U.S. for medical purposes, teletherapy units were shipped to developing countries.

In fact, Goaiana, Brazil happened because of that type of situation. So we don't want to create that type of situation and we need to consider the international angle of this business sa well.

All of this that I've been mentioning about how we're going forward, is going to be produced in a Commission paper. In the November timeframe we owe the Commission options. The feedback from this workshop is the keystone of those options we're going to tell the Commission, because we can come up with options today, but what we can't come up with, without your help, is the impacts of all those options.

So we look forward to a productive two

days and thank you for your attention.

[Applause]

MR. RAKOVAN: Our first presentation will be given by Kevin Crowley of the National Academy of Science.

DR. CROWLEY: Well, good Monday morning, everybody. I notice everybody's a bit subdued this morning. People aren't quite awake yet.

My name is Kevin Crowley. I'm the director of the Nuclear and Radiation Studies Board at the National Research Council of the National Academies.

I'm actually here today as a substitute. My colleague, Dr. Micah Lowenthal, was the study director for this project, but unfortunately, he couldn't be here today. He's in Vienna because we're releasing another report on international fuel cycles.

So if it looks like I'm reading the notes, I am reading the notes. There are some points that Micah asked me to be sure that I made as we went through the slides, and so I will try to do that.

I also want to point out that, as I will tell you in a minute, the work that I'm about to describe was done by an expert committee that was appointed by the National Research Council. There are at least three members of the committee here today. I won't be with you for the full workshop but they will so. So I want to introduce them to you, and if they wouldn't mind standing up.

Steve Wagner from the American Red Cross. Ruth McBurney who is now the--is it the executive director of the CRCPD? Okay. And I understand that Len Connell is here. Len is from Sandia National Laboratories.

So if you have questions or feedback on the report, those are the three individuals that you would want to talk to during the workshop.

Okay. Well, let me start this by saying that what I'm about to describe was requested by the United States Congress. The study was requested by the United States Congress in the 2005 Energy Policy Act. I will show you the Statement of Task for that in a second. As we do for all requests that we get, whether they're from Congress or a federal agency, we put together an expert committee to do the study, and I will show you the roster for the committee at the end of this presentation.

But I wanted to let you know that the

study was chaired by Dr. Ted Phillips, who is a distinguished radiation oncologist at the University of San Francisco. He's also a member of the Institute of Medicine.

And the other experts on the committee were from a number of different fields, including accelerator physics, radiation protection and regulation, medical physics, nuclear security, blood pathogen research, material science, nuclear engineering and public policy.

So we had a very broad committee that we brought together to do this study. Next slide, please.

Here is the study task, and I'm going to read this to make sure that we all understand what it was we were asked to do.

We were asked to look at current industrial research and commercial, including medical, uses of radiation sources, and identify uses for which the radiation source can be replaced with an equivalent or improved process that does not require the use of radioisotopes, or can be replaced with another radiation source that poses a lower risk to public health and safety, if it is involved in an accident or a terrorist attack.

The study should explicitly consider technical and economic feasibility and risk to workers from such replacements, and I want to make a couple of important distinctions about this task.

We were asked to look at potential replacements. We were not asked to look at security enhancements. Now obviously that is something that the Nuclear Regulatory Commission has to do as part of its mission. That was not something that Congress asked us to do.

The other thing that we were asked to do was to look at high-risk radiation sources, which are the IAEA Category 1 and Category 2 sources, and in terms of cesium, because I know that's the radioisotope of interest in this workshop, a Category 2 source contains between 27 curies and 2700 curies of cesium, and a Category 1 source would be anything larger than that. Next slide.

So what I want to do is just give you the main messages from the report and then I want to talk about the cesium because that's of interest in this workshop, and then I will backtrack and talk about some of the other recommendations.

So here are the main messages from the report. They're sort of a mixture of findings and recommendations. Applications of radionuclide sources are important and beneficial. Area denial and its costs must be considered in the evaluation of security risk from these sources.

Nonradioactive replacements exist for nearly all radionuclide sources. However, not all of these are practical or economically attractive now, but most are improving. There's a need to take actions to implement near-term replacement of cesium chloride sources, and here I want to make an important distinction.

Replace cesium chloride sources. It does not say replace cesium. Okay. And finally, adopt policies that provide incentives to replace other Category 1 and 2 sources. Next slide.

So let's now turn to some of the messages in the report about cesium chloride sources.

Really, two main messages. Because of its characteristics and where the sources are located, radioactive cesium chloride is a greater concern than other sources for some attack scenarios. Rob Lewis talked about some of the characteristics of cesium chloride that make it a concern--its dispersibility, solubility, penetrating radiation, the high source activity for many of the cesium chloride sources in use today, as well as its presence across the United States in facilities such as hospitals, blood banks and universities, many of which are located in large population centers.

This fact is made worse by a lack of a permanent avenue for disposal of these sources. That is, there are some disused sources that are sitting in licensee storage facilities and there's really no pathway for disposal of these sources. Next slide. So here is the recommendation that was made.

It says that in view of the overall liabilities of radioactive cesium chloride, the U.S. Government should implement options for eliminating Category 1 and Category 2 cesium chloride sources from use in the United States, and to the extent possible, elsewhere.

The committee had three options for achieving this. First, discontinue licensing of new sources. Second, put in place incentives for decommissioning existing sources, and third, prohibit the export of cesium chloride sources to other countries except for the purposes of disposal in an appropriate licensed facility.

Rob Lewis mentioned to you the lessons learned from the cobalt irradiators. The committee took that lesson in making the recommendation about not exporting cesium chloride sources.

The committee recognized that current users and owners of cesium chloride sources might need incentives to decommission their existing sources because many of them still have value, and of course there are fairly high decommissioning costs.

The report provides some options for how this could be achieved. For example, buying out the remaining present value of sources, or changes to DOE's offsite source recovery project's policy. Okay. Next slide.

Let me now turn to some of the other messages in the report.

These are not necessarily directly relevant to cesium chloride. The committee noted that there are approximately 55,000 Category 1 and 2 sources in 5000 devices, and that the sources have very important uses for cancer therapy, sterilization of medical devices, irradiation of blood in laboratory animals, nondestructive testing of structures and equipment, and exploration for oil and gas.

And so the committee's recommendation was that replacement of radionuclide sources with nonradionuclide radiation generators should be done with caution.

There's a bit of a, what I might call "a ying and a yang" in this report. The community is saying proceed cautiously. On the other hand, the committee is saying you really need to replace cesium chloride. So there's a certain tension in the report that I want you to be aware of.

I would point out that the committee is made up of experts from fields that use radiation for the benefits of society, and many of those members use radiation in their own activities, and so there was a lot of discussion within the committee about how far they really wanted to push on replacements, including replacements for cesium chloride.

But in the end, I think the committee felt that action was, needed to be taken on cesium chloride. Next slide.

And some of the reasons for that are shown in this slide. Security and safety risks motivated the request for the study, and as Rob pointed out, radiation sources, including cesium chloride sources, can pose significant risk to individuals but are unlikely to cause deterministic health effects to large numbers of people.

The committee concluded that the widest-ranging and most long-lasting consequences from, for example, a terrorist attack, would be economic and social disruptions, not large numbers of individuals dying, and the economic and social disruptions would come from contamination that leads to denial of areas, of land areas.

The committee noted that the IAEA source categories, like Category 1 and 2 that I told you about earlier, are based primarily on deterministic health effects, that the Nuclear Regulatory Commission and Department of Energy have looked at contamination criteria, but the committee concluded that those criteria, at their present state of development, were not adequate.

The USNRC and DOE looked at contamination, asked the question, Could a source contaminate a half-a-square mile kilometer area above the threshold that requires cleanup? But the committee noted that for some sources contamination could be much greater than half-a-square kilometer, and the committee recommended that the NRC and DOE take the next step, and consider the area source a radioactive source, potential to cause area denial. Next slide.

The committee noted that lower hazard replacements exist for nearly all applications of Category 1 and Category 2 sources. However, at this time not all of the replacements are necessarily practical or economically attractive. But most of them are improving and many of them are viable now, and there are a number of examples in the report of--in fact there are several chapters in the report, that go into some detail about potential replacements.

For example, particle accelerators can be signed to operate as radiation generator replacements. In some cases, such as self-shielded radiators, which I know is a concern to this group, x-ray tubes can replace some sources.

Contract irradiators already use E-beam irradiation for some applications, and an x-ray facility could be a feasible replacement for cobalt 60 gamma irradiation in some cases.

Linear accelerators for radiotherapy have already replaced cobalt-60 teletherapy devices in the United States, except for the gamma knife, and LINAC vendors are trying to penetrate that market as well.

The development of new technologies, especially in some areas of ultrasonics and x-ray sources, has provided alternatives to gamma radiography for nondestructive investigation.

Neutron well-logging tools that use americium beryllium sources are beginning to see competition from accelerator fusion sources in californium-252 sources. There are alternative radionuclides for cesium chloride. Cobalt-60 can sometimes be used in the place of cesium, and alternative material forms such as metals, oxides, and minerals, rather than salts. Specifically some alternatives to radioactive cesium chloride include radioactive cesium glass, and a mineral form of cesium, pollucite. Next slide.

The committee recognized that these replacements probably would not take place without some government incentives. So the committee recommended that the U.S. Government should adopt policies that provide market, regulatory, and certification type incentives to facilitate the introduction of replacements and reduce the attractiveness and availability of high-risk radiation sources. And again, there's a fairly in-depth discussion of some of the possible incentives that could be adopted.

For example, making licensees bear more of the full life cycle costs of radiation sources, particularly for disposal of cesium chloride and americium-241 sources.

Revising the requirements for decommissioning funds for Category 1 and 2 devices, to increase the up-front costs for higher-hazard sources.

I mentioned this earlier. To enhance DOE's offsite source recovery project, to include the buy-back of devices that still have use value, provided that the devices are replaced with lower hazard devices.

And of course the Government could impose charges on all sources, or just new sources based on hazards or risks.

These are options for government agencies to consider, and I want to make an important point here, which is we are a private not-for-profit congressionally-chartered organization. We are an advisory organization. We do not make public policy. The committee has made recommendations to the government. It is not up to the government to determine whether and how it should implement those recommendations. And then my final slide.

Just in closing, this is the committee roster. These are the committee members who carried out this study. Thank you very much for your attention.

[Applause]

MR. RAKOVAN: Thank you, sir. And we apparently have about 75 copies of the study on the registration table. So get them while they last.

Our final presentation before we take a quick break is by John Jankovich from the NRC, who's going to be going over the Cesium Chloride Working Group overview and general conclusions.

MR. JANKOVICH: Good morning. I am here to present you an overview of the report, and I will describe the relationship here of the group who prepared it, the Cesium Chloride Working Group, and they prepared it for the Radiation Source Protection Security Task Force.

And as you notice, I am with the Nuclear Regulatory Commission as co-chair of this Working

Group. The other co-chair is Dr. Brendon Plapp from the State Department. He's also here with us today.

A little background, and to put things into perspective, I like to say a few words, how this Working Group came about. We all go back to as far as 2005, act of Congress established the task force, Security and Protection Task Force, and Congress also assigned the task force to write a report by 2006. That report was delivered to the president and Congress in August of 2006.

And one recommendation of that report is about my Cesium Chloride Working Group, specifically Recommendation 12-2, and this is a quote--important.

It says there should be a Working Group and the Working Group should assess feasibility and phasing out of cesium chloride in highly-dispersible form.

This is a clear assignment and it has three elements. I want to emphasize it because our report, what we produced, clearly addresses these assignment, specifically the--go back a second.

We produced a study to assess feasibility for phasing out cesium chloride in highly-dispersible form. So when I come to the conclusions, please note, that's what we are addressing here.

And let's go then to the next one, please. I like to point out, really, how we came about producing this report, and on this Working Group there were ten government agencies involved, because the scope of the work goes beyond the NRC.

And in addition, of course as you know, the NRC in the agreement states regulate nuclear material in partnership with each other. Therefore, we had a representative from the Organization of Agreement States on our Working Group. There were a total there of 33 people working on it. We began our work at the start of last year, in January, and we finish this year in August, and we worked, meeting for worktr sessions, every month on the average. That means we were not just talking. We were working on the report.

And we also didn't want to produce a report which comes from an ivory tower. So once we established the major issues to be addressed, we prepared a white paper to outreach to stakeholders.

And this white paper was presented to the government and industry sector, coordinating councils. We asked them to distribute the white paper to their members and give us comments. We did receive a number of comments, in writing,and those are collected in one appendix of our report.

And we submitted our report to the task force on September the 12th. I'd like to say a few words about it.

Our due date was the end of August. We were late only 12 days. Considering the complexity of the issues, how many agencies were involved, how many individuals were involved, I don't think it's too much of a delay. Many of us who have some home improvement projects going, we would be happy with a 12 day delay only as you know.

However, let's go back, be serious again. This report is official use, for the official use at the moment, and the recipient of the report, the task force itself, hasn't briefed about this one. But the task force members and the NRC thinks that the work is of sufficient importance for this workshop, and also not just that the report is important. This workshop is important. That's why the decision was made to present the results here, even before the task force itself hears it.

One more comment, please. That this is, the report is a product of these individuals. They are technical experts in their field. They don't represent agency points of view from those ten agencies, plus the Agreement States. And this is one mosaic in the overall picture that Rob Lewis has presented earlier this morning. NRC, other government agencies, have many initiatives going on, and this is just one element, one mosaic in the overall picture. Next.

I want to put our report into perspective for you, and these are the caveats, these are the limiting conditions, what you should consider.

First of all, our assignment was primarily to address the domestic use. We have some comments on international use. You will see that later.

We restricted our considerations to our Category 1 and 2 sources, and dispersible and soluble form. Again, I want to add one more point of view to what we have heard from the National Academies. This form, what is used in the present time, the physical form, is like the Tic-Tac candy, compressed powder, which is dispersible and soluble. That's the issue. That's what we want to solve.

And as we proceeded in our work, it became clear at the beginning, that there are various applications for the use of cesium chloride sources. They differ by the purpose, how they are used. They differ by the activity level. They differ by the facilities who are using them.

Therefore, we made the distinction, clear distinction for research irradiators, blood irradiators, and calibrators. And when we come to our conclusions, we have this graded approach to the conclusions.

One resolution doesn't fit all these modes of applications, that's what I want to emphasize, there are different modes, and the solution to the problem also differs according to these modes of application.

In our work we of course looked at the current regulations. There are administrative and physical requirements for security at the moment. There are import/export regulations.

We were aware that the National Academies produced its report. I want to put again our work in perspective to the work, what the National Academy has done. They had a much broader assignment. As we have heard, they were to address all users of radioactive materials and sources.

Here, we are limited only to cesium

chloride. Even their final conclusions had a number of suggestions about cesium chloride. We focused only on this one isotope.

Now here we come to the point, how we did our work. We developed a number of options. It ranged from no action to complete ban. And we reviewed and developed pros and cons, and consequences for all these options.

Based on that, we went through a screening process. Next slide, please.

Here, for using the proper word, I am showing words considerations to reach conclusions. These are the filters, the weighing factors of what we used for each of those options. And these factors are grouped into key considerations and some additional factors.

Of course the key considerations are focused on improving security, because that's the purpose of our work here. And we realized from the beginning, that there is competition between the beneficial use of this isotope versus the security requirements, and we had to overcome that.

And then let's define alternative technologies. This was also one heavy weighing factor in our analysis, and for the purpose of our report, we defined alternative technologies, you know, in different physical form. Less soluble, less dispersible, or in other isotope like cobalt, or completely new technology, just as we have heard from the Academies' presentation. That's alternative technologies.

And for each of those options they reviewed safe and security disposal questions. In addition, of course there are other factors. When to introduce any change. That's very important. How to apply those changes to the various modes of application, and there could be incentives by the government to facilitate the process.

We looked at the transportation issues. Transportation is important for a number of reasons. As we know, there are no, sufficient number of transportation packages for these large activity sources at the moment, and the costs are also very significant, and our Working Group recognized that.

We looked if education and information campaigns could facilitate the process. This is not just for the public but also information campaign for the professional community like us here in this room.

If everybody sees the goals clearly, and sees the way to reach that, we can be much more effective than otherwise. We analyzed the role of the government for all these options, what are the consequences, what are the costs.

Regarding the costs, we came up with an itemized list of cost element, and we came up with some estimated dollar values for all of those.

Results. I'd like to sum up here the overall conclusions, and please note that this one slide expresses, in condensed form, the total findings of our Working Group.

So a week from now, if somebody asks you what were the findings of the Cesium Chloride Working Group, what their report contains, think of this, and I like to point out here what these results are.

Again, our assignment was assessment, feasibility, cesium chloride dispersibility. So we say immediate phase-out would not be feasible. That's our conclusion. Because there are so many factors involved, and timing and consequences are very crucial.

However, stepwise phaseout, again I say phaseout, in other form, could be feasible. Another conclusion. How we go about it. The goal here challenges would have to be overcome. Challenges in plain language, I would say are the preconditions that must be in place before stepwide phaseout or other phaseout could be implemented. And I talk a little bit about these challenges.

Sufficient time is needed till replacement technologies, which are well-established and broadly usable, are available. And then disposal pathways must be available. So for stepwide phaseout, or other phaseout, these things are crucial.

And these preconditions cannot be placed randomly, they have to be in a sequence, and then sufficient time must be given to them. And then in the meantime, the interim security measures are very important.

That slide presented the overall conclusions. However, we went further, and we provided step by step methods for the task force to follow up, if they choose to. We call that the Recommended Path Forward, and these six elements are the major avenues that must be implemented to achieve our goal.

I'd like to say a few words about each

one of them.

One is the Working Group concluded that we need to continue the security upgrades to supplement the existing requirements, and then establish a process for determining additional upgrades and the need for them. As you know, the Department of Homeland Security and Department of Energy are implementing this voluntary initiative to have a hardening project, and we encourage that.

But in addition, we put here kind of administrative term. Need establish a process. that means the government should establish a process to continually evaluate the risks and take appropriate action, if needs.

Our recommendation two, initiate rulemaking or other processes. This is very important, because the Commission has other means to achieve the goal, and, for example, issue a policy statement or something like that. And the objective of this process should be to eliminate further licensing or ban the exports. These two functions must go together.

Furthermore, we recommend that there is need to develop a government-facilitated disposal pathway. This is one of the most critical elements in the overall approach, because there is no transportation package. There is no commercial side where to take these sources. And we don't recommend interim mass storage, because transportation to that site involves risk. Storing a large number of sources at a site involves risk. Further transportation creates further risks.

We recommend to implement incentives in a prioritized fashion, either for phasing out, or obtaining replacement technologies.

We also support short-term and long-term research, and because the alternative technologies are not commercially available on a large scale, they may not achieve the same purpose as the present technology.

And finally, we make some comments, quite a few comments about the international considerations. Most of us who are working here in the U.S. are not aware what the U.S. can do internationally, and whatever decision, rule or requirements we put in place here, will have implication on other countries.

And having the State Department on the Working Group was most useful, and we have a long list of considerations for the international considerations. Thank you.

[Applause]

MR. RAKOVAN: We're going to take a quick break and let you stretch your legs, probably get started here about 9:55.

(Whereupon, the proceedings in the foregoing matter went off the record at 9:39 a.m. and went back on the record at 9:59 a.m.)

FACILITATOR RAKOVAN: Welcome back. We're going to do a quick swap in the agenda real quick. I'll be going over the ground rules right before we start the discussions, but first we're going to have the address by Commissioner Lyons.

And to introduce him, I'd like to introduce Charlie Miller. He is the Officer Director for the Office of Federal and State Materials and Environmental Management Programs at the Nuclear Regulatory Commission. Charlie?

MR. MILLER: Thank you, Lance. For those of you that don't know me, I thought I'd take one moment to just identify the different roles that I play and how they're central to everything that we're doing in the workshop.

We heard about the Energy Policy Act Task Force this morning, which the legislation provided for the fact that the Chairman of the Nuclear Regulatory Commission would chair that task force. And I do chair the task force meetings on the Chairman's behalf, so the overall task force activities are very important to me.

Secondly, I'd like to point out that the increased control orders that we do have in place, that you've heard a little bit about, were done under my purview. And I signed those orders out, so I have a stake in that aspect of it also.

Thirdly, any rulemakings that would result from our deliberations here, or proposed rulemakings, would be done out of my office also, so how -- the path forward from here is extremely important to myself also personally.

And Rob had talked about the options paper. One of the important things to remember from the workshop is the fact that NRC is an independent regulator. We do not promote or deny any opportunities. We do not have a commercial interest whatsoever in what's going on. It is our job to make sure that public health and safety and the appropriate security measures are put in place.

Finally, I'd like to point out that because this is an issue that involves nuclear materials, our agreement state partners are extremely important. Currently, between 80 and 85 percent of the nuclear materials regulation in the United States are done by our partners in the agreement states, and I'm happy to see a number of representatives from those here today, as well as our federal partners. It is important as we go forward that all our stakeholders are represented.

Finally, I'd like to have the pleasure of introducing the Honorable Peter B. Lyons, who was sworn in as a Commissioner of the Nuclear Regulatory Commission in January of 2005. During his tenure, Commissioner Lyons has emphasized that the NRC and its licensees must remain strong and vigilant components of our nation's integrated defenses against acts of terrorism. And in that regard, he has been a consistent voice for security matters as well as our partnerships with the agreement states, who he recognizes as our partners in this activity.

Commissioner Lyons has had a very distinguished career at Los Alamos Laboratory, followed by service on the Hill. He was a science advisor on the staff of U.S. Senator Peter Domenici and the Senate Committee on Energy and Natural Resources.

He is a native of Nevada, and he received his Doctorate in Nuclear Astrophysics from the California Institute of Technology, and he earned his undergraduate degree in Physics and Mathematics from the University of Arizona.

He is a fellow of the American Physical Society and was elected to 16 years on the Los Alamos School Board, and spent six years on the University of New Mexico Los Alamos Branch Advisory Board.

He is a resident of Virginia currently, and without further ado I'd like to introduce Commissioner Lyons.

(Applause.)

COMMISSIONER LYONS: I am not sure which mic I'm using at the moment. Is it this one? Yes, let's just use that one.

Thanks, Charlie, for the kind introduction. And some of you may have noticed in what Charlie said, he mentioned 16 years on the Los Alamos School Board. I sometimes think that being on a School Board was the best preparation I could possibly have had for serving at the NRC.

(Laughter.)

I am pleased to be here today, and I

very much appreciate your willingness to participate in this very, very important workshop. There can simply be no question that the uses of cesium-137 chloride sources benefit the world's medical research and industrial communities and the public, and benefit them very substantially. However, preserving these benefits, coupled with achieving adequate security, is a very real challenge.

As I think you know, after this workshop the NRC staff will be developing recommendations for Commission deliberation. The discussions at this workshop will provide highly valuable input for this process. Because of the importance of these sources to society, it is imperative that we hear from you to help frame a strategy and a possible timeline to address this issue.

I want to thank the NRC staff and all of the participants who have worked so hard to make this workshop possible.

I need to emphasize that I am providing only my own personal views today, and certainly not necessarily those of the Commission. I will keep my remarks relatively brief, and I will be happy to take a few questions. I might even be able to provide answers, but at least I am happy to take questions, and we will see what I can do on answers.

I should begin by pointing out that the NRC has not made any decisions regarding the suspension of the use of high-activity cesium-137 chloride sources. The information gathered at this workshop, combined with other studies, will provide useful insight for the Radiation Source Protection and Security Task Force's discussion and consideration of the continued use of cesium chloride sources. That task force is made up of 14 federal agencies and representatives from the Organization of Agreement States and the Conference of Radiation Control Program Directors.

The security of radioactive materials has been, and continues to be, a top priority for the NRC. Applying a risk-based approach, the NRC has enhanced security of radioactive materials, and has reduced the potential threat from an RDD or RED type of attack. The security of these materials has been enhanced through additional requirements on access control, detection, trustworthiness, accounting, and other measures.

Nevertheless, NRC continues to work closely with its domestic and international partners to continuously assess, integrate, and improve its security programs and, when deemed necessary, to make risk-significant radioactive materials still more secure and still less vulnerable to terrorists and terrorist actions.

One such example of this coordination is the government-sponsored -- through DHS and DOE -- voluntary program to enhance the security of high-activity cesium chloride irradiators by making design changes to further delay unauthorized access to the sealed sources. This is referred to as the hardening program. It is a voluntary program, and the NRC and agreement states have notified the user community about the program through careful communications.

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

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

However, I would like to briefly review a number of points that I believe have relevance at this workshop. High-activity cesium-137 chloride sources, as I think everyone in this room knows, are used for research and for industrial and medical purposes and devices regulated by the NRC and the agreement states. These devices include self-shielded irradiators, research devices, and detection and dosimetry calibrators.

Today, Russia's Mayak is the only manufacturer of high-activity cesium-137 sources for the international market. The commercial distributor of the Mayak sources in the U.S., as you know, is REVISS. The form of cesium-137 in such sources is the chloride form, cesium chloride, which is both very soluble and very dispersible.

Some research and development of alternative forms for cesium-137 has been performed and indicates that less soluble and less dispersible materials may be able to be developed for use in some cesium -- high-activity cesium sources. However, Mayak will need time to develop commercial production lines for sources that would use a less dispersible form.

We need your suggestions to determine, and hopefully agree, on an appropriate balance between increased control requirements and the continued use of these sources, until alternative forms can be made available or until feasible alternative technologies become widely used.

Prior to 9/11, regulations of the NRC and the agreement states contain both safety and security components that were appropriate for that time. After 9/11, the safety and security requirements were enhanced through the use of increased security controls that aligned the IAEA Code of Conduct recommendations.

