Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title:	Public Meeting on the Draft Policy Statement on Cesium-137 Chloride Sources
Docket Number:	NRC-2010-0209
Location:	Rockville, Maryland
Date:	Monday, November 9, 2010

Work Order No.: NRC-536 Pages 1-180

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

PUBLIC MEETING ON THE DRAFT POLICY STATEMENT ON

CESIUM-137 CHLORIDE SOURCES

+ + + + +

TUESDAY

NOVEMBER 9, 2010

+ + + + +

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

PRESENT:

KENNETH BAILEY, Facilitator

BERNIE BOGDEN

JOHN SCHRADER

MARY SHEPHERD

STEPHEN V. MUSOLINO

SUSAN LEITMAN

KEVIN NELSON

MICHAEL TAYLOR

RONALDO MINNITI

BRIAN DERMOTT

ARNOLD EDELMAN

PRESENT (CONT.)

JOHN ZARLING

ROBERT DANSEREAU

ROBERT J. LEWIS

JOHN P. JANKOVICH

CYNTHIA G. JONES

SARENEE HAWKINS

C-O-N-T-E-N-T-S

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

8:31 a.m.

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

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

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

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

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

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

My name is Cynthia Jones. I'm the Senior

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

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

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

So to advance our discussions today, and to provide additional input to those of you that were not able to attend yesterday, let me share with you some of the key points on the issues that were presented at yesterday's sessions. Please note that this is only a very brief overview of the many discussions that took place. A full meeting summary and complete list of participants at this workshop will be posted on NRC's cesium chloride website that is listed in both the Federal Register notices and then I've again listed on the last slide of this summary.

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

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

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

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

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

As we heard yesterday, a Task Force subgroup also completed a study to assess the feasibility of phasing out the use of cesium chloride sources and concluded that immediate phase out of these sources would not be feasible because the sources are extensively used in a wide range of applications in medicine, industry, and research, with significant health benefits to patients. However, the task force also reported that a gradual step-wise phaseout could be feasible as alternatives become technologically and economically viable and if disposal pathways are identified.

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

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

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

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

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

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

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

We also heard a regional NRC perspective regarding the use and status of security inspections that were designed to verify and implement the security requirements for these Category 1, 2, and aggregated quantities of Category 3 sources. These security inspections began in 2007, after the increased requirements, so-called increased controls, were issued. Specifically, we heard that initially licensees experienced some growing pains with regard to the new security regulations as far as how best to implement the requirements, but overall, increased and steady improvements by licensees in the source security area has now been seen.

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

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

Operationally, we learned that cesium chloride is not regulated any differently than any other isotope that requires increased security and control. Regulators and inspectors stated that licensees appeared to be willing and have planned to accept any increased burden for security involving the future Part 37. However, lack of disposal options was cited as a great concern for them as there is currently no disposal pathway for cesium chloride sources in the U.S.

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

We also heard from our partners, the Agreement States, who are partners in regulation. Agreement States are defined as those states that have signed an agreement with NRC authorizing the State to regulate certain uses of radioactive materials within that State. The Agreement States regulate about 80 percent of the radioactive sources in the United States. They continue to see a decrease of security violations as the years have passed since implementation of these Orders and increased control indicating that a great deal of increased knowledge and the implementation of trustworthy and reliability checks and required fingerprinting has been done.

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

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

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

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

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

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

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

Next we heard several licensees' perspectives of security requirements for cesium chloride sources to offer us an alternative way to look at physical security. One licensee looked at the risks and needs of the use of cesium chloride and viewed it from the perspective of the protection of a scientific asset. Some universities put together both short-term and long-term programs for security systems of these sources. Faculty at several institutions stated that there is a scientific necessity for cesium chloride with no alternative.

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

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

Several licensees noted that currently concerns with x-ray machines do not meet their needs for throughput. They noted that hospitals have taken additional voluntary security measures to make it even more difficult to tamper with or move these licensed devices. In this respect, several licensees noted the assistance of the Department of Energy, National Nuclear Security Administration, the Global Threat Reduction Initiative, or GTRI, which have assisted in enhancing cesium chloride sources' security even further beyond what is required by regulatory requirements.

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

Some consideration of what are the ramifications of denying someone access based on a poor credit check is something the human resource departments are having to deal with currently. In addition, it was noted that the increased number of credit checks done on an individual can be detrimental.

