THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH/NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY (NIOSH/NPPTL) PUBLIC MEETING

Friday, October 13, 2006

NEW AND CONTINUING RESEARCH

Commencing at 8:33 a.m. at the Crowne Plaza Pittsburgh South, Pittsburgh, Pennsylvania.

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P R O C E E D I N G S

OPENING REMARKS, NPPTL OVERVIEW

MR. BOORD: Good morning, everyone.

Welcome to the second day of our public meeting to discuss NPPTL activities. I trust that you all had a pleasant evening in Southwestern Pennsylvania last evening.

Actually this was the first real taste of winter that we have had this year. So I don't know whether you brought that weather to us or exactly how it got here, but hopefully it didn't diminish opportunities to experience a little bit of the area.

For today's meeting, I would just like to go over a few of the agenda items. The first presentation that I will deliver this morning, I'll share it with MaryAnn D'Alessandro. And we will talk principally about the PPT, personal protective technology cross-sector programs for the Institute.

We will give you a little bit of the background on what is being done regarding the PPT cross-sector.

Then for the technical presentations, we will follow the schedule as identified in the agenda, and Dr. Ron Shaffer will be leading those presentations from our research branch.

The presentation that's scheduled for 11:10, which is the customer satisfaction summary, that was the information that we covered at yesterday's meeting that MaryAnn had addressed to the audience. So that presentation will not occur today. So we won't repeat it.

And I think with those adjustments, and if our researcher presentations can stick roughly to schedule, I think that we should be able to adjourn our meeting by 11:30 a.m. without very much difficulty, which I think will be good these for those of you who need to travel today.

Again, I will repeat that our meeting objective for these two days of presentations is to provide program information to our stakeholders and customers.

So our interest was not so much to report results, but basically to inform what we are doing,

where we are going, and the types of things that we are finding.

As I mentioned, the discussion this morning will address some of our personal protective technology issues. As far as the logistics for the rest of the meeting, we will follow the same patterns that we had yesterday.

Following the presentations, if there are questions, we would ask you to go to the middle of the room, address who you are, who you represent, and then follow through with the question.

The entire process is being recorded and videotaped, so everybody knows that we do -- will have a record of the meeting.

And before we get into the discussions on the personal protective technology cross-section, I would like to ask Judy Coyne to make some announcements or requests.

ADDRESS BY MS. COYNE

MS. COYNE: We are trying to get a new cable so that we are not lime green over here.

I am the communications coordinator and

responsible for outreach program. Those are my mannequins over there, and my hands.

When I go to different shows, I like to have products to take with me, and my mannequins dressed appropriately. For the firefighter show, I like to have them dressed, and I like to have equipment on display that relates to firefighters.

If we are in the mainstream -- like we went to the local general show a couple of weeks ago -- it was a community event -- I would like to have various respirators on display and safety equipment, whether it's -- all kinds of PPT. My mannequin was dressed with ear protection, safety goggles, and a respirator. And I like to have them on display in our building also.

So what I need is I need samples of all kinds of personal protective equipment. And I want to give everybody a fair representation, and also high quality, high resolution photos that we can use in these types of presentations.

Some people have been really forthcoming in providing photos to me. And if you just give me

your card, I will be happy to send you an email with my official request.

So I will be here the rest of the day. And to those that have already helped me, thank you so much. It really makes my job a lot easier.

So thank you.

NIOSH PERSONAL PROTECTIVE TECHNOLOGY PROGRAM

MR. BOORD: Thanks, Judy.

The slide that I have on the screen now is the slide that identifies the various divisions and offices -- divisions, offices, and laboratories for the Institute. And as I mentioned yesterday, there are 16 different offices and laboratories. NPPTL is one of the laboratories comprising the institute.

The research program and the research activities for the institute are being geared around the industry sector program portfolio that I discussed yesterday.

The industry sectors are as identified in the right-hand column, the agriculture, construction, through wholesale and retail trade. The cross-sector programs are identified in the

center column of the slide. And the personal protective technology cross-sector program is being managed by the laboratory, by NPPTL.

As discussed yesterday, and mentioned by Frank Hearl, the institute is working with the National Academies of Science to review the various programs and research activities for the laboratory. In that regard, we have already started to follow through that review process.

Two of the program areas have already been through the National Academy review. And those are the mining program and the hearing loss cross-sector program.

The mining program has, as I say, has completed the review. And the National Academy report on that review will be available on the NIOSH website in November for those of you who are interested in seeing that.

The hearing loss review has also been completed, and that program, I believe, is available on the NIOSH website currently.

So those two are available.

The respiratory disease studies National Academy review is scheduled to begin with the first meeting with the National Academies on October 26 and 27. And that is an open public meeting, so if you have an interest to engage and participate in that activity, the dates are October 26 and 27.

Other sector programs that will go in front of the National Academies over the next six months include the construction program and the personal protective technologies program.

We are scheduled to have our Academy review beginning in June of next year. So that gives you a little idea of the future direction for the NIOSH activities and the research program portfolio.

Regarding the personal protective cross-sector program, as I mentioned, the laboratory is responsible for developing that program.

It should be noted that the activities relative to personal protective technologies for the institute are not uniquely concentrated at NPPTL. We are responsible for identifying the program and

leading the program, but there are other divisions and laboratories that are engaged in various PPT activities.

The cross-sector team that we have assembled to prepare our package -- and our National Academy package really has two components to it.

The first component is a strategic planning and strategic direction for the future activities for personal protective technologies. And the second component is an evidence package looking backwards in time to identify what has been done and the outputs and the impacts of the previous work.

So our personal protective technology cross-sector team is engaged in both of those activities.

That team is being managed -- I am the program manager for that team. And our program coordinators are Maryann D'Alessandro from the laboratory, and Jeff Welsh from PRL, who many of you may know. And the program assistant coordinator is Angie Shepherd, who you heard from yesterday.

The team, the composition of the team is comprised of members from around the institute. So you can see the team membership identified on the slide. And you will note notice that there are representatives from DSR, DRDS, DSHEFS, DART, and PRL actively engaged in the process.

Plus, there will be other participants in preparing the evidence package and preparing the strategic planning that will come in and provide input to the team, but then not be there as a continuing team member.

So this is the team that we have assembled for the program.

And at this point, what I would like to do is turn it over to Maryann, who is a program coordinator, who will walk through some of the activities that we have already completed, where that program stands, and give you some idea of what the direction forward for PPT cross-sector is.

PPT CROSS-SECTOR HISTORY AND DIRECTION

MS. D'ALESSANDRO: Good morning. I just want to walk through what we have been doing over

the past year so you see how active the PPT cross-sector is within NIOSH and how NPPTL fits into that overall structure.

First quarter 2006, which is October through December last year, the PPT cross-sector met weekly. That was Les and I and Jeff Welsh. And we developed a draft mission, vision, definition, and logic model or value creation system, as you saw Les present yesterday and the day before, and discussed the strategy for the PPT cross-sector.

And then, beginning in January 2006, we began monthly meetings with the entire team. And over that time, we refined that mission, vision, and definition in the logic model with the entire team, which, again, encompassed all divisions within NIOSH and a big sector of NPPTL.

After that was refined -- actually, here's the mission, vision, and definition then that now -- this is for the overall NIOSH -- for the institute, NIOSH mission, vision, and PPT definition. And then NPPTL is a smaller, more focused part of that.

So the mission is to prevent work-related

injury and illness by advancing the state of knowledge and application of personal protective technologies. And the vision is be the leading provider of quality, relevant, and timely PPT research training and evaluation.

And we spent a lot of time going over what the mission and vision should be, and we thought that this was a pretty good representation of overall what the PPT mission and vision statement should be for the cross-sector.

But we are interested in your feedback, and we will be opening a docket on this as well. And that hasn't been opened yet, but we look forward to your input there.

And then with the definition, the technical methods, processes, techniques, tools, and materials that support the development and use of PPE worn by individuals to reduce the effects of their exposure to a hazard.

We wanted to make sure that the PPT did not include things like flashlights, for example, things that would be handheld, or environmental

sensors, that the PPT definition encompassed those things that would protect you from various hazards. And that's how we resulted in the definition that we have there.

Again, we do look for feedback. This is draft at this time, and our package is not due to go to the National Academies until next spring.

I don't know if you can see this, probably not. But we will be posting this logic model -- can you see that at all or is -- not at all. Okay. We will post this ...

But if you remember the value creation system that NPPTL has, talks about inputs to our activities, the activities that are being conducted throughout NPPTL.

I'll put that we expect the intermediate outcomes and end outcomes. And this is what this encompasses. But this is for all of NIOSH, so it's a lot more detailed.

And when we put this together, we also included certification. We pulled that out of the overall logic model. So that is included

separately, but it is also within there. But it's easy to identify that because we thought that was a very important part of what PPT is doing in the institute, so we pulled that out. But it was really difficult to develop this because of the unique rule that certification plays in the NIOSH.

Most of the programs that are undergoing review have just a research component. Therefore several have other components to them, like the health hazards evaluation program.

But really NPPTL, the certification program is unique to NIOSH. And that is something that we really have to figure out how we are going to describe this, describe our past, and then how we move forward into the future for the National Academies when the review happens.

But we will post this along with all of the slides that I have here today. But if I could just -- is that easier to see?

That covers the same things that are in the logic model, and I'll just briefly go over what we have considered in putting together our past and

moving forward to the future.

The inputs that we have been looking at are, first of all, what the industry sector goals and draft goals are.

As Les talked about, all of the eight sectors in NIOSH, the industry sectors which include mining, construction, health care -- I'm at a loss, but all of those eight industry sectors. They are all developing goals and draft goals at this time. And we have considered those inputs into what PPT goals should be.

We have also looked at all of the surveillance data that is out there, all of the surveillance data that NIOSH has collected and surveillance data that is being collected in other places.

We, of course, have considered stakeholder needs, something NPPTL has always done, but NIOSH has not necessarily done that very well in the past. So we are including that.

Also, townhall meeting feedback. The NORA program and NIOSH had many townhall meetings last

year. We went through all of the feedback from those meetings. Everything that had a PPT component to it, we looked at and saw where that fit into where PPT should go in the future.