Concerns about safety and security of radiation sources and devices have grown partly in response to fears that radiation sources could be used to make RDDs, or, as you know, referred to more often as a dirty bomb.

Congress directed the NRC, through the Energy Policy Act of 2005, to take several actions. Among them, we were required to undertake a study by the National Academy of Sciences to identify the uses of high-risk radiation sources and the feasibility of replacing them with lower risk alternatives.

The National Academy recommendations called for stopping the licensing of new cesium-137 chloride irradiator sources, prohibiting the export of such sources, providing incentives for decommissioning of existing sources, and replacing existing sources with possibly a less dispersible form of radioactive cesium -- with cobalt-60 or with non-radioactive alternatives.

Others have called for the complete replacement of cesium chloride sources, including, as you are probably well aware, House Bill H.R. 6816, which is entitled the Nuclear Facility and Material Security Act of 2008, and consistent with another recommendation of the National Academy study entitled Radiation Source Use and Replacement.

I very much agree with the National Academy that any effort to replace these radiation sources with alternative technologies should proceed with caution in order to minimize disruption in vital areas of industry, medicine, and research. To that end goal, as you know, the NRC is holding this public workshop to ensure that all stakeholders are afforded an early opportunity to provide input on any potential regulatory changes.

The Commission believes that a balanced

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

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

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

As we consider these difficult issues, we need to pay very careful attention to the consequences of our actions, to avoid unintended consequences, both domestically and internationally. Thus, any resolution, in my mind, would benefit from an international consensus, to avoid driving some applications offshore, and to prevent sources of concern from becoming more readily accessible in other countries.

It may be useful also during this workshop to discuss when security becomes sufficient. For example, should nuclear powerplants that use these sources be required to replace them, despite the enhanced security that is in place at such facilities?

You could also offer valuable input to two additional questions. How feasible is it to stop licensing cesium-137 chloride sources now with a goal of complete replacement within 10 years? And, second, what should be done with the replaced sources and devices? How should we solve the disposal issue? And should we prohibit export of these sources and devices, as the National Academy suggested?

As I noted earlier, the NRC and its federal partners need broad stakeholder input on the potential impacts of actions and the range of alternatives that can potentially address issues associated with removing high-activity cesium chloride sources from use. We clearly need your views on economic and societal costs associated with replacing these sources, including the effectiveness of replacements or in impacts-to-research programs, if they are not available.

Additionally, we need to understand the effect on your programs if such sources were replaced by X-ray machines or other alternatives -- for example, maintenance and efficacy issues and cost issues. I, for one, very much look forward to the staff's recommendations on the issues associated with cesium chloride sources, and those recommendations are going to be informed by the dialogue of this workshop, as well as from input from previous and also ongoing studies.

I do appreciate your attention. I hope you have a productive, informative workshop, where a variety of different points of view can be discussed, debated, and better understood by all of you.

With that, I am willing to take a few questions, with the obvious caveat that I would be speaking only for myself, and that this early in the deliberations I will be fairly careful in what I say, too. If there are questions, I'll try.

FACILITATOR RAKOVAN: If you have a question, please come to use the microphone.

MR. MORGAN: Hi. I'm Tom Morgan from the University of Rochester. Most of what I have heard today is in the purview -- within the purview of the NRC. However, disposal doesn't appear to be. That's a huge political decision. How do you see this playing out -- disposal playing out -- versus all the other regulations?

COMMISSIONER LYONS: Well, there is certainly no question that the country now is facing a real challenge on disposal options for all sources. The closure of Barnwell certainly complicated a system that was already strained.

There are some possible commercial options that still may come online, but this may be something that, depending on the feedback from this workshop, depending on the success that some of these newer commercial options may have or may not have, it may be very reasonable for the Commission to entertain direct communication with our oversight committees in Congress to point out the concerns raised by the lack of disposal options, and to, you could say, ask or plead for congressional action to resolve those issues.

You are quite right that the NRC, per se, does not have the necessary authorities to solve this problem, but we are piece of any solution. Congress may well have to be involved before this is over.

Any other questions?

(No response.)

Again, I wish you great success for the conference, for the workshop. It truly is a very, very important contribution, and I appreciate your taking the time from your schedules to provide that input. So thanks very much.

(Applause.)

FACILITATOR RAKOVAN: Thank you, sir.

I would like to take a moment now to go over some ground rules for the discussion panels. The roundtable discussions will essentially follow the five issues detailed in the Federal Register notice, with one session devoted to each issue. We're going to have some different panel members for each discussion, and expect that those sitting at the table will be the primary participants for each session.

We received far more expressions of

interest for serving as panel members than we could accommodate, unfortunately, as we have attempted to ensure a good balance between the various groups and perspectives sitting at the table. Therefore, we apologize that we could not put all those interested parties on the panels. However, we are going to do our best to make sure that all participants, whether they are seated at the tables or not, have an opportunity to participate in discussions.

Now, I have got Cyndi Jones over here, and I've got Michelle Killian over here, and they are hopefully going to help us keep honest in terms of which panel members need to be up for which discussions, and also make sure that those people have their tents designating kind of their seats, and so we know who they are when they speak as well.

At the start of each session we may have some initial statements made by participants. As established before the meeting, these statements should take three minutes at the most, to allow sufficient time for discussion on each issue. I would really appreciate if you would help me keep to that. If you start kind of going over the three-minute mark, I'm going to take some steps to kind of -- well, please help me keep to the three-minute mark.

(Laughter.)

If you have any PowerPoint presentations for a presentation coming up, try to get it to Michelle over here as early as possible, so that we make sure that we have it on our computer.

Following any initial statements, we will open up discussion for the designated issue. If you are sitting at the table and you want to make a statement, you can either raise your hand to get my attention or you can put your name tent sideways, assuming it will stay up. Again, I will try to get to everyone in the order that I see you.

If you are in the audience -- and I will try to go to the audience at specific times -- you can see we have got a couple of mics in the center aisle, and if you just want to approach the mic. Or I'll be looking at the crowd a couple times, if you just raise your hand, then I'll kind of give you a nod.

But, like I said, we're going to try to let everybody participate, but we are looking to the panel members to be the primary people who are having the discussions.

If things come up that aren't pertinent

to the topic at hand, I'm going to put it on one of these flipcharts over here. I think you will notice on the agenda we've got some time for "parking lot issues," and hopefully we'll get to those towards the end of the day, especially if they are important topics that we want to discuss, but maybe they are just not in the flow of what's being discussed at the moment.

Please note that this is a public meeting, so we will be discussing only publicly-available information, asking that participants please do not -- please do not discuss specific security-related information about your facilities. There also should be no discussions about specific scenarios or additional security measures that should be added to a certain device.

This type of discussion could potentially cross into safeguards or classified information quickly, and they are not appropriate for this workshop. So I appreciate your help in that.

We are transcribing today's meeting to fully document the discussions. So there is a few things that you can help us out with in terms of making sure that we get a clean transcript for the meeting. First, if you are going to participate in a discussion, please make sure you use a microphone. When you do make a comment, please try to give us your name and any organization that you represent, at least the first few times that you make a comment.

Also, hopefully with the microphones, but let's try to keep one main conversation going at any given time. Side conversations probably won't find their way to the transcript, and they also take away from whatever the main discussion is.

You can also help us cut down on background noise by turning off or silencing your cell phones or other electronic devices. Heard a few of those going off already, so, if you could go ahead and do that, that will really help us out.

We can take written statements that we can include as part of the transcript. If you have something that you'd like to submit, you can either give it to me or any of the people that you see that have been helping out at the workshop, or at the registration table. All those will make their way officially onto the transcript.

Both John Jankovich and Cyndi Jones, the workshop coordinators, are going to be available throughout the meeting in order to answer any questions you might have.

And let's just try to remember that we are here to discuss these issues, not reach a consensus. There's a pretty good chance that we're not all going to agree 100 percent with what everybody else says. And that's all right. When someone has the floor, please give them the floor fully, and show them the respect that you yourself would like.

A few logistic information -- if you did park over here in the parking lot for the Convention Center, we do have free parking that we can give you. Just stop at the registration table and let them know, and you'll be able to park for free. They have got vouchers. If you haven't figured it out yet, restrooms are down here and on your right.

Obviously, you've probably noticed that we've got lots of food going on. There will be food out pretty much during the morning and afternoon sessions. Lunch, you're on your own. I believe they've got a restaurant down here, but there is a few restaurants that are within a quick walking distance towards Rockville Pike as well. So when we take a break for lunch, you are on your own for that.

We do have this room for two complete days. So if you want to leave some of your materials, like in a specific chair, it should be okay. I'm not sure that I would leave computers or anything like that, but just in case you don't feel like lugging your copy of the National Academy's report home with you, if you set it on a chair and put something with your name on it, or something, it should be fine.

And, again, just one more plug, if you could fill out the public meeting feedback forms. I just signed out a memo the other day that publishes the results that we had last year, and we do have specific information, trends, specific comments that were made, etcetera. So those really do help us improve on our public meetings.

So having said all of that, let's go ahead and move to the first panel and first topic, Issue 1.1, which is feasibility of the use of other forms of cesium-137.

Michelle, do you want me to go ahead and read off the participants?

MS. KILLIAN: That would be good.

FACILITATOR RAKOVAN: Okay. The

participants that I have listed for this are Albert Aloy, and I apologize if I slaughter anyone's name, David Coppell, Mark Maiello, Brad Patton, John Schrader, Thadium Stirchanko, and Lynne Fairobent. If you could all go ahead and come up and take a seat. I think Michelle has specific places that she wants to put you, so if you could try to match yourself with your tent.

(Pause.)

Okay. I'm going to assume that we have everybody up here that we need.

I have a statement that I have been asked to read. It is from Abba Zubair, M.D., Ph.D., from the Mayo Clinic. Unfortunately, no one from the Mayo Clinic was able to make it today, so I'd like to read the statement that he had planned to read. I've got the letter, and I'll just go through it right now.

"It is regrettable that I will not be able to attend the upcoming workshop that will discuss the security and continued use of devices that contain cesium-137 chloride. To supplement the letter I previously sent you" -- and this was addressed to Cynthia Jones -- "I would like to have read into the record some of the important points that were brought up by my Mayo Clinic colleagues regarding cesium blood bank irradiators.

"Bullet 1. Irradiation of blood is medically necessary for some patients to prevent transfusion-associated graft versus host disease. The 2005 nationwide blood collection and utilization survey reported over 2.5 million blood components were irradiated in the year 2004.

"Next, cesium chloride blood irradiators are the most reliable, efficient, and low maintenance blood irradiators available. All hospital blood banks are staffed 24 hours a day, seven days a week. Therefore, with the recent increased security requirements, we believe blood bank irradiators are sufficiently secured.

"If the decision is to allow all cesium chloride containing irradiators, then the ban should be limited to new irradiators. The cost of replacement of cesium chloride irradiators, with X-ray irradiators, would create a hardship for many hospitals and blood banks. At a minimum, the government should provide the funding for removal of existing cesium-137 blood bank irradiators.

"X-ray blood irradiators are the most likely alternative to cesium chloride blood irradiators, but they are not currently as efficient or reliable as cesium chloride irradiators, and may not be as efficacious based on conflicting reports in the literature. X-ray blood irradiators are associated with relatively higher maintenance costs.

"The current manufacturing capacity in the U.S. is not capable of replacing cesium chloride irradiators in a reasonable period of time. Therefore, the waiting time to purchase an X-ray blood irradiator is over six months, and this will significantly get worse if cesium chloride irradiators are outlawed all at the same time.

"My assessment of opinions among colleagues in the transfusion medicine community is that existing measures taken to ensure security blood bank irradiators are adequate. Any measure that will limit their use should be enacted over a reasonable time to allow for removal and replacement of existing cesium chloride blood irradiators.

"Thank you for giving us this opportunity to offer our opinions and suggestions. We look forward to the outcome of the workshop and NRC's decisions."

And it is signed Abba Zubair, M.D., Ph.D., Director, Transfusion Medicine and Stem Cell

Therapy, Mayo Clinic.

All right. Did anybody time me? Was that under three minutes?

(Laughter.)

Did I hope to my own -- okay.

If we could go around the table and have the panelists introduce themselves briefly. To use your microphone, that's -- all you need to do is hit the center and it should come on. Lynne, do you want to start us out, please?

MS. FAIROBENT: Lynne Fairobent. I'm the Manager of Legislative and Regulatory Affairs for the American Association of Physicists in Medicine.

MR. SCHRADER: I'm John Schrader, REVISS Services, and Vice President of North American Operations, and also Radiation Safety Officer.

MR. PATTON: I am Brad Patton from Oak Ridge National Laboratory, involved in cesium source fabrication work.

MR. MAIELLO: Mark Maiello, Radiation Safety Officer for the Pearl River, New York facility for Wyeth Pharmaceuticals.

MR. COPPELL: And I'm David Coppell. I'm Manufacturing and Technical Director for REVISS

Services.

MR. ALOY: I am Albert Aloy from St. Petersburg Institute.

FACILITATOR RAKOVAN: Thank you, everyone.

Just switched to the lapel mic, so hopefully you can all hear me. It sounds like I'm coming through okay.

Why don't we go ahead and start with our discussion of 1.1. Michelle, do you want to put up the first question, then, please?

(Pause.)

Something go wrong?

MS. KILLIAN: Yes.

FACILITATOR RAKOVAN: Of course. Do we have a paper copy that I could read it from? Do you have another copy?

(Pause.)

As we are waiting to do that, does anyone have an opening statement that they wanted to go through? Please.

MR. PATTON: I have some viewgraphs.

FACILITATOR RAKOVAN: Into the microphone, please.

MR. PATTON: I have some viewgraphs --

FACILITATOR RAKOVAN: If you could introduce yourself.

MR. PATTON: -- if you could put them up, please.

FACILITATOR RAKOVAN: Could you introduce yourself, please, the first couple of times that you speak?

MR. PATTON: Brad Patton from Oak Ridge National Laboratory.

FACILITATOR RAKOVAN: Thank you. Do you have some viewgraphs?

MR. PATTON: Yes, sir, I do.

FACILITATOR RAKOVAN: Okay. Do we -- does Michelle have them in the computer already?

MR. PATTON: Yes, she does.

FACILITATOR RAKOVAN: Okay. Well, unfortunately, that might be -- we're experiencing technical difficulties. Please stand by.

(Laughter.)

Thanks, Lynne.

All right. Question 1.1, are manufacturers -- this is feasibility of the use of other forms of cesium-137. The question is: are manufacturers currently considering the use of other forms of cesium, other than cesium chloride? If yes, what are such considerations?

Hey, look at that. Okay. Michelle, do you have the charts? Can you put those up, please?

MS. KILLIAN: Is this for Lynne?

FACILITATOR RAKOVAN: No. This is for Brad Patton.

(Pause.)

MR. PATTON: Can I get up here where I can see?

FACILITATOR RAKOVAN: Yes. You can use the podium if you'd like to while you're giving your presentation. Certainly. Thanks.

MR. PATTON: I am Brad Patton from Oak Ridge National Laboratory, and I would like to give you some history of cesium chloride production at Oak Ridge, which hopefully will put some of the discussion in perspective later on in the day.

Next viewgraph, please.

ORNL produced cesium chloride from 1950 until 1989. Approximately 56 million curies of cesium chloride were distributed over that timeframe. And the specific activity of material that we produced was always greater than 18 curies per gram, and many times as high as 25 curies per gram. And that is important as we go through the discussion I think, and getting a concentrated source is very important to the discussion we are having.

The cesium chloride we produced was produced both in bulk material, breast pellets and powders, which were distributed to other manufacturers to produce sources, and we also produced sources ourselves. And you see in this photograph we had a different -- a number of different source types that were produced at ORNL.

Next viewgraph, please.

Our process was very simple, and I think that is why we are using cesium chloride. The material -- the bulk material was separated at the Hanford facility, the DOE Hanford facility. It was shipped to ORNL, and the process simply was to dissolve the material, to filter it, and then solidify the material again into the cesium chloride form, and then those were cold-pressed into pellets.

Again, this is a hot cell operation, and this is the simplest way to produce the material, and that is why cesium chloride I guess was chosen as the source form of interest, plus the fact that you get some very high specific activities associated with the material.

Next viewgraph, please.

During that period in the early 1980s, ORNL did experiment with other source forms. And pollucite, which has already been discussed today, was one of those source forms. And we actually produced cesium-137 material with pollucite. Unfortunately, the specific activity is more like 10 curies a gram that we -- that we -- resulted from this process, roughly half the specific activity that we had in general in our cesium chloride.

Another source form that we make at ORNL is californium sources, and this is a cermet, which is a ceramic encapsulating a metal matrix, and it's used commonly from ORNL now. It's a palladium and cesium oxide cermet, and ORNL is experimenting with cermets for spent fuel and proposes cesium-type cermet, which both would be insoluble and also non-dispersible.

As I put in the box here, these are all more difficult processes, and all have to be done in a hot cell environment.

Next viewgraph?

In summary, ORNL has a lot of experience in handling cesium chloride, also experience in other source forms. We have no plans to be in the cesium production business, but we are interested in developing new source forms and reviewing source forms developed by other agencies.

And based on our experience with how easy cesium chloride is to produce, and the specific activity that you get with cesium chloride, alternate forms will be more difficult with lower specific activities, and we believe the phaseout would need to be driven by some sort of regulatory requirement.

FACILITATOR RAKOVAN: Thank you, sir.

Did we have any other opening points for this particular issue?

(No response.)

Okay. So let's just go ahead and open to discussion, then. Anybody have a point that they'd like to make on this particular issue, work towards -- sir, please, if you could introduce yourself, at least for the first few times.

MR. COPPELL: Yes, thank you. It's David Coppell here again from REVISS Services. I think many of you will know that REVISS works closely with Mayak in a partnership for manufacturing and distribution of radioactive sources, including large cesium sources.

And I just wanted to respond to the first question, question 1.1, are manufacturers currently considering the use of other forms of cesium? Well, the answer is, quite simply, yes. In fact, I think it is probably common knowledge that other forms of cesium have been available for some decades, not for this type of product.

And I think what has been explored at the moment is the potential to extend and probably modify the manufacturing technologies for those alternate forms, so that they could be applied to the manufacture of large cesium sources for the applications that we are discussing.

The only thing I would say is that these development programs are not very quick or very easy. I think as Brad pointed out in his presentation just now there are some technology challenges that we need to go through, and so at this precise stage we are not quite in a position to be able to make some firm proposals. But I think our expectation would be that within a very few months that would be possible.

FACILITATOR RAKOVAN: Okay. Anyone want to piggyback on that, or make a different discussion point? Sir, yes, if you could introduce yourself, please.

MR. MENNA: My name is Blair Menna. I'm from Best Theratronics. A question for Brad, I guess, and it's probably just a yes or no question. I gather from your presentation that it is very feasible technically. We -- we have the technology to develop a non-dispersible form of cesium.

MR. PATTON: Yes, we do have the technology to produce those forms. But I guess the question is whether we can get the specific activities high enough to serve the uses that you now have for the source materials. But, yes, I think the source could be developed that are non-leachable and non-dispersible, but you are going to have to add -- have some additives there, and the specific activity will be necessarily lower.

MR. COPPELL: Dave Coppell again here from REVISS. Just to add a couple of points to that. I agree with what Brad says. That's certainly a challenge. It is not the only challenge. I think in developing the alternative forms we will need to understand more clearly what the target is going to be in terms of solubility and leachability, and also what the target is going to be in terms of dispersibility.

And then, having gone through the technology development program, there will be a matter of cost as well. We will need to come to that at some stage.

MS. FAIROBENT: To both of you, what sort of timeframe are we realistically talking about? If we had an alternative form today that was readily available, what timeframe could it be brought into market to substitute out the cesium chloride form?

MR. PATTON: Since we are really not in the business right now --

FACILITATOR RAKOVAN: Sir, I don't think your microphone is on. Yes, red light is on when it's on.

MR. PATTON: I would refer to REVISS on that. Since we are really not the producers at this time, that would be their -- their statement, please.

MR. COPPELL: Okay. Thanks, yes. The simple answer is I am not exactly sure. It will be a few years. It is going to depend I think on -- well, a number of factors, but particularly the commercial viability. Obviously, this is going to go faster if there is more funding available to support it, so there are a lot of factors involved in making an assessment of time scale, but let's say a few years.

FACILITATOR RAKOVAN: Please, if you could go ahead and step to a microphone and introduce yourself.

MS. SHEPHERD: Mary Shepherd, J.L. Shepherd and Associates. With the having of the -- of the output by going to a more indispersible form, there would have to be consideration for either the placement of the device because of the size of the sources would be either double to replace the source or to look at the technology. Is half a curie output -- half a curie output feasible for the -- replacing into existing devices? There is not the physical size to put double -- a capsule that is twice the size inside an irradiator.

And the question for REVISS would be: would there be a means of replicating the current curie output in the same size?

MR. COPPELL: Well, the simple answer is, no, not really. The specific activity and volume-specific activity of the replacement product would be lower. There is no doubt of that. And there are some other effects as well, such as self-absorption of the radiation in a larger and more dense material.

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

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

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

MR. WASIAK: Obviously -- Tom Wasiak from Best Theratronics. We haven't done very extensive analysis of that situation, but we looked at it briefly. And I think the entire -- doing it in the field would be probably prohibitive and likely impossible. There might be an option of doing something in the facility, kind of swapping the radioactive shielding component. That might be an option.

I also would like to say -- kind of follow up on the previous comment that the impact of using different form of cesium varies, obviously, with the design of the equipment. And it's not the same for all kind of equipment and all applications. So in our case it might be easier in case of blood irradiators -- obviously, you have to compensate in some way for a loss of specific activity and possibly, you know, increased volume or increased number of sources.

But it might be possible, with some, you know, medium size design changes. In other case, more significant changes to the design of equipment would be required, and probably loading these type of sources to the existing pieces of equipment might be impossible.

FACILITATOR RAKOVAN: I've got a few panelists who haven't made any comments yet. I'd just like to open the floor, if they would like to go ahead and step up and say something at this point, after this gentleman speaks, of course. Sir, if you could introduce yourself.

MR. SULEIMAN: Orhan Suleiman with the Food and Drug Administration. You talk about reduce specific activity. Twenty percent, 50 percent? Give me a ballpark figure. And how would that have -- what sort of an impact would that have in terms of irradiation time for commonly-used applications? Are we going to go from five-minute times to five hours? Or are we going to go from five minutes to 10 minutes? That has a lot to do with the practicability and the applicability of such changes.

MR. PATTON: Well, you saw my viewgraphs. In the pollucite, we really -- basically was half what the cesium chloride was. And I don't know if there's other experience there, but I think half or lower may be -- depending on how much -- again, we don't know what the requirements are for dispersibility or leachability. I mean, depending on what those requirements are, how much better is good enough, it would drive that specific activity reduction.

MR. SULEIMAN: I know, but I can only think one thing at a time, so I want to -- I want to understand the reduced --

(Laughter.)

-- activity and intensity, and then I could worry about the other issues. But I think -- is reducing the activity going to be so bad that it can't be -- it won't be practical in the working environment? And what are the average times for using these irradiators for applications?

MR. COPPELL: Well, I'm not sure I can add much to what Brad just said. If you're looking for a typical number, think of half. Whether that's still -- is still viable from an applications perspective is really a question more for the equipment manufacturers.

And I think we're all a little concerned about getting numbers set in concrete too early, but just for order of magnitude think of maybe half.

MR. SULEIMAN: Thank you.

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

MR. MOSHAASHAEE: Moji Moshaashaee,

Schering Corporation. I just had a question. When you change the constituency of the cesium chloride itself, you have additives. Does that change in any way the gammas that are -- you know, the basically beautiful gamma that we get from the cesium sources that we get right now? Do we get uniform -- uniform, actually, gammas?

MR. COPPELL: Provided you design the material that you incorporate -- matrix material that you incorporate this in correctly, the answer is no.

MR. THOMAS: I'm Jerry Thomas of Via Christi Regional Medical Center in Wichita, Kansas.

FACILITATOR RAKOVAN: If you could turn the mic up a little bit, please.

MR. THOMAS: Oh, absolutely. Excuse me.

FACILITATOR RAKOVAN: Thank you.

MR. THOMAS: I'd like to give Orhan a direct answer to your question, and that is how long of the irradiation time. We currently are irradiating at about 12 to 15 minutes for a source -- pardon me, for a blood sample. Consequently, if we double that time, the throughput is going to be 24 to 30 minutes per sample.

Consequently, to meet the workload that

we currently have, we are going to have to have an additional irradiator capability. I think that is going to be the case in many large blood banks is that the current irradiator capacity is not going to be sufficient with the lower specific activity source in the irradiator.

MR. MOSES: Paul Moses, Best Theratronics. If you look at the different models that we have in the gamma cell line, which holds the cesium source, you are looking at the higher loaded units to be in compliance with the AABB and the FDA. You would be looking at little over a minute to be in compliance with a fully loaded unit, GammaCell 1000.

The GammaCell 3000, which holds multiple blood bags, you are looking at a cycle time of around two and a half minutes on a new unit fully loaded. So after you've had a unit for it sounds like -- in the gentleman's case here -- for maybe 20 years --

PARTICIPANT: Fifteen.

MR. MOSES: -- 15 years --

(Laughter.)

-- yes, you are obviously -- your cycle time is going to drop a little. But that just speaks to the reliability and the longevity of this kind of product in the marketplace.

FACILITATOR RAKOVAN: Do you want to -- okay. Rob, do you want to go first?