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

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

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

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

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

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

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

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

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

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

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

America's Blood Center stated that they do concur with the intent and language of the draft policy statement to (1) continue to have access to cesium chloride irradiators, to provide an important public health benefit; (2) to improve designs to enhance safety and security; (3) to find alternative forms of cesium chloride to reduce the risk; and (4) to develop pathways to safely dispose of cesium chloride.

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

Of the 26 irradiators, 15 have had GTRI enhancements. NIH noted that the increased security controls have resulted in lots of additional training since 2005, between radiation and security staff. And several licensees stated yesterday, "NIH also noted a noticeable change amongst researchers in the use of security with radiation sources."

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

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

For the researchers that use both x-ray

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

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

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

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

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

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

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

(Applause.)

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

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

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

Mr. Bogden.

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

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

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

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

I'm sure many of you are well aware.

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

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

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

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

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

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

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

What I'd like to briefly go into now is what we call our Nuclear Site Security Program. It's not rocket science. Basically, our Field Office has an area of responsibility, so to speak. And we want them to know what is out there in their territory, what critical facilities, WMD facilities. Obviously, on the nuc/rad side, commercial nuclear power plants. Like I said, we don't expect them to have immediate recall of every single licensee that's in their territory. However, we like for them to have a general understanding of the higher level sources or sites such as research and test reactors, and like I said, like high-level irradiators, things like that, cesium chloride sources, and those type of higher-level radiological sources. So that's a primary mission for them to do that outreach. And I'll discuss that briefly in a few minutes.

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

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

On the other side, basically, we also

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

In the last couple of years what we've tried to do is, like I said, we've had this well-established program with the commercial nuclear power reactors, but what we've decided to do is to go beyond that. I mean we intend to be very proactive so we decided to conduct even more outreach in the last couple of years or so and trying to focus on high-level radiological sources which is the source of literally -- no pun intended -- the meeting today. These high-level irradiator type facilities with cesium chloride sources. It's not specifically limited to those sources, but obviously they're a major, major focus because of the inherent nature of the material, high levels of radioactivity and potential for utilization and radiological dispersal devices. So, of course, there are concerns.

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

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

I want to make it very clear, these are not security inspections in any way on our part. They are conducted as an independent program of the FBI, basically just to provide situational awareness on the part of our FBI offices with these sites. If not already established, who are the security points of contact, the local law enforcement. They should already know the FBI very well, of course, that they have these relationships established and that the FBI gains an understanding of the security controls in place there, not to assess them, not to inspect them at all, but just gain an understanding of how they work, notifications, making sure that the FBI is notified as quickly as possible in coordination with local law enforcement, so we can respond to an incident as it's occurring, and hopefully prevent that incident, prevent the material from being lost, stolen, so to speak.

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

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

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

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

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

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

Dr. Jones alluded to the DOE, NNSA Global

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

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

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

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

(Applause.)

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

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

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

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

(Laughter.)

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

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

DR. NELSON: Jacksonville, Florida.

MR. BOGDEN: Jacksonville, Florida area. Well, Jacksonville, I can't quote off the top of my head, but there's a Joint Terrorism Task Force in that area and it would be Jacksonville Field Office with those state and local agencies working together. I can't say everyone knows everything else that's going on, but that is the primary conduit where actually state and local law enforcement and other local agencies as well working together sitting side by side dealing with whatever issues need to be handled including, perhaps, something that you made reference to. I can't say that everything will be discovered by everyone, but that's one of the primary conduits for information sharing.

And I think your other question was in relation to?

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

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

DR. JONES: Bernie, one question that comes to mind is in the case that Dr. Nelson just mentioned in Jacksonville, when there is a person identified as a person of interest, after these checks are done, is that the responsibility of the licensee or of the local law enforcement to get back to each other. If, for example, he didn't hear back from FBI in six months or so, should he make the contact with the individual officer with the local law enforcement to see how this can be closed? I think there's some sense from licensees we heard yesterday that there may be some open ended issues and they're not sure how to go about or if they have a need to go about closing that somehow with local law enforcement.

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

FACILITATOR BAILEY: Any other questions?

DR. JONES: Thank you.

(Applause.)

FACILITATOR BAILEY: If we could have the next group of panelists take the stage, please? And while we wait on that, just for your information, the Task Force report that Charles Miller mentioned yesterday, there has been copies made and they're out front on the desk, so please help yourself to a copy during break or during the lunch time, 90 copies.

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

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

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

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

MR. SCHRADER: John Schrader, REVISS Services.