And also, of course, the national priorities. The mining issues are high priority right now. Pandemic influenza considerations are also high priorities. And also the feedback from our committee on PPE has well has been an input to developing the goals that we have at this point.

So now, we have developed draft goals, and now we are trying to identify where is the best fit for the various goals.

Should -- the goals that we have, once we identify activities that should be conducted and be associated with those goals, where they should they fit. Should they be activities be conducted intramurally? Should we put them extramurally into the grant process? Should we recommend they go other places other than NIOSH? Or should we do them in-house, like a lot of our activities went through a contract mechanism?

So we are doing all of that up front before we look at our current activities that we are doing just so we don't try to focus on what we are doing right now and say that this is where we should go in the future.

So we are looking at all of the needs from those inputs.

Now we are seeing where do all of the things that we should be doing fit into what we are currently doing. Then we will identify and prioritize the gaps, and then develop measures and metrics.

That's where we are right now, trying to put measures and metrics to the goals that we have developed and expand upon those goals for various industry sectors.

The current activities are on the right-hand side, and we are currently developing content for the website. Each sector and cross-sector that is being evaluated by the National Academies has to describe the past with a website and evidence package. We are putting that together

right now.

Rand is being used as a consultant. Primarily, so far, they have helped us with the logic model, in refining that. And then we are also looking at what current external PPT activities are going on that we may be able to exploit.

We have developed quad charts for all of our projects, which include the objective of all of our programs, who the stakeholders and partners are, milestones that are achieved, and what we anticipate the outputs and outcomes to be.

And we have to develop for each of those projects compendiums, so just descriptions of all of those projects and where we intend for those to go.

For the first quarter of 2006, we are refining the mission, vision, definition, and logic model that I showed. We are continuing the monthly meetings that we have had.

And in addition to the monthly meetings with the whole team, we have broken the team into separate groups. We have a health and a safety group.

And then within those two groups, we have groups that focus on respiratory protection or inhalation hazards, dermal hazards, or protective clothing and ensembles, hearing protection, hearing loss hazards, head protection, and eye and face protection.

In the second quarter, we -- that's what we have done already. Gone over that. Now, here we are with the goals. Somehow they got backwards.

The first goal that we came up with, Identify and develop performance requirements and evaluation criteria for PPT to achieve harmonized standards to improve the quality and performance of PPE through all lifecycle stages.

That's a mouthful. It encompasses a lot, and it will be broken down into a lot of subcategories. And that's currently what the teams are doing at this time is breaking that 1.1, 2, and 3 down further and focusing on each industry sector and aligning what all of the sectors are doing in their goals with the PPT goals that we have.

The second goal is to develop

informational materials to provide guidance to identify appropriate PPE for all lifecycle stages.

The second stage, after we have the first, go ahead, develop the standards that are needed in the performance requirements. Then guidance is needed to address those issues that were developed in goal one.

And that is part of the second goal, guidance in all of those areas, and where we should be focusing, and in those five areas that address the hazards that I mentioned.

Then in Goal 3, conduct research to address personal protective technology knowledge gaps and improve existing technologies. Then the end of the -- beginning and the end of the cycle is to identify what the research is that should be conducted to address the standards needs that have been identified that then could be put into the standard and then into the guidance ultimately.

So now, for the remaining fourth quarter '06 and now this first quarter of 2007, we are continuing this evidence package development to

describe the past and the history of the program. And then we are also incorporating partner and stakeholder lists and letters.

What we need to do is -- what the National Academies did with the mining and the hearing loss programs is they went to the stakeholders and the partners that they had identified in all of their projects and they actually contacted them and asked them to come in.

So what we were going to do is solicit people up front who think that they should be involved or could have a role in what we are doing and get them involved up front in the process instead of at the end.

And that's what we are doing now is identifying who those partners and stakeholders are in PPT and perhaps seeing what has been developed in the past, perhaps letters that came in on success stories or areas where we needed to improve and how we responded to that and get those stakeholders involved.

So when the docket is opened, I would

encourage you to, if you are one of those partners or stakeholders, to indicate that you would be interested in participating in this process.

In the second quarter '07, we will continue to refine and finalize the evidence package, and we do intend to get that out for others to review and provide input prior to submitting to the National Academies in around the May time frame.

So, again, we do want your feedback. And if you have any questions, Les or I could answer those or anyone on the team. Most of the team members, or a lot of them, are in the room. And thank you for your attention.

Are there any questions?

NPPTL PRIORITIES

MR. BOORD: Thanks, Maryann.

I think yesterday in the presentation, I went over some of the priorities for the laboratory.

And I just want to run down those priorities because I think it's kind of important that you can see through the course of what we presented yesterday and the discussions and some of

the comments that have been made, the discussions that we have today and the presentation that we just had relative to PPT, I think you can start to see perhaps some thread winding through everything that we are doing, and our focus for the laboratory, our standards focus.

I think in the presentations yesterday, you certainly heard and see the connections that we make between our research and development programs and national, international, and federal standards.

Partnerships. Partnerships are key to be being able to accomplish anything. So partnerships continue to be a driving priority for the laboratory to make things happen.

Personal protective technology evaluations. And our focus is to improve the technology of evaluation for our respirator certification program. Okay.

Some of the things that Heinz discussed relative to -- and Bill Newcomb relative to our quality assurance program module and our TIL programs that we talked about, these are

improvements to the way we certify our equipment.

Science Center of Excellence. The keywords there are robust evaluations.

We know that the institute is going down the road to work with the National Academy as the premier review activity. And that activity and association with the National Academy is impacting NPPTL and the programs and projects that we have going on with the National Academy in parallel to the institute activities.

And the PPT cross-sector is moving forward for a major review by the National Academy next year.

Outreach. Again, outreach is very important to us. We have talked many times, and you have heard many times in the presentations yesterday about the outreach activities and our interest to facilitate and create dialogue with our stakeholders and partners. It is important to keep the ship moving forward and forward in the right direction.

Human resource excellence, it is imperative that as we look inside and inward towards

our operation in the institute, that we have a good human resource focus so that we are accomplishing things with qualified people and expertise.

So I think that you can see that there is a thread that's weaving through all of the activities of the laboratory and certainly are achieving performance excellence.

Our APEX program is really, for the laboratory, it's kind of the web that pulls everything together because it's what gives us the direction and the drive to do the outreach, to sponsor and support the evaluations.

So the APEX program is really the mechanism that we use to keep things going and to accomplish our objectives.

So with that, what I would like to do is -- we are -- I'm going to go backwards. We are going to have a slight agenda change. And I will introduce Dr. Ron Shaffer who will give an overview of some of the research activities.

Following Ron's presentation, we will take a short break. And that break will be used to try

to get our projector set up so that they can operate on both screens.

So with that, I would like to introduce Ron.

GENERAL REMARKS ON THE NPPTL RESEARCH PROGRAM

MR. SHAFFER: Thanks, Les.

For those of you who are on this side of the room and are going to have trouble seeing the slides, I only have eight of them in this presentation. This is a longer version of what I did yesterday when I introduced the poster session, so there's not a lot of -- there's no data, no pretty graphics in particular.

But if you did want to see, I suggest you move over to this side of the room or towards the back because you can see the slides a little bit. But these will be posted to the web for download at a later time, so you can certainly see them later.

I wanted to give basically an overview of the research branch.

Following my discussion, and after the break, we will have four technical talks about

specific projects.

But I just want to give you, again, the high level overview of all of the types of things that we are working on so you can see the diversity of projects and maybe see something that piques your interest where we can work together on the project.

For those of you that were here yesterday, in my introductory remarks and also for Maryann's discussion at the end of the day yesterday, you learned a little bit about a survey that we conducted with the Office of Personnel Management, a stakeholder survey, manufacturer survey.

Well, one of the questions in that survey was respondents were asked about their awareness of the NPPTL research portfolio.

And the part of the responses that we got back were -- I think manufacturers were about 30 -- gave us a favorable rating about 38 percent of the time, users about 56 percent of the time.

So obviously there is an opportunity there to improve our outreach efforts. And so part of the discussions this morning -- my speaking here is to

really try to improve that a little bit.

So today, I'm just going to talk about the projects within the research branch, not about the research projects that were discussed in the afternoon yesterday that are undertaken by policy and standards development.

The focus areas for the laboratory, as I discussed yesterday, are these four, respiratory protection, certainly the bread and butter for the laboratory. Sensors and electronics, primarily where it's integrated with personal protective equipment.

Protective clothing ensembles, and then human performance. Human performance being trying to understand how PPE affects the user, what kind of burden it places upon the user.

We have a portfolio of research projects, and it will range somewhere between 10 to 15 projects at any given time. They are all at various stages of development.

And so you will see today, we have got projects that are at the very early formative stages

where we don't even have a protocol written. We are still working on that, trying to get our partnerships developed.

Some very mature projects that are at the end of their life stage and have been very successful.

So, for example, some of the work that Ziqing will talk about later, that's a project that's been around since about 2001-2002 time frame. And it's had a number of publications.

Pengfei Gao has a poster on a decontamination of chemical protective clothing, again, another project that's been around since about 2001-2002 time frame. And we have seen a number papers come up, a very productive research project.

So we do have a diverse mix of new ones as well as the projects that are at the end of their lifecycle.

And all of the projects that we will talk about today have a standards focus to them. They impact a standard or some policy or recommendation

that CDC or NIOSH puts out. The standard could be an ASTM standard, an NFPA standard, or as well as in something in 42 CFR. So we have projects that span that entire gamut.

The staff at the lab, we have about 20 researchers, including contract staff that support the group, the postdoctoral fellows. I think 13 of us are federal employees, the diverse backgrounds. Six Ph.D.s, degrees from the industrial hygiene to chemical engineering to chemistry. So a very broad background.

The budget of the research branch is on order of 2 to 4 million dollars a year, depending upon the priorities of the lab and the needs of the research projects.