MR. LEWIS: Rob Lewis from NRC. I would like to hear, if I could, some additional words from the panel about creating a market. And, in particular, the panel seemed to indicate that there wasn't a technological obstacle to a new form, but there wasn't a market-driver. And, you know, a regulatory action could create a market, of course, to drive a new form for the U.S.

But, as we all said, this is a worldwide business, and there is only one producer in the world, which is Mayak. And would the regulatory action in the U.S. also create a market for the rest of the world, or -- or, you know, how can we do this in isolation? Even -- is there enough market force to sustain two different forms -- a cesium chloride form for the rest of the world and a different form for the U.S.?

MR. SCHRADER: John Schrader, REVISS Services. We have had this discussion internally quite a bit. It is going to depend on what the costs are to make the changes, whether they are going to be able to pass a lot of costs on, obviously.

We are looking at probably having to develop a new process line to be able to develop the new source material. Whether there is a sufficient market out there right now to be able to maintain two lines where you have cesium chloride on one and where you have this new material on another -- again, it's going to all depend on what the development costs are and what the sales costs will be.

FACILITATOR RAKOVAN: Please.

MR. ALOY: Excuse me. Because I am not very fluent in excuse, maybe I speak in Russian and use the --

FACILITATOR RAKOVAN: No, that's fine. That's fine.

MR. ALOY: I can -- I would like to stress only that we have no technology for a new alternative form. We have only the scientific results and scientific resources and scientific bases of different alternative materials, like pollucite or glasses.

But technology means that equipment, operational personnel, and hot cell installation.

And so just only the first approach to the change for a new alternative materials we have.

And also, in Russia we have the testing in the -- with surrogate materials, not with the real initial form. Initial form is cesium nitrate is initial form to transform into the ceramics or into the glasses. So we have no technology for pollucite or alternate forms. We have only scientific approach, and we need enough time to implement the scientific approach into real technology.

And also, we need to understand that the cesium chloride, due to crystalline form properties and physical property, has free volume into the real sources. This is free volume in the design sources, about 25 volume percent.

So we can use this additional volume to receive the volume activity, specific volume activity, equal approximately -- it's about 90 percent to the activity of the cesium chloride. This is only -- just my remarks to the discussion.

FACILITATOR RAKOVAN: Thank you, sir.

MR. COPPELL: Yes. Can I just add my support to that comment on behalf of the manufacturers? I am trying to be careful to say that we believe that we can develop the technology. But I support what Mr. Aloy says. We don't have that technology right now. We have a track record of use of non-dispersible versions for forms of cesium going back some time, which leads us to believe that it is feasible.

But, really, we need some more months, as I said at the outset, maybe six to nine more months, to -- to assure ourselves, and then be able to make a proposal. And thereafter, then actually industrializing that technology, bringing it to market, assuming that the commercial environment existed to justify it, would take a few years.

FACILITATOR RAKOVAN: If I could -- I'm sorry, I had a gentleman who stood up earlier. If you want to -- please. I cut you off earlier, and I wanted to give you a chance. I'll get to you next, sir, I promise.

MR. WASIAK: Just a brief comment. I guess it -- some of the questions earlier it was assumed that a 50 percent drop in specific activity automatically means that the irradiation time would have to be doubled.

It is true in some cases, but I think by, you know, installing more sources where you have that capability, or in other means, this can be compensated to some extent, and may not necessarily mean drop of -- or extension of irradiation time twice the previous value, right? So partial compensation, if not full compensation, may be accomplished by certain design changes.

FACILITATOR RAKOVAN: Yes. Sir?

MR. MAIELLO: Mark Maiello again from Wyeth Research. You know, we are starting to touch on the money issue now a little bit. And I'd like to remind everyone here that even pharmaceutical companies have budgets and --

(Laughter.)

-- we are -- we are starting to hear rumors. You know, again, I hate to bring up anecdotal information, but, you know, we are hearing rumors that new irradiators may cost, you know, hundreds of thousands of dollars.

In the present economic atmosphere, even companies like my own are struggling. And prior to this, they were struggling on their own without the present economic burdens, research lines and research avenues in most pharmaceutical companies.

And I know there are some of my colleagues here, so correct me if I'm wrong, there are -- those research avenues were drying up. So, you know, budgets are rather tight. Unless these new -- and with all due respect to the panel members, unless these new sources are competitively priced, with the non-isotopic versions, for companies like mine that do not need a mono-energetic photon beam, they will switch over. That's what I'm hearing from my management and the scientists that use these devices. They will switch over to X-ray type devices.

Again, it is probably too early to determine what the cost of these things will be, but it is something to keep in mind.

MR. JARDINE: Let's see, Les Jardine, a consultant. And I have worked the last 12 years in Russia, including the Mayak site.

Just I want to add what is missing -- and everybody should bear in mind -- the cesium comes from an operating reprocessing plant. There is one at Mayak. There is none in the U.S.

That plant purposely designed a process to recover cesium nitrate. That doesn't exist in France, where there is another operating plant. To take that product, as Albert Aloy said, to another form requires the scientific basis, which the institute has developed. But what's required are the engineering study to decide how to fit that in an operating reprocessing plant in their hot cells. And that is where this time comes in.

And it's my personal judgment, having worked feasibility studies and others in Russia, it's a five-year process to take it to another form in an operating plant at Mayak. That's why I'm supporting the notion of three years, but it's not -- and just bear in mind, in Oak Ridge, what could they do? They don't have any cesium nitrate. We don't have the reprocessing plant.

So somehow, you know, as an operating reprocessing plant you have to develop a whole remote operated production line and continue the scientific work. And it's a five-year timeline, is my experience in Russia.

And I should just add, because I may not comment again, and there has to be the cooperative agreement between the governments to allow that work to take place. That's missing. The U.S.-Russian government to allow that work to happen is missing.

FACILITATOR RAKOVAN: Orhan? If you could introduce yourself again, please.

MR. SULEIMAN: Yes. Orhan Suleiman with

FDA, but these are clearly my professional questions. I have accepted the fact that the activity, although reduced, could probably be -- you can use more of it, and it will probably be feasible. It sounds like industry is up to the challenge.

The more fundamental issue is the chemical, non-dispersibility form, and how that works out economically I have no idea. But, obviously, it is feasible. I just wanted to get that clarified in my mind.

So it sounds like it is very, very much possible to come up with a solid, non-dispersible form of cesium, and it's -- probably with sufficient activity, in larger amounts, that would fulfill the tasks necessary. How that plays out economically, as I said, I'm not going to participate in that decision, because who is going to manufacture it, who is going to put it together is a different issue.

But the scientific issues, the technical challenges, sound like they're soluble. I mean, they're -- they can be resolved.

(Laughter.)

They can be resolved.

Am I correct on those two points? We probably could get a forum that would be adequate, and we probably could get insufficient activity. I mean, that's what I'm hearing. I don't really need your answer. That's what I've come to the conclusion myself.

FACILITATOR RAKOVAN: Anybody want to go into that territory?

MR. SCHRADER: I was just going to say I think it's a correct conclusion that it is a solvable issue. I wouldn't go so far as to say, yes, it's -- the money is -- you know, how much is it going to cost? Is it -- we can solve the problem, but can people afford it when we get it solved?

Secondly, I would just kind of add that everything is dispersible with enough exposure behind it.

MR. PATTON: I guess I might make one more comment. I guess it was mentioned that there is some void volume in these sources, so there is -- we could reduce the void volume in the cell -- I mean, into the -- in the source and also decrease -- or increase, I guess -- the amount of material in a given volume.

But I would like to caution that we do want to keep safety in mind as well. And barium grows into these materials. It has different forms. So we need to look at the thermal expansion and make sure we don't develop a source that is not safe in the process of changing the source form. So all of the testing, and so forth, needs to be done to make sure that the source form is safe as well.

FACILITATOR RAKOVAN: Dr. Aloy, you had --

MR. ALOY: We need to find not only the physical forms, but also to provide the results -- positive results after the testing of these forms in optimal design, because we have after the studies some ceramics or glasses, we provide the test for compatibility, for fire, and for some additional tests for specificity.

And not -- we have good results after this testing. So it's not only the problem to find the alternative forms and produce. It also needs along the way for testing purposes alternative forms and the design of sources for specificity. We have standards and -- followed by these vendors in all the testing.

MR. COPPELL: Well, I think I'm at risk

of repeating what a number of other people have said. I agree with the point that Brad made about the -- we do need to take care of the question of safety and allowing sufficient void volume in cesium. But in estimating, maybe a half the content activity in a source made to a new format, I think we are making allowance for that. I don't really want to complicate the issue by going into the detail of what that means.

And I also agree with the comments that Mr. Aloy made about, in terms of the performance of these sources, there is a long road to go down to convince ourselves that the improvement that is delivered from a change in physical and chemical form is adequate to meet everybody's needs and expectations. And that is particularly true in terms of dispersibility.

I think we have had a couple of conversations and discussions about leachability or solubility, if you want to call it that, and that's a relatively simple term to understand. And it's a relatively simple concept to measure and validate.

But when it comes to discussion about dispersibility, which of course is another concern, then I don't know that there is any very clear guidelines right now. And I think part of the process of developing the technology will be to develop an understanding of what is acceptable in terms of dispersibility.

FACILITATOR RAKOVAN: Anyone care to piggyback on that, or make another point? Please introduce yourself, sir.

MR. POWELL: I am Brian Powell. I am from Constellation Energy, nuclear power. And I guess I am trying to get an understanding of this from a practical perspective. So what I'm understanding is that to calibrate our instruments, for example, we are going to need twice the material. We'll basically have to replace our calibrators, and that -- there is going to be some increased cost with this new solid type of source.

I don't know if there's a ballpark number that it's going to be 10 times as much per curie, or 1,000 times more per curie, or a million times more per curie, but that would be something that I'd like to know.

And the other thing is, which I'm hearing some things being touched on, is industrial safety issues. You know, does making these new sources introduce other things that we are going to need to be able to monitor for besides just radiation? Chemicals leaching out, things like that?

FACILITATOR RAKOVAN: Just wanted to interject from that question. Just keep in mind that, you know, we are having this workshop because it's part of the process. We haven't made any decisions on how we're moving forward on this at this point. So just kind of wanted to throw that out there. We're -- you know, we're just discussing these issues.

Did anybody want to react to the gentlemen's statements?

MR. COPPELL: On the subject of cost, I mean, I think it's obvious to the industry that this isn't going to work if the cost of the new technology is that significantly greater, or, more particularly, if the cost of the new technology is more than alternate technologies. Then, clearly, it is not going to be very attractive.

So that has got to be borne in mind, and it is being borne in mind in terms of our development activities.

I think, though, that you need to recall that the costs will be split into two parts, really.

The first part is a development cost, and that could be quite significant to the industry, and, of course, the risk is that that development cost will have to be incurred before there is any revenue or, indeed, any guarantee of any revenue. And that is part of the discussion we need to have.

And then, there will be a manufacturing cost once the technology is developed and installed and considered operational. And that is not yet assessed, but we understand that it needs to be realistic in terms of market accessibility.

FACILITATOR RAKOVAN: I am going to use a pause, since I see no hands. Lynne, do you want to go ahead and give your presentation?

Michelle, if you could bring Lynne's presentation up? She has just got some general information from the medical perspective that she wanted to share.

MS. FAIROBENT: Thank you, Michelle.

As I introduced myself earlier, I am Lynne Fairobent with the American Association of Physicists in Medicine (AAPM). And since this issue surfaced and the NAS panel had been charged with their task, AAPM and the medical community has been looking at this issue.

Next slide, Michelle.

AAPM's mission, just for those who may not be as familiar with us as others in the audience, is to promote the highest quality medical services for patients while advancing the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists. And we currently represent about 6,000 medical physicists, primarily in the U.S., but we also do have international members.

Next?

The use of radioactive materials in medicine I think can easily be stated and not disputed, that it has resulted in many lives being saved that otherwise would not be. Cesium chloride irradiators are just one example of the way in which this occurs.

AAPM is concerned that the prohibition or elimination of the use of cesium irradiators could result in a decrease in the standard of care that currently exists in this country. As a result of that -- next slide -- AAPM conducted a survey in August of this year to assess our members' experience with irradiators across the board.

The results of the survey are skewed toward hospital-base or university-base irradiators, but it should not affect the general overall conclusions and trends.

Next slide.

The survey was distributed to all AAPM members, as well as members of the RSO, the Radiation Safety Officers' listserv, and other medical organizations had access to this.

We received 363 respondents, 297 had irradiators. 84.6 of those used cesium-137 as the source. 9.3 percent used conventional X-ray units. Six percent used medical LINAC accelerators or LINACs.

The cesium units represented all of the major vendors. Only 10 percent were purchased within the last two years, and seven percent planned on replacing the units within the next five years.

Next slide.

Twenty-five percent of the cesium units had some malfunction, but most were repaired in less than seven days. This is an issue that keeps coming up as we discuss and debate the difference between the cesium chloride irradiators and transitioning to the X-ray units.

Of the X-ray units, 35 percent had malfunctions, with 44 percent being repaired in seven days.

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Of the cesium units, only 40 percent are used for blood irradiation, and I think this is key to keep in mind -- is the other irradiation uses of these irradiators. With 25 percent used for material, 25 percent for animal irradiations, and 10 percent was unspecified as other uses.

Of the X-ray units, 50 percent were used for blood irradiation, 19 percent for material, and 32 percent for animals. Of the medical LINACs that were used in this modality or use, 40 percent were for blood irradiation, and 11 for animals, versus the primary use of LINACs, of course, is to treat patients -- human patients and veterinary patients -- for the treatment of cancer.

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In conclusion, we feel that both types are usable. The conventional X-ray irradiators seem to be fairly reliable. However, they represent only a small minority of the irradiators currently in the field, and they have slightly more down time than the cesium units.

The cesium units, on the other hand, we know to be extremely reliable. Their users, in general, have no plans to replace them unless there is an external factor that is going to drive them to that.

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We believe that the forced removal of cesium irradiators would result in a large loss of resources, both radiation sources and funds, not only from medical facilities but research institutions as well.

Next slide.

In considering the cost of alternative technologies, one needs to include not only the cost of the replacement, but the calibration and maintenance of the equipment, the cost of downtime for the critical use equipment, such as the blood irradiators. And a quantifiable cost for the alternative blood sterilization during equipment down time needs to be assessed and needs to be possible, as well as the human cost for patients who need blood.

In many cases, the comments we receive from the survey, if an X-ray unit is being used for blood irradiation, and it is down, oftentimes the backup is the cesium irradiator at someone else's facility if they do not have one at their own institution.

Next slide.

It is easily demonstrable that cesium chloride sources utilized in blood irradiators have a much more reliable performance record than machine-produced technologies. And both the cost and continuity of operation or failure should be considered financially, and then the possible impact on human life.

Over the course of the rest of today and tomorrow, we actually will be sharing more data as a result of a couple of the other questions that are being asked. But there is a huge increase in concern in the research community on the viability of transitioning, for clinical trials work, from using a cesium irradiator now to -- if one has to transition to the X-ray unit, can one in fact demonstrate the equivalency to FDA in order not to jeopardize the clinical trials work that has been done currently, and not have to go back and start at square one.

Thank you.

FACILITATOR RAKOVAN: Thanks, Ms. Fairobent.

Michelle, if you could go ahead and bring up the question again.

Anyone have any reaction to the presentation that Ms. Fairobent just gave, or any other issues that they'd like to throw around in terms of question 1.1? Please.

MR. MAIELLO: Mark again from Wyeth Research. Lynne, that was very good. The -- again, the anecdotal information I will give you from my institution. And, again, if my colleagues find that this is inaccurate, please go to the microphone.

I'll step back a little bit about what -- you know, about what I commented on earlier. The pharmaceutical companies are a little strange. They do things with research lines in mind, and that research often changes.

In my own institution, the use of the irradiators is basically two different types, one for irradiating small animals, the other for irradiating cells. The group that irradiates the cells would agree with the equivalency issue that you brought up, because when asked directly by me they said, yes, it would be potentially troublesome, because the literature has used the -- the literature shows that researchers have used the cesium sources most frequently for irradiating cells. And perhaps research that was conducted with an X-ray machine, with its broad spectrum, would be questioned.

On the other hand -- and this was part of my comment before -- the group that irradiates with animals -- irradiates the animal lines would probably not care. However, I will say this. The researcher who I questioned, who was in charge of the irradiator, said to me a few days ago it would be potentially feasible, if the money is there, to purchase -- to keep the irradiator, assuming no regulatory issues arise, and buy an X-ray machine at the same time, and use it exactly the way you described it -- as a potential backup for the X-ray machine if the X-ray machine fails, and we have heard about the higher maintenance and potentially higher breakdowns. And so the irradiator would still be there, assuming, of course, that no regulatory issues arose to force us out.

So the situation is never quite clear. It is always gray. And when given a choice, people will often take the choice, especially if -- I have to say it -- if the money is there, they will take the choice.

FACILITATOR RAKOVAN: Okay. A few more comments, and then we're going to move on, please.

MR. McBRIDE: I'm Bill McBride from UCLA. I'm a radiobiologist. I'm representing ASTRO here. It's the American Society of Therapeutic Radiation Oncology.

Yes, I'd like to say that there are actually -- you know, from a radiobiological point of view, I'll state the obvious. An X-ray is not a gamma ray. There is a big difference between them.

I think the -- you know, whenever it comes to the usage of these machines, they are all used for different purposes. And, actually, switching -- I mean, I disagree entirely that small animal users could switch easily to X-rays. That just isn't true. I think that it would take a lot of effort. Most of the work that has been done with small animals have used cesium.

I think that in particular for things like whole body radiation setups cesium is a much better kind of -- for all kinds of technical reasons. I think making that change is going to be expensive, it's going to use more animals, you are going to get into a whole new recalibration system. And I think it is not just a simple matter of, you know, taking the animals and saying, "Okay. Let's use X-rays." I don't think it's going to be that easy at all.

So I think there are disadvantages, certainly, to using X-rays for many studies, not all certainly. There are some situations where the transition can be made without a great deal of difficulty, but they are other situations where it is just going to be very difficult indeed.

FACILITATOR RAKOVAN: One more hand, please?

MR. NIXON: Grant Nixon with Best Theratronics. As the world's leading manufacturer of self-contained irradiators, in both the X-ray technology form and in the cesium form, I would agree wholeheartedly with that comment. The use of X-ray technology does not port well to the research irradiator applications, specifically with regards to irradiating animals. There is a big difference between the mode of dose deposition.

When you're dealing with low-energy photons that are inevitably part of the X-ray spectrum, you will end up with a lot of photoelectric differentiation in terms of the absorbed dose. So unless you can genetically engineer a mouse not to have any bones --

(Laughter.)

-- you are going to be -- you are going to be stuck with using a high-energy gamma research irradiator for the foreseeable future.

Thank you.

MR. KAMINSKI: Hi. Joe Kaminski, NIH, but I'm not speaking on behalf of the NIH. I'm a radiation oncologist. Again, we treat with X-rays, high-energy X-rays, and, of course, you know, a mono-energetic 660KeV gamma -- that's cesium -- is useful. But certainly other sources, such as cobalt, could be used, which would more mimic the high-energy X-rays which we used clinically.

So to disregard X-rays -- and, again, we can use LINACs for some animal use, although it is expensive. But there are alternatives, such as high-energy X-rays. So --

MR. SVAJGER: Hi. I'm Mark Svajger with Fluke Biomedical. We are a large calibration facility. I just have a statement and a question. First of all, the statement. Any changes will cause the price of calibration to go up. And we are already probably one of the most costly facilities right now, at, let's say, $200 an instrument.

So when we're talking about, like the gentleman from Constellation Energy, is it going to be 100 times more, a million times more? That will all impact us as we use our equipment to survey our facilities.

Number two, my question is, if we change -- this is more or less for Brad, I guess. If we change from a powder form to more of a ceramic form, are there any more inherent errors or variables with that?

MR. PATTON: Maybe others can -- I think there might be some self-shielding, but I think someone mentioned earlier that the energy of the gamma is going to be the same in these different forms. And there might be some self-shielding if you bring in some cermats, you bring metals or other things into it. But I think you will get the same type energies, which I would think would be of interest to you.

MR. ALOY: I can say that because the ceramics or glasses contained only elements with the atomic weight, the self-absorption is not -- will not change very sharply from the cesium chloride.

So the properties will be very close to cesium chloride.

MR. MAIELLO: If I might just get back to that issue briefly about the use of both machines at a facility. First, let me say, don't shoot the messenger. I'm only repeating what the scientists tell me.

And maybe the confusion bespeaks more to the -- where we are about this than anything else. And if they haven't researched it very well, then they are making statements about using both kinds of machines, you know, with one as a backup. On the other hand, the end point that we used the machine for is simply the knocking down of the immune system of the animal. It is not to do anything else.

Now, whether that -- you know, certainly a mono-energetic photon is not needed for that, but the -- it is true that the broad spectrum of the X-ray machine may induce some secondary effects that scientists have not considered. But, again, that is because of where we are in this entire issue. They are hearing these things, that these cesium sources may go away and they are beginning to explore whether or not the alternatives are available.

Now, I do know -- I have made contact

with a few other scientists at other institutions, and they use the machine -- the X-ray machine for exactly the same reason we do -- to knock down the immune system of the animal, so that oncological compounds can be tested on the tumors that the nude mice grow rather quickly.

FACILITATOR RAKOVAN: Sir, I'm sorry. I'm going to interrupt real quick. Right now, I'm just trying to bring us all in. We're focusing on feasibility of the use of other forms of cesium-137. If you'd like, I can't put like in a parking lot kind of the X-ray stuff, because we are going to hit on that later. Do you want me to put it up there, or do -- to --

MR. MAIELLO: As I understand, that is going to be another question.

FACILITATOR RAKOVAN: Yes, yes. We're going to get to that.

MR. MAIELLO: We can hold that off until then.

FACILITATOR RAKOVAN: Okay. I just wanted to kind of bring us back.

Lynne, I saw you had your tent up earlier?

MS. FAIROBENT: I think the only comment

I wanted to make on -- with regard to a LINAC being used instead of cesium chloride, while we are awaiting development of an alternative form of cesium perhaps, is that in many of the medical institutions where they may use the LINACs for blood irradiation, they have to schedule the blood as if they were scheduling a patient for treatment. And oftentimes the LINAC may not be available, because patient treatment tends to take priority, as I think most of us would agree it probably should.

So if there is -- if the X-rays are being used and there is down time on that, and the LINAC is the backup, it may not be available due to patient treatment schedules.

FACILITATOR RAKOVAN: As you've noticed, we've put the other -- the next question up, which I think we've been covering anyhow. It's question 1.12, is the use of other forms of cesium feasible? If so, please describe desired methods, and discuss any benefits or obstacles. Again, I think we have been covering this, unless -- if someone has a specific additional topic.

Sir, if you can introduce yourself one more time.

MR. MENNA: Yes, Blair Menna again from

Best Theratronics.

I just want to key in on the word "benefits" there. And one of the things that I think potentially may be feasible and would certainly be extremely beneficial is, if we went into reprocessing cesium, wouldn't it be wonderful if we were reprocessing the existing cesium chloride? So the benefit would be that we -- we would essentially defer the disposal problem. We wouldn't have to find an immediate storage solution for that.

Assuming that the specific activity drops off, and assuming that there is a switch to alternative technologies all together, I am wondering whether or not we couldn't essentially reprocess cesium, have enough return from the field that then would be returned for applications in a less dispersible form.

So I see it being a benefit. I don't know whether any of the source manufacturers could comment on the feasibility of doing that.

FACILITATOR RAKOVAN: If you'd like to.

MR. COPPELL: Okay. Well, just briefly. Yes, I understand, Blair, what your proposal is there, and it does sound attractive, doesn't it?

There are one or two obstacles that we may have to overcome before we could recycle cesium that is currently in circulation, not least the fact that a lot of that material is quite old already. Cesium has a half-life of around 30 years. And so material which is well into one half-life may be 15 or 20 years old. It is really questionable whether that would be reusable anyway.

We are already looking, as we have described, at the potential reduction in specific activity of an alternate form of maybe a factor of two. If you make that worse by using 15-year old cesium, or 20-year old cesium, I'm just not sure it is practical. But it is -- it is something that is being considered.

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

MR. COPPELL: At the risk of getting into too much detail, I agree with that. But, of course, the cesium-137 decays to barium. The barium is -- can be separated after the cesium, so it -- in effect, the effective specific activity of the material doesn't decay with the same 30-year half-life as the cesium-137 does. You can recover some of this lost activity by removing the barrier.

FACILITATOR RAKOVAN: Please introduce yourself.

MR. JONES. Yes. Rick Jones, just private citizen. I represent myself.

(Laughter.)

Just hearing the dialogue, it -- what I'm hearing is the users are expressing criteria that has to be met. Manufacturers are kind of responding to that, and these are kind of drivers from both sides to inform the decision.

As a path forward, something to consider, not making more work for federal agencies, but it would seem a getting together of the users to create the criteria that they need in the different uses of these sources, and then compiling that, and then communicating that to the manufacturers, gee, how would you meet these criteria, would really go to help inform what can and can't be done and in what timeframe, how much money would it take, how many years of development.

If it's five years just to create the product line, how many years of testing would it require to accept the product in the different users for blood irradiators, for your radiation of animals, cells? You know, how many years of just testing of the new product to make it acceptable to the user community?

But I just -- in listening to this, it seems like a collection of user needs communicated to the manufacturers to then respond to see what they could do. And perhaps that could be something the federal agencies could do in informing the answers to these questions over time.