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

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

I'll start with just a little background of us. REVISS Services has been making sources for a considerable length of time. We started in 1940, as The Radiochemical Center in Amersham, England. In 1982, we were privatized by the British Government into a company by the name of Amersham International. In the early 1990s, Amersham management established a trading company to work with the Russians to supply radioactive isotopes into the manufacturing operations. The Joint Venture, or REVISS, included the Russian companies of P.A. Mayak and Techsnabexport.

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

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

In our Joint Venture, REVISS provides the design, development, quality and regulatory systems, logistics, sales, finance and administration for the operation of our business. Mayak is the primary contractor for our sources, including cesium chloride and cobalt sources. And Tenex provides us with other radioisotopes for our creative products.

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

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

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

Mayak has been working on several options in parallel with the glass and ceramic looking at the most viable options to demonstrate that these products will deliver improved performance. The development work includes the maximization of cesium content, the dose output without the need for radically designed equipment in which cesium chloride is currently used.

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

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

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

We are measuring these results by testing based on, where available, ISO standards, primarily ISO-9978 and ISO-2919. And we have developed testing protocols that are as close as possible to other recognized standards.

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

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

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

For leachability, using the test methodology and the ISO standards, we have achieved less than 1 percent, however, when accumulated over a 30-day period, we're seeing approximately a 3 percent leachability for the ceramic materials and a 5 to 7 percent leachability for the glass material.

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

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

As part of this on-going process, we are also investigating the potential for returning and recycling cesium chloride as part of this program. In order to be able to offer a cradle to grave service for the replacement of cesium chloride, or the new form of cesium source in the future, but, after listening to Blair and Mary yesterday on the hardening of things, I'm not sure that's going to be a real viable alternative.

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

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

That's all I have to say. Thank you very much for allowing me an opportunity to speak this morning.

(Applause.)

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

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

If this surmise is correct, then the direct source capsule exchange into existing irradiators may not be possible. There's one reason for that. The old Oak Ridge sources that we used to use are a completely different size than what's commercially available from REVISS now, so there's no direct source replacement from an Oak Ridge source to a current REVISS source if somebody wants to upgrade. You have to buy a new irradiator body.

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

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

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

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

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

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

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

(Applause.)

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

The last two speakers have covered most of this, and also earlier speakers, but cesium chloride is important to medicine and medical research. And currently there is no alternative. Accelerators and x-ray machines are expensive. They're much less reliable and more costly to maintain. Many operators are not looking forward to a switchover to something like this. Machines also take up a lot more space for things like chillers and associated equipment and space is a premium in hospitals. So many of the hospitals are finding this technology undesirable from a space aspect alone. There will be a financial impact on the medical community no matter what alternative is chosen, and if one is chosen to replace cesium chloride, if it were to be replaced.

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

Just to show you this, Fred Harper himself, this is the facility he's been using for many years at the Sandia National Laboratory. I would bring your attention to the aerosolization chamber in the upper portion of the slide where Fred can use up to a half a pound of explosive material. So what he can do is he can essentially stress whatever material he has under test in the actual conditions in terms of how the shock wave would interact with the material in real life. So we have a very good scientific answer.

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

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

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

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

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

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

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

And New York City came to Brookhaven Lab directly. If you're not aware, New York City is the only city in the country that licenses radioactive material. They're an Agreement City. After the Republican National Convention where there were a number of security reviews done prior to that event, the city realized that it was worthwhile to go review the security for all their licensees, not all their licensees, but some of their licensees for them to get an idea of the status of security.

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

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

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

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

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

To conclude, changing the physical form of cesium does not eliminate the potential impact from a dispersal. Re-engineering the physical form will be costly. Significant economic impacts and effects to the medical industry will result to replace cesium with any alternative such as an accelerator x-ray technology. The residual risk of cesium chloride following the implementation of the ICs is at least in my personal line acceptable or close to it. And opportunities exist for cost effective improvements to security.

(Applause.)

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

MS. FAIROBENT: Yes, Lynn Fairobent with AAPM.

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

FACILITATOR BAILEY: Thank you. Any other comments?

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

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

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

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

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

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

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

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

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

FACILITATOR BAILEY: Thank you.

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

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

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

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

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

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

What's absent is a driver. An incentive. That goes to the cost issue, but also what's absent is a kind of an integrated path forward. And what I'm worried about despite what the policy statement says, we could reconvene in ten years and have this same discussion which if you looked ten years ago, even before security was an issue, people were looking for alternatives for cesium chloride. How can we go forward?

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

They say that we're at 50 to 70 percent of the cesium volume in any particular source so that the source would have to be 10 to 30 percent larger to be able to get the same characteristics. That would give us the opportunity to design the devices to be able to withhold these new sources to get the same characteristics that we're getting out of cesium chloride today, but implement those over time.