The work that we do is a mix of in-house work and work that we fund at universities. In the earlier days of the lab, it probably was more heavily weighted towards work that was funded at universities or other government agencies, and that was while we were building up our in-house capabilities.

We have had a number of renovations done to our labs, so we have expanded our capabilities. So now we are probably a little more weighted towards in-house research. But we still try to keep a balance of extramural and intramural research.

And what I'm going to do is, the next slides, I'm going to have one slide or two on each one of these four focus areas.

In the area of respiratory protection, this is basically -- slide categorizes how we break up the research.

Basically, you know, the hazard or the inhalation, the total inward leakage to a respirator user primarily comes from two means, either particles or gases would penetrate through the filter or the cartridge, or they cause a leak around the face seal.

So we obviously have projects that are interested in both of those areas.

In the aerosol filtration studies work, I'll be talking a little bit later about work that we are doing in nanoparticles, and there's a poster

obviously about that.

Sammy Rengasamy talked about some bioaerosol work that we did, and that also is a poster over on this side of the room.

Ziqing Zhuang will talk later about the respirator fit test research that we have been doing, primarily in the area of facial anthropometrics, measurements of human face, and number of applications of that technology that he will be discussing later.

And then in the area of influenza pandemic. So this is what we would consider more of an emerging issue. And we have got one project listed here under that category, and that's a project that is titled reusability of filtering facepiece respirators.

Although it does cover more than just the reusability, it also considers re-aerosolization and risk assessment, you know, handling a respirator that's been used, been potentially exposed to an infectious aerosol.

That's a new start for this fiscal year.

Jon Szalajda will have a presentation about that later.

In the area of the sensors and electronics, our focus at the lab has primarily been on end-of-service-life indicators, either new sensor technology or mathematical models. And Jay Snyder will have a presentation after the break that will go through this in a lot more detail.

Protective clothing ensembles research is a major focus area. If you look at the breakout of our projects by funding or by budget, about 50 percent of the work goes in respirators or sensor projects that are all focused on respirators, and the other half of the funding goes towards protective clothing and human performance, which are closely aligned in our projects today.

So this just -- this slide just lists the various projects that we are currently working on. And there are posters on the first two, Pengfei Gao has a poster over here on the decontamination of chemical protective clothing. And Angie Shepherd has got the poster and the display over there on the

emergency medical protective clothing.

The EMS project supports NFPA 1999 work. And Pengfei's work on the chemical protective clothing has resulted in at least one work item at ASTM on some software that he has developed for automating permeation calculations for chemical permeation testing.

The third bullet on here is development of bench and MIST protocols for particulate penetration measurements through protective clothing and ensembles. That's a new start for us -- actually, it was an FY '06 new start.

The first year was primarily spent researching the area and getting some preliminary data in order to write a proposal. That proposal has been sent out for peer review.

We got the responses back a couple of weeks ago, and Pengfei and his team are currently going through the process of revising the project plan based on the peer reviewer's comments.

The last project -- and, actually, I should say that part of the nanotechnology talk I

will give later is actually -- is an aspect of this -- the third bulleted project as well.

The final project listed as a new start for FY '07, so it is at very early formative stages of just conceptual planning of how we want to execute that project, and that's going to be led by Angie Shepherd.

And the focus of that project is to look at various preconditioning methods that are used in NFPA standards, such as the 1971 structural firefighting and 1994 protective ensembles for terrorism response.

And she will be looking at things like laundering, abrading, heating, and flexing and attempting to correlate that with wear trials.

And that's an area where NFPA has indicated a need for some good scientific data in order to support the performance requirements and test methods.

In the area of human performance, we have the poster over in the back corner there on Project HEROES. This is certainly something we have spent a

lot of time working on. This is a project that is funded by the Technical Support Working Group, otherwise as TSWG. It's actually managed by the International Association of Firefighters, the IAFF.

And our piece of the project is to focus on the physiological testing of that prototype HEROES ensemble.

And we have also been heavily involved in developing the standards, revising the NFPA standards that would support this type of a new technology. John Williams is the project officer of the first two efforts on this slide.

The second one physiological models and countermeasures is more of a broader project that's looking at new test methods for assessing the burden of PPE, looking at cooling garments and also physiological monitoring equipment.

And the -- both projects have gone -- at least the protocols for how we are doing the testing have both gone through external peer review and either are currently in data collection mode or subject -- trying to get the subjects signed up for

the testing.

The final bullet is a new start for FY'07, so that's why you don't have a poster on some of the new -- the very new projects. We just don't have enough material even to put a -- to really create a good poster on.

That is project entitled metabolic evaluation of N95 respirators with protective covering. So this bullet actually could go under the respiratory protection slide, but it really does focus more on the human performance.

The idea behind that project -- let me explain this in a little more detail because it might be of interest to this audience.

The National Academy of Science's Institute of Medicine produced that report that was discussed a number of times yesterday on the reusability of face masks.

One of the recommendations that came out of that report was that it -- to extend the lifetime of an N95 respirator, you might want to use a surgical mask to cover the respirator. The idea is

that if droplets came into contact with that, the surgical mask, you could take that and off and potentially reuse your respirator. Again, this would primarily be only used in an emergency situation, like a pandemic where you had a shortage of respirators.

What got us thinking a little bit about that was how would that affect the metabolic gas responses inside the mask.

We certainly know that there are a number of papers that have come out that show that higher levels of CO2 in healthcare workers wearing respirators can give headaches and generally make it, you know, something you would not want to wear for six, seven, eight hours at a time. And so how would having an extra piece of material in front of the respirator affect that?

And so we are doing a very simple set of experiments with the automated breathing and metabolic simulator to look at the CO2 and oxygen levels inside a N95 respirator while the surgical mask is worn and then while there was no surgical

mask, and doing some comparisons.

So that project, the proposal has -- is certainly in internal review right now. It has been written.

So that's the projects that we have. I just want to emphasize a few key points here.

We have a standards focus at the laboratory. I think that's evident in reviewing the posters and talking to the researchers. Our projects support various ASTM, NFPA, ISO standards as well as 42 CFR, and guidance and policy recommendations that CDC or NIOSH puts out the door.

So we have a very clear linkage in what we call r2p, or research to practice, where we have got an end outcome in mind for the projects at the very beginning.

You will see that we have a diverse mix of projects from across all four focus areas.

Most people, you know, when they know -- hear of NPPTL or NIOSH think respirators, and that's what we -- that's all we do. But, actually, we do have a broad mix and have been very diligent in

making sure that we have a really good 50/50 type split of protective clothing and respirator research.

And finally, I just want to make a few remarks about research to practice.

Through partnerships, obviously this is where you can get involved. Certainly, whether you're a user or a manufacturer, there is opportunities to help us improve the research, which will ultimately benefit you as well.

Input can happen through, you know, appearing before the National Academy of Sciences to make a presentation or participating on a committee, through the various focus groups that Maryann and her team put together.

You can be involved in peer reviewing our proposals or peer reviewing the projects at the end of the -- or not the projects, but the outputs, the reports, the manuscripts at the end of the project.

So there is opportunities to participate from beginning through the end.

And certainly if you have ideas for

research that you think we would should be doing, we don't have a docket number open for that, but certainly an email to me or anybody on the management team, we will be happy to consider those within our process for selecting our research projects because certainly we don't have the, you know, the monopoly on all the great research ideas that are out there.

So we certainly welcome your input into the projects and how we select which ones we work on and which ones we don't.

So with that, I will close and take any questions. And then we will, like Les said, we will have a short break while we try to fix the projector.

And Jay's presentation has a lot of great graphics in it, so we definitely need to -- and lots of data. So we need to make sure the projector is fixed, or we move to this side of the room.

So any questions? All right. Thanks.

MR. BOORD: Thanks, Ron. So we will take a few minutes break to fix the equipment, and we

will give you an announcement before we begin.

Thanks.

(A recess was taken.)

MR. SHAFFER: We are going to -- because we had the break a little bit earlier, we are going to go ahead and do all four technical presentations back to back with Q and A in between them. And then we will wrap it up with a few remarks by Les Boord, our director.

So with that, I will turn it over to Jay Snyder, who is going to talk about our end-of-service-life sensor program.

END-OF-SERVICE-LIFE SENSOR PROGRAM

MR. SNYDER: Good morning, again. Seems like we have done this before, same time, same place, only a day difference.

And I thought the problem had been solved of being ambidextrous with two laser pointers simultaneously with having only one projector, but I see we have got two back, so bear with me.

This morning, for the next 20 minutes or so, I wanted to talk to you about our

end-of-service-life program and give you some details regarding it.

And in doing so, I will be covering a cartridge simulator, which we have constructed and I have brought with me today. So if you would like to see that, please stop by later. I would be happy to show that to you.

It also has a sensor arrangement in it, et cetera.

And I also wanted to give you some real details about our CMU sensor development program, which we have been working with them for the past several years.

Yesterday, I mentioned to you about some of our stakeholders' interests in end of service life, but the one I didn't mention that is really quite important is the regulatory requirement that OSHA has in their 1910 standard, which says that an end-of-service-life indicator shall be used, with the caveat that, When available.

And when it's not, then other factors need to be brought into play such as using mathematical

models or breakthrough test data. And all of this needs to be a part of the respirator program.

So in trying to assist our stakeholders in that effort, we have developed an end-of-service-life program, and it's a two-pronged program.

The short-term part of that program -- we thought we could do something relatively quickly -- was in the area of mathematical models. And I talked to you about this in some detail yesterday. I will briefly say that currently, breakthrough is for a single vapor with the effects of relative humidity. It's available on the OSHA website or from NIOSH by CD.

We are planning later this year to release multivapor, which will calculate a service time for a respirator cartridge with five organic vapors and the effects of relative humidity.

And GasRemove is on hold until we are able to generate some data to support it.

Now, in considering an end-of-service-life program, one of the things we certainly need to do

in the sensor area is consider the certification criteria.

And if we look at the NIOSH certification criteria, we notice a significant fact. And that is that a system should alert the user when 90 percent of the service time has been consumed, and 10 percent remains. So what we are really talking about is an almost end-of-service-life system.