Thank you.

FACILITATOR RAKOVAN: Thank you, Mr. Citizen.

(Laughter.)

I'm going to go ahead and try to get through a few of the questions. 1.13 I believe we have up already. Would the affect of density loading, with different forms of cesium, preclude the use -- their use in existing devices? And also, would it require modification of existing devices? If anyone has any specific points that haven't been made on this topic, now would be a good time to interject.

Sir, please, step in.

MR. ALOY: Just only from the scientific point of view, not as a producer, because unfortunately I represent a different Mayak site. And as the people from Radio Institute note, I had an opportunity to participate in this very important meeting.

But from a scientific point of view, I can say that -- that feasibility study, we need to have in at once to change the technology. And this is a task for optimization. From one point of view, this is a safety, then cost, then technology availability, and the physical and allegation properties, and all together we need to combine -- have good initial data based on the scientific research and development technology, and then calculate all of this in the optimization option -- for optimization option.

And, of course, we need to move to each -- from one site, the users from other sites, distributors and producers and scientists and technology specialists. So we need to understand also about the secondary risk when we use the new technology, which accompanies a new process.

And this is -- will be a more complicated process, but from -- very simple answer for this question. I think -- this is my private opinion -- that, yes, we can develop a very good new ceramic or glass forms, with good density of cesium-137, which will satisfy the user's needs.

But we need to move to each -- okay.

FACILITATOR RAKOVAN: Thank you, sir.

Anyone else want to build off of those comments, or give another perspective? Sir, if you could introduce yourself again, please.

MR. WASIAK: Tom Wasiak from Best Theratronics. I guess I may repeat the previous comment, but I guess this question specifically asks -- so speaking about our family of irradiators, GammaCells, if you read the question as, would it preclude their use in existing devices, without absolutely any changes? I think the answer would be yes.

But if you look at it, you know, with some small to medium to large design changes, the answer would be it would be possible, and different forms of cesium would not be precluded in this application.

FACILITATOR RAKOVAN: Thank you.

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

FACILITATOR RAKOVAN: Could you bring -- just go ahead and bring the microphone down. There you go.

MS. SHEPHERD: Okay. Better?

FACILITATOR RAKOVAN: Much better. Thank you.

MS. SHEPHERD: Mary Shepherd, J.L. Shepherd and Associates. I think it would have to be a cooperative effort with the source manufacturers and the irradiator manufacturers to develop sizes that would be interchangeable or requiring different kinds of modifications. I think it's way too soon to say a yes or a no at this point in time, because we don't know what the new forms are going to be, what the sizes will be, or if they would be interchangeable.

FACILITATOR RAKOVAN: Very good point.

Please introduce yourself, sir.

MR. GERSABECK: My name is Edward

Gersabeck. I'm with U.S. Department of Agriculture. We currently own and operate nine Huseman Category 1 irradiators that we use primarily for sterilizing insects. And in our line of work we simply can't tolerate too much of an increase in time, which you're sort of implying if you had increased -- decreased your activity by about a half, because in our line of work the time is critical because we try to destroy the gonadotropic tissue in the insects. But if they are in those irradiators too long, we start getting secondary damage to the insect.

So -- and I'm not sure if -- maybe if there is someone from NRC here, if we had to redesign the Huseman to accept a higher amount of material, would that imply having to get a new license as well for those? Because we also own the license to the Huseman irradiator.

Thank you.

FACILITATOR RAKOVAN: Any further discussion on this particular question before we move on to the next?

(No response.)

Okay. Michelle, 1.14. Is it feasible that high activity, e.g. IAEA Category 1 and Category 2, cesium sources will be available in alternative material forms? If so, what is the estimated timeframe for manufacturing?

Please, go ahead.

MR. COPPELL: Well, I think to some extent we have covered that already. I think the answer is probably, though we need a few more months to come up with a firm proposal. And with regard to timeframe, well, a few years. Don't know quite what that means, somewhere between two and five I guess, probably nearer five.

FACILITATOR RAKOVAN: Okay. Please.

MS. SHEPHERD: Mary Shepherd from J.L. Shepherd and Associates.

FACILITATOR RAKOVAN: If you could speak up just a little bit. Do your best.

MS. SHEPHERD: I'm freezing.

(Laughter.)

Mary Shepherd from J.L. Shepherd and Associates. One thing we haven't discussed is what we did with the chloride sources, that the DOE did -- was a 100-year accelerated aging test, and I don't know what the timeframe would be on that before, you know, any licensing could be performed. I just -- I didn't know what -- if we had even thought about those yet.

FACILITATOR RAKOVAN: Want to take a stab? You seem to be a very popular guy at this panel, so --

(Laughter.)

-- maybe I should just assume that you are going to be addressing the questions.

MR. COPPELL: It's a good point, Mary, and you -- it is one of the issues that we need to consider, as well as the question of solubility/dispersibility, the third element that I would probably cite as being a technology issue, which we need to include in the development program, is to work out how stable these materials are over a period of time in the matrices that we developed for them.

It's easy enough to say, well, they should be okay, because we've had -- we've had a lot of ceramic and glass materials with cesium in them around for 30 or 40 years. But I'm not sure how much evidence or data there is about how they perform once they are 20 or more years old. So it's an issue. We do need to do some accelerated lifetime trials on them, but it's assumed to be part of the program. We have not forgotten it.

FACILITATOR RAKOVAN: Further discussion

on these issues? Please. If you could introduce yourself, sir.

MR. MINNITI: Yes. I am Ronnie Minniti from the National Institute of Standards and Technology. I have a question. When --

FACILITATOR RAKOVAN: Could you turn up the mic?

MR. MINNITI: Yes.

FACILITATOR RAKOVAN: Just bring it up closer to you. You can just turn -- you can move it. There you go.

MR. MINNITI: Okay.

FACILITATOR RAKOVAN: Don't be afraid.

MR. MINNITI: Yes. The summary that was made at the beginning classified the different applications in three basically, right? Research irradiators, blood irradiators, and calibration. So I think I speak on behalf of the people that need calibration of instruments.

So the question is -- we are talking about here about periods of time, a few years, right? And I think I heard this morning saying that it will depend on the market and how many irradiators will be needed. So, hypothetically, if some of the -- for these -- for some of these applications, like blood irradiators, it's decided that other forms -- other alternatives are going to be used.

And then, the only people who would need another form of cesium would be the calibration facilities. This is approximately something between 10 and 20 percent of the current irradiators in use. So in that case, would the manufacturers be interested in pursuing this? I guess that's the question, because then that would increase cost of making sources, right? As opposed to -- do you understand the question or --

(Laughter.)

Yes. Well, it looks like you are going to --

(Laughter.)

MR. COPPELL: I think if I -- can I reinterpret the question? I think what you're saying is that if a number of the applications for cesium sources dropped off the list --

MR. MINNITI: Yes.

MR. COPPELL: -- and other technologies were used for them, would that increase the cost of the remaining --

MR. MINNITI: Yes.

MR. COPPELL: -- smaller volume of cesium sources?

MR. MINNITI: Yes.

(Laughter.)

Well, no, that's obvious, but what concerns me is that, okay, well, if this is not -- I guess it's a comment more than a question. But if that's the case, then will there be a replacement -- a possible replacement for calibration of instruments? If it's decided that, okay, we cannot pursue -- the manufacturers of sources are not going to pursue another form of cesium, because then the cost is too high for just a few users, right? Which is maybe 100 out of currently 1,500 calibrators out there. Then, that would become a problem, right, for those -- for that particular application. So I guess it was just a comment.

FACILITATOR RAKOVAN: I think we are going to get into some of those issues later in the panel.

One last comment before we move on to the next question? Sir, if you could introduce yourself again, please.

MR. POWELL: Yes, Brian Powell, Constellation Energy. So I'm representing nuclear power.

And just looking at this question up here, is it feasible that high activity, IAEA Category 1 and 2 cesium sources will be available in alternate material forms? And it's just a comment. In the current cesium-137 form, cesium chloride, we are already covered, as far as safety and security and these sources. We have taken all our steps to make sure that those are protected.

And that wouldn't change if those sources were in a different form. So I'm kind of looking for the benefit of spending all this time and energy to follow this path when we already have things in place to protect them. And we are going to do the same thing, regardless of the form that this source is in.

FACILITATOR RAKOVAN: Okay.

MR. KAMINSKI: Joe Kaminski. To address that question, I guess, is -- the concern is the solubility of the cesium-137 chloride. Just I'm also on the emergency preparedness side, and dispersibility, and the ability to leach into concrete, and so forth. So if it gets released, for example, in the City of New York, let's say, while you're talking about economic impact, that could be billions of dollars. That could be underestimating it.

So, I mean, it is a real potential, and that's why there is concern. And, again, I don't speak on behalf of NIH. So --

FACILITATOR RAKOVAN: Okay. Any further discussion before we move on to the next question? Okay.

MR. ALOY: Unfortunately, we have not the standards for dispersibility properties of these materials. We have standards for leachability, we have standards for the mechanical properties study, for fire testing, but we have not -- IAEA regulation hasn't standards for dispersibility. What does it mean?

Because any materials may be dispersed in small particles with action from explosion, for example, or from other mechanical forces. So maybe we need to develop these standards or testing -- testing procedure for dispersibility, to meet these requirements. It's my opinion.

FACILITATOR RAKOVAN: Okay. Yes, please.

MR. COPPELL: Yes, I agree. Maybe I -- I think we all understand that the risk is that this

-- this gets close to the security issue. But I think we -- we are going to have to work out what we mean by "dispersibility," how exactly are you going to try to disperse it before you can do anything to assess its performance in those circumstances and compare it with other options. It's tricky. I don't know how we go about that, but we need to find a way.

FACILITATOR RAKOVAN: Okay. We've got two more questions I'd like to get through before we go out for lunch. Question 1.15, since all of the cesium chloride is manufactured in Mayak, Russia, is it known if the cesium source producer can modify its production processes? I think I know kind of who this question might be focused on.

(Laughter.)

Are you okay with addressing it, sir, or --

MR. COPPELL: Yes, okay. I mean, but I think we have more or less addressed it a couple of times. It is -- the answer is, in principle, we think so. It depends on just what the technology involves. As Dr. Aloy has said, you know, it -- the technology development must include development of facilities for production, must ensure that we have validated the product to make sure it does what we think it does, as well as just the scientific element of, can we make this material in a less soluble, less dispersible form.

I think, you know, that the view within the industry is the answer is probably. We need a few more months to come up with some firm proposals, and then we need to look at whether it is commercially viable.

FACILITATOR RAKOVAN: Dr. Aloy?

MR. ALOY: It is well known that new forms, like the pollucite or glasses, you need to use a higher temperature. It is a high temperature process. During this high temperature process, the cesium alterations have made -- will be higher, and we will have more secondary waste in comparison with cesium chloride production.

So this is the task for optimization of the process. And, of course, we need -- this is my own opinion. Mayak all the time go ahead and develop a new technology, but we support this study by R&D in the institute. And so I think that in the near future they can do new forms.

MR. PATTON: This is Brad Patton again. It was pointed out earlier that we, in this country, aren't doing reprocessing, but there is a lot of research going on about reprocessing now. And some of those flow sheets include separation of fission products.

I think we need to consider looking in the long term, if we are separating cesium-137 and developing waste forms for cesium, we need to think about the applications here for irradiators, and perhaps some waste forms that we might develop could also be used for irradiation sources.

So I think as we begin to develop new waste forms and look at reprocessing in this country we need to consider the use of some of those materials for irradiation sources.

FACILITATOR RAKOVAN: Any additional points before we go ahead and move on to the final question on this topic?

(No response.)

Okay. I think it's already up there already, but question 1.16, would other entities in the U.S. or worldwide engage in manufacturing sources with alternative forms of cesium-137? Anyone have any thoughts that they'd like to share on this particular issue? Stab in the dark? Lynne?

MS. FAIROBENT: Brad, I have a question

for you. You said Oak Ridge was not interested in getting into the production mode for cesium. But has there been discussion among the broader DOE community as to one of the other labs stepping up into this role?

MR. PATTON: Of course, we all work for the Department of Energy, so it's up to the Department of Energy to task us with production material. But I guess, again, as rightly discussed earlier, we aren't doing reprocessing in this country. The cesium we have, which is significant, is older. And we could remove the barium, but we still have the inert cesium that's in the material. And so it's a lower specific activity, which would be lowered further by some of these source forms.

So it would be up to DOE to decide that, and I don't see anyone, you know, discussing it at this time.

FACILITATOR RAKOVAN: Please.

MR. COPPELL: Yes. I guess the issue is that a lot of the costs involved in this, effectively entry costs for establishing a facility or a plant to manufacture these products. And for somebody who doesn't manufacture them right now, the entry costs are higher than extending the capability for somebody who does. I guess that's the issue.

FACILITATOR RAKOVAN: Okay. Any further discussion on any of the topics involved with Issue 1.1, feasibility of the use of other forms of cesium-137, before we take a break for lunch?

(No response.)

I know, it's very encouraging for everyone to rush up with a comment, isn't it?

(Laughter.)

Okay. Let's try to get started promptly at 1:00. The next panel will be feasibility of the use of isotopes other than cesium-137. If you are a panelist, please just come right up and take your seat at the table. We'll start again promptly at 1:00.

(Whereupon, at 11:54 a.m., the proceedings in the foregoing matter recessed for lunch.)

FACILITATOR RAKOVAN: Why don't we go ahead and get started.

ISSUE 1.2: FEASIBILITY OF THE USE OF ISOTOPES OTHER THAN CESIUM 137

The next topic that we will be discussing is Issue 1.2, Feasibility of the Use of Isotopes Other Than Cesium 137. Why don't we start by going ahead and having our panelists introduce themselves if we could start over here on the left please.

MR. CONNELL: My name is Leonard Connell. I study radiological and nuclear terrorism at Sandia Labs and I was the lead on the Red Teaming Analysis, the attack videos which some of you may have seen on looking at the vulnerability of the cesium chloride machines and also led the team that designed the upgrade kits for those cesium chloride irradiators.

MR. FIKE: I am John Fike, the University of California at San Francisco. I'm a radiobiologist. I'm here on behalf of the Radiation Research Society.

MR. KAMINSKI: Joe Kaminski, National Institutes of Health. I'm a radiation oncologist and previously in my other life also head of a laboratory and I'm involved also in the emergency preparedness side.

MR. McBRIDE: I'm Bill McBride, UCLA, Radiobiologist. I'm representing the American Society for Therapeutic Radiation Oncology and I also lead a CMCR which is one of the center for countermeasures at UCLA.

MR. RING: I'm Joe Ring, Harvard

University Radiation Safety Officer. I am presenting a summary of my faculty's comments.

MR. COPPELL: I'm David Coppell. I didn't get any calls over lunch. So I'm still technically Manufacturing Director for REVISS Services.

(Laughter.)

MR. NIXON: I am Grant Nixon. I'm a Senior Radiation Physicist for Best Theratronics and in a former life NDS Nordion. We are the largest manufacturer of self-contained irradiators both in terms of x-ray, technology and cesium chloride.

FACILITATOR RAKOVAN: Thank you, gentlemen. Before we dive into the questions, I believe a few of you had statements or presentations that you wanted to go through. So if you would like to go first, that would be fine.

MR. FIKE: John Fike, representing the Radiation Research Society. I'd like to make a very brief statement primarily regarding the scientific impact and potential consequences of banning, in particular, cesium sources.

As I said, I represent the Radiation Research Society which is about 1500 members. It's a multidisciplinary group of biologists, physicists, chemists and clinicians and while there are multi-faceted and extensive interests across these people, there's a common goal of advancing the understanding of radiation effects and advanced of radiation medicine.

The work by these individuals is supported in a big way, hundreds of millions of dollars, by a variety of governmental sources and nongovernmental sources, NIH, DOD, DOE, NASA, DHS, NSF and others. So it's a big component of federally-sponsored research and I'd like to just summarize the concerns of the Radiation Research Society in just three major points.

We did a poll a couple months ago and about 80 percent of the members indicated the cesium irradiators were used by them and over half of them were critically dependent on it and when I say this, 80 percent of the people said that the loss of these irradiators would be either major or catastrophic to their research efforts.

The second point is, and may Bill McBride will speak more to this in a moment, Radiation Research members play in a central role in the development of medical countermeasures to meet the threat of radiological nuclear terrorism. If cesium irradiators were eliminated, this development would suffer a serious setback and made our country more vulnerable and I mean that in the context of the timely development of effective countermeasures.

And, lastly, Radiation Research members are actively involved in the development of innovative cancer treatments involving all types of radiations. Cesium irradiators are critical to much of this work and if they are eliminated, this could have a very significant impact on the advancement of radiation medicine.

That's my statement.

FACILITATOR RAKOVAN: Thank you, sir.

MR. McBRIDE: Just on behalf of ASTRO (American Society for Therapeutic Radiology and Oncology) I would like to echo John's comments and expand on a little bit of that. I mean, I think there really is in terms of the countermeasures program the majority of the eight centers of which UCLA is one use cesium sources as the main kind of workhorse for all of this activity and this is a major program which has been undertaken by the government to try and counteract exactly the kind of terrorists' acts that we're really thinking of in this forum.

I think that we should also realize that there's a lot of radiation research which has been done which is not totally directed towards a kind of terrorist attack, but from the point of radiation protection for the population as a whole since really the last war and before even. And also in the medical kind of sphere using radiation in a therapeutic sense really has saved many, many lives and it's a major cancer modality. Over 50 percent of patients with cancer get treated with radiation and are cured. So limiting our sources, limiting our availability of these sources, really is going to have a major impact upon the research which goes on.

I'd like to just kind of stress that there are lots of user groups out here and we hear from blood bank users which are an important group. We've also heard someone talking this morning about zapping mice to knock down the immune system. The radiation research is a lot more sophisticated than that. We're dealing with the effects of radiation on many different organ systems and tumor systems and this requires a lot of different kind of approaches, the uses of radiation, and cesium is one of the major ways in which we do this kind of research.

We have a record of well over half a century if not a century of research using these kind of sources and it's the transition to any other kind of modality, whether it be x-ray or cobalt, is not going to be trivial.

MR. KAMINSKI: Again, this represents only my professional opinion and I'll just pose a question first and it's obvious. But should we pursue safer forms of cesium-137 or technologies assuming they exist and are economically viable to the enduser and I think all of you would agree that we should because if we don't the potential impact of not doing so could be substantial as already mentioned.

I'm certainly not arguing for any one single solution. We need alternative forms of cesium-137. If they are currently available, then we should look into that and x-rays obviously are another potential form, another potential source, and potentially even other radionuclides. Of course, this should be done over many years and it needs to be carefully orchestrated so it doesn't interrupt research in blood banks, for instance.

Thank you.

MR. RING: Could I have Joe Ring's slides please?

I've attempted to collect a wide variety of input from my faculty and it's very important for us to stress that much of the work that we do is basic scientific research and it is used to develop therapeutic interventions for disease among other things.

We work in primary areas. Next slide please. I was trying to get going. Cancer therapy, blood transfusions, DNA damage studies, space travel, molecular biology, immunology, stem cell and radiological terrorism effects, a very wide range. We're using it for a very wide range of research and that means that many of things that we're identifying may be slightly different.

One thing I did come to find out is I'm not going to argue with a Harvard faculty member when he tells me or she tells me that there are differences. Cesium-137 is the instrument of choice for much of the research. It is the standard. It is the standard because it has uniform irradiation effects. It has very unique cell interactions.

This is one of the areas where I got very clear guidance from my faculty. They want me to show you this book. This book documents, it's a long-standing reference, the unique effects from cesium and from radiation. The cell damage ends when the irradiation ends and it's very important to most of our faculty. It has very well characterized interactions.

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

There's been lots of discussion about potential alternatives. That raises an awful lot of angst and concern for my faculty. They say there is very different biological mechanisms which mean a lot to them when they work at basic science. They're working at very small levels in the cells and there's a picture that shows you there. Just graphically, you can see that it's different response mechanisms. I don't want to go into the details. But the alternative sources give different effects because their effects vary with the energy of the sources. They see very strong differences in the irradiations done between x-rays and strong differences between cobalt and cesium irradiations.

The chemical agents really react by a very different methodology that presents them a fair number of problems. Chemical reagents react by diffusion. Therefore, they see a gradient across whatever they're trying to study in reactions and, even more, there is no clear endpoint. That endpoint continues after a period until the chemical agent wears down and that chemical agent has different effects in the cells. So they see very different reactions from chemical agents that are different by substantial means from other irradiation sources and radiation sources in general vary amongst the energies.

The faculty really is looking for a way to move forward. They're very concerned about the grants and contracts which are federal money and the impact on that and the ability to continue competitive science research. They are very concerned that this will drastically impact science and that we need to look at alternative studies and whether or not they can be correlated. There is a huge dataset out there of studies that have been done over the last 40 or 50 years that cannot be correlated with new studies done by another mechanism. So we have a validate or cross validate that historical dataset.

We should investigate alternative physical forms to cesium so that we can minimize that risk. One of the things that they recommend very strong in the short term is to look at hardening of the sources. I know there is some discussion with that.

I got an awful lot of interest from my faculty and I will tell you that they really made a point. Harvard faculty don't usually get involved. They demanded that I have a meeting and they demanded that I show up to talk to them and they presented significant volumes of scientific data to show this is different and it is of importance to them.

Thank you.

FACILITATOR RAKOVAN: Before we move to the questions, any further statements by the panelists? I have one on the far side. Are you going to use the podium?

(Off the record discussion.)

MR. CONNELL: Again, I'm Len Connell from Sandia Labs and my role has been on the National Academies to really help inform the committee on the differences in the risk, the radiological terrorism risk, between the different radionuclides. So I brought this. I don't have a presentation.

But this is cesium chloride and if we filled up to about this level, that's about 1,000 curies of cesium chloride. As was mentioned in most sources, it's a packed powder, but packing it into pellets doesn't really effect the dispersability very much. This is about 1,000 curies of cobalt and since we're talking cobalt-60 I thought this was kind of to frame the debate between two, about 7 grams of cobalt.

Now we have two very interesting accidents that have occurred with both of these types of material. The one was mentioned before was in Goiania in `87 and it involved about 1400 curies of the cesium chloride. We know from that accident that because of the solubility of the cesium when it got onto the ground it went into solution, it mixed with dust particles, the dust went onto the tops of those nice Spanish tiles and, as was mentioned before, you can't just rub it off. It actually chemically bonds with these building surfaces. So a huge expense in clean-up. A large difference between that and cobalt. Seventy grams of the cesium chloride in that teletherapy unit in Goiania produced roughly 70 tons of rad waste that had to be disposed.

About a year later, a cobalt teletherapy machine in Juarez, again similar problem. It was abandoned and people stole the material and sold it to a junkyard for scrap metal.

Now the cobalt in the teletherapy machines, it's not this slug. It's actually little BBs about a millimeter in size. Some of those also got dispersed in the city. In that case, it was a matter of the responders going around with the radiation detector, finding the pellets, picking it up, putting it in a pig and the problem was solved, a huge difference in the consequence. Not even looking at the radiological terrorism and all the different mechanisms of dispersal, we know from those two datapoints there's a very significant difference in the consequence.

So that's what has driven my concern

about the cesium chloride. By switching to cobalt, we don't completely solve the problem as was mentioned by others. Anything can be dispersed if you work hard enough at it. The difference with the cobalt of course is there's much more work that has to be done.

I hope that that frames the debate a little bit. Thank you.

FACILITATOR RAKOVAN: Thank you.

MR. KAMINSKI: I just want to make one comment that I didn't totally agree with. I certainly don't agree with the mechanism of action being different between x-rays and cesium. Certainly, the depth dose profiles are different in small animals and so forth. It might be more ideal to use a cesium source than, for instance, like cobalt source where it d-maxes that 0.5 centimeters where you might need to use bolus. But certainly the mechanisms are the same.

MR. NIXON: I'll show you if I could make a comment on your comment. In terms of dose deposition, even though the depth dose profiles even if you were to find similar profiles in water, it's very different in terms of the way it interacts with the matter. X-ray tubes generally produce a broad spectrum. A significant portion of that spectrum is in the low energy sector and that's up to and including say up to 150 kilovolts, KeV.

Most of these photons interact differently when they come into contact with atomic constituents that are of higher atomic number. They react via the photoelectric effect and that's why when you get an x-ray radiograph you get this contrast that appears between bone and tissue. Even though you get a similar depth dose profile in terms of the total attenuation of the beam throughout the sample, the actual deposition in the individual constituents inside that ensemble is quite different. In fact, if you're going to go below 320 kilovolts it could be as high as two to one.

FACILITATOR RAKOVAN: All right. Hold on. The topic at hand is feasibility of the use of isotopes other than cesium-137. We are doing opening statements. If you'd like we can put this topic in the parking lot. You just have to tell me what I'm supposed to put up there. I'm all right with that. Do you guys want me to put it in the parking lot?

MR. NIXON: I think that would be for the next session.

FACILITATOR RAKOVAN: Okay. Can you hold on to discuss it until then?

MR. NIXON: Okay.

FACILITATOR RAKOVAN: Okay. I thought we had one more opening statement here to do. Correct?

MR. NIXON: Yes.

FACILITATOR RAKOVAN: If you could wait until you get to the podium to make sure that we have you on the transcript.

MR. NIXON: Presentation Number one. So, as I said earlier, we are the -- My name is Grant Nixon. I'm a radiation physicist with Best Theratronics and formerly NDS Nordion. So as such we are the largest manufacturer of blood irradiators, both x-ray and cesium based, in the world. Next slide please.