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

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

FACILITATOR BAILEY: Next question, comment.

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

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

FACILITATOR BAILEY: Thank you.

DR. MUSOLINO: I agree with that, but the issue that remains in my mind is that cesium chloride right now is a very hard target and while there's a long-term desire to replace the form which certainly I would not disagree with either, we still have to keep in mind it's sitting in a hard target now and the NRC has achieved their objectives of security with the cesium. Even if you find that cesium may be extremely expensive to replace ten years down the line, I still think there's a viability to it with proper security.

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

(No response.)

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

ISSUE NO. 5: FIELDS OF USE FOR CS-137 SOURCES: BLOOD IRRADIATION, BIOMEDICAL RESEARCH, CALIBRATION

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

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

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

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

DR. LEITMAN: Susan Leitman from the

Transfusion Medicine Department at the National Institutes of Health.

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

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

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

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

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

PANEL PRESENTATIONS:

ROLE OF CESIUM IRRADIATORS IN TRANSFUSION

DR. LEITMAN: Blood components are irradiated for one reason: to prevent transfusion-associated graft versus host disease. TAGvHD is a rare but devastating complication of transfusion. It is mediated by immunocompetent transfused T lymphocytes, which can engraft, proliferate, and mount a severe immune reaction targeted against the HLA or human lymphocyte antigen of the host. The host can be severely immunocompromised and, thus, not reject the transfused passenger lymphocytes or, by very unfortunate chance, the transfusion recipient may share an HLA haplotype with an HLA homozygous donor and not be able to recognize the donor lymphocytes as foreign, even though the recipient is not immunosuppressed.

Patients at risk of transfusion-associated TAGvHD, starting from youngest to oldest, include recipients of intrauterine transfusions -- the immune mechanisms of the fetus are not fully developed -- recipients of postnatal exchange transfusions; fetus receiving exchange transfusion for hemolytic disease of the newborn, infants, and children with several congenital immunodeficiency states; allogeneic and autologous hematopoietic transplant recipients, who can get chemotherapy and radiation conditioning, some combination of the two, to allow grafts to take hold; patients with hematologic malignancies, Hodgkin's disease, non-Hodgkin's lymphoma, and acute leukemia; and patients with unusual solid tumors, not the more common kinds but neuroblastoma, glioblastoma, rhabdomyosarcoma -- these are reports of patients who have developed this process -- and patients receiving the newer highly immunosuppressive period analogues, fludarabine, cladribine, pentostatin. That is important because they are given for non-malignant indications, such as lupus and severe autoimmune disease, indications for which physicians don't recognize the patient might be at risk of TAGvHD. And, lastly and perhaps most frighteningly, non-immunocompromised recipients of HLA homozygous haploidentical blood products, either because they're derived form a related donor or an HLA match donor or by unfortunate accident from an unrelated or random donor.

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

Japanese HLA haplotypes are less highly conserved. And so what you can see if I can get the pointer is that the risk of a parent-to-child transfusion causing a lethal TAGvHD is 1 in 100 in Japan. And that risk compared to the risk from an unrelated donor goes down, but it is still appreciable, 1 in 900 chance of this situation occurring when you look in U.S. Caucasians, the parent-child risk is about 1 in 500, sibling 1 in 900. And in the unrelated setting, it is a 1 in 7,000 chance that a recipient will get an HLA homozygous product with a shared haplotype.

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

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

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

The outcome, unfortunately, the reason why we are here is that it is universally fatal, nearly the numbers are fatal. By the time the reaction is recognized, it is grade 4, and it's untreatable. And the death is usually infectious due to severe neutropenia.

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

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

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

The dose is simple. There is general agreement that a minimum dose should be 2,500 centigray (cGy) targeted to the midplane of the canister holding the blood product. Circulating lymphocytes are, as this audience knows, among the most sensitive of mammalian cells to radiation. And a dose of 1 or 2 hundred cGy is enough to eliminate mitotic potential. But in bulky, irregularly shaped blood components, there is a level of safety added and, thus, the dose of 3,500 cGy.

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

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

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

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

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

There is Best Theratronics that makes Gammacell models. And there is the Shepherd Company, JL Shepherd and Associates, which makes numerous different kinds of irradiators. And I can't list them all here.

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

Performing dosimetry to validate that the dose you want distributed is, in fact, distributed throughout the canister. It is fairly easy. One can use radiation-sensitive films put into water or various thermoluminescent dosimeter chips or MOSFETS embedded into plastic or lucite, put them inside your canister, irradiate them, and send them off to be read, not complicated.