Now, those of us who have worked in the area of industrial hygiene, we think we have seen or heard all of the horror stories, a new one pops up. Here's one that is rather interesting.

An individual working for a manufacturing company wears his respirator religiously for seven years. At that point in time, the company decided to send him to a training class.

And the individual was looking over the schedule of topics and put up his hand and said, Excuse me, but I see there is a topic here called change-out schedules. Does that mean these cartridges don't last for the life of the respirator?

Well, we think that if we hang some electronics on with flashing lights, it will cause some interest in the user to inquire as to what that's about and hopefully pay more attention to changing out the cartridges.

I have included this slide to give you some idea of the complexity we are dealing with when we are looking at multiple solvent assault of an organic vapor cartridge.

In this case, this is an actual cartridge which we have assaulted with approximately 400 parts per million of three compounds. You see the arrow pointing to the concentrations, the assault concentrations. In this case, we had acetone, trichlorethylene, and xylene. And the interesting thing about this is the fact that we get breakthrough first with acetone, and then trichlorethylene, and then finally xylene.

But as we see here, we are good for the first 50 to 60 minutes. And then acetone breaks through. But its ultimate concentration is almost twice that of the assault concentration. And that's

true also of the trichloroethylene.

So it becomes quite a significant situation to not only model and calculate, but also to develop a sensor system to handle.

This slide indicates the concept that we put forth in attempting to produce an end-of-service-life electronic system.

It's one in which we place multiple sensors inside the bed. And as the wave -- as the wave of solvent comes through the cartridge, it effects a response by the sensor. That information then is transferred to the user in some form, in this case, multiple LEDs flashing.

Back in 2005, May, we did an external peer review of our sensor program. And we had seven external reviewers come in and evaluate it. They represented regulatory agencies, user groups, respirator manufacturers, and sensor experts.

And the recommendations that came out of that were essentially to continue our interaction, our work with CMU, on sensor development, but also to expand the experimental program to include the

effects of sensor placement, temperature, relative humidity.

And we came away with a warm and fuzzy feeling about that because those were actually the initiatives that we had included in our research program. It's just that it hadn't matured far enough that we were doing that. So they were in our plans.

As a part of that effort to achieve those things, we built a cartridge simulator, which I have shown here in a cross-section. It amounts to a block of aluminum, which you see here on my right, an example that I brought along.

Inside, there's a chamber, an isolated chamber which we can pack with 50 grams of carbon. We can also place a sensor at most any location inside the carbon bed, as well as some external measurement devices where we can measure temperature, humidity, and, in this case, using a GC probe to confirm the concentrations that the sensor would see.

This is an animation of assembling the

cartridge simulator with the various components. The green part you just saw go in was the sensor. The black was the carbon bed, and then finally the retention.

This is the inside of the simulator showing the carbon retention material at the bottom with a sensor being located here in the center and our GC probe here on the side extending to the center near the sensor location.

Here we have a loading of the various steps in the cartridge simulator.

First we have showing the sensor exposed, a bed of -- a partial bed of carbon being placed in the simulator. The second slide shows the sensor being fully covered. And, finally, the capping with the fine screen to prevent leakage of carbon out of the simulator.

And down here in the corner, you can see the actual sensor board and the retaining ring that's used to secure the sensor system as well as the carbon bed.

Here we have some information we have

generated from the simulator. I thought one of the important characteristics of the simulator should be that it passed NIOSH certification for a respirator cartridge, organic vapor respirator cartridge.

And, in fact, it does because at the conditions we run here, using a thousand parts per million carbon tetrachloride, the 50 grams of carbon. Air at 32 liters a minute at 50 percent relative humidity, we should have a breakthrough of at least -- or a service time of at least 25 minutes.

Well, in this case, without the sensor, we get 96 minutes. And with the sensor, we have got 75 minutes.

So what we see here, we are certainly well within the NIOSH certification requirements. We see some diminution in performance as a result of the sensor. That's most likely due to its size and thus displacement of carbon in the bed.

Here's another chart showing the simulator data with the GC probe simultaneously. What we have done here is located the GC sampling probe at the

center of the bed, midway through it, at half height, and also collected data at the very end of the bed.

And the idea here is to demonstrate that we can get adequate data from the center of the carbon bed.

And interestingly enough, the service time for the full bed is 88 minutes in this case, again, at a thousand parts per million carbon tet, 32 liters and 50 percent relative humidity. While we are starting to see what would be defined as breakthrough for five parts per million at the center of the bed at 44 minutes.

It turns out in this case, it's exactly half, but that's not always the case. It does very little.

One of the other questions that commonly is raised is what about the relative humidity effects on the carbon bed.

So here I have got a plot showing the carbon in the -- packed in the simulator. Again, 50 grams. And we are exposing it to 75 percent

relative humidity gas stream at 30 liters per minute.

And what you can see here at the beginning, the carbon actually reduces the level of humidity in the exiting gas stream significantly. We dropped from 75 down to around 30. And we hold there for approximately 500 seconds. And then suddenly, we begin to get a rise in the relative humidity at the exit of the carbon bed.

But it doesn't go up to the 75 percent immediately. In fact, it rises somewhere around 50, 55 percent, and then asymptotically approaches the 75 percent over hours and hours. So it's a very slow process.

But we do see this significant change occurring early on, and then a leveling off.

So we think we can work with that in our sensor system because we hopefully will just see this as a baseline shift, this area here as a baseline shift in the sensor response.

One of the other interesting pieces of data we have gleaned from the cartridge simulator is

the temperature effects, and, in this case, the temperature effects caused by subjecting a carbon bed to relative humidity.

And you can also get temperature changes in the bed when you add an analyte because there is the heat of absorption, and that typically is an exothermic process.

Well, in this case, we started out by subjecting a bed of carbon, again, 50 grams, to an airstream of approximately 25 and a half degrees centigrade and relative humidity of about 30 percent.

And we continued to run that, let it equilibrate for about 20 minutes, and then jacked up the relative humidity to 80 percent. And you can see we get a significant -- I'm sorry, 60 percent. We get a significant rise in temperature of almost four degrees, and then it begins to diminish.

We left it run for a short period of time, and then added a gas stream of 80 percent of relative humidity. And you can see we got another temperature rise.

Continued on for a short time, began to see a diminution in temperature and then reduced the relative humidity to gas stream to 30 percent. And we see a significant drop off in temperature.

Now, at this point, we said, Well, let's see what adding an organic contaminant to the gas stream does. In this case, we added a couple of hundred parts per million isopropyl alcohol. And as you can see, we got a significant rise in temperature of the carbon bed. And when we turned the alcohol off, we began to see a diminution of temperature back to a normal ambient.

Obviously, temperature is a factor, and variations in temperature is a factor when you are attempting to place sensors inside the carbon bed.

This is a breakdown of our sensor system that we are currently using in the cartridge simulator. It consists of a silicon chip with six sensors on it. You see the six here that I'm identifying with the arrows, three of which are exposed to the environment and three are covered to protect it from seeing things like the organic

contaminant.

What we think we can do with this is by incorporating a four-way bridge, is to use those covered sensors to subtract out backgrounds such as temperature and noise.

The sensors consist of a spiral electrode arrangement. Looks similar to a burner on your electric stove, which you have got gold electrodes in a spiral fashion with a three-micron gap between those.

This entire section you see here, which is representative of the sensor over here, is a hundred microns in diameter.

And onto that, we jet a very special polymer. It has some unique properties in that it's a conductive polymer. This polymer series is called polythiophene, unique in that it is a polymeric conductive material as opposed to most polymers, which are insulators.

This is a cross-section of how that sensor is constructed.

It starts out on a silicon wafer, you see

at the bottom. Onto that is a surface of 500 angstroms of silicon dioxide. And plated onto that is 20 angstroms of titanium. And finally onto the titanium is deposited 600 angstroms of gold.

The reason for the bimetal system is because gold doesn't adhere well to silicon dioxide, but titanium does. So we use the titanium as the initial layer to adhere the gold, which is our final topical layer that we are very interested in.

Then onto that, we use an inkjetting process, similar what you would use in an inkjet printer to deposit microdroplets of these polythiophenes, which I just explained to you about being a conductive polymer.

You also see these wells on the side labeled SU8. Those are simply supports that are -- polymeric supports that are built up for supporting the cover plate.

And then all of that is contained in a two and half millimeter by two and a half millimeter silicon wafer that we then wire bond to the outside world.

It is placed in a TO-5 panel, which is a very common electronics package used in the electronics industry. The sensors are bonded from these bond pads to connections on the TO-5 package by 50-micron gold filament wire. You may be able to see some of those here on the sides.

As I said earlier, the entire package is approximately a quarter of an inch in diameter.

That then is capped, again, with the TO-5 package. And we have a hole in the center for our gases to enter into the system. That is then covered with Gore-Tex to help us get some additional filtering.

We use the Gore-Tex to help us prevent carbon fines from getting into the sensors. Since the carbon is conductive, that would be a problem, getting those in contact with the sensors. We also use it to inhibit some of the transfer of moisture into the sensor system.

And then this entire package is covered and placed inside the cartridge simulator.

And finally, I thought I would include

some data showing the response of the sensor system.

In this case, we started out with a bed of carbon, not the simulator in this case, but a bed of carbon in which we got a baseline, then began adding isopropyl alcohol to the point that we started to see breakthrough in the bed.

And this then is the sensor response that we see. And finally, when we turn the IPA off, the isopropyl alcohol, we saw a diminution in sensor response. So it did give us a warm and fuzzy feeling that we in fact could get a response from organic breakthrough.

While the system I have talked to you about now looks a little cumbersome, it's not our ultimate goal. Our ultimate goal would be to take the sensors you have seen, add the electronics to it, put that all into a single chip package, and add an antenna.

Reduce that about the size of a carbon particle so we could then distribute those throughout the bed of the cartridge. And having an antenna on it, we could then transmit RF power to

it, poll the sensor, take some readings, and have it transmit information back to a central processing unit. This would all be done wirelessly. That information then could be fed in some format to the user, either in the form of LEDs or a digital display.