In terms of a quick summary of some of the questions and our position, as a manufacturer, we would say that for most of our applications that we sell units for cesium chloride could possibly be replaced with cobalt-60 energies or sources for most applications from a radiation physics perspective. Unfortunately, for current designs of self-contained irradiators this is not always easy because of the shielding requirements of cobalt are much greater. Next slide please.

As such, we can look to other isotopes that differ from cobalt-60 such as europium-152. This isotope has received considerable press as a possible substitute for cobalt-60 due to the cost of cobalt-60. The problem with europium is it's a fairly broad spectrum radioisotope and although it has a good long half-life there are issues associated with its handling, manufacturing, the availability in terms of manufacturing as well, and more difficulties in terms of the filtering of the low energy components.

Cobalt-60 is the only isotope as a manufacturer that we would consider as a possible substitute for cesium chloride in self-contained irradiators. But as a simple hand-waving argument or scaling argument can demonstrate, the shielding requirements are approximately two to one and the use of tungsten or depleted uranium which nobody wants to touch anymore will not alleviate that basic fact by very much.

Now in terms of attendant risks associated with the transport of cobalt sources, because cobalt has a 5.27 year half-life versus a 30 year half-life of cesium-137 most units will have to be resourced over a period of five to ten years if they are to meet the requirements that they are put to initially. So with that transport comes other issues, security of the transport, possible accidents, etc., and, of course, all the ALARA-associated risks that health physicists like to jump all over.

Thank you.

FACILITATOR RAKOVAN: Thank you, sir.

Okay. I think we might as well go ahead and go to the questions. We could do this similar to the way we did the discussions this morning. For those of you at the table, if you just want to give me one of these (Indicating) or put your tent up, then I'll try to go to you. For those of you in the audience, the same kind of thing. If you give me a wave or if you want to approach the mike, I'll try to go to people in the order that I see them.

I thought that this morning went very well in terms of a back and forth and we had very good participation. So I'm hoping to keep that going.

As we have 1.1 up there or 1.21(a), can cobalt-60 be substituted for a radioactive cesium chlorine for any applications, (b) if so, what types of applications, and (c) if not, why not? And there are only three questions for this panel. So we'll see how much time we need to discuss each. So don't be shy.

MR. KAMINSKI: The answer is yes. It could be substituted. Whether it's better, it could be in certain situations such as if it's a large animal where a 660 KeV may not be penetrating enough to give a homogenous dose if you're radiating a monkey or something like that. But in those cases probably most academic facilities have LINACs that could be used on the weekends or potentially at night.

MR. McBRIDE: Yes. I mean, the answer is yes. You can use cobalt. Do we have the facilities in most academic places? Probably not. I think also there are issues. Certainly if you're doing a monkey, I think cobalt is fine. If you're doing mice, there are other kind of issues in terms of set-ups and things like build-up that you mentioned in terms of depth doses and so on.

One of the great things about cesium is that non-radiation physicists and biologists can use it without any problem at all. It's a very simple machine, a very reliable machine. Whenever you start moving into cobalt machine for doing the same kind of things, you need a lot more back-up. You need better dosimetry. You need just a different kind of set-up completely from what we have at the moment with cesium.

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

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

The point is that, and all I can speak

is for the University of California, San Francisco (UCSF) and I'm not on their space committee, but nevertheless the idea of putting in a much bigger room heavily shielded that would be required for cobalt would be very problematic. A) There's not space there and B) just the idea of renovating a whole room and getting a very heavy, big, shielded cobalt unit behind a barrier like that I think would be very problematic, not only economically but practically, and I think that has to be considered, at least, from the research perspective. I can't speak for blood irradiators. Maybe it's the same issue. I don't know.

MR. CONNELL: Can we hear from JL Shepherd? Mary, can you talk about whether there are cobalt-60 mouse irradiators existing and how feasible that is? I spent several years working with the manufacturers on all these different applications. So I just wanted to hear from them.

MS. SHEPHERD: Mary Shepherd, JL Shepherd and Associates. Not a lot of people using cobalt are using them for small animal research. It's mostly large animal research. When you go to large animal research, you need to have a shielded room like the teletherapy rooms. Most of those have disappeared from this country. So the cost for doing a completely shielded facility to do large animals is quite expensive.

Cobalt primarily is used now for biologicals, CDC research, all the real nasty biologics that are dose rate dependent. I'm not going to go any further than that.

The weight of a cobalt machine is not such that a replacement cobalt machine could not go into an animal facility that is not on the ground floor because buildings cannot take the weight. You're talking a replacement for like a Mark I that can go anywhere from 4,000 to 6,000 pounds. You're talking 14,000 pounds on a little bit larger footprint and therefore the entire animal facility would need to be relocated. Most of them are not on the ground floor for security reasons and for other like PETA and other issues like that. So the whole institution would have to change the whole facility plan or build a whole new secure facility just for the replacement.

MR. KAMINSKI: And again, this is my professional opinion that I would not switch from a cesium-137 source for small animals to a cobalt. I think that would be a mistake because again the cobalt-60 d-maxes at 0.5 centimeters. So certainly you wouldn't be getting a homogenous dose through the animal.

MS. MOSES: Paul Moses, Best Theratronics. Formerly, we used to be Atomic Energy of Canada and then we turned into MDS Nordion and very recently we became Best Theratronics. Going back to even Atomic Energy of Canada, we had access to probably more cobalt than anybody in the planet just based on our nuclear reactors.

We looked at both cobalt for research applications and, of course, for the blood community. It would have been very easy for us to use cobalt. It was easier for us to get and less expensive. But the thing is when you actually look where blood banks are located and we did that. Being in marketing, you sit and say where is it going to go, how is it going to get there, how much is it going to cost and you look the money associated with that.

So if you look at most blood banks, they're on a 3rd or 4th level. You have to go up in an elevator. So you go to the elevator and you say, "Okay. How much can this accommodate" and you very quickly realize that cobalt's not going to fit into the blood bank communities partly because they're huge. It has a half-life of 5.2 years. Cesium is 30.2. So you're looking at constant replacement.

There's a lot of issues like that, business issues, that are a concern when you start looking at cobalt to replace a cesium unit. But, once again, weight is a big concern as to where they would go and you can't get a cobalt unit up on a third or fourth floor when they weigh 6,000 or 7,000 pounds.

MR. MORGAN: Tom Morgan, University of Rochester. I just wanted to put an underlying exclamation point. Not all irradiators that are being used in research are self-shielded irradiators. A number of us have irradiators that are in shielded rooms because we need to be able to irradiate parts of animals. So if I had to change out the source to cobalt-60, that room isn't shielded for cobalt-60.

PARTICIPANT: I must say joke. All irradiators are not created equal. We all know that.

(Laughter.)

I had actually a scientist who came to me and he said, "I want to irradiate just the head of the mouse." So being an engineer and being a health physicist, I designed a real good shield around the body and left the head exposed to cesium-137. Can you do that with cobalt-60? Absolutely with the high energy that's cobalt-60 and I could accomplish that.

MR. SVAJGER: Just to add to I'm sorry. Mark Svayger of Fluke Biomedical. Just to add to the open air exposures and not a shielded device, 11 meters, 2,000 curies of cesium requires a meter of high density concrete walls and that's on the ground level. So if a hospital has three levels, you have your floor and your ceiling to account for. So that's an added expense.

Also to put it in perspective, it costs us $250,000 in 1999 to design this new facility and at that time it was going to cost us just $500,000 just to tear it down. That's just the concrete and the structures themselves. Thank you.

MR. POWELL: I am Brian Powell again. Constellation Energy. Looking at nuclear power and what I'm thinking about is the radiation protection aspects of the cesium versus the cobalt or an alternative source. And from my perspective or from our industry's perspective, we use cesium to calibrate our instruments for a reason because we have cesium being produced in the reactor. We need to have a way to see what kind of dose our workers are getting so we can give them good reports at the end of the year that this is how much exposure that you received.

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

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

MR. COPPELL: Yes, Dave Coppell here

from REVISS Services again. This may be a statement to the obvious I suppose, but the incentive for considering cobalt as an alternate to cesium chloride really goes back to the presentation that Len Connell made about the potential dispersability, solubility, clean-up costs and so on.

The question in the *Federal Register* specifically refers to a comparison between cobalt-60 and cesium chloride. I guess the question we ought to ask ourselves is how do you stack up the comparison between cobalt-60 as one option and a less dispersable form of cesium-137 as another option.

MR. McBRIDE: If nobody is going to answer that, I'll say the latter.

(Laughter.)

FACILITATOR RAKOVAN: Anyone? Please.

MR. CONNELL: I'll make a comment about that. That's a very good point and I've talked a little bit with John Schrader and David about the dispersability issue and whether if we were to start with pollucite form whether we could design it in such a way that it minimized certain dispersable effects. So one good thing about designing it from scratch is we could try to build some of those aspects into it.

But as was mentioned I think before, there really are two properties we're looking at here. One is the solubility issue which is what you really are solving when you go from the chloride to the pollucite or if you go to cobalt.

And the other one is dispersability and that's a much more difficult aspect because the question is what do you mean, like was discussed in the earlier session, by dispersability. How dispersable? What kind of a particle size are you trying to prevent? And we end up quickly getting into classified information. But that is something that we have to consider. And by going to pollucite, you really do solve mainly the solubility issue and a pollucite behaves in terms of an explosive dispersal similar to ceramics and that really doesn't completely solve our dispersal problem.

As we're looking through these different alternatives, again as I mentioned in the introduction, if we go to a radionuclide alternative to cesium we are reducing the risk because we're actually making it more difficult to disperse, but we're not eliminating the risk. The only way to eliminate the risk is to go to an non-radionuclide alternative like the x-ray machine. And being from my perspective, not being a user, but being a student of radiological terrorism, that would be my preferred option.

As we look through these things, I'd like to really understand much better where we could use x-ray machines, where we couldn't. If it's a cost issue, that's something the government can balance. Because the other thing we need to look at as we talk about cost is we need to look at the cost of maintaining cesium chloride in the U.S. and that's an additional cost for security as most users probably already realize.

But it also involves an increased cost to try to train the police department in trying to respond to a terrorist incident and it involves the cost of if a terrorist actually does acquire this source and disperses it. What is the cost of a terrorist incident using that material? And you have to weight that based on the probability of that and nobody really knows what the probability of that is.

But after 9/11 we got a lot of complaints that the government didn't connect the dots. So here's a case where we're really trying to connect the dots and look where the holes are in our security, where our gaps are, and trying to plug them and that's one of the reasons why we're trying to look at other options for cesium chloride.

MR. SULEIMAN: Orhan Suleiman from FDA. Limiting myself to the question, the feasibility of the use of isotopes other than cesium-137, you're obviously talking about other energies and if you're talking about calibration, cesium is ideal for some applications. It's absolutely terrible for others. So you limit yourself by taking cesium.

Are you talking about eliminating cesium from all commerce for all calibration applications just because of its chemical and mechanistic form? I think you would be doing the scientific community a disservice by taking this specific nuclide out of the picture completely. If you're talking about terrorism and being afraid of things, I deal with explaining risk to people every single day. And so at some point, when do you block yourself up in a corner with a wall and just not expose yourself to anything?

The NRC has a tough task here. There are societal benefits of cesium. There are scientific benefits of cesium with its unique energy. It's used as the nuclide for many, many calibration applications. But then again, in its current form, it also raises some risks. But I think in terms of the specific question, isotopes other than cesium-137, you're going to create a hole if you eliminate cesium-137.

MS. DANIELS: Sameera Daniels, Ramsey Decision Theoretics. This is addressed to Dr. Connell. I read through NA's, National Academy, report. What confused me a little bit, maybe it was because of the way it was presented, from, let's say, a period from 1999 to 2003, I think, or 2005, that was a time range where incidents occurred and I was wondering if you could just summarize the number and what kinds of incidents that you have been concerned about.

MR. CONNELL: Do you mean terrorists incidents?

MS. DANIELS: Yes.

MR. CONNELL: This is not a very good venue for discussing that, but what we've learned is that terrorists are getting more knowledge about these radionuclides and what's important. I mean you can go to the Jihadi websites and read about it and they've read the same things that you've all read in the papers that come out of *USA Today* and *The Washington Post* and NGO type reports that have discussed these things and so we are concerned.

Then we see incidents in London with doctors being terrorists and that kind of raises the flag again about what's the vulnerability at hospitals and universities for these things. These aren't places that typically have a real strong security culture. So that raises our concern about risk.

When we talk about calibration machines that are at nuclear power plants, again that's not the same kind of a risk factor.

FACILITATOR RAKOVAN: Ma'am, if you're going to speak, I'm going to have to ask you to use the microphone.

MR. CONNELL: I hope I answered your question, but there's not much more I can say about that. I'm not trying to scare people, but when we look and do these studies we look at all the different radionuclides out there and we try to find out where are the risks and that's what we did with the National Academy study and that's why we ended up with the bigger concern with cesium chloride because of the past experiences with accidents that involved cesium.

MR. MINNITI: I am Ronaldo Minniti from National Institute of Standards and Technology. Anyway, to answer that question, I guess I talk on behalf of all calibration facilities and I think most of the people will agree with me that for calibration purposes and when I say "calibration" I mean calibrating the radiation detector instrument, cesium cannot be replaced by cobalt because we rely on the energy. Energy of cesium is 662 keV and energy of cobalt is much higher. So the answer to that is no, it cannot be replaced and then it's B. If so, what type of applications of calibration of instruments. If not, why? I think I answered that.

I guess I had a comment for Len about the security. So I'm done with the question and this is the comment or question. If we would increase the security in the facilities that have cesium chloride, then as you say there would be a terrorist which would like to get a hold of cesium. Now if he has increase security, would he prefer to get something else, cobalt for example? I understand that because the cost to clean up cobalt would be much less, but still do you have still the psychological or social impact? Thank you.

MR. CONNELL: Well, that's a concern that you want to have a risk balanced across the spectrum. But again from my perspective, I'm looking at where the long pole is in the tent right now. Where are the high risk factors right now? What do we need to do in the near term to try to reduce that?

The stop gap was one of the things that was discussed earlier that Commissioner Lyons mentioned, this hardening program, where we're trying to go back in and retrofit these machines and we've done the Red teaming assessment. We know where we would attack them and so we're trying to cover up those zones that are vulnerable and make it more difficult for someone to gain access to the machine and that actually enhances the increased controls which it kind of fits together well with that in that we want time delay. We want time for the police departments to be able to get there and prevent that kind of a thing.

If that forces the terrorists to move to cobalt, well, we already have the increased controls with cobalt and, as I mentioned, cobalt, anything can be made dispersable, but it takes more skill.

It takes a larger team, more equipment, more money and more time and the time is of the essence. That's the critical factor here. If you steal it and then you have to use it, that takes time. That's why cobalt is less risk.

MS. MOSES: Just a quick one. In a comparison between cesium and a biological disaster, biological terrorism, how you would relate or what would be worse?

FACILITATOR RAKOVAN: I think we should just maybe move on from this. Remember we're here to talk about the feasibility of the isotopes other than cesium-137. I have one person I need to go to first.

Ms. Shepherd, please.

MS. SHEPHERD: Mary Shepherd, JL Shepherd and Associates. One area we haven't talked about is non-proliferation and tracking of plumes like Chernobyl-type power plant accidents. Cesium is your recognizable peak and the Cesium technology I don't think will be replaceable with cobalt or other methods. It's non-proliferation power plant accidents and we would lose a significant tool.

MR. KAMINSKI: Just one remark. Again, it's my professional opinion. I won't say that again, but I agree. I think we definitely need cesium-137, just alternative forms.

MR. MINNITI: One thing I forgot to mention, regarding replacements I think for calibration purposes again, in the case of a radiological incident, we count on emergency responders, police, firefighters, police personnel, walking into this incident with a calibrated detector. They rely on that to know that they're going to ensure safety for them and for the public.

So I guess my point is again cesium has been established as the workhorse for 40 years and if we would look for an alternative, it would have to be something that has similar energy. So maybe another form of cesium could be a possible solution. Cobalt as I said before no. I guess what I'm trying to say now imagine if we are not careful about the replacement. If we remove cesium away, I guess the impact for this particular case is you would have emergency responders walking into a radiological incident with non-calibrated instruments and we would be creating a new risk. So it would defeat the purpose of this whole ruling anyway.

MR. CONNELL: Ronnie, can I ask you a

question about calibration?

MR. MINNITI: Yes.

MR. CONNELL: Because we really didn't pay it as much attention in the National Academy study because again we only have 100 of these out there and they are usually much lower curie quantity.

But can you explain to me? Do we really need 100 of these outside in the commercial facilities? Can we draw them back in to maybe just a few labs and have smaller quantity? Do we really need 400 curies or more to do your calibrations?

MR. MINNITI: The reason high activities are used is again there are three manufacturers here that can correct me if I'm worry, but I think that most of the sources that are used for calibrating instruments go all the way up to most of them 400, 500 curies and there are a couple for the nuclear power plants that go up to 1200 curies.

The reason, you can ask why is it so high. These detectors are measuring a broad range of exposure rates. So this is why you need these high activities because you want to calibrate at the low end of the scale. But also you want to reach rates of 100 R per hour for example or in the case of the nuclear power plants, they put these teletectors very close to the source and they want to shoot over that range.

I think if someone would ask me personally if we can live with what activities we could live in the instrument calibration community, I would say that probably with 1200 curies and below would be fine. So that would limit the Category 2 range. Right? I don't know if that answers your question.

MR. CONNELL: I had one more hand and then I'm hoping to move onto the next question.

MR. SVAJGER: Mark Svajger with Fluke Biomedical. To answer your question, we calibrated in the range of up to 100 R per hour so that it will exceed your 400 curies statement. Plus we also calibrated in hour per second for, for example, nuclear power plants.

MR. CONNELL: Okay. So let me ask you. If I'm interested in doing a very high dose rate, could I use cobalt for that and just use cesium, cobalt and a lower energy nuclide to kind of give you the spectrum, the response function?

MR. SVAJGER: Once again, cobalt-60 is about 1.1-1.3 MeV and cesium is 0.6 MeV. So many of the detectors are also energy dependent. But certain things can be done with cobalt-60. But most everything we do is cesium-137. And to take an account most radiation measurement instruments, they have a wide range from low keVs in the 10s and 20s to upper 1.4 to 1.3. Thank you.

FACILITATOR RAKOVAN: Okay. One more comment from someone who promised he'd be brief.

(Laughter.)

MR. MINNITI: To answer your question, the detectors are TLDs. These are thermal-luminescent dosimeters and people use this, I don't know, probably most of the people are familiar, but for radiation protection and there are hundreds of thousands of those in the U.S., probably more than one million. I came up with this number just by talking to only a few of our people we interact with. That's basically the Navy, Air Force, Army and a couple other private sectors.

But anyway TLDs are -- The readers that are used for TLDs are calibrated with cesium and I just thought you were asking why and these are calibrated at doses of 5 gray. This is the highest dose. We're talking 100 Roentgen (R).

The reason why you used the high

activities which was your question is you want to irradiate these TLDs in a reasonable amount of time. I mean you could irradiate these doses per days, but you have to do this. These are large amounts.

FACILITATOR RAKOVAN: I'm sorry. I think we're going to have to move onto the next question.

1.2-2 and I think we've gone into this a little bit, but can the shielding challenges for cobalt-60 be addressed by switching from lead shields to more effective tungsten or depleted uranium shielding? And there was a note. Consider that tungsten shielding is more expensive than lead and manufacturing depleted uranium shielding is a very specialized, expensive operation that requires NRC or agreement state licensing for its entire life cycle.

Shielding discussion. No one in the mood to discuss shielding. All right. We have a couple people.

MR. MENNA: Blair Menna from Best Theratronics. I'll just take a quick stab at it. Tungsten is very expensive. The metals market recently has just been going crazy. The subject of home renovations came up earlier in the morning.

You know if you're been pulling wire in your house extension that it's gone up. Copper has gone up hugely. Tungsten, we've seen huge leaps in the price.

We are worried about the cost of redesigning an irradiator to accommodate a larger cesium source. Thinking out loud, I would suggest that it would be cheaper to redesign a lead unit to accommodate a larger non-dispersable season source than it would be to make one of the irradiators out of tungsten. The cost would be prohibitive.

MR. AKABANI: Depleted uranium by itself --

FACILITATOR RAKOVAN: I'm sorry. Could you identify yourself?

MR. AKABANI: I'm My name is Gamal Akabani. I used to work at Battelle Pacific Northwest and one of my main projects was depleted uranium and the depleted uranium by itself does carry out a confounding factor because of the fact that it produces lots of x-rays and therefore it will be something that has to be taken into consideration when you irradiate either animal experiments or things like that. I know it's very heavy, contains some of titanium. However, it's by itself, I would consider it to be probably not cost effective.

MS. SHEPHERD: Mary Shepherd, JL Shepherd and Associates. Tungsten is a very long lead time item now. If you go to a manufacturer trying to obtain it, it's sometimes six to nine months out for large quantities and depleted uranium besides the licensing problems has a bad reputation with a lot of countries around the world and at one point there was much more restriction towards its use as a lead alternative for shielding and so there would have to be some kind of regulatory interface to be able to use depleted uranium. But it is very expensive and it's also still a strategic material in the Unites States. It used to be up to a couple years ago.

FACILITATOR RAKOVAN: Anyone want to expand upon those comments or make a new point?

(No verbal comment.)

Okay. Let's go ahead and move onto the third question then, 1.2-3. What are the attendant risks associated with cobalt-60 source transportation? The note: Consider the shorter half-life of 5.27 years of cobalt-60 radiation sources. It would require that they would be replaced more frequently than cesium-137 which entails the transportation of both fresh and used sources. I think this was brought up someone previously, but transportation.

MS. SHEPHERD: Mary Shepherd, JL Shepherd and Associates. You exponentially increase your risk for a transportation accident with the more shipments you have on the road.

I don't think we have time to go into all the transportation issues now, but tomorrow 99.9 percent of all U.S. transport containers are no longer useable.

There are two basically nuclear waste containers, two models, that are certified in the U.S. market. Some of the international containers are in applicable for U.S. domestic use with the NRC, but that's not granted yet. We filed extensions for special permits and we have a new container in testing. That's a very long and expensive process.

So right now, as of tomorrow, there is very little domestic options for any kind of source transport for Type B quantity of radioactive materials.

MR. RING: Joe Ring, Harvard. If you

tried to replace the sources in transgenic facilities with ones that are shorter, you have a significant issue with changing the source out and bringing it in and out of the transgenic facility. It's very important that those facilities stay biologically clean for the purposes of the residents and that certainly is against what we need in the transgenic facility.

MR. JARDINE: I'm Les Jardine, Consultant. I just add to our memory here. This will add to the waste disposal problem for which there is no answer. Yes, it's five years half-life, but it generates a lot more waste all these operations for where there is no endpoint.

FACILITATOR RAKOVAN: Further discussion on transportation issues or for that matter any issues associated with feasibility and the use of isotopes other than cesium-137?

Charlie, I'll get to you in a second. I'm sorry. I had a hand back there first.

MR. WASIAK: I would like to go back for the moment to the comment that I think Len made regarding different forms of cesium that the pollucite or ceramic would only address part of the problem meaning the solubility, not necessarily the dispersability. Could you give us an idea or your opinion? If addressing both aspects would it fix 100 percent of our problems. Addressing the solubility problem only, how much of an improvement would that be if we only address that part with alternate forms of cesium?

MR. CONNELL: That's a real tough question to answer, Tom. Again, if you look at the Goiania incident, the solubility was a big factor in the way the material spread itself around and got bonded to surfaces. So I think it's a big improvement. How I would quantify that, I mean, that's just -- Because there are so many different -- I mean, what we really need to go through and maybe this will come up tomorrow when we talk about risk is we need to look at all the different pathways by which a terrorist can use this material and think through all those different paths and try to look at the relative probabilities of those and then see what the impact is of changing the dispersability.

It's a complicated process, but I would relate it to like a PRA-type analysis. You look at the different, you know, a thought tree and then try to assign probabilities and look at the different progression. But I think there's a way to do it. I don't know if you can come up with an exact number.

But I do believe that the solubility issue is a big issue and if we remove that it takes a big chunk out of the risk. It doesn't remove the fact that you have to go around and -- Now if you have an oxide that's not soluble and if you still have very, very tiny, you know, 100 micron particles of oxide, you have to go around and pick them up. But, at least, it's not chemically bonded to the concrete. So that makes it feasible to mechanically remove it. It still would be expensive, but it won't be impossible to clean up in a nondestructive way.

MR. WASIAK: I guess the reason for that question was primarily to kind of assess the viability of the alternate form of cesium. Because if it doesn't really help us that much, then it's really maybe not worth doing. But my expectation was that addressing the solubility problems significantly and dispersability to some extent would get us quite a significant part of the way there.

MR. CONNELL: I think it does a good job. I don't think the government has really sorted through the complete effect of that yet. I think that a lot more analysis needs to be done to look at the impact of having a material that's not soluble, but it's still dispersable.

MR. MILLER: Thanks, Lance. This is Charlie Miller from the NRC. Lance, I would like you to get a couple of things in the parking lot.

FACILITATOR RAKOVAN: Can you speak a little bit more into the mike.

MR. MILLER: As I listen to the discussion thus far, there's a number of things I would just like to throw out for consideration for the rest of the workshop. One is that we've had a lot of good discussion over the course of the day concerning cesium chloride, various forms of cesium chloride alternatives, some alternatives, cobalt so far or x-rays.