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

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

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

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

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

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

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

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

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

The PM contract I am told is very expensive, nearly $90,000 over 3 years, which covers 2 PM visits per year. That is preventive maintenance, two power supplies in case they go, and one tube.

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

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

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

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

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

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

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

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

DNA or RNA and interpolates between pyrimidine basis.

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

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

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

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

Permanent welded closure of the rear of the irradiator, making access to isotopes extremely difficult, if not wildly improbable, and securing the irradiator itself in a locked cage or room.

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

(Laughter.)

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

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

If you are located here, getting ready to release a blood component, here is our platelet storage, agitator. Here is our red cell storage, a refrigerator. And then we irradiate, and then we release. Here is the computer, the sign-out computer. So it is all very efficient.

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

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

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

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

(Applause.)

CONDUCT OF BIO-MEDICAL RESEARCH IN VIEW OF Cs-137 IRRADIATION

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

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

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

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

Again, we find use for the irradiator in a number of different situations. Dr. Leitman again has covered these. This involves thousands and thousands of patients annually. And certainly we care for these types of patients at May Clinic and other hospitals across the United States.

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

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

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

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

And, again, as mentioned by Dr. Leitman, we want to do this as soon as we can. We want to be able to give the blood to patients as soon as we can after we irradiate the blood because we have noticed an increase in potassium through leaky cell membranes, which tend to occur after irradiation. So the sooner that you can give the blood to the patients after irradiation, the better.

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

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

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

We do a large number of transplants at Mayo Clinic in Florida. And there have been cases that have been reported of graft versus host disease in solid organ transplants. So this started the process of us looking at this more closely.

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

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

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

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

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

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

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

And I think it is interesting that we

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

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

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

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

So what are some of the issues that we have with the use of X-ray irradiators? Capacity is certainly one of them. Uniform irradiation. I like to do dosimetry as a health physicist. And I have yet to see a good peer-reviewed prospective case study comparing X-ray irradiation with gamma radiation. If there is one out there, please see me after my presentation. I would love to look at that and maintenance costs.

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

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

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

But depending again on the volume of the bags and the number of bags in these X-ray irradiator units, are you irradiating them to the point that you want them to? Are you being able to irradiate them to 25 gray?

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

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

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

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

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

This was taken from the International

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

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

And I will stop my presentation again by emphasizing the fact that we are talking about real patients here. Removing cesium chloride irradiators for blood transfusion products simply is not -- we can't do that right now. And you are impacting potentially. If you move forward by eliminating the irradiators right now, you are impacting patient care. And I think that is a very important message that large users of irradiators want to leave with this workshop that has been put on.

Thank you.

(Applause.)

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

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

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

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

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

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

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

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

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

Cost. We have to look at getting rid of all of our equipment. And there have been several talks earlier on how much, the cost of replacement units. We are looking at roughly about $300,000 a unit plus disposal costs plus installation costs.

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

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

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

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

Thank you.

(Applause.)

ISSUES IN CALIBRATION TECHNOLOGY IN VIEW OF CS-137 SOURCES

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

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

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

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

And I guess my point here is to say that we calibrate -- well, not NIST but in the U.S., we calibrate more than one million radiation measurement instruments of this type. And for all of this, cesium is used.

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

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

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

So here is a picture. What I want to show here is that there is a large number of applications and where all of these instruments are used. And it goes from low levels, from environmental levels, all the way up to industrial levels.

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

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

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

So, anyway, basically to meet these requirements, what do we use? We use cesium irradiators. And the range of activity of these irradiators varies from the millicurie range, which is category 3, all the way up to 1,200 curies, which is a category 2 and is a matter of this discussion.

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

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

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

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

In addition, there are lots of national and international protocols and document standards and guidelines that rely on cesium. So, for example, if you just get ANSI 13.11, this document standard relates to the testing of personal dosimeters. And it is written in there that you have to use cesium to test this, again, in the same way you have other standards as well that rely on the use of cesium irradiators.

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

So I think that's it. Thank you.

(Applause.)

STATUS OF ALTERNATIVE TECHNOLOGIES

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

(Laughter.)

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

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

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

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

Now, for anyone that hasn't seen a research irradiator, these are what they look like. Now, our name is X-RAD. They range from 160 or 450 keV. The most popular one of them is the 320, which is based on an orthovoltage system. They are self-contained.

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

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

So that is my presentation.

(Laughter.)