Back in 2004, we did place an announcement in the Federal Register asking for companies, manufacturers who would be interested in partnering with us to come forward and work with us on the integration of sensors into respirator cartridges, and these were the companies that volunteered to work with us.

We also sent that same notice out to our electronic mailing list. And, again, these are the companies that responded.

And we expect to be working with them in the first quarter of 2007 on actually integrating sensors into the cartridges for testing purposes and evaluation because we think that integration is a major part of this program.

Back in June, we released a sensor program

newsletter that we intend to continue. This was done via the electronic mailing list. So if you didn't get that, and you would like to have it in future versions, which we do expect to send out as we have significant developments in the program, please get your name on the list so you can get a copy.

And finally, while I have been talking today specifically about the respirator application, the idea here is to produce a sensor system that's capable of being utilized in personal protective equipment in general. And we think this application has that capability.

So with that, I will open it up to any questions you might have.

MR. SPAMPINATO: Is this on? You showed a slide -- Phil Spampinato, ILC Dover.

You showed a slide where you mentioned that the sensor lowered filter performance, and I think that slide was something like 20 or 25 percent, and there was other information there, and you had a comment about it.

But do you see an inherent lowering of filter performance because of the presence of either the sensor or the chemicals involved here?

MR. SNYDER: Given our current configuration, yes, I do see a lowering occurring. However, that's not our ultimate configuration. These are really only experimental devices at the moment. They are large.

Our next iteration of this will be significantly less.

MR. SPAMPINATO: Thank you.

MR. SELL: Bob Sell, Draeger Safety.

Have you done any conditioning tests to look at the reliability of the sensor in the system?

MR. SNYDER: No. We haven't gotten to that point yet. We are just getting sensors to the point that we can collect data in this format.

Once we are comfortable we can do that and reproduce it, we will be doing things like that.

MR. HEINS: Bodo Heins, Draeger Safety, Germany.

To point the same out what Bob just said.

All these methods you have seen here, or you showed, very, are very good for laboratory measurements of such things, but I invite you to come to see how a canister cartridge is be done. It is something which happens in seconds.

How will you fit all of this stuff into the cartridge or canister? And the biggest question then is who has to pay for that.

It's everything which is thrown away afterwards.

MR. SNYDER: Well, let me comment on that.

I would like to work with the volunteer companies that we have got.

MR. HEINS: Yes. But are we waiting one and a half year already. We are rather disappointed that it is going so slow because it is a very important topic, but you have to follow your --

MR. SNYDER: We share that disappointment.

MR. HEINS: One of the major questions which has to be solved before is, Who is responsible for an accident which happens? Because a number of possibilities, what should have gone wrong.

First is that the sensor was wrong. It was wrong calibrated. The user didn't notice what the sensor showed, and a lot of other possibilities.

The biggest one probably in this case is that your sensor afterwards are different measurements. They are reversible. So if something happen, you cannot find out what that test time of the emergency case happened with it.

So, you know in your country, this can be very expensive.

MR. SNYDER: We recognize those issues, and we agree that they are important. But we think that we need an operable system first before we can those issues.

MR. HEINS: Okay. And I understood right that you at this time only had for OV, or at a maximum four or five OV gases sensors available.

MR. SNYDER: Yes. We have only been working on OV.

MR. HEINS: Because my concern is that it's much more interesting or important that we, for example, if you look to the CBRN topics, for this

types, for to have something.

MR. SNYDER: One of the virtues that we really like about this sensor system that we have been working out with CMU is its versatility. It is a multiple modality system. We are not locked into just a chemo resistant device.

So we think it will be capable of expanding to other agents that are not organic.

MR. HEINS: As far as I understood, your reactions here, chemical reactions at this time only possible for OV, and I have no idea if you have already something against other stuff, like gases or vapors.

Okay. But one very important point is the 90 percent requirement.

I think this is a requirement from the past which you have to think over. As I said some minutes before, the sensor will measure everything of what is going on actually, and that it doesn't stop at one time.

So and to show when 90 percent is done, that belongs also to the environment or the

conditions around. And if it changes something, then it immediately has to show something different.

MR. SNYDER: I think we need to demonstrate that we can't (sic) meet our requirements first. And if, in fact, that is the case, then we visit a requirement such as certification.

MR. HEINS: Did you ever calculate the costs for such an equipment? Not only the sensor, but you also need the measurement unit, too.

MR. SNYDER: Yes. One of the considerations that we have continued to have throughout this development program is to attempt to keep sensors under a dollar, and the electronics in the 20 to 50 dollar range with the electronics being reusable and the sensor being considered disposable.

MR. HEINS: For each canister? The cost for each canister?

MR. SNYDER: A dollar for the sensors for canister. But the electronics would be associated with the facepiece and removable so that they would be reusable.

MR. HEINS: But for one mask and one user only, so you need to have a lot of additional equipment.

And what is going on with the twin filter system? Do you need to have two of those things?

MR. SNYDER: No. We think the electronics will be such that it can monitor both cartridges, for example, if you have a two-cartridge system.

MR. HEINS: And another point which is going into the cost is that this sensor needs to be calibrated, and I guess this calibration will be only valid for a limited time. And I expect much less than the storage time of the canister.

It will reduce the storage time of canisters in this case and makes this, again, much more expensive.

MR. SNYDER: Again, a very good point.

We need to look at storage and aging of these devices to determine what the effects are.

I can't answer that question yet, but it's obviously a very important issue.

MR. HEINS: Okay.

MR. SMITH: Thank you. Simon Smith, 3M Canada.

You showed the effects of the humidity and additional solvent on the temperature.

I just wondered if your mathematical models are using -- take into account those temperature changes.

MR. SNYDER: Yes, it does.

Well, you -- in the model, you have to put in the ambient temperature.

MR. SMITH: The ambient, yes. But then the elevation, is that taken account of?

MR. SNYDER: No. That's handled by some other factors in the equations. Essentially, we have used Weaver (phonetic) equation, added some palangi (phonetic) potential theory to derive those.

MR. SMITH: Yes. Thanks. I think those were my only concerns. Thanks.

MR. VINCENT: John Vincent, North Safety Products.

Has any market research been done on what users, or premium users would pay for this kind of

technology? And, if so, could you share that with us? Premium and price, what they would pay for cartridges and these electronics for the facepiece.

MR. SNYDER: Yes. We had a research road map document developed for us several years ago by the Naval Research Lab, and we chose them because they had extensive experience in sensor development.

But they looked at various aspects, talked to user groups, respirator manufacturers, and so forth, and did come to some conclusion on cost.

And that was that an order of $2, 2.50 additional on a cartridge would be acceptable.

MR. SAVARIN: Mike Savarin, Bullard Technology, or just Bullard now.

I just want to say something on behalf of maybe the group. As someone now looking on the -- on the outside looking in, I think this all looks quite fantastic, the latest technology, new way of thinking about going about some of the issues.

From my perspective, I think it is extremely encouraging, although some of the commentators have obviously made it clear that has

taken quite some time, which is in my opinion is no surprise.

The group, of course, is going to want to consider when are they going to get something real, are real effects considered, and how much is it going to cost.

Yet the fact is we can't be anywhere near something practical in terms of costs yet. So I'm not quite sure why we are all hammering and thinking about how much the cost is going to be when it is pretty clear that -- what generation are we in now? I don't know if it is the fifth.

MR. SNYDER: Yes. In fact, the fifth has just gone to the foundry.

MR. SAVARIN: So it's looking like a few away yet from all of these facts that people are considering.

So I want to thank the group for letting me have an insight into what some of the critical aspects beyond what is some of the technology that you have proposed and put forward in your work today.

Thanks.

MS. FEINER: Lynn Feiner, North Safety Products.

In the real world, cartridges are not used continuously, but they will be used for an hour. Then they may be put away for a couple of days and used for a couple of more hours.

And have you taken that into consideration, and are you working that into your models?

MR. SNYDER: Yes. Interesting you bring that up because we do have a program this year which we are calling an extension of the multivapor model, which we are looking at just that aspect of it, that is people utilizing for a period of time. Then you have an interval of nonuse and reusing them again.

So we are attempting to do something about that in terms of our modeling program.

MS. FEINER: And when you are looking at organic vapors, are you looking for an organic vapor family rather than for specific organic vapors?

MR. SNYDER: In the modeling?

MS. FEINER: Yes.

MR. SNYDER: No. It's for an individual compound.

MS. FEINER: Okay.

MR. SNYDER: In fact, the models have a library of about 1,400 compounds of data in there, so you can go in, identify a compound, either by its IUPAC name or its common name.

And you can then locate data which you need to plug into the model for it, such as molecular weight, the vapor pressure, et cetera, polarizability.

MS. FEINER: Okay. Thank you very much.

MS. DEMEDEIROS: Edna DeMedeiros, North Safety Products.

Jay, I'm wondering in your experiments, okay, have you done what Lynn was saying where you take the cartridge, you expose it to chemicals. Then you put it away. Then you take it again, expose it to chemicals, put it away.

What's the effect on the sensor?

MR. SNYDER: Can't answer that yet. We

haven't done the experiments yet.

MS. DEMEDEIROS: So you're not to that point yet.

MR. SNYDER: That's correct.

MS. DEMEDEIROS: And your models that you are discussing, those are basically based on Jerry Wood's work?

MR. SNYDER: Yes.

MS. DEMEDEIROS: All right. Okay. Thank you.

MR. SNYDER: Okay. Last question.

MR. HEINS: Bodo Heins again.

You should point out what's the main purpose of this end-of-service-life indicator, should be -- is it for the user to be -- to get a warning when he has to go out, or is mainly as the first end-of-service-life indicators has been a topic for the employer, that he knows when he has to buy new cartridges.

Okay.

MR. SNYDER: It's designed to protect the employee.

MR. HEINS: And another --

MR. SNYDER: In a couple of ways.

As I mentioned, hopefully with having something obvious like this in the system, it would generate more interest in finding out what about change-out schedules and what about changing your cartridges, but the bottom line is to provide additional protection to the user.

MR. HEINS: Okay. And the last remark again to the environmental conditioning.