One of the things that the NRC has to ponder when formulating our decision makings is to where we go with this is how far do we go as a regulator. Okay. Nothing that we're going to do is going to give zero risk except complete elimination of radionuclides. I think that's recognized. So the question becomes what is an acceptable risk and that's something we should be thinking about as we go through and formulate our comments.

Some stakeholders here are coming at it from a security perspective. Like Lance, some are coming at it from the manufacturing perspective. Some are coming at it from a research perspective. Some are coming at it from a medical perspective. Some are coming at it from an industrial calibration perspective.

The other piece that I'd like to get a little bit better handle on, we've kind of talked around it some, so if anybody has any insights to this especially the manufacturers and distributors, is it's obvious from the discussion so far based upon the stakeholders' input that one size doesn't fit all. So therefore if we were to look for alternatives, what percentage, for example, of the cesium chloride would be eliminated if we went to alternatives for various utilization, in other words, for blood irradiators versus calibration versus research aspects of it so that if we do make decisions that are different for each how much are we really reducing the risk by the actions that we're taking?

And I guess finally I would just like to -- We don't live in a zero risk society. We're not going to get there as I said. So therefore if we are to promulgate, if we were to go forward and promulgate, some kind of ruling-making on this activity, part of our rule-making activity requires a regulatory analysis which has to factor in cost/benefit of the actions that were taken. It's important for us to have that information so that we make informed decisions as we go forward.

Those are some things that I would just like to put in the parking lot and hope that we can get better information on as the workshop goes on and is concluded or anyone who wants to issue written comments or supply comments to us after the workshop these are important considerations for us as we go forward and make recommendations to the Commission as the NRC staff.

Thank you.

MR. McBRIDE: Can I just ask you a question before you go away?

MR. MILLER: Absolutely.

MR. MENNA: You said getting rid of radionuclides. Are you talking only about the high level or what level or --

MR. MILLER: Yes, if you're going to talk about complete, if you were removing the risk completely of using cesium chloride or cobalt or any radionuclide, the only way you eliminate that risk completely is not to use it at all from a radionuclide perspective. So there's a recognition --

MR. MENNA: But get rid of low level radionuclides as well?

MR. MILLER: That's all it's going to take. Yes, any utilization of it at all in any form is going to give some form of risk. The question becomes what's that accepted level which I think is the point that we're trying to ponder.

MR. RYAN: Mike Ryan. I'm a member of the ACRS, Advisory Committee on Reactor Safeguards. Charlie, I couldn't applaud you more for bringing up the issue of risk. On the one hand, we've talked a lot today about how cobalt-60 can be used to replace cesium in an irradiator which kind of presumes the question we've decided cesium doesn't work. How about we ask the other question? What would it take to make a cesium irradiator have a risk profile that was acceptable by whatever metric you wanted to use?

Asking the alternate question is a way to analyze how do you make it better rather than what can we substitute and I think when you do that in a risk-informed way and think about all the risks, the risk of a terrorist, the risk of them getting to the material, the risk of them getting it and doing something bad with it and all those things which is the event side and then thinking carefully and systematically about protections that you have or don't have now or should have or might have, we can really kind of sort it out.

This last question on transportation to me comes in from left field. What does this have to do with irradiators? Transporting cobalt or cesium on its own merit has a risk and I'm sure you're concerned about Type B casks sort of going away. Three of my favorites expire tomorrow. So that's a whole different question.

But I would just urge that we focus on the risks. What are the risks we're trying to mitigate and how can we systematically mitigate them and then how do we ask the questions? Instead of presuming cesium has to go away, we can say if we really want to keep cesium, what does it take to give it the risk profile that would be acceptable from a risk-informed regulatory view?

MR. KAMINSKI: I haven't heard anybody

including the NRC or NAS advocating elimination of cesium-137, but I think at least according to the NAS report they do suggest eliminate of cesium-137 chloride, at least, category 1 and 2 and just one reason is just due to the solubility and that's a significant economic impact it would have on society if a terrorist event happened.

MR. RYAN: It is true it is soluble. I agree 100 percent. It is salt. But where is the evidence that says on a risk metric that that's the most important thing about cesium-137? If it's properly secured, properly confined, properly contained, by whatever mechanism you want to think up so that it prevents that action, that solubility may become less significant from a risk point of view and I think we're giving that up too quickly.

MR. KAMINSKI: I agree with you, but can we mitigate the risk and is it still economically viable?

MR. RYAN: That's exactly the question we're posing.

MR. KAMINSKI: That's our question.

MR. RYAN: Exactly the question. I think we need to systematically think that through before we throw it away.

MR. CONNELL: I thought Charlie brought up some points about the different modalities here. If you look at calibration machines and they're at nuclear power plants, you have one security risk. If you have cesium chloride at a university with graduate students that are foreign, you have another kind of risk. Hospital, blood banks, a different whole spectrum. So you look at each one differently and maybe you can come up with different solutions.

Maybe for the blood banks for those that are not using a very high through-put, an x-ray machine is a good option. For United Blood Services or the Red Cross where they have a lot of through-put, maybe you consolidate your cesium chloride there and you increase the security and really beef it up at those facilities. There are different ways of dealing with this problem in terms of risk reduction.

MS. SHEPHERD: Mary Shepherd, JL Shepherd and Associates. I think the risk associated with transport is probably when radionuclides are at their most vulnerable that's why it should be looked at significantly, much more so than in a secured facility and that's being addressed through other modalities. But I think it's a reason why that was brought up here.

And regarding the solubility and dispersability, ever since we've had above-ground testing we've had cesium all over the world and I don't think we've cleaned up everything we've done from our own above ground tests, much less everybody else's besides Bikini Atolls and different areas like that. It's there. It's part of the environment.

FACILITATOR RAKOVAN: Any further discussion on feasibility of the use of isotopes other than cesium-137? Mr. Suleiman.

MR. SULEIMAN: I think I want to sort of second the previous comments because if cesium-137 is so long-lived you just don't change it out very frequently. So it's transported less frequently. It's accessed less frequently. That has to figure into the risk probability paradigm somehow. So, in some ways, you could make an argument that cesium-137 is actually more secure because it doesn't have to be handled or it doesn't have to be changed out or replaced as often.

You really have to look at this thing from the total life cycle from manufacturing to eventual storage or elimination. If you phase them out, then you have to get rid of all these all over the country or you'll just let them decay away. So you just have to identify all the variables and assign some guesstimates into the risk.

MR. KAMINSKI: Just one comment. Having worked with a cesium irradiator a few years ago and, of course, measures have been implemented to increase security and so forth since then, it's not too difficult and if I wanted to I could have gotten a hold of it back then.

FACILITATOR RAKOVAN: Go ahead.

MR. COPPELL: Sorry. David Coppell from REVISS Services again. I guess I'm not sure what to contribute to this discussion from a manufacturer's perspective. We, of course, make both cobalt sources and cesium sources.

This is inevitably about balance and risk. Of course, it is and I guess everybody understands that. I hope we're not going to ban cars in order to reduce road accidents. What we're looking at is whether or not here there's an opportunity to fit air bags or whatever and I guess for me with one set of demands which is reduce the risks associated with how a terrorist might handle cesium-137, but another set of demands from users who say it's really not very easy to substitute cesium-137 with any other isotope. Then I guess that we are trying to plan a furrow of finding a way of manufacturing cesium sources that meet both sets of requirements and that's just what we hope to come back with in a few months.

MR. POWELL: Brian Powell, Constellation Energy. As far as I understand, the sources of concern already, Category 1 and 2 sources of concern, already, are required to have a transportation security plan. So I guess I'm asking the panel what is the difference between the -- Is there a new proposed transportation security plan for cobalt-60 that's different than the cesium-137 one or any of the other isotopes are concerned or are we already covered sufficiently by the existing plans that we've implemented?

MR. RING: Joe Ring, Harvard. I would like to respond to that in the general security. I think the real issue with cobalt-60 is that you have to replace it much more frequently. Therefore, it's on the road an awful lot more. Cobalt irradiators can last a comparatively short time as compared to cesium.

And I would like to make a comment about the security of the current irradiators. I've gone from a few thousand people having access to them to 400 people who now coordinate the access and I will tell you that those 400 people think it is extremely difficult to get access to an irradiator these days and when they go through the process and they have to have an escort by a security guard through multiple systems, it is difficult for them and it really has greatly impacted their research.

MR. KAMINSKI: Just to make one comment about cobalt and, of course, I think cesium needs to be used in certain cases for animal research also. But the specific activity tends to be higher with the cobalt source and you can load more also at the time. So at least according to an NAS report, they estimate replacement about every 15 years instead of every 30.

FACILITATOR RAKOVAN: Okay. Another one. Maybe we should just get you a lapel mike like the one I have.

(Laughter.)

MS. SHEPHERD: I'm sorry. In regard to shipment security, Mary Shepherd, Shepherd and Associates. In regard to shipment security, there was a *Federal Register* announcement that did not go into the safeguarded areas, but there will be more security for all kinds of aspects starting out with manufacture and distribution licensees that will probably filter down through the whole licensing community and I think it's -- I don't remember the number, but it came out in August.

FACILITATOR RAKOVAN: Any further discussion or should we go ahead and take a half hour break?

(No verbal response.)

Okay. We'll come back in a half an hour and start promptly a few minutes before 3:00 p.m. with Panel 2. Off the record.

(Whereupon, at 2:26 p.m., the above-entitled matter recessed and reconvened at 3:00 p.m. the same day.)

MR. RAKOVAN: Okay. Let's go ahead and get started again.

We're going to move on to Issue No. 2, which is use of alternative technologies. If we could really quick just go and have the new panel members at the table or we might as well go ahead and ask everybody who's at the table regardless of whether you're new or not to introduce yourselves, starting on the left there.

MR. FITZGERALD: Yes, I'm Bill Fitzgerald. I'm from the National Institute of Environmental Health Sciences. I'm the Radiation Safety Officer there.

MR. GORLI: Jed Gorli, Medical Director, Memorial Blood Center, speaking on behalf of the American Association of Blood Banks, or AABB.

MR. SVAJGER: I'm Mark Svajger, Radiation Safety Officer and calibration service manager for Fluke Biomedical, and I hope this is employed. It's really just nonactive here.

(Laughter.)

MR. SVAJGER: Yeah, we're hurting right now. Thanks.

MR. KIRK: Yes, I'm Randol Kirk from Rad Source Technologies.

MS. GILLEY: Good afternoon. My name is Debbie Gilley, and I'm with the Advisory Council for the Use of Medical Isotopes for the NRC.

MR. SULEIMAN: I'm Orhan Suleiman. I'm with the Food and Drug Administration's Center for Drug Evaluation and Research. I also wear a dual hat because I also participate with the Medical Use Advisory Committee for the NRC.

MR. WAGNER: Hi. Good afternoon. My

name is Steve Wagner. I'm with the American Red Cross. I'm a scientist at the Holland Laboratory.

MR. KAMINSKI: Joe Kaminski, NIH. Again, I only represent myself.

MR. McBRIDE: Bill McBride, again, representing Astro.

MR. RING: Joe Ring, Harvard, representing the summary of our faculty.

MR. NIXON: Grant Nixon, radiation physicist, representing Best Theratronics.

MR. RAKOVAN: Thank you all.

As usual, I think we might have a few statements to start the panel out with. So if anyone has a statement they'd like to make now. Okay. Start at the end there.

MR. FITZGERALD: Again, I'm Bill Fitzgerald. I'm the Radiation Safety Officer at the National Institute of Environmental Health Sciences, and I'm representing the researchers at the NIHS.

You can go on to the next slide.

The NIEHS is one of the 27 institutes and centers of the National Institute of Health. We also are home of the National Toxicology Program. We focus on environmental influences in the development and progression of human disease. We are located in Research Triangle Park, North Carolina.

Next slide.

We have a J.L. Shepherd Mark-431. This is kind of a model, or Mark-168(a). It has about 22,000 curies of cesium in it when it was purchased. It has been in service for more than 30 years. The dose rates we were able to achieve when we first purchased this were greater than 113 gray per minute, and we have more than 40 ongoing research projects.

There's been hundreds of research projects using this irradiator over the last 30 years, but ongoing right now we have about 40.

Next slide.

So I spoke to each of the researchers who used the irradiator and then tried to break down their uses of it into classification, and I have five classes here to let you know how to use it.

And then I also asked them for some alternatives. What would you do if you lost the use of the irradiator? What would you do as a means of getting your work done or your research done?

So I broke it up into these five classes: feeder cell, oxidation of proteins, loss of bone marrow viability, chromosome aberration, and DNA study and repair states.

The first one with the feeder cells, the doses range usually from about 30 to 80 gray. This research has been going on for about 30 years.

The alternatives to that is you can use X-ray. Some of the researchers said that this may be an issue and that there's such a spectrum with the X-rays, but they thought that they can overcome that by hardening up the beam a little bit.

You can also use chemical treatments. It is widely known that you can use chemical treatments to stop the production of these cells. The problem though is that when you're doing basic cell research, some of this is genotoxic and so it kind of nullifies what you're trying to accomplish, and so in some cases you may be able to use some chemicals, but in most of the cases where we're looking at basic research, you're not going to be able to.

But this is an alternative that they brought forward and said in some areas they would be able to do that.

The next slide, please.

The oxidation of proteins is something

that has come out recently. We've been doing this for about five years. The thing with this is that you're trying to form hydroxyl radicals and concentrations enough to oxidate the proteins, and these dose rates that you need are really large. They're around 23 gray per minute.

And, again, this research is only about five years ongoing. You need ranges from about 100 to 2,800 gray, which are just really long doses, but the researcher really kind of reached in and said, well, he might be able to use some laser flash photolysis to do this kind of work, but he said it may change the type of work they're doing, but if he lost the irradiator he may be able to do that.

Next slide, please.

The bone marrow viability, this is something, again, that has been going on for a long time. You're talking about doses five to ten gray. It has been going on for about ten years. Again, they thought you could use X-rays to take care of this. There are chemicals that you could also use, but again, here we go. When you're using a chemical, it is also toxic to other organs in the mouse or the animal that you're working with, and so that may be a problem.

So it may work for some research, but not for others.

Next slide.

And in the chromosome aberration, again, five to 40 gray here, about 30 years of research. Again, even before the radiator that we had on site that used X-rays for some of this work, most of what we're doing this in is lower forms of animals. So we're using flies, nematodes, and things like that.

The nematode people said that they thought they could use a UV cross-linker. There's some research that says that might work. It may not, depending on the thing, but that's mainly limited to the worm community. And, again, the chemicals is also limited to the worm community.

The next slide, please.

With regard to our DNA repair studies, this is what this research is about. We're looking at research that's specific to direct ionization of direct effects of low ionizing radiation. It deals with double strand breaks and resection of randomly broken DNA.

We use yeast to model that because yeast has about 500 fewer times less DNA than on a human cell. So we knew more about yeast a long time ago, but that means you have to have a higher dose to do that. So that's been ongoing.

The high dose rates are needed for a short time because the repair starts, and just a point about the animal studies. The animal strains that we use are specific. We make it specific to the radiation dose. We know what the outcome is. If we had to go to another form of radiation, we'd have to recharacterize that, and that would take many years of research.

And then finally, the last slide, please.

And it's basically our clinical points are that for some researchers we feel that there are alternatives to gamma radiation, but for most of the research we're looking at direct effects of ionization, and we don't think there is any alternatives to gamma radiation because that's what we're studying. So I just want to make that point.

Thank you.

MR. RAKOVAN: Thank you.

MR. GORLI: Next slide.

I'm speaking for the American Association of Blood Banks (AABB), and I just wanted to make some over arching comments at first.

AABB is not tied to any specific single technology. That said, the details do matter. We need to use irradiation to achieve a specific end. That end is to prevent transfusion associated graft versus host disease, which once it happens in a patient is generally fatal and not treatable.

Irradiation consistent with AABB standards has shown to be 100 percent effective in the prevention of this complication.

Next slide.

Leaving X-rays to the subsequent slides, cobalt is less desirable in that you've already heard about its increased shielding requirements. At least in half of our applications they're in hospitals where the blood bank is generally opposite the operating room, not the morgue.

Linear accelerators are generally not uniformly available around the clock.

I do want to make the point that pathogen inactivation has been shown in vitro to largely abrogate the need to irradiate product. So down the line when products are available, these DNA cross-linking reagents may be a viable alternative, and I don't think we're part of the worm community.

Next slide.

That said, since there was a request for quantitative data, we did do a survey of all our constituents. It was done with a pretty short lead time. So we did not have uniform response. We did get 345 responses from 195 centers. We very specifically called the list and did not call the ABC or the Red Cross centers because they were having their own direct surveys, which you will hear about from their representatives shortly.

Next slide.

The preponderance of centers do, in fact, use the cesium devices for the reasons you've heard, reliability throughput and economics. Some, and only a relatively small number, have X-ray irradiators, and this becomes relevant in the statistics.

Next.

Now, there was significant difference in the down time reported cesium versus the X-ray devices. For cesium, less than five percent had more than 30 days down time versus 21.4 percent. In fairness to the X-ray devices, that was a relatively small number of centers, however.

Next slide.

The economics, again, are not equal.

Although a cesium irradiator may be slightly more expensive up front, the maintenance costs have been estimated to be more than 300,000 over the lifetime of a cesium device, and this is from the National Academy report.

Next slide.

And hence, in recommendations, if you can see in the background, that is a balanced scale. So we want to balance both the risk and benefit as well as cost and benefit. If cesium irradiators are replaced, economic considerations should be not only the cost at time of disposal, but the availability of replacement devices and reimbursement of all additional costs.

Thank you.

MR. RAKOVAN: Okay. Anyone else on the panel have an opening statement or presentation?

I guess we'll just keep on moving this way.

MR. KIRK: Good afternoon. I am from Rad Source, and Rad Source makes a new type of X-ray emitter, which has very, very high dose rates, and the abilities to do things that have never been able to be done with a point X-ray source.

Next slide.

We have built a number of different configurations using this emitter. Probably the most successful one so far is the one up in the right-hand corner, the RS-2400. The IAEA has just completed a review of that unit and has begun the process of getting an article accepted for publication, and that should be out probably three or four months, and it talks about its application in SIT.

The one that we have labeled the RS-3400 there is actually a new type of blood irradiator which has just been submitted for the 510(k) review. I'm not going to say anything else about that right now other than that it's in process, and it is actually kind of a vertical version of the RS-2400. So hopefully one of these days you'll be seeing it around.

Next slide, please.

Based on all of those products, we can pretty much match any application. I don't think I mentioned. I forgot the highest dose rate unit there does ten kilogray per hour as far as output. So if you think about that, that's considerably more than you would expect from a conventional X-ray.

Reliability, the one thing that's

changed since we designed the first X-ray irradiator about ten years ago is that we now have an emitter that actually can be repaired. You don't have to throw it away if it goes bad. You can open it up. You're going to replace the filament. You can do whatever is necessary, pump it back down, and recycle it into the unit or another unit.

Thirdly, I think if you start considering the fact that you have to consider the disposal costs when you're thinking about irradiators and you think about having a tube that you don't have to replace, that cost becomes competitive.

That's it. Thank you.

MR. RAKOVAN: Ms. Gilley.

MS. GILLEY: On behalf of the Nuclear Regulatory Commission’s Advisory Committee on the Medical Use of Isotopes (ACMUI), Subcommittee on Cesium Chloride Alternatives, I would like to provide the following opening remarks and a little bit about our draft report that we'll be providing to NRC next month.

Cesium chloride irradiators are responsible for saving lives. The standard of care that exists in this country will be compromised if the use of cesium chloride is prohibited or eliminated.

The members of the subcommittee are Darrell Fischer, who is a patient advocate; myself, as a member of an agreement state; Ralph Lieto, who is a medical physicist; Orhan Suleiman, who is a representative from FDA and is sharing the table with me today; Dr. Bruce Tomadsen, who is a radiation medical physicist; Dick Vetter, who is a radiation safety officer at a large, major institution; and Dr. James Welch, who is a radiation oncologist.

The National Research Council's report made several assumptions that seemed questionable to the ACMUI. The subcommittee investigated these concerns and raised the following comments by the ACMUI.

Our concerns, first, are the need for cesium chloride irradiators. We're also interested in the liability of alternatives that are available out there, and we also would like to bring to the table and discuss the current security requirements that our licensees have had to go forth and do in order to maintain adequacy for their license.

The original report that approximated

ten percent of the blood that was used in the United States was irradiated. We've had discussions with the hematologists and oncologists who indicate that for their particular practices, the values range between 15 and 40 percent. These patients that are involved have depressed immune systems and need the irradiated blood.

The lower number probably comes from a higher fraction of trauma cases where irradiation is irrelevant.

For animal irradiation for research, research on stem cells and other systematic therapies increasingly requires whole body irradiation of the animals, usually mice, before infusion. This research is growing and may soon lead to treatments for current untreatable conditions.

Without irradiators available -- next slide -- hematology and oncology patients would suffer potential death for the lack of irradiated blood. Without irradiators available, much of the stem cell systemic drug research would not be able to proceed.

We looked at the alternatives for cesium chloride irradiators. These alternatives are conventional X-ray units and linear accelerators. Both have been and are used for blood, animal, and material irradiation.

Throughput is lower for the X-ray units that are currently available out there. With 48,000 blood product units, X-ray tubes, and 50 units per day operations would replace the tube every 3.7 years, adding to the cost of running the unit.

Issues with the X-ray unit for animal irradiation -- next slide. We're behind -- would include the different RBE compared with the Cesium-137, possibly of a factor of two for the lower energy units, and the dose rates can have an effect on the biological effectiveness as well as the anesthesia, more difficult.

Penetration may require irradiating the animals from several different directions.

MR. RAKOVAN: Can we make sure we've got the right slide for you up there? I think we're a little lost.

MS. GILLEY: Okay. Next slide. Next slide. There we go.

Medical linear accelerators are another option. I apologize. If the radiotherapy department's accelerator is used, time available for blood in animal irradiation becomes a problem. These linear accelerators are used for the treatment of cancer and are usually very busy. Many institutions run two shifts a day in order to accommodate patients.

And if it's not being used in the radio therapy department, accelerators because of their price tag become a problem at $1.5 million as the starting, getting in price for an accelerator.

Next we'd like to talk about security. Since the National Research Council's report raising the concerns about these units, several things have changed that are not a part of that report. One is the security of the users has been enhanced through the requirement of background checks and fingerprinting, and this is in response to orders issued by NRC, increased controls and security in orders or amendments by the agreement states.

The security of the facilities has been enhanced following the directives of the Nuclear Regulatory Commission. That means we've gone in and required the facility to make additional security capabilities to prevent access to these devices, and it has also been enhanced and should be enhanced through a hardening situation where we can actually go in and prevent the source from being removed from the irradiator.

Next slide, please.

Following these three security enhancements, the units present little hazard for unauthorized source removal or disruption. The lack of such security was a major factor for the production of the original national academy of science report.

In summary, we feel that irradiation facilities are essential for irradiation of blood and research. We believe that forced replacement of Cesium-137 base units would force many facilities to stop irradiation because of the large expense. Since most of the facilities are nonprofits and have few resources for funding new X-ray units and maintaining the units.

And if not leading to the termination of irradiation, the replacement would put a large financial burden on the facilities which use and have little funding.

Thank you.

MR. RAKOVAN: Okay. We might as well continue this way. Anyone else have statements that they'd like to start out with?

MR. KAMINSKI: I'd just make one statement just about the mechanisms of X-rays.

MR. RAKOVAN: Could you get a little closer to the microphone, please?

MR. KAMINSKI: The mechanisms of X-rays, low energy X-rays and higher energy, for example, photons or X-rays. I just jotted down some stuff as we were talking, but the mechanism of knocking out electrons is different between low and high photon energies, for example, photoelectric and Compton, respectively. But the damage is primarily done by double strand breaks, as you all know out there.

The reason why we see bone at low energies is due to the extra-celluosseous matrix, but indeed, there are dosimetric concerns at the osseous interface and depth dose issues with lower energies. But, again, I don't think in the majority of the cases these are relevant too much to animal research as they can be factored into the picture, and that's pretty much what I wanted to say.

But, again, I think cesium, getting back to it, cesium does have a good depth dose profile for small animals and I don't personally think we should advocate eliminating it. Just the form of cesium 137 should be changed.

MR. RAKOVAN: Any other panelists want to make initial statements?

MR. NIXON: Hi. This talk was prepared with my colleagues, Tom Wasiak and Paul Moses and Blair Menna.

Next slide, please.

So just to give a brief perspective from our view as a manufacturer, we are a manufacturer of both X-ray and cesium chloride irradiators. So we have dogs in both sides of the fight. We come out a winner no matter which way this works out.

(Laughter.)

MR. NIXON: So we like to consider ourselves more or less an independent broker, to give you the straight goods. I mean, we offer both technologies. We want to do what's best for our customers.

So are they already commercially available, X-ray units to substitute cesium chloride or cesium-137 and cobalt-60? Well, it depends on the application, of course, and it depends on what you mean by "substitution."

Currently, we have models available for low volume, low throughput, self-contained blood irradiators in X-ray form. We offer the Raycell, which is the 510(k) approved modality available to the U.S.

No, in terms of high volume, high throughput, self-contained blood irradiators, and in terms of a comparison with the gamma cell 3000 Model II.

And in terms of research irradiators used for stem cell research and so forth, as a manufacturer, we do not feel that existing units available in the marketplace today can supplant the use of cesium chloride or cesium-137 based self-contained irradiators on account of the voltages being too low at this time.

In the near future or in a few years' time perhaps we will have prototypes available. At this time, because of the low energy components, you get too much dose differentiation between tissue and bone, and as my colleague expressed, you get these interface effects that lead to overdosing, and these overdosing effects vary from one specimen to the next on account of the shielding issues associated with low energy photons.