FACILITATOR BAILEY: Thank you.

(Applause.)

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

STATEMENTS & ROUND TABLE DISCUSSION

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

This is primarily for the medical panelists. You were very convincing. Thank you all for the presentations. They were very convincing, very convincing arguments for why you just can't go with the Pinto. I think I understand that.

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

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

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

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

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

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

We can do a -- right now we definitely because of the transportation container issues and COC for the cobalt blood irradiators has been retired. So at present if you're going to reload a cobalt irradiator, it's a portable hot cell. When the new ones come on board, we are back to swapping out and shipping, you know, just doing an irradiated body swap-out.

MR. REIS: Thank you.

FACILITATOR BAILEY: Thanks.

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

DR. JANKOVICH: John Jankovich from the NRC.

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

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

In addition, there are the licensing questions, too. The devices, the irradiators are not approved for losing cobalt sources. Then there is the site licensing question. And this makes the switchover practically impossible.

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

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

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

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

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

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

MR. LEW: -- for UCSF.

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

MS. SHEPHERD: Mary Shepherd, Shepherd and Associates.

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

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

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

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

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

FACILITATOR BAILEY: Thanks.

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

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

FACILITATOR BAILEY: Thanks.

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

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

(Laughter.)

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

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

That's it. Thanks.

FACILITATOR BAILEY: Any additional questions or comments?

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

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

FACILITATOR BAILEY: Thanks.

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

Just outstanding presentations. We can't thank you enough for providing your information on X-ray cesium medical use. It is extremely valuable for the Commission to have sound science and basic facts about how they're used on a daily basis and nationally. And that is going to be extremely helpful when John and I and others take the comments from this workshop and work it into the policy statement. So thank you very, very much.

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

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

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

And I would like if you could provide your thoughts on how the policy statement should be revised or does it need to be revised to adequately reflect the activities that you do and why cesium is needed.

Thank you.

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

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

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

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

And so my message again would be I think that the policy statement is good. It allows some flexibility. But I am concerned that the other members of the Task Force may not understand the need currently for cesium chloride and why we just can't stop using cesium chloride.

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

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

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

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

DR. JONES: Thank you.

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

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

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

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

(No response.)

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

(Applause.)

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

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

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

FACILITATOR BAILEY: Enjoy your lunch.

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

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

(1:03 p.m.)

ISSUE NO. 6: STATUS OF DISPOSAL

PANEL MEMBERS

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

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

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

MR. ZARLING: John Zarling, NNSA, GTRI.

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

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

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

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

(Whereupon, there was a show of hands.)

FACILITATOR BAILEY: Okay.

PANEL PRESENTATIONS:

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

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

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

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

We believe the best home is 30 to 600 meters underground or under several feet of concrete and soil. So the Department of Energy is indeed working on coming up with a disposal methodology, disposal approach for greater than class C waste that includes cesium chloride sources.

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

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

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

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

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

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

Specifically -- and I wanted to point this out that the ~~Low-Level~~Low-level Radioactive Waste Policy Act Amendments, LLRWPAA, not the easiest thing to say, basically indicated that the federal government is responsible for disposal of radionuclides that exceed the definition of class C. It didn't say anything about B or C. It just said that we're responsible for greater than class C.

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

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

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

It also required us to report to Congress before any final decision was made on where we would be going with the greater than class C waste and the creation of a disposal facility. So that is something that we are working to and developing in the near future, an approach on dealing with what types of waste, where we are going to be going with the waste, and also preparing the report to Congress that will authorize us to actually make a decision on where we are going to put the waste.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So, in addition to those, we have a

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

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

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

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

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

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

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

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

We do have experience. As I mentioned, NRC has approved on a case-by-case basis a disposal of greater than class C in slit trenches below, 30 meters below, surface. And, of course, on top of it was a lot of low-level waste. I think it was at Barnwell or U.S. Ecology. I think that is where it was approved.

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

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

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

So where are we in terms of our schedule? We are hoping to issue the draft EIS January of next year. That is our target date. It is currently undergoing review by senior management. And we are hoping by the end of the month that we will get to ahead and actually publish the document.

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

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

We are hoping to issue the final EIS in 2012. And at that same time, we need to submit a report to Congress. That report to Congress we need to identify basically what we have in the EIS. What are the quantities of waste? What are the options for disposal? What are the legislative changes or regulations that need to be developed? What are the costs associated with each of those methods? And we also need to present to Congress, how can we recoup the money for the construction and operation of that facility?