If you place these sensors inside the charcoal bed, what is obviously the case here, the canister will no longer be vibration tight, and this is a requirement.

If you have cable, it's more difficult. If you have no cable, the sensors will move inside the charcoal bed.

So have a look to the vibration tightness or -- approval for the canister if you would fit your canister -- your sensors in. Excuse me.

MR. SNYDER: Good point. I appreciate you bringing that to our attention.

That's obviously a point that we should take into account as we are looking at the integration of these sensors into cartridges.

MR. SHAFFER: Let's thank Jay for his excellent presentation.

And I hope we fixed the automatic fast forwarding of the slides. This is why you should never do a public meeting on Friday the 13th. I'm convinced of that now.

With that, I'll turn it over to Ziqing Zhuang. He is going to talk about NPPTL respirator fit test panels.

NPPTL RESPIRATOR FIT TEST PANELS

MR. ZHUANG: Okay. Yes. Good morning. First of all, I would like to thank my -- the team. Dr. Ron Shaffer has been helping me with the PCA analysis. And then Dr. Bruce Bradtmiller is the president of Intertek, and he was one of the principal investigators for the Army survey in '88 and has been in this field for many years.

And then also, this is the company that help Alan Hack develop the Los Alamos panel.

And Dennis Viscusi, he also has been working with me on this project. And also I was able to get Dr. Ray Roberge to help with another aspect of the project to look at body mass index and facial dimension. And then I was able to get some summer student and also my Ph.D. student to help me to work on this project.

Yeah. We all know that it is important to have a good fit test panel because they have been, yeah, relied upon to provide sizing reference for respirator in many applications. And as soon as the LANL panel was developed, they were used to do fit testing on various model respirator. And then those data were used to establish the first set of APF.

And then also, yeah, as I mentioned earlier, they have been used to develop a respirator. And then currently we have the Total Inward Leakage program, and we need this kind of panel also. Otherwise the testing may not be -- meaningless.

And then also various researchers have used the panel to include subject in the past.

Historically, yeah, at that time, back in earlier 1970, there was no civilian data. And so the Air Force data was the only data set available at that time.

And then so they cover -- they show that data was representative of the U.S. adults, and then face length, face width, and lip length was selected at that time. There was no scientific basis. There was no study to look at correlation between facial dimension at all.

And so basically, just use common sense or follow some of the idea from the Air Force, that when they designed the oxygen mask, they used lip length and face length to look at their size.

And then there is the LANL panel for testing full facepiece respirator. And it is based on face width and face length, and it range from 93 a half to 133 and a half for face length. And then for face width, it is from 117 and a half to 153 and a half.

And based on -- basically they use the mean of the male and mean of female subject and just

add two standard deviation to the mean of the male and the mean of the -- and subtract two standard deviation from the female to come up with the boundary.

And then for the upper lip and lower right corner, very few subject were there, so they delete those cells. And that left a 10-cell panel. And these are the number of the subjects that they recommend that we should sample from each cell.

And this is the one that's for testing half-mask respirator, and it is based on lip length and face length.

And it is similar. This time, it's not four column. It's like three column, and only two cell was deleted. But we still have 10 cells here. And each of the cells, these are the numbers that we will sample from each cell.

So right after the panel was developed and, yeah, we would have -- yeah, there was some concern. And then, but lately, we, yeah, look at the demographics of the U.S. population. And now it has changed a lot over the last 30 years. And then

also there some evidence that military data may not represent the diversity that you will see in the civilian population.

And we also have some scientific evidence as early as like 1975, as I mentioned, there is a study, like a fit test program that they -- fit test about like, yeah, 1,467 employee. And while they are doing the fit besting, they measure the employee, and they find out there are more than like 12 percent of their subject were outside the LANL panel.

And at that time, they recommend revision of the panel. And then also, Bureau of Mines in 1978 did a survey of, yeah, 48 male, and they look at the bivariate distribution of face length and face width. And they found out it is significantly different from the LANL panel. So -- and they said, oh, that's their Cartwright panel for male worker. And that is a very small sample. But that's what they claim in their study.

And then, yeah, we have various study later on. One of them is Ken, Dr. Ken Ostenstep

(phonetic) at University of Alabama, and I also talk to him as well.

And in his study, he found out lip length did not have any correlation with respirator fit. And that's one of the dimensions that Los Alamos used, but it's not relevant to fit.

And then also, lately, we have CAESAR project. It's called Civilian American and European Surface Anthropometry Resource. And this is a project conducted by the US Air Force. And they have about like 40 comments from different industry, the aircraft industry, automotive industry, and also the apparel industry as well.

So they -- but what they did was to measure like civilian American, except they focusing on whole body. Like they scan the subject using the whole body scanner, and they only measure like limited dimension was the traditional measurement.

So unfortunately, by the time I know that they have such a project, they only measure two dimension, and it was too late to ask them to do any other measurement, to add any other dimension.

So -- but I was able to use the face length and face width information and to look at how they differ from the LANL panel. And then at that time, I found out that like 16 percent of the subject were outside of boundary.

And so with that, we started to create a database of our own, detailing the face size distribution of the current U.S. respirator user. So we went to, like various industry in eight different state and national survey.

So whereas the data, we were able to confirm that. The Air Force is not reflective of the anthropometric distribution anymore. And that paper was published back in 2004.

And we also concluded that we need to revise the panel or come up with new panel.

So today I'm just focusing on the development of the new panel that are representative of the current US work force.

So we used the data that we collected back in 2003, and that paper was published last year, November of last year in the JOEH Journal. And we

described our study. We published the summary statistic for male and female. We also did a comparison between our data and the military data.

And just, you know, confirmed that our data like, yeah, it represent more diversified population and different from the military data.

So in that survey, we use a stratified sampling approach.

We look at male and female. We have white, African-American, Hispanic, and other. We combine Hispanic -- we combine Asian and Pacific Islander and also Native American into one group.

And we also arbitrarily like divide the population from 18 to 65 into three interval, like from 18 to 29, to 30 to 44, and 45 to 65. And our final tally of the database is 3,997 subjects.

And we use the 2000 US Census data to weight our subject, to match the U.S. adult, like 18 to 65. Then we -- so our estimates covered national estimate also. And at that time, we used traditional tools to measure 19 dimensions, and then we also scanned one-fourth of the subjects.

So the approach that we are using to develop the new panel, the first one is just we still use two dimensions, which is called bivariate distribution, and the other one is principal component analysis.

Yeah, the bivariate panel has been developed since like 2004, so it has been around for a while. But the PCA panel, it's the first time -- the first word is different, and now we kind of, yeah, keep on changing it and revising it.

And the criteria for selecting the dimension, the approach that we use is like it needs to be relevant to respirator fit. And what we can do is, now, it's not like '70 anymore. So we do have 30 years of information that -- eight study out there look at.

So we did the literature review, and we also talk to the expert, the ISO committee, the manufacturers. And so based on that kind of information.

And for -- we selected the two dimension for the bivariate panel. But for the PCA, we add

some more criteria.

We think that if the dimension you exclude and can be well predicted by the other one that you include, then that will be good. So you cover the facial characteristic very well.

And the number of -- the dimension is -- also, originally, you do all the measurement, and some of them are a little difficult to measure. You need to pressure the hair a little bit. You get a small number. Or if you don't press that much, you may get a larger number. And there are a lot of dimension that we try not to use, and select the one that we can measure with a little bit of accuracy.

And so the dimension -- yeah, this is the principal component analysis, and -- yeah. Principal component analysis defines a new coordinate system using linear combinations of the original variables to describe trends in our data.

And for our data, you may see that, like the subject on the left, after you finished analysis, you can identify which subject as small or they are large or they in the middle, or medium, or

maybe short and wide, or long and narrow.

So based on the literature review, we also look at our own study between fit and facial dimension also. And so we publish another paper there to report our finding and also summarize what people found in their studies.

And then also, at the ISO committee, the committee also look at this kind of things, and they said -- they also look at -- select dimension, what dimensions should be looked at or should be selected. And so -- and then -- so at that time, we think that lip length may not a good dimension to use.

And so the bivariate panel, we still keep 10 cells, and the 25 subject. We did not address that. Just keep whatever Los Alamos used at that time.

And then what we did was that we tried to make sure that at least two subjects for each of the cell. And then the real of the cell, like you want to match the population, the distribution of the population to your sample size as much as possible,

and then face length and face width were selected to define the bivariate panel in which may be used for both half-mask and full-facepiece respirator.

And this is the new panel. And you can see the range is quite different from the Los Alamos panel. It range from 98 and a half to 138 and a half, and 120.5 to 158.5. And then we kind of label them from one, two, three, four, five, six, seven, eight, nine, and 10. And these are the subjects that we recommend that you, yeah, can select from each of the cell.

I think they are all two subjects except Cell No. 4, where you come in five, and Cell 7, where you come in four person.

And this other percentage that we estimated for the population work force, whatever you want to call it, we don't have any profile like how many male, female for respirator user. We don't know how many like -- like each -- in each group, we didn't have that.

So all we can tell is like we can get the national statistic and then the work force, the

users group. They do it different from that. So that's our estimate.

And it's -- yeah, the results are 25 percent of the population are in Cell 4, and Cell 7 is 21.3 percent.

And based on that, that's why those two cell we recommend sampling more subject. And then the rest of the other cell have a range from 3.5 to 10.5. And so even some of them are larger than the others, we still recommend that it's important to sample at least two subjects from each of the cell.

And this is the scatter plot of the data of the subject that we have. And we still have some people with wider face. Our data, we cannot include. And we only -- but the panel does cover more than 95 percent of the population.

And these are the dimension that we use for the principal component analysis.

And, again, like this is the dimension that we use like based on the criteria that I mentioned earlier.

We look at literature review. We look at

expert opinion. We look at correlation analysis.

And these are the nine dimensions that we do not use. And then -- but they can be predicted by the 10 dimensions that we included in the PCA panel, with an R square of like .83 for maximum frontal breadth and p-value for that is .01.