Next slide, please.

Are X-ray units cost effective considering initial capital costs, et cetera? Well, if they weren't cost effective people wouldn't be buying them. So I would say, yes, they're cost effective, but as most people realize that are in the business, there are more costs associated with that modality by its very nature.

Life spans of typical X-ray units, at least from the history we have to date, is that they can be used or serviced and used over a period of five to ten years or as cesium units. We have cesium units that are 40 years old out in the field today that are still running.

There's more servicing of auxiliary components associated with X-ray technology. Calibration of the beam, very difficult from a dosimetry perspective. I worked in dosimetry for ten years, and most of the tubes out there use an X-ray, cabinet X-ray equipment are of the order of 150 kilovolts or around 60 kilovolts. Very challenging to properly characterize and to find consensus, and even the experts in the field are constantly revising their recommended protocols.

Next slide.

And is there any indication that performance of the alternatives will improve or worsen with respect to Cesium-137? I think technology usually advances forward. Things tend to improve.

On the other hand, there will always be an inherent limitation because of the extra complexity. Like any process, you want to make it more lean. You want to have fewer components that can go wrong in order for it to be more reliable.

In the case of X-ray generation, more things can go wrong and will, and there's no getting around that.

Tubes have been manufactured for over 100 years, and almost the same could be said for high voltage power supplies. There's only so much that can be done.

Next slide, please.

And in terms of alternative technologies, what time frame? What's the time frame future availability of each alternative? And what's the cost, capital cost, operational cost, end user costs?

Very, very early in the history of the use of these kind of technologies, way too early to tell what the overall cost will be; very difficult to estimate. A lot depends on developments that are going to occur in the near future.

I'll leave it at that. Thank you.

MR. RAKOVAN: Thank you.

Please.

MR. McBRIDE: I'd just like to add a little bit to that. I mean, I think the cost depends to a certain extent on the applications. Astro did a breakdown of the costs of X-rays compared with cesium units for research applications, and they reckoned that it's probably going to cost about five times as much to run an X-ray machine as the cesium source.

A lot of this actually goes into physics time. The actual calibrations, the maintaining the machine, and just, you know, getting goods at a homogeneity of fields and other issues which are really important if you're doing, for example, you know, small animal work, which is tough, I think, for X-rays anyway, but it does depend to a certain extent I would say upon the application. You certainly are looking at a higher cost, also bigger supporting.

MR. SULEIMAN: I want to just add a few points that needed to be emphasized. Radiation is the only prophylactic treatment for graft versus host disease. There aren't any alternative methodologies. I've been assured by some of my colleagues, actually Dr. Phillips of the Center for Device and Rad Health, who will be on one of the panels tomorrow, that basically in terms of FDA clearance, hardening of these irradiators shouldn't impact on us in any way, shape or form in terms of getting them cleared.

So this has come up in other types of discussions where people have accused FDA is going to -- this is going to cause significant slow-down of the process, but this should be transparent to us.

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

And the fear was that any explosion would basically cause contamination, and I unsuccessfully argued that, by gosh, if there was going to be an explosion, I'd just as soon have it in a nice, shielded room than elsewhere.

But it was obvious I was clearly outnumbered. In a democracy you know when to sort of back off, but that phobia -- and I would be very concerned professionally and individually to basically make some decisions without having all of the scientific risk and all of the advantages and disadvantages of all of these technologies on the table.

And there are clearly alternative technologies, but the economic issues and questions haven't been answered, at least to satisfy me, but I suspect it hasn't answered a lot of other people either.

MR. RAKOVAN: Okay. Real quick, before we continue, I just wanted to go ahead and read kind of the intro to these questions that was in the Federal Register notice.

An alternative technology is defined in

the context of this document as a technological process that provides the same societal benefits as the devices that utilize cesium chloride at the present time, but without the use of radionuclides. Some of the potentially feasible alternative technologies include such processes as X-ray irradiators or electron beam irradiators.

Previous reports, such as those prepared by the Radiation Source Protection and Security Task Force and the NAS referenced above addressed the issue of alternative technologies to a limited extent. A more extensive examination of the feasibility of these and other alternative technologies is needed.

Therefore, in considering Issue No. 2, use of alternative technologies, there are four main issues that should be considered and discussed.

The first one we have up here, Question 2-1, are X-ray generators already commercially available as substitutes for applications that do not require the gamma rays with Cesium-137 and Cobalt-60?

MR. KAMINSKI: I can answer at least for the Cobalt-60. The answer is yes. I mean, we do it clinically every day. For Cesium-137, again, for small animals that energy is ideal, but X-rays, I think, in many cases would be satisfactory.

MR. RAKOVAN: Further discussion?

MR. WAGNER: Thank you.

The American Red Cross uses Cesium-137 irradiators. We have 32 units in the field. We also have seven X-ray devices. There are seven Raycells and one RS-3000. We have 32 regional blood centers.

The X-ray devices are 510(k) cleared, and so they're available for use for irradiating blood. So we use both devices.

MR. RING: Joe Ring, Harvard.

One of our faculty members in a foreign laboratory that he runs, he has been able to use X-ray machines to inactivate mitosis in cells. However, he's found them problematic in that he has to actually have two instruments so that he can do his work, which basically doubles the cost.

MR. RAKOVAN: I had a gentleman who was standing at the second mic. If you could introduce yourself, please.

MR. MORGAN: Tom Morgan, University of Rochester.

We're a Level 1 trauma facility for

seven counties in central-western New York. We choose to irradiate all blood products. That's 28 to 30,000 units a year.

So my question for the manufacturers are: how many of your irradiators would I have to purchase to meet that 28 to 30,000 units a year, assuming a rate of 75 to 90 units a day, you know, 365 days a year?

MR. RAKOVAN: Somebody want to take a stab at that one?

Please.

MR. WAGNER: I'm not a manufacturer, but I know that the irradiation time for one of the X-ray devices is about five or six minutes, and you can fit basically three blood bags in at a time. So I'm a little bit slow at math, but I guess you can go through it yourself and sort out how many you would need for your facility.

MR. KIRK: I'm not going to comment on a 510(k), but the device that we use to develop the unit would probably do somewhere around five, 500 mL bags of blood in the three minute range. I don't know exactly what that calculates out to, and I'm not sure that's what the submission says, but I know from the IAEA work that's about where it would be.

MR. GERSABECK: My name is Edward Gersabeck. I represent the Department of Agriculture.

I think we take the lead in small animals because our insecteries produce anywhere from 1.5 to two billion sterile small animals per week for release both in the United States and overseas. We actually own all three technologies. We have several cobalt based irradiators. We have several Husman cesium based irradiators. We actually own some of the X-ray technology, and I know you've asked for non-anecdotal type of information. So let me give you our perspective.

Over the last three years, we've invested over $1.6 million in three X-ray machines, and we have found them so unreliable that we this year purchased for three-quarters of a million dollars a cobalt machine for in insectery in Panama and just over a million dollar machine for our Moscamed facility in Guatemala.

Our position is at least for insectery type uses, that we're probably at least two years away for the technology to actually be usable or to be recommended, but for our department we have chosen not to pursue X-ray technology in our facilities overseas.

One thing we became aware of is as these machines age and go off warranty, we'll have to establish our own engineering staff to rewire or replace the filaments in the machine, which means have to establish a workshop. We have to train personnel.

So besides the increased electrical costs in operating these machines, there's ongoing additional labor and training to keep these machines in operation.

Thank you.

MR. NIXON: If I could interject to the discussion, can we speak to the specifics as to what technologies are available for what applications today?

MR. RAKOVAN: Anyone want to step in and address? Please.

MR. SVAJGER: Maybe someone in the NRC staff can tell me this, but there's got to be a heck of a lot more licensees than just blood irradiators, and this morning I heard 1,100 facilities using blood irradiators. So there has got to be tenfold, 100-fold more licensees than just that.

So what I'm saying is let's not just

focus totally on blood irradiated entirely. There's a huge percentage of cesium chloride as well.

With that I'll sign off.

MR. McBRIDE: Well, I guess I have a non-blood irradiator. I'm a cell irradiator and an animal irradiator.

You know, I think that we are kind of trying again to put everything into one kind of bucket here, and I agree with you, you know, that really there are different irradiators for different purposes, and as a radiation biologist who kind of spends my life, and, you know, irradiating and looking at cellular, molecular and whole animal processes, you know, it's important to have that availability of resources.

So I use cobalt. I use X-rays, and I use cesium sources, and I use them under different circumstances for different purposes, you know. And to break that down, I's probably need an hour lecture to actually explain the complexities of doing all of these different types of studies.

If you're looking at the rapid molecular assays for radiation end use responses or DNA damage, that's a very different thing from looking at the response of gut or brain in a mouse or a rat.

So you really need the flexibility, but whenever it comes down to it, you know, the cesium sources are the work horses for all of this.

This is the kind of big base. They can be used by people who have no knowledge of radiation and no knowledge of physics. They can just walk in and irradiate their cells, their feeder layers or whatever, walk out again and, you know, it is very easy, very low cost, really no backup almost. I mean, it really is a very cheap process.

Going to X-rays, you've heard about the lack of reliability. They are a lot more costly, and the lost of cost, as I say, goes into physics to actually get good dosimetry whenever you're trying to do, in particular, animal radiations is tough, in particular if you're doing small bits of animals, you know, rather than your whole body irradiation.

I think the availability of X-rays and cobalt is a big problem. You know, we've got five cesium sources at UCLA. We have got one X-ray source which isn't working. We've got two cobalt sources, one of which we use for big animals, but you know, we would have to replace all of those cesium sources with X-ray machines, which as we said are not really all reliable whenever it gets down to it.

And also are not user friendly for the people that just want to walk in, irradiate some cells, and walk out again. It's more complex than that whenever it comes to the considerations of using X-rays.

So I think that, you know, it's really a big mistake to kind of limit the sources in any way at all. We really need to kind of maintain all of these sources really for different purposes, you know, and certainly there are some of these purposes that people will use cesium because it's available and it's easy and they could use another source, but there are other purposes where we can't do that. Cesium is essential.

There are other purposes where X-rays are better. You know, that's the way it goes. It just depends on what you want to use the radiation for. So we can't lump all of these together.

MR. KAMINSKI: I just want to say I agree. We definitely need Cesium-137. Again, we need to seek out alternative forms. I think it's important.

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

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

I am a physicist, and I do do numbers fairly well. The gentleman behind me from Rochester suggested that he needed to do 30,000 units of blood a year. Thirty-six thousand five hundred would be 100 units a day. So let's take that number.

One of the source manufacturers said he could do five bags in three minutes. He needs to do 20 times that to keep up with a day. Twenty times three minutes is an hour. Let's take another hour for in and out time. That means that basically between two and three hours of duty a day on the X-ray machine is perfectly adequate. I seriously doubt that you'll have to buy more than one blood irradiator to handle that load.

I was very disappointed with the attitude that I heard on a couple of people's part, but mostly of the Advisory Committee on Medical Uses. Nobody is actually talking necessarily about taking away your cesium gamma spectrum. We're talking about taking away cesium chloride, and let me point out that the only nuclear or -- pardon me -- radiological terrorist scenarios you can dream up that kill a lot of people use and exploit cesium chloride.

I'm not at liberty to discuss what those are, but they're pretty bad.

You've talked about security. Well, security is not just in the fingerprinting or even in the locks and keys. It's in an ongoing security check that prevents good employees from going bad. I could mention the name of Aldrich Ames and Hansen, just to name a couple of good employees who went real bad.

So to say that you've implemented the security measures is not to say that those security measures can ever be considered adequate unless you have really intrusive, ongoing personnel monitoring.

I think we are going to have to face the fact that cesium chloride in a water soluble form is going to have to come out of circulation.

Now, I'll make two points about reliability. First is as far as skills needed, every dental technician can run an X-ray machine. It's not that hard to build an X-ray machine that's got a switch on it, on and off. It really isn't.

When I was a grad student, a post doc, and a professor doing high energy and nuclear physics, many accelerators were considered the most unreliable instruments ever built by the hand of man. They are now one switch on, one switch off, operated by a technician in medical treatment centers.

Yes, they do break down, and yes, they have to be repaired, but that's true of almost everything.

Thank you very much.

MR. KAMINSKI: I just want to echo your thoughts. I agree with everything you've said concerning alternative forms of cesium-137. We have to look at those, and I think it's critical to remove cesium chloride from common use.

MR. SULEIMAN: Yes, I always have trouble interpreting questions, but I'm looking at 2.1, and if it's a question of 662 keV photons, I don't see X-ray or anything else replacing it. So for some types of application, scientific radiation biology, whatever, I don't think there would be if you were to eliminate it completely.

And I also think the issue is going to translate less into what's the alternative for cesium as to what's the alternative for the chemical, you know, physical form of how the cesium is. I mean, that's my sense of where we're going.

MR. POWELL: Brian Powell, Constellation Energy representing nuclear power again.

As far as the question, I'd like to answer it from our perspective in a broader sense. When we were faced with the regulations that asked us to take a security of our radioisotopes, we took that very seriously, and it would be a real challenge for someone to get into any of our plants to try to get a hold of something that they shouldn't.

We have the full background and the fingerprints and the ongoing security investigations that were mentioned before, and we're at the point now where we're looking at alternatives not just to things that are up for discussion today, the cesium, but you know, some of the other isotopes of concern that were used, for example, the ones that we need for the radiography.

We're looking at replacing the iridium, cobalt, selenium with the pulsed X-rays for the smaller diameter piping. So it seems like, you know, we could increase the security measures to a level where we could be patient until these alternatives to the cesium chloride were available, then I think we would be happy to replace them as they became available, but they're not available.

We're doing what we can in the meantime, and we're taking a bigger and broader look at eliminating all of our sources of concern if we can.

Thank you.

MR. RAKOVAN: All right. The gentleman right next to the -- please.

MR. THOMAS: I'm Jerry Thomas, Wichita, Kansas.

Focusing specifically on X-ray generators and nothing else, when we look at the quality assurance required as well as the calibration that's been pointed out by others, my focus is specifically on the hospital and the blood bank arena. I ask the question: do we have the qualified and trained and skilled individuals?

Yes, I recognize you can turn them on and off, but the comment on the linear accelerator is there's a substantial quality assurance program associated with an accelerator before you turn it on with a patient every day.

That same type of program would have to be in place for any use of X-ray sources, I would think, in the irradiation of blood products. Consequently, not only do we need to think about this as an alternative, but do we have the resources available across the country in the heartland of the country and the west of the country where we don't have necessarily the level of expertise that is sitting in this room or in our universities?

And I recognize that industry has made this pretty much turnkey in their current products, but again, there is a quality assurance issue that I think needs to be looked at very critically before one jumps into the X-ray source as the only source.

MR. FITZGERALD: Just to go back to the question that's up there, are there alternatives where you don't need cesium or cobalt gammas? I mean, I think our researchers at NIHS said yes, there are applications where that's true, but for the most part, the majority of our research does require the cesium-667 or whatever keV. That's what they want and that's what they need.

So we do have people who would be willing to use an X-ray source if we had it for some mechanisms to do some of the work, but the majority of our work requires the cesium irradiator.

MR. GORLI: Jed Gorli, AABB.

I'd just like to point out that lean and disaster preparedness are inimicable. While we try to have as efficient systems as possible, and I cannot gainsay the elegant mathematics of our recent presenter, we do not function as a constant steady state manufacturer, but rather we need to be prepared for the bus accident and generating a lot of stuff fast.

So in certain cases, but no means all, there may be reasons either for reliability or throughput that one might need additional X-ray devices. This is not a matter of feasibility. This is, however, a matter of economics.

MR. NIXON: I just want to speak a bit to some of the points or opinions raised by Peter Zimmerman.

In terms of manufacturing X-ray equipment, one has to understand that although X-ray technology is not new, it has been around for 100 years, the application used when you do blood irradiation, it's different from the history of development of the X-ray tube the way it was used in the past. The new operational modality involves irradiating cycling in periods, say, five minutes at a time, first as a continuous operation, say, in an X-ray scanner instead of an airport or the odd explosions out of a hospital. That's brief.

So speaking to that point, when you change the application and how a device is used or how a technology is used, very often you find yourself facing many problems.

And I want to speak to another aspect, too. With regards to cesium chloride having to be banned because it's bad, bad, bad, until there's a viable alternative form of cesium-137 available on the marketplace, I mean, the best one should expect from reasonably thinking, reasonably calculating people in terms of risk analysis, in terms of cost and so forth is that you mitigate as much as you can until something is available.

Now, the nuclear industry is the most heavily regulated industry in the world. When you compare that with the proliferation of X-ray technology, for instance, you have to consider that there will be terrorism uses of X-ray technology as well. I mean, one can envision a portable generator being put into a truck or on a float and driven through crowds, maybe this happening 100 cities at a time. You know, how are you going to stop that?

So where is the regulation being applied to, say, that alternate form of technology?

So you have to think outside the box

sometimes and, you know, do the best you can, put your money and your resources to attacking the biggest problems.

MR. ZIMMERMAN: I am certainly aware that the blood irradiation problem is different from the tooth irradiation problem. Nevertheless, we are talking engineering in what is, indeed, a mature science with mature technology. It is not something you will have tomorrow, but if the decision is made to do the replacements, you'll have it on the market in a small number of years, easily totable, easily tabulatable on the fingers of one hand.

Now, as to your questions about thinking outside the box, believe me, those of us who have done for the last five years a lot of worrying about radiological terrorism, we are aware that you could take an X-ray machine and put it on a float, but we would question the ability of you to get a power supply to make it reliable and so on. We would suggest that right this minute cesium chloride powder looks a higher hazard that portable X-ray machines in the hundreds of kilovolt range with very large beam currents.

We would say spend the money right now to begin exploring alternative forms of cesium.

Yes, I know you want to preserve the spectrum of the photons from cesium because if you do not, you have to do a lot of research to calibrate a spectrum of let's just say 500 kilovolts against 680 kilovolts, and you don't want to do that if you can avoid it.

I'm a physicist. I understand that, but I also understand the other risks that we run with cesium chloride as the source of the cesium photon.

MR. KAMINSKI: And I think the greatest risk is probably damage to the infrastructure and not so much to people. I mean, of course, you'll have long-term effects, but acute effect in radiation dispersal device would be minimal. It's just billions of dollars to clean up if someone decides to release it in New York or any other large city.

I mean, you're talking a major economic disaster. You think what we're going through now is bad.

MR. RAKOVAN: I had a couple of hands I wanted to get to. I think you had yours up.

MR. LIU: I'm Bill Liu with University of California, RSO.

A question for the American Red Cross. In the case of your machine irradiation of blood products, in the places where there's a single machine and that machine is not working and perhaps it takes a week to bring back into service, how is that problem remedied?

MR. WAGNER: We have several sites that only have X-ray devices and no gamma irradiators. In the Red Cross we have the ability though to ship blood pretty efficiently. Otherwise we wouldn't have regional centers.

I guess now is as good a time as any to talk about breakdown just for a moment. Among our 32 cesium-137 chloride irradiators, there have been 51 instances of breakdowns during the last three years. For the X-ray devices, there have been 21 occurrences of breakdowns of the Raycells in the last three years.

Of course, we have fewer devices, and when you do it per device and figure out the breakdown rate, there's about a 66 percent increase in the breakdown rate when comparing the Raycell devices to the cesium devices.

For the most part, in 66 percent of the breakdowns the device could be repaired within one day, usually by on-site staff or a local contractor. However, two repairs took 26 and 37 days to complete and probably involved off-site, non-local service. The average time for repairs that were greater than one day was 15.5 days, plus or minus 12.2 days, and this compares to 37 percent of breakdowns that could be repaired in one day for the gamma irradiators.

And in addition, those irradiators took more than one day to repair, averaged 15.4 days plus or minus 12.3 days for the gamma irradiators, again, indicating probably that off-site service was necessary, and of course, this makes sense because as we know, the gamma irradiators are a regulated device with safety concerns and require specialized staff many times to fly in sometimes from other countries to repair the device.

MR. RAKOVAN: I have two hands in the back of the room that I wanted to go to.

MR. WASIAK: Tom Wasiak from Best Theratronics.

I have a couple of comments regarding the information provided by the gentleman who put an amount on the back of the napkin or maybe in his head and compared the, let's say, blood irradiators to the X-ray equipment. I think part of that was the dental X-ray equipment, let's say.

As we kept hearing from many people around here, the current state of technology is such that X-ray equipment for blood irradiation, for example, which is the main application, most units being used right now, is not quite there as where cesium is. It may not be there for a long period of time. It will be improving. No doubt about it, but in comparison with dental X-ray, I think we'll get there, but there is significant differences in technology, although it's all the same X-ray. The major differences are just listed, a couple of numbers.

Dental X-ray equipment uses in terms of power probably a couple hundred watts. Blood irradiators use about, you know, 6.4 kilowatts, right? In terms of high voltage, dental equipment uses 30 kilovolts, let's say, or low energy. We are using 160 kilovolts.

In terms of irradiation time, they are only on, actually tubes, for a split of a second for dental X-ray. For blood irradiation, they run continuously for five, six minutes.

Yes, it's still the same technology. However, technological differences are big enough to cause certain technological troubles. That's unfortunately the current state of technology. It will improve. It will take time.

Another little point, I just wanted to clarify the numbers. I think the gentleman referring to the numbers mentioned that there is an X-ray irradiator that can irradiator five bags at the same time with irradiation time, two minutes. Unless I misheard it, I'm not aware of that X-ray irradiator, though I'm aware of cesium blood irradiator that can meet these numbers.

The only blood irradiator that is currently on the market irradiates two to three bags at the time, and it takes five to six minutes. So if you do that math, including 50 percent for loading or additional 100 percent of time for loading/unloading, irradiating 100 bags a day would take ten hours of continuous operation with breaks for loading, unloading and so on.

So just a point for clarification.

MR. MOSES: Paul Moses, Best Theratronics.

In speaking to the Red Cross, I'm very familiar with the Red Cross account, and we would have probably the largest number of units within the Red Cross family of sites.

When you speak and talk about breakdowns and different numbers, I think you have to take into consideration that some of the Red Cross units have been out there for 25, almost 30 years. So when a unit is that old, what will happen -- and it has happened. I could name specific sites -- but they have actually broken down. We've had to fly down, fix them, and this is like a unit 25 years old, mention to them, you know, this unit paid for itself 22 years ago.

(Laughter.)

MR. MOSES: And it might be a good idea that you just bought a new one.

And the thing is that when you start looking at the numbers, you have to be mindful of when you're talking of an X-ray unit that's only been out there for a short time versus a cesium unit that's been out there forever.

MR. WAGNER: Paul, I agree with you totally. Just for information, of the 32 irradiator devices that we have, I know the age of 27 of them, and the average age is 15 years basically, plus or minus five years. So if you want to make a donation to the Red Cross, we can --

(Laughter.)

MR. WAGNER: -- purchase some units.

Also, what Paul did not bring up, but which I think is important, is that no one really knows what the lifetime of these X-ray irradiators are. You know, the manufacturer, we've heard ten years, but there's no data out there that says how long they will last, and until they last 30 years they're not equivalent at least in terms of lifetime presumably as the irradiators.

And so it's possible you would have to go and replace them possibly more frequently. I don't know because there's no data out there.

MR. SULEIMAN: I've got to add balance back to this discussion. Those of you who understand X-ray technology, some of the high output computed tomography X-ray tubes, the reproducibility and accuracy of modern medical imaging technology and output, the technology is clearly here and has been here for many, many years. So to imply that the technology is not capable to put reproducible output over a period of time is, in my opinion, just wrong.

However, maintenance and quality control, if you neglect a high quality car, it's not going to last as long as a less expensive car that's maintained on a regular basis. So the issue with electronic products more so than the radioactive sources is to require long-term maintenance and calibration and so on.

But to imply that the technology is not up to the task is wrong. It's the human factor, the maintenance, the calibration. So there's little doubt in my mind. Energy aside, unless you can come up with an X-ray source that can generate a 662 keV photon, that for scientific applications the non-radioactive technology is clearly, you know, capable. And, again, I'm not addressing economics. I'm not addressing the market for this sort of product. You sell a lot more CT scanners than you do blood irradiators.

MS. GILLEY: Debbie Gilley.

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

MR. KIRK: Randol Kirk from Rad Source.

Look. With an X-ray machine, you have to treat the tube as a consumable. It is. There's no getting around it. It's no different than the light bulb in your house. If you leave it on 24 hours a day, it's only going to last half as long as if you only run it at night.

So anybody who doesn't think about that, who doesn't, quite frankly, manage up front or preemptively look at tubes, power supplies, that sort of thing, to have them switched when they need to be is always going to have down time. It has got to be a joint effort in order to make sure that you are ahead of the curve with an X-ray machine because it's always going downhill.

MR. RAKOVAN: I think we've already kind of gone into the next question already. Michelle, if you want to bring it up, Q 2-2. Are X-ray tubes cost effective considering the initial cost, operating costs, and requirements for more maintenance, for periodic calibration and replacement than radioactive sources?

I figure since we were talking about it, we might as well have it up there. Anybody want to continue on that particular question topic?

MR. KIRK: Randol Kirk again.

Actually we think we have hit on a relatively good solution. It's a matter of having the availability of being able to open up the tube, repair it, close it up again and reuse it. Again, this is a brand new concept.

The best we've been able to do so far is somewhere less than 1,000 hours of use. We think we can get considerably higher than that, but even at 1,000 hours, if you think about the calculations that were just done here a little while ago, two hours a day or whatever they were, 1,000 hours is a year and a half before you have to do anything to the tube, and that's a huge, huge operation to irradiate that type of blood. I would guess only the Red Cross would come close to those kinds of numbers.