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

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

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

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

So a fairly quick, big picture overview. In 1985, we had the Low-Level Radioactive Waste Policy Act Amendments. 9/11/2001. We had the notice of intent in 2005. And now we are working to issue the draft EIS with the hope that, indeed, we will have that draft out in January and finalized in January of 2012.

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

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

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

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

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

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

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

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

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

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

Thank you very much.

(Applause.)

LICENSEES' PERSPECTIVE ON STORAGE AND DISPOSAL OF CsCL SOURCES

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

(Laughter.)

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

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

So I think the most important thing as a licensee you can do is if you buy a new source, whether it is cesium chloride or any other device containing radioactive material, is to see what kind of support you can get from the vendor in returning that specific source.

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

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

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

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

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

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

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

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

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

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

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

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

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

Certainly there are questions that parties are asking that should be answered, but I told myself when I first started my career as a health physicist over three decades ago when the Low-Level Waste Compact Act was passed, I thought, "Wow. This is great. This is going to be the answer." Well, three decades later, I am still waiting for that answer to appear to me in the State of Florida.

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

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

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

So that was those were some of our

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

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

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

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

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

In 2009, they were licensed to receive low-level radioactive waste. And they disposed of about 750,000 cubic feet of radioactive material generated at Fernald, Ohio during the Cold War. They project that in 2011, they will be able to start accepting class A, B, and C waste from the Texas Compact and also accepting class A, B, and C waste from DOE.

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

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

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

We further recommended that federal and

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

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

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

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

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

(No response.)

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

(No response.)

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

(Whereupon, there was a show of hands.)

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

That is my presentation. Thank you.

(Applause.)

DISPOSAL OF CsCL SOURCES THROUGH DOE'S OFF-SITE

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

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

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

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

This kind of goes back to what the previous speaker said. While secure storage is a temporary measure, the longer sources remain disused or unwanted, the chances increase they will become unsecured and abandoned.

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

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

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

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

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

We work with the NRC to prioritize the recoveries. The higher the activity of cesium or cobalt, the higher priority that it will receive for recovery.

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

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

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

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

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

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

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

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

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

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

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

While this is great that there is disposal there, however, it is very limited disposal there. In the New Jersey, South Carolina, and Connecticut, the disposal limit is ten curies, which doesn't help with the blood irradiators. You know, it's somewhere between class A and class B waste.

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

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

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

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

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

We as GTRI, OSRP do recover higher-activity sources, but we also -- in both actinides and other sources, but once we recover them, we take ownership, but we have very limited disposal access as well. So that is not a solution either.

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

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

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

So Los Alamos I guess in September of 2009 let a contract for a new type B container. And AREVA won that contract. It was originally designed for the long-term storage shield, which is the use with the IAEA mobile hot cell.

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

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

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

Now, during the meeting with the NRC, they were a little concerned with taking credit for shielding of the device. They did say, you know, we would have to look at that by a case-by-case basis. And AREVA is working on that currently, but it is a problem.

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

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

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

So, as we were thinking about that problem, we maybe start working on a new type B. The large B is what we are going to call it, where it is going to be a much larger container that, instead of taking cried for the shielding or the device, we are going to look at shielding for the large -- you know, build a container, a 10-160B-type large container or the GE2000 large-type container with a lot of shielding.

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

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

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

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

Thank you for your time.

(Applause.)

DOE/NNSA RECOVERY PROGRAM

ISSUES ASSOCIATED WITH PICK-UP OF SOURCES

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

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

We look at the Task Force's challenges and recommendations related to disposal. They're really talking about disposal. They don't address the long-term storage issue.. But NRC has captured the need for the disposal. And we do see that for the presentation, DOE is working towards finding a solution and developing capacity for disposal.

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

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

I think I heard from one of the speakers that there is some firm in Germany that recycles cesium, but I haven't heard anything here and I don't know if that has really been evaluated and if so how much that would really reduce some of the disposal issues or quantities for disposal, I should say.

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

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

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

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

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

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

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

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

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

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

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

And who can repair sources? What would that cost? And is it even a viable option for something like this? These are questions they raised I have no answers to.

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

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

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

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

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

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

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

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

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

The phenomenon of leaching was new to me and I think probably new to quite a few people. I think we need a little more research and understanding of that process or that phenomenon.

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

Thanks.

(Applause.)

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

STATEMENTS & ROUND TABLE DISCUSSION

MR. WAGNER: Steve Wagner, American Red Cross.