So the one with the smallest R square is bitragion coronal arc, which is the one going above and then come down to the -- on the other side. And that's the one that I -- yeah, we think that is highly variable, and it's a little bit difficult to measure and may not be that related to respirator fit also. So this are the kind of dimension that we can exclude.

And this is the results. We run the principal component analysis. Back in the '70s, if you want to do this kind of analysis, it may take you a year or so. But now computer can do it for us, and quickly, just, yeah, several seconds or one minute or so, you can get the results.

And we included 10 dimension. We can also get 10 principal components, and that's the

analysis.

And then we have a set of eigenvalue. And then the cumulative is like just add whatever like, yeah, of the eigenvalue for each of the component, and then we have a total -- like percent of total variance, each component can explain. And then we can also calculate the cumulative also.

So and then one of the rule of thumb is like the eigenvalue. If it's less than one, you should not look at those component anymore. And that's one of the purpose to do the principal component of analysis.

Basically you can look at less variable, but then it can explain most of your variation and then do whatever you want to do with that.

And at this point, we -- early on, the earlier version of the PCA panel, I look at three dimension, and I think that's too complicated to use. And so we kind of scale back. But if we use this type of rule of thumb based on our -- like sadisco (phonetic) test or -- so we kind of decided to keep two principal component only.

And then these are the eigenvector, which is kind of -- a set of coefficients. And one is like PC1 is a bunch of original measurement, all the ten dimensions times the corresponding coefficient. And the sum is that score for that particular person.

And then PC2 is different, like it -- so the first one, they are all positive. And so the larger the dimension, the larger the PCA score, that's why you may have from small to large.

But the second one, sum of the coefficient, the loading, lateral loading, like .3598, these are the significant ones, very important, but then they are positive.

Like face length, nose protrusion, they are positive. That means like if face length is longer, PCA2 is larger also. And then -- but on the other hand, we have some negatives. That means if, like the face width or bigonial breadth or interpupillary breadth, like these are the dimensions of -- like the wider, the smaller the PC2 component.

So when you look at that figure or the distribution, the people on the left tend to be like the first principal component, they are small, and then it go to medium and large.

But then if you look at the vertical, Y-axis, the second principal component, then the people at the bottom, the smaller PCA2 variable, then they are wide.

They have wider face and then wider nose and then shorter face as well. And when the people on top, they are kind of opposite. They tend to have longer face and narrow nose. And so this is based on the distribution of our data.

This is the new principal component analysis panel.

And so the ellipse cover about 95 percent of the population, and the standard smaller ellipse cover about 35 percent of the population. And that can be changed.

Like some people recommend up to 50, and also some people say like a medium size can fit can fit 70 percent of the population.

So but at this point, from a sampling approach, you can do whatever you want.

And, basically, we, yeah, divide the ellipse into four area, like one, two, three, four. And in the middle, it's the same things. And so we have eight cells. And these are the estimate of the population in each of the cell.

And you can see the total column. Like 14.7 for Cell 1. They are all very uniform, around 15 percent. And in the middle like, five, six, seven and eight, it's about an 8 percent or 9 percent.

So the total is like 96.8. And these are the kind of number of subjects that we recommend to sample. And, again, this is a number that we do not do any statistical analysis to come up. We just keep on using the same number that has been used in the past.

So we did some comparison of the two panel. For the bivariate panel, it is very easy to understand and use. And since we came up with this panel, 3M already recruited subjects. And they were

able to put together two panels, identical, like all 25 subjects, and then all together 50 person.

They also did some fit testing on the data -- on the subjects. So it's very easy to use, and they only measure about a hundred people of their employee.

And then for our own TIL testing, we measure about 146 subjects. And most of them -- we used 87 of them. But then they are all one way -- like -- in one of the cell. And we excluded about 4.7 percent of the subject.

And so very easy to recruit subject.

And then, yeah, like in comparison with the LANL panel, like when I look at our subject, like 146 subjects, I did not see any subject. Like if you use lip length and face length, I did not see any subject in Cell 1, 3, and 6 of the LANL panel, and only one subject in Cell 2.

So from that, it kind of like validate the development of the panel here based on just a couple of the sample, like our own subject, and then the subject in 3M.

But then the bivariate panel may not exclude end user faces, like -- because you only look at face length and face width. And so someone has a larger nose, then you may still include that subject, or you don't consider that characteristic.

But then we did use our database. We also did a simulation to measure how many subjects you need to measure to fill the panel.

And on the average, like we get 91 subjects. It range from 34 to 264.

And then for the PCA, on the other hand, it is complicated and more measurement, 10 versus 2, but it's very like to include unusual face. You look at -- it's extremely long, extremely large, or very short nose. Those are the people that like, yeah, you can exclude them.

And then from our simulation analysis, you only need to measure 58 subjects to come up with the 25-subject panel. And the minimum of subject to measure is 28, but you can -- you have to measure as many as like 144 to fill the panel.

And so another advantage of the PCA is

like dimension including the model correlated with those excluded, too.

So at this point, we have developed two panel. And respirator designed to fit this panel, I expect it to accommodate more than 95 percent of the current US civilian work force. And both panel represent an improvement over the LANL panel used today. And it's up to the certification body or standard to select which one to use.

And this is, yeah, future follow up.

Right now, we are looking at differences among age or race and gender. And we also would, yeah -- in fact, I did some comparison study between the bivariate and PCA using the TIL data. And I was able to -- they all fit the panel, even the slide that Doug showed yesterday, scattered a lot. But if you look at a smaller -- like you group some of the cell, you can see very good pattern, particular for PCA.

Like if you have a large respirator, it tend to fit the people in the large cell. And then for small or medium, like we can see good pattern

there except all you do is counting. And we have a hundred more, and I can count maybe most of them. And it's kind of like not a statistical test, and I do not -- we need more discussion to make any valid conclusion there.

And then, on the other hand, we also do some headform using our three-dimensional data. And then the picture on the, yeah, right is our first generation of headform.

And so this is one individual from the medium. But then it is just too much like individual. So right now, we are looking at the second generation, trying to average them.

So average the dimension for the people in each of the cell based on a certain like sizing scheme, and then pick the one that are close to the average. And then -- and then maybe average a few subjects.

So by the end of the averaging, then we do -- that headform will not be a single person. It will be more representative a group of people.

And then we also have a study in China

that was that was like sponsored by, yeah, seven manufacturers, and, yeah, it was last year. And then we have finished the data collection and are doing some analysis right now.

And then in the lab, we also look at respirator fit, and we are also trying to measure three-dimensional parameter and see would that be a better prediction of respirator fit.

So this is a summary of what we have published, and then one is in the queue right now. It has been submitted.

So, again, each one document -- each of the step, that what we did, and address particular question scientifically.

And they have all been like going through peer review also. Even it's not as rigorous as like National Academy of Science Review, at least we need to get our leadership division to approve. And then before that, we have to get a review, four to five internal reviewers to review them.

And then after I submitted them to Journal, the Journal also have reviewer they have

there, like three people and the editorial review board editor to review it.

So it's not like an eleven member panel, NIOSH panel, but at least it has been going through a long period of peer review.

So, again, like this is my own view, do not represent a NIOSH at this point. So whatever NIOSH decided to use, that would be NIOSH policy.

Thank you.

Any questions?

MR. HEINS: Bodo Heins from Draeger Safety.

I cannot remember if I probably already gave you the suggestion. In the country where I live, in the north of Germany, in Schlesweig-Holstein, the capital city is Kiel.

And in Kiel, there is a university, and there is a professor who is working since several years on a survey for these dimensions.

Probably you should contact him because he is working a long time on it, and he has a lot of knowledge about that.

Thank you.

MR. ZHUANG: Good. I will get the information from you. Thanks.

MR. SPAMPINATO: Phil Spampinato from ILC Dover.

I couldn't tell from -- your presentation was very good, by the way, very comprehensive.

MR. ZHUANG: Thank you.

MR. SPAMPINATO: The any effect -- if any effect was there from deformities, for example, a broken nose, do you -- do you believe that the research and the data that you have would allow this 95 percent successful fitting, even in the face of deformities?

In other words, were they part of your sample population and so on?

MR. ZHUANG: That need to be investigated. Right now, like, we just make sure that these the kind of boundary for the subject.

But, again, when you only sample 25, it could be in the middle. It could be on the edge. So whether, like once you select 25 and how good it

can fit the population, that need to be verified. We cannot cram that.

But at least it cover the population, their facial characteristic, but how good -- and even by a certification test, you cannot be sure that it will fit everyone. No, that's not the case.

But then, like the panel, you can use it, so you can recruit subject. You can -- and do your own tests. But it will give you, yeah, good results, like from fitting characteristics standpoint.

MR. SPAMPINATO: Thank you.

MR. ZHUANG: Okay.

MS. DEMEDEIROS: Edna DeMedeiros, North Safety Products.

Ziqing, once it gets past the National Academies, because that's where it is now being reviewed, is NIOSH planning to adopt this and replace the Los Alamos panel for certification testing?

MR. ZHUANG: I guess that question can be answered later on. At this point, I am just working

on it. It will be up to policy branch.

I guess that Bill Newcomb is considering right now, and, yeah, Les also.

MR. BOORD: Yeah. I think in our presentations yesterday, we talked about our TIL program.

MS. DEMEDEIROS: Right.

MR. BOORD: And that would be the obvious place that we would -- that we have considered the panel, and we will continue to consider it.

So, yeah, I think eventually it will be -- work its way into certification through our TIL program.

MS. DEMEDEIROS: Do you think it would also take over for the isoamyl acetate?

MR. BOORD: I think eventually, that's the vision.

MS. DEMEDEIROS: Okay. And it would be more -- go out like to a Leonard certification?

MR. BOORD: Yeah. Actually, the TIL program, the concept is that that will be addressed through rulemaking processes.

MS. DEMEDEIROS: Okay.

MR. BOORD: So I see these different research activities coming together in the TIL program going through rulemaking into our certification activities.

MS. DEMEDEIROS: Okay. All right. Thank you.

MR. PFRIEM: Dale Pfriem, ICS Laboratories.

For Les, first a plea, then a question. Please hurry up.

And then second, when you put this into the certification procedures, if you would consider both panel methodologies so that those of us who would choose the more complicated method and deal with that, but then not have to scour the cities, looking for a Size 2, for instance, you know, less work, if you could give us that option. And those who have 500 employees from which they can choose from test subjects, they can use the simplified method, if you know what I mean.

MR. BOORD: Yeah. I think it's a good

suggestion, and it certainly will be considered as we go forward.

MR. PFRIEM: Thanks.

MR. BOORD: Thank you.

NANOTECHNOLOGY AND PERSONAL PROTECTIVE EQUIPMENT

MR. SHAFFER: Let's thank Ziqing for his excellent presentation.

Obviously, I'm Ron Shaffer, and I'm going to be giving the presentation on nanotechnology. I want to start off by acknowledging my coauthors, Pengfei Gao in the front row here, and Sammy Rengasamy, who is in the second row there.

Pengfei has done all of the work that they will be talking about today related to protective clothing, and Sammy has led the contracts or conducted the studies involving respirators, so I wouldn't be up here talking if it wasn't for their efforts in getting this presentation together.

This is the overview of the talk today. To start off, I will just tell you a little bit about nanotechnology and why there is some interest in it.

I'm going to spend a lot of time talking about the NIOSH document that's out on the web now. It's called our, Approaches to Safe Nanotechnology document. And because all of the findings and pieces of information are taken right out of that document today.

And then I will talk about what efforts we have done, literature studies and measurements on respirators, respirator filter media, and then protective clothing.

So what are nanoparticles? The definition is listed here. It is particles having a diameter between one and a hundred nanometers. So that's, you know, less than .1 micron sized particles, so they are -- let me see if I can -- so you are looking at basically right in this range and on down, so particles here and one smaller.

So those are the types of things that would be the smogs, fumes, tobacco smoke, viruses are particles in that size range.

Those are all naturally occurring or incident particles. What most people are concerned

about now are what is sometimes called engineered nanoparticles. So those would be things like carbon nanotubes, quantum dots, and things like that, things that are grilled -- not grilled, but grinded or milled during manufacturing that produce very, very small particles.

In fact, you know, that is becoming more common today. I mean, now you have got -- you certainly can buy pants from Dockers that have a nanocoating on them, your nanopants.

Nanoparticles are used in coatings in tennis balls. They are putting carbon nanotubes in the panels for car parts, for the autobody parts for a car.

So nanotechnology is expanding in its growth, and there has certainly been a lot of concerns that have raised recently about the health concerns of worker exposure to nanoparticles.

And this really isn't coming from NIOSH. This is coming from the manufacturers, the people that actually make those types of the products are coming to NIOSH and saying, How should I outfit my

employees? What type of respirators should they be wearing? What type of clothing should they be wearing?

And so we are being almost dragged into this by the large number of responses we are getting for questions.

So this is a slide that just outlines some of those health concerns. Make it very clear, I'm not a toxicologist, and everything that is listed on this slide is taken from the document that is shown on the slide here.

This is the -- NIOSH's Approaches to Safe Nanotechnology document. It's available on the website. I have got the link there. Certainly with that, you can contact me. I'll be happy to send you a PDF copy of this report.

Basically it summarizes everything that NIOSH knows about nanoparticles and nanotechnology and the Occupational Safety and Health concerns.

This document was generated by our -- we have a NIOSH steering committee I will talk about on the next slide that has generated this document.

If you go to that website and you look at the -- and you download the document, there is actually links on there where you can provide comments. There is a Federal Registry notice that has been set up to provide comments on our approach.

So if you think that we have missed some key literature references or we are understating or overstating the problem, please feel free to put comments into that docket, which you can get to through the website.

So I'm not going to read the words on here. I specifically just want to point out the third bullet, because the key point there is that the nanoparticles, generally speaking, have a larger surface area than the larger particles. That surface area is what gives them their great properties and why they are being introduced into so many products today. But it is also the reason why there is some additional health concerns.

So in the NIOSH Nanotechnology Research Steering Committee, the NTRC, it's a cross-divisional group. NPPTL has four

representatives, myself, Pengfei, Sammy, as well as George Bokosh (phonetic) who leads in the application side, we are looking at all aspects of the problem.

So we have got research projects in toxicology, risk assessment, measurements. There is even some interest now in looking at, you know, explosions and things like that. So it's a broad based program.

Obviously at NPPTL, our focus is in the controls area, in particular, PPE.

So, you know, why are people interested in this? Well, it has been brought to our attention that there is some concerns out there that nanoparticles could penetrate through PPE at higher rates than larger particles.

And it's not just, you know, my opinion on that. That has actually been documented in probably 20 or more research gap reports that have been written by a number of government agencies.

EPA, UK's Health and Safety Executive, all have indicated that PPE studies should be high

priority to make sure that the smaller particles don't penetrate at a larger rate than the larger particles.

In fact, there even was a recent hearing in Congress on this issue where they emphasized that more research really needs to be done on the occupational safety and health aspects of nanotechnology.

So we initiated two research projects, one looking at air purifying respirators and one looking at protective clothing.

We recognize that we can't do this alone, and we have established a number of partnerships. The big one that we established this summer was a memorandum of understanding with Dupont.

The Dupont company leads a consortium of about 15 to 18 large companies, the Intels, Proctor & Gambles of the world, that have a complementary research program to also look at a lot of the same issues.

So the memorandum of understanding spells out how we are going to collaborate with them to

share data, make sure that we are using common test platforms so that we can mutually get the best kind of data published in the review editor.

Also ASTM and ISO have been using some of the NIOSH reports in developing new standards. There is an E56 committee at ASTM that looks at nanotechnology, and they have a subgroup that looks at occupational safety and health.

And ISO also has a committee that is looking at this.

In addition, we have formed some partnerships with universities, and I will talk a little bit later about the work we have done with the University of Minnesota Center for Filtration Research.

So I will start off, I'll talk about what's in the safe working practices document from a respiratory protection aspect.

This slide just shows, it's the standard model describing single-fiber filtration theory, showing the basically the four mechanisms that particles get captured.

So on the X-axis is particle diameter, and on the Y-axis is filter efficiency.

I will interchangeably use penetration, which is just one minus -- penetration is basically the inverse of the efficiency. So if something is a hundred percent efficient, that means there was zero percent penetration. So I use those interchangeably.

So in this case, a higher number is good.

So filtration theory is and has been experimentally confirmed very well down to, say, about 20 nanometers, 20 nanometer particles, which is about the same size limit that the -- on some of the TSI commercial filtration systems cut off at.

So there is very good data down to there.

What's less, at least well experimentally verified is what happens to the smaller particles. In fact, there was one paper that was published as an abstract at a filtration conference that suggested that there was some -- an effect called the thermal rebound effect, that the particles literally bounced through the filter, particles less

than 20 nanometers.

And so what we decided to do was to collect some experimental data to verify that the filtration theory, single-fiber theory, is indeed intact for those smaller particles and valid.

So we -- at this time, we didn't have our research aerosol lab set up, so we got a contract awarded to University of Minnesota Center for Filtration Research, had them construct a nanoparticle test system, measured particles smaller than 300 nanometers through various types of filter media.

So these were not actual respirators, but they were the filter media. And just to verify that filtration theory holds for the smaller particles.

That report was -- that work was completed, and a final report was given to us in April. I'm pleased to say that that's actually available now on the NPPTL website. If you go there and look under research programs, you will find a link to the Minnesota report.

We are trying to get that cross-posted on

the NIOSH nanotech website so that you can get it from a number of different places if you want to take a look at.

But the Minnesota group is in the process of getting this published in a peer review journal as well. So the data will be available a number of different ways.

I will talk in the next few slides about the conclusions and some the data for the Minnesota, but I just wanted to mention that we have continued along with this project. And Sammy Rengasamy has developed a proposal that is currently in internal peer review right now that would extend the studies where we can basically are building a test system at NPPTL.

We are going to validate the previous work with NIOSH-approved respirators and also going to look at the effect of particle size on the face seal leakage.

So this is the test system that Minnesota developed. And I'm not going to go through all of the details here, but just wanted to point out that

they used silver nanoparticles in the size range of about three to 20 -- three nanometers up to about 20 nanometers size is the particles that you can generate with this furnace based system.

And this is some data from Hollingsworth (phonetic) and Vo's fiberglass filter media. So, again -- let's see if I can do this -- so, again, we are looking at penetration as a function of particle size for four different filter media.

And this data suggests that the smaller particles get captured very well by the filter media. In fact, for some of the particle sizes, they basically were not able to get any of the particles through the filter media.

They also looked at electret filter media. And again, you see a similar effect, that the penetrations are very small for the very small particle sizes. And this is through five different types of filter media.

Through the Center for Filtration Research, 3M is a member of that. And they collaborated with us, and Minnesota contributed some

data, where they tested the same types of filter media, but tested them at a setup in their laboratory.

So what you see here is combined, the data from the previous slide with some of the 3M data, so you can see the distribution from, say, three nanometers up to 300 nanometers or so.

So you see a very good connection between the two lines and, again, confirming that the smaller particles do get captured very well by the electret filter media. And that you see a less penetrating particle size in the range of 50 nanometers or so for those types of filter media.

So the summary from the Minnesota contract was that penetration decreased with decrease in particle size less than 20 nanometers.

The filtration theory or the filtration data supported the single-fiber filtration theory down to three nanometer in size. And we saw no evidence for thermal rebound.

Since the Minnesota work has been done, a group in Germany has also done similar experiments

and found similar findings. And I think there are other couple of research groups across the country, the Dupont folks as well, that are also in the process of -- with different particles generation system, are finding similar results.

So this is the interim recommendations that are in the Approaches to Safe Nanotechnology document.

Obviously our advice is still that respirators may be necessary when other control methods are not adequate.

There are no exposure limits for engineered nanoparticles, and the decision is still based on professional judgment. But what we can say about the respirators is that there certainly has been no deviation from single-fiber theory for the particle sizes that we have tested and Minnesota has tested.

And that you get -- when used within the context of an OSHA respiratory protection program