MR. RAKOVAN: I'm hearing some disagreement from the crowd. If somebody wants to take that to the microphone and explain it.

MR. GERSABECK: Yeah, this is Ed Gersabeck with USDA again.

We're operating our irradiators, our two gamma cells and two Husmans in Guatemala 22 hours a day, seven days a week, and even with the guarantee of 2,000 hours on the rad source tubes, the best we've been able to get is about 700 hours, and even if you got 2,000, that would only be 80 days or less than three months. So we'd be into this continuous rebuilding the tubes.

And we've been quoted a price of if you didn't have your machine shop capabilities, if you just go out on the street and buy a new tube, the last price we were quoted was $50,000 which got us interested in starting to set up our own machine shop and training our own engineers to actually replace these tubes.

So there is a lot of hidden cost and, as I say, in a continuous operation, I'll give you an example. If we're irradiating 300 million flies per day, which is basically what USDA is doing, at a cost of $1,500 to $2,500 per million, to have a machine go down, we are losing a horrendous amount of money per day until we get that machine back up.

Our down time on the Husman irradiators, even the gamma cells has never been more than one shift, six to eight hours, and a lot of that is just going into town and getting a new motor for the mechanics of it.

So in our industry, in our protection of agriculture where we're sterilizing insects, the reliability has to be there. You know, every day, seven days a week we can't shut down or we just start losing a lot of -- because you can't shelve living animals. You can't just put them on a shelf for a week until you get a part in. I mean that's the reality of what we're doing.

Thank you.

MR. KIRK: I would like to remain professional about this, but --

MR. RAKOVAN: Please do.

(Laughter.)

MR. KIRK: -- I really feel that some of the circumstances represented there are not accurate, and I'll just leave it at that.

MR. RAKOVAN: Any further discussion on this question? Yes, please.

And thanks to you three guys on the end there for all sharing the mic. I appreciate that.

MR. SVAJGER: Regardless of the use of X-ray tube or you need to replace a tube or reload a cobalt safety source, they're both pretty expensive as opposed to cesium which goes on and on and on.

MS. SHEPHERD: Mary Shepherd, JL, Shepherd & Associates.

Red Cross is not the only 24-7 user of blood irradiators. Every major metropolitan hospital with an oncology department, and if you're a large metropolitan area, multiple hospitals operate in this modality. I think UCSF is one of them, and there are many, many centers across the country that especially if they're doing oncology.

Neonatal work, UCLA does not outsource blood irradiation. Their protocol is in house only, and I think there's a lot of other places that are like that. It's imperative that it's not just a couple of hours a day. It really depends on the center and what the work they're doing.

And bone marrow irradiations, also extremely complex and patient demanding.

MR. KIRK: I just wanted to ask what kind of numbers of units that that -- the 24 hours a day doesn't answer the question. It's what kind of units does it.

MR. WAGNER: In the Red Cross, for fiscal year '08, 475,000 units were irradiated, and we believe that demand for irradiated blood has increased by about ten percent in the last year, and I might also comment that I believe that there's probably more blood irradiation at the hospitals than there are at the Red Cross, and there are some good medical reasons for this, for red cells. When you irradiate red cells, they release potassium and that released potassium can be harmful to neonates.

And so the hospitals prefer to irradiate the blood at site so that they can get the blood red cells at least to the patients who need it soon rather than later during storage.

For platelets, they could be irradiated at centralized facilities, but the hospitals already have gamma irradiators.

MR. GORLI: The AABB collects data via the NBRDF. Over two million blood products were irradiated in 2006. There's over 20 million blood products produced annually. Therefore, that's the genesis of the about ten percent figure. Obviously it's a higher proportion of platelets.

Wearing my MBA hat I would simply point out that Paul Moses has pointed out that the market answers the question. They're for sell and they're selling. That said, the Red Cross data, the ABC data, and the AABB data, all find that they're about ten percent of the total irradiators out there.

So they're selling, but if they were as cost efficient obviously they'd be selling more.

MR. RAKOVAN: Any further discussion on this question in terms of cost effectiveness before we move on to the next?

(No response.)

MR. RAKOVAN: Okay. Let's go ahead and put Question 2-3 up there. Is there any indication that the performance of the alternatives will change, improve or worsen, with respect to cesium-137?

We may have touched upon this already, but does anyone have something that they'd like to continue the discussion on this?

Please.

MR. MINNITI: Yeah, it's Ronnie Minniti from NIST.

This question is probably for Mr. Kirk. Correct me if I'm wrong, but I believe the maximum voltage, the state of the art today, is around 300, 400 kilovolts for X-rays, and that translates if you filter such a spectrum to get a monochromatic spectrum, you can get maybe up to 200-something, 250 keV. So can you go higher than that?

And if not, what do you think about that in the future, if that's possible or not?

MR. KIRK: Well, hint, hint, we have written a grant request to put together a machine that will operate at 500 KeV, and at 500 KeV with this new technology we're using, you have enough photons that you can filter very, very hard and still have enough left to do something with.

So, yes, we believe it's possible. Is it today? Is it tomorrow? No, it's probably in the same time range as anything else.

MR. MINNITI: Okay, I guess, but what would be the main energy then? We would be talking around 400 tops, right, or maybe even less than that?

MR. KIRK: Yeah, if you were to go to 500, then you would probably have a distribution from maybe 275 to 380 or depending on what you were filtering with and if you could optimize that.

MR. MINNITI: So is it correct to say then that the technology is not there today or --

MR. KIRK: Oh, no, I'm just saying it will be three to four years before you can even get to that level.

MR. MINNITI: To that level, but not to 600 KeV.

MR. KIRK: I think that --

MR. MINNITI: I think that it's a fair question since this morning when we were talking about the other alternative about the cesium form, right, we were asking, okay, if this would be available and we had an answer for that. So I think we should explore that question, too, for this other alternative.

MR. KIRK: I think it would be difficult to go much beyond 500 keV as a peak.

MR. MINNITI: As a peak.

MR. KIRK: As a peak.

MR. MINNITI: Yeah, okay.

MR. KAMINSKI: That would just be for a standard X-ray tube. I mean, certainly there are other ways to increase the energy, such as LINACs, linear accelerators and so forth that we use clinically so that 18 mV or whatever, of course, if you need to go that high, but it's much more expensive.

MR. MINNITI: Yes.

(Laughter.)

MR. RAKOVAN: Got a question in the back. If you could introduce yourself, please, sir.

MR. ROGERS: Yes, sir. Steve Rogers, U.S. Army Primary Irradiation Standards Laboratory.

I noticed most of the discussion so far has been on irradiations. I'm from the calibration side of the house. Between ourselves and the secondary laboratories beneath us, we calibrate tens of thousands of survey instruments and dosimeters per year, and we have noticed a significant difference in instrument response between calibration of X-ray and calibration with cesium-137.

Now, I know we're talking specifically about cesium chloride, but if cesium-137 were to disappear in any form and be replaced by X-ray, we're talking about a lot of instruments that would have to be recalled for recalibration out of cycle at significant cost and adverse impact to our soldiers trying to accomplish their missions, as well as manpower in the calibration labs themselves, and at several of our facilities we're short handed already.

Thank you.

MR. RAKOVAN: Further discussion on Question 3?

(No response.)

MR. RAKOVAN: Okay. Let's move ahead on to the final question, 2-4, regarding the availability of alternative technologies. (a) What is the time frame of future availability of each alternative, and (b) what is the cost for each of the alternative technologies, capital cost, operational cost, cost to users?

Again, I think we've kind of talked about this a little bit, but if there's further discussion on this issue or any of the other issues that we've covered in terms of use of alternative technologies.

MR. NIXON: There's been a lot of talk about the availability of technologies in the context of prototypes. As a manufacturer who has lived the life cycle of starting with a prototype and working into a marketable product that has an acceptable or semi-acceptable degree of reliability, there is a big difference, and there could be a fairly long learning process involved.

So I just wanted to caution people into thinking in terms of time to market of a viable work horse X-ray technology to supplant the use of cesium-137. We're talking several years down the road, and that's after the prototype comes to market.

MR. RAKOVAN: Further discussion?

MR. GORLI: Pathogen inactivation for plasma and platelets is actually licensed in Europe, but it probably can't catch on until all cellular products have a licensable treatment. Red cells is still probably several years away, but Dr. Wagner could probably comment more accurately.

MR. WAGNER: I think red cells are back to square one with respect to clinical trials, and as you know, you have to go through a number of clinical trials successfully and then regulatory review. So I don't see that around the corner soon in the States.

MR. RAKOVAN: Further comments? See on the end, please.

MR. FITZGERALD: With regard to alternative technologies, I just want to say that at the NIH as a whole, there are over 20 cesium irradiators. So jus the capital cost of just replacing those alone, I understand that the government is going to write a big check hopefully in just a couple of days, but that kind of puts pressure on the rest of us to hold down cost. So I just want to make sure that's understood.

MR. RAKOVAN: Please, if you could introduce yourself.

MR. CONNELL: Len Connell at Sandia.

With all of the discussion about cost, and I know --

MR. RAKOVAN: Sir, is the microphone on?

MR. CONNELL: Is it on?

MR. RAKOVAN: Yes. Please just stay that close if you would.

MR. CONNELL: Oh, yeah. Okay. Just a discussion about cost. One of the things we also brought up in the National Academy's report and it was just discussed here about the market right now has shown that there's a ten percent, you know, intrusion in the market with X-ray machines, but one of the things we noticed in the National Academy study was that a lot of the costs are not actually seen by the user and particularly the disposal costs.

Again, it's hard to judge what that cost is because we don't have a real disposal capability right now. All we're doing with the off-site source recover program is we're taking your cesium sources and we're storing them.

If you started to look at the true cost of disposal and if we were to really ask your users to pay for that, I think you might see the market change a little bit. So that's one aspect I don't want you to forget, is that the user cost is not the true cost to society, that all of us as taxpayers are ultimately going to have to pay to dispose ultimately of these sources.

And we already mentioned about the terrorist cost. You know, we don't really know what the probability of one of these events are, but as has been mentioned, if you had a terrorist event involving cesium, the economic consequences could be pretty high.

Thanks.

MR. RAKOVAN: And actually I think we'll be talking about some of those issues tomorrow in a few of our panels. So that's a good advertisement.

Thank you, sir.

(Laughter.)

MR. MORGAN: Tom Morgan, University of Rochester.

I asked a vendor about how much it would cost to dispose of the cesium-137 blood irradiator. He quoted me $35,000 to pick it up and dispose of it and $70,000 for rental of the Type B container for shipping. So there's a particular cost point, and that's one month old.

MR. RAKOVAN: Sir, sir, sorry. Go to get to a mic.

MR. MORGAN: I asked this individual, "What would you charge me to take this thing off my hands?" And he told me it was $105,000, broken out as I just said.

MR. RAKOVAN: All right. Any further discussion on this particular issue? I've got one more or two more hands.

MR. COPPELL: Yes, hi. It's David Coppell from REVISS here.

I just wanted to comment on the issue of disposal cost for cesium-137. I agree it's difficult to work out what they are because there is no disposal route right now. We're all in the situation where we have to adopt long-term storage techniques.

However, my understanding is that pretty much all of the Cesium-137 that's used in the world is actually separated from spent fuel. So this material isn't generated particularly for this purpose. It exists anyway, and the responsibility and the task of storing it and ultimately disposing of it will exist whether or not we use it for this application.

MS. SHEPHERD: Mary Shepherd, Shepherd & Associates.

One thing we did not talk about was the carbon footprint of using a gamma irradiator versus alternate technologies, the expense of the electricity, the amount of electricity that it takes to run these machines, whether that be a PET or an X-ray or linear accelerator, and in today's uncertain world with fuel what it is, it's an important point to bring out. What does it actually cost to run all of this different technology electricity-wise?

MR. RAKOVAN: Go ahead.

MR. WAGNER: Yeah, we've done some calculations for the Raycell for blood bank. I really can't speak for all of the other applications because obviously they're different for every application, but for one site that uses two Raycells, a single Raycell instrument with its use was estimated to cost about $2,000 per year per instrument, and so if we had to replace every gamma irradiator with a Raycell, I think it would cost us about $60,000 a year more in electricity and water and sewage cost.

MR. RAKOVAN: Okay. We seem to be kind of moving in that general direction anyhow. So why don't we go ahead and take a look at the parking lot issues since we've got about a half an hour left of today, if that's all right with everybody.

Charlie, I think the first three came

from you. Did you want to address those or did you just want me to throw them out as conversation topics?

If you're going to talk, I need you on a mic, man. Sorry.

MR. MILLER: You know, the intention of my comments were to try to capture that as part of the default process for the parking lot, and I think it's going to take the full discussions of the whole conference before we can ferret those out completely.

MR. RAKOVAN: Okay.

MR. MILLER: So they were intended to just keep people's consciousness as to some of that.

The other comment I'd make, while it's not on the parking lot, is for the benefit of everyone in the room, although I know many know that, currently the Nuclear Regulatory Commission has no regulatory authority over X-rays, but the states do, and so suddenly if that were the only technology available, it would solve the Nuclear Regulatory's problem, but it certainly wouldn't solve the state's problem.

(Laughter.)

MR. MILLER: So I just wanted to make

sure that people were aware of the fact that , you know, as we ponder the alternatives, the NRC has to ponder also what's within our regulatory purview and what do we do about what's in our regulatory purview, and I'll let the states speak for themselves, although they do have to deal with this from those things that we do regulate. The states regulate that with a compatibility in a way that we do.

Thank you.

MR. NIXON: I wanted to just reiterate when we talk about cost, outside the security issues the cost to patient care not only here in the continental United States, but in the rest of the world if the use of cesium or cesium chloride today were to be banned, patient care would be compromised all over the world. Many countries do not have reliable power supplies and so forth. We construct our cesium irradiators with back-up power supplies so that they can operate in times of power outages and so that patient care is not compromised.

So that is a relative major advantage of cesium based technology over electrically generated irradiation.

MR. RAKOVAN: Mr. Wagner? Your tent is

up. So did you? No? Okay. Sorry.

Any additional discussion? Please, if you could introduce yourself if you would.

MR. JARDINE: Would it be appropriate to comment on 1.1 again?

MR. RAKOVAN: Right now as far as I'm concerned, I think the whole day is open for discussion.

MR. JARDINE: I just want to come back to the question since the manufacturers were not here from Mayak, primarily to our U.S. visa control problem, but having worked with Russia and having done seven of these engineering studies with Russians on different parts of plutonium processing basically and three at Mayak, I wanted to make this statement that we have to realize that cesium comes from the one reprocessing plant in the world that designed a process, separate cesium nitrate. It cannot be done in France or Japan. The U.S. has no capability.

The Russians have been looking in the past at alternatives to cesium chloride, and they're looking today at alternatives, and it's basically a glass and a ceramic. I will not be specific. Those options exist. The Russian process, as I said, would take about five years.

What it consists of is parallel engineering studies and design with the scientific development and science and R&D, and it's basically a one year technical economic feasibility engineering study that compared two options, glass and ceramic.

In parallel, the scientific institutes prepare data on what these forms are in the glass and ceramics so that the engineers can decide which option is best after one year.

The next step if they're able to select one option is to go to the next step of engineering, which is one year in parallel as the R&D continues on the one form or two forms.

But I have a problem, and the Russians I think would, of deciding which form because there's different issues fabricating a powder, a ceramic or a glass, and the range of capsules that have to be filled for the different customers that Mayak has. You cannot pick a single option. These technical and engineering feasibility studies will identify these issues in collaboration with the Russian institutes.

Quite frankly, it's my opinion our U.S.

laboratories would not be very useful to this process because they don't really know how to contribute and often, quite frankly, can't work with the radioactive materials.

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

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

I'm aware that they're thinking about it and they're doing it, but that's the time line and the basis for five years, and they do have options of glass and ceramic to be decided upon, and that first year study will determine the cost and then verify it's feasible from the engineering standpoint at the Mayak facility.

Thank you.

MR. RAKOVAN: Okay. Ms. Fairobent.

MS. FAIROBENT: Yes. I have a question for you. During the time that they may be retooling to look at the ceramic or glass, are they still able to to produce the cesium chloride form? or would they be shut down out of production and if so, what sort of stockpile do we have if we're not pulling cesium chloride out of use until an alternative form is available?

MR. JARDINE: I think she said during the first year. They would continue, my assumption. I'm not Mayak. My assumption is they would continue to produce the revenue generating cesium chloride until they were in a position to make a decision how will they best proceed to install the new facility or processing line, next door in a different hot cell, different building or have to fabricate a new one.

So I anticipate they're now market driven. They'll continue to produce these sources and find a way to bring on the second process, which is high risk and may not work. It's not a known technology.

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

MR. FORASTE: Yes, good afternoon. My name is Steve Foraste. I'm representing QSI Global.

We're a manufacturer of cesium products for industrial uses, and we don't use cesium chloride except for as a feedstock, but I have been to the plant in Russia where our sources are manufactured, and we make a few thousand of these a year, but what we're making are things that are about three orders of magnitude below a blood irradiator source.

One of the problems with scaling up our process to handle the blood irradiator is disbursability. The cesium when it's put into the glass is raised to such a temperature that a lot of it is actually lost in the plant. A big part of the quality control in manufacturing this is trying to optimize the yield in the plant.

So while I understand that cesium chloride is a very large danger as far as disbursability in a terrorist scenario, if we were to scale up our existing process today at Mayak, we would have a disbursability issue at Mayak.

They're famous for a large one about 51 years ago, but I wouldn't want to repeat that today. I know David made a presentation on behalf of REVISS on where cesium glass is today, but I can say that our glasses are not up to the task yet for blood irradiation.

MR. RAKOVAN: Very good. One thing that I wanted to point out, I apologize. I forget who brought this up to me, but the question to keep in your head that I put on the parking lot, the gentleman said during the lunch break, I believe, or one of the breaks, would it be great for NRC to have an Advisory Committee for this and what the thoughts were on that. So he asked us if I'd put that under the parking lot and I wanted to do so.

So just something to have in your head. He said this is a complex issue. So there's an advisory committee of some sort needed for it.

MR. RAKOVAN: Sir.

MR. MORGAN: Tom Morgan, University of

Rochester.

I brought that up, and the Advisory Committee on the medical use of isotopes I'm sure has been very useful to the NRC, and this is such a complex issue. There are so many stakeholders, so many different paths that we have to walk to make sure we get it right that that was my recommendation for the committee.

MR. RAKOVAN: Please. If you could please introduce yourself.

MR. PHILLIPS: Bob Phillips, FDA.

This morning the people from Russia were indicating that they had a long development program to develop alternate sources. They're also the only source of cesium iodide chloride in the world. Given the resurgence of nuclear power in the United States because of our energy problems, does anybody see any future for reprocessing to come back to the United States?

MR. RAKOVAN: Anybody want to touch that one?

(Laughter.)

MR. SULEIMAN: It's above my pay grade.

(Laughter.)

MR. NIXON: I'll just make a small

comment. I wouldn't profess to speak for anybody in the U.S., but cesium is usually extracted as part of a bomb making project, right? It's a separation when you're extracting plutonium from spent fuel.

So those are the conditions that lead to the production of cesium as far as I know it.

MR. RAKOVAN: Any further discussion? Please, sir.

MR. ALOY: Albert Aloy from Radium Institute, St. Petersburg, Russia.

I would like to correct you because it's the cesium that's the byproduct from reposition (phonetic) of spent nuclear fuel, not recovered from plutonium. Now we have developed the new, simplest, purest process which oriented only for uranium extraction from the spent nuclear fuel, and plutonium is not now the main valuable product, and our approach is because we use only the mixture of new plutonium and the transfer uranium elements in future, and the reactor is a fast reactor.

So I would like to correct you because our purpose is not plutonium extraction during the processing, but of course, we have also very old vests, the same vests like in the Hanford site or in Savannah River where the cesium is a byproduct like

Strontium-90 collected in a big amount, and because of this different tanks with different history, the Mayak people can study the ratio between stable isotope of cesium and Isotope-135 and the long-lived cesium isotope and cesium-137 and select the same product which corresponds mainly for the purpose of irradiation, of irradiation sources.

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

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

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

And so I think that the main risk is on the border of the country. It is terrorists may use outside from USA cesium chloride to spread it inside in the country, and because inside the country it's too difficult and control use of these sources.

This is my opinion.

(Laughter.)

MR. ALOY: But main risk, main level of risk, of course, from using cesium chloride outside of developed country, of Europe or USA, Canada.

But cesium chloride very attractive for this developing country, for cost and for long-lived service.

MR. KAMINSKI: Just to make one fast point, you know, what worries me is having cesium chloride in these Third World countries and then shipping it over in a lead cased container or whatever, and we know the ports aren't monitored very well, I mean, and it's not that difficult to conceive of an event here in the U.S. either.

MR. ALOY: I'm sorry. I am not understanding what you said.

(Whereupon, translator spoke with Mr. Aloy.)

MR. ALOY: But I think the revised case involves a controlled system in Russia, and the control is very strong, on the top level. Yes?

MR. COPPELL: Maybe just to repeat the question, I think the point you were making was the bigger risk may be the cesium chloride that's somewhere in use in a developing economy might be appropriated, shipped into the U.S. or into Europe or anywhere else disguised essentially, and encapsulated in some shielding material that makes it difficult to detect.

MR. RAKOVAN: Sir, if you're going ot say something, I'm sorry. I'm going to have to ask for your mic to be on.

MR. COPPELL: Yeah, so I think everybody recognizes that, and I think it's the reason why this is an international issue really. I mean, of course, here in the U.S. what you can address is what you can control in the U.S., but equally everybody else has to participate because this is an international concern, and we need to find a way of resolving it in a way that minimizes the risk internationally.

I was just going to say one thing about the comments earlier regarding time scales for development of a potentially alternative technology for cesium at Mayak. This morning I made the point that there is a program; there is a project which is receiving a lot of attention at Mayak and which the general director of the whole of Mayak is fully aware of and very focused on.

The reason why I think we're being a little bit unclear about time scales is because they're not very clear about them yet. So I really don't think it's particularly helpful for us to actually try to fix in our mind an exact time frame right now.

It's going to be a few months before we're in a position to actually make a clear statement about what's going to be involved, how long it's going to take and what the other implications, for example, cost implications might be.

I realize that everybody is focused on this issue right now, but I think if we could just have a little patience, give our colleagues in Russia until maybe spring or early summer next year, I'm fairly confident they'll come back with something that is detailed to the extent that we can use it.

Thanks.

MR. SULEIMAN: This is a really, I guess, stupid question, but if you take powder and put it in some epoxy, I guess it's going to cook or whatever, but where are the chemists? Could somebody explain what would happen with that kind of effort to solidify the powder?

MR. RAKOVAN: Anybody up for talking epoxy?

MR. SULEIMAN: Wouldn't it affect the disbursability? I mean, I'm sure this has been looked at, but I'm just curious. Somebody has got to know the answer to that.

Why is making it a non-powder so difficult?

MR. MORGAN: Tom Morgan, University of Rochester.

I'll try and take a shot at that. Epoxy is an organic compound. With that much amount of radioactivity you're going to have tremendous radiolysis, and it's going to break down. It isn't going to work in an epoxy.

MR. COPPELL: Sorry. I agree with that, absolutely. You generate an awful lot of radiolysis products, which means that it's pretty difficult to encapsulate it in anything, and pretty soon, you end up with a kind of gooey black mess, which is going to be --

MR. RAKOVAN: What's wrong with that?

MR. COPPELL: Well, it's going to be pretty disbursable and fairly soluble. The cesium, if it's put into the mixture, let's call it, as a salt, which is usually chloride, but it doesn't have to be; it could be sulfate or nitrate. Then either way, by the time you've broken down this epoxy compound which isn't going to take very long, then you've just go soluble cesium left.

So it really needs to be in a matrix which can withstand a significant amount of radiation damage without changing its nature, which is why everybody talks about either ceramics or glasses.

MR. ALOY: I would like to say again about the testing of the performance of the sources. Because we have the double encapsulated in stainless steel sources with welding each capsule, and some capsules we need for testing for fire. It's 800 Centigrade at half hour. During this testimony, epoxy raising or as an organic compound will be decomposed with high pressure inside, and welding area will be destroyed.

So it is impossible to use any compound containing organic or water inside in the capsule. So only ceramics or glasses, inorganic materials may be used, and we compare these properties as a feasibility study because one material may be easy for production, but other material may have more performance properties for resistent to reachability.

So we must compare and now all studies performed on surrogate materials, and maybe after one year you'll hear data to compare properties with the real Cesium-137.

Maybe I not understand your questions correctly.

MR. RAKOVAN: Last comment of the day.

MS. SHEPHERD: Mary Shepherd.

The testing that we're discussing is a special form capsule testing that's usually required for transportation and for licensing issues. There's special form and there's NASI testing that's involved with the manufacturer before you're allowed to distribute or transport. And that's a whole other factor that's trying to be addressed, and those are real requirements unless the IAEA and the other governmental agencies change those requirements for the production of any kind of source, special form.

MR. RAKOVAN: Okay. Looking at the agenda for tomorrow, we've got registration starting at eight. I'm sure we'll have more food out. We'll be starting promptly at 8:30, starting on Issue 3, and then we'll move on to four and five tomorrow.

So we'll see you all tomorrow. We'll be in the same room.

(Whereupon, at 4:53 p.m., the workshop was adjourned, to reconvene at 8:30 a.m., September 30, 2008.)