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

I guess my question is, has anyone been doing any thinking about intermediate term storage for disused or abandoned sources in such a way that it could be held in a secured fashion, perhaps protected by the government, perhaps taking advantage of the fact that there are Department of Defense facilities that might be able to guard these sources, unwanted sources, better than civilian organizations? And has there been any thought about how there might be some intermediate solution prior to putting into place a long-term disposal?

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

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

And, as I said during the talk, there is -- we do have limited disposition capabilities, but we don't have -- we can't dispose of absolutely everything. So we do -- at Los Alamos plus other secured storage sites, we do take some of those sources in if we do know that they are there, going to be unprotected.

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

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

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

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

And we will prioritize, you know,

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

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

MR. ZARLING: Yes.

FACILITATOR BAILEY: Thanks.

MS. FAIROBENT: Lynne Fairobent with AAPM.

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

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

MR. ZARLING: And I forgot to mention that during my talk. We also do work with CRCPD in the SCATR Program. And the way that is working right now is in states with disposal options, SCATR Program will collect the smaller, lower-activity sources and in all-radium I'm going to say in all-radium because radium does have disposal at American Ecology up in Hanford.

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

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

FACILITATOR BAILEY: Thank you.

Mary?

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

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

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

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

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

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

It comes to a secure facility. Our company is involved in increased controls, and we are doing the GTRI upgrades. At that point in time when a new source goes out, it goes out to a client that is a licensee who also meets the increased controls.

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

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

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

The nice thing about a recycling, you're transferring the source to a specific licensee in that transfer to -- like somebody with a license, whether it's a facility that transfers it to another university and a hospital, you don't have the continuing liability. The person who gets that source has the residual liability for that source.

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

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

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

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

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

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

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

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

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

And another point I wanted to make. On our sources since we have been doing this a long time, the legal shipping limit used to be .05 microcuries. That's what you were allowed to distribute years ago when you are talking about the old sources. You will often see 0.5 microcuries, which was legal at that time.

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

FACILITATOR BAILEY: Thank you.

Any other questions or comments?

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

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

MS. SHEPHERD: Mary Shepherd, Shepherd and

Associates again.

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

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

FACILITATOR BAILEY: Cyndi?

DR. JONES: Cyndi Jones with the NRC.

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

MR. ZARLING: John Zarling from NNSA.

That's correct. The hospital was going

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

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

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

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

Thank you.

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

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

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

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

And if any of the panelists could, just for the record and for our knowledge as well and for the individuals that will read this transcript in the future, you said that there was a very limited number of type B containers in the U.S. Can you give us a ballpark figure of what "very limited" means? Is that less than ten? Is it less than 100? Is it two? Just kind of a ballpark figure would be good I think for the Commission to have on hand.

Thank you very much for your presentations.

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

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

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

There are other containers out there that can do sealed sources but only sealed sources. I don't know. When I say, "only sealed sources," I'm not talking devices, you know. That's why the 20WC-type container, DOC spec 20WC-type container was a great container because you can do a device. Some of these other type B containers out there, certified type B containers, the cavity size is not large enough to accommodate a lot of the cesium chloride devices.

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

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

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

I would say that truly for the application that GTRI does, it's the 20WC right now. There is the GE2000, but that's a scheduling nightmare on that. There are only three of those total in existence, and they are heavily used by GE to move their material. So you may have a two-week period of time once every three months to use the container. So it's not an option for a recovery, an emergency recovery.

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

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

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

(No response.)

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

(Applause.)

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

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

WRAP-UP AND CLOSE

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

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

Also, I would like to thank you for your time. I know that your time is very valuable. And to be here, you took away from your businesses or even in some cases from patients. And that's very significant for me personally but also for all of NRC. So we very much value your views here today.

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

(Applause.)

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

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

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

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

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

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

We got a lot of good feedback in the last couple of days on the increased controls in Part 37 and how those activities fit into what we say in the policy statement. And I think we have to look there to make sure we're saying everything the right way.

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

DR. JONES: January.

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

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

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

You heard Mary just make a comment, from JL Shepherd, about arrangements to retake the -- think about the end of the life of the device before it's purchased and put in place, such as returning to vendor. I think there are some issues we can explore there on what we have in the policy statement, distinguishing between existing devices in the field and new devices in the future.

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

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

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

We will, at NRC, move forward in a very deliberative way and fully consider the uses. And everything the Commission said today has been very clear about that. We have to consider the uses, the beneficial uses in any decision about the future uses and, as we heard this morning, the real benefit to patients versus the theoretical detriment to other actions. And we are very mindful of that. We hope we are. If we are not, tell us.

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

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

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

(Applause.)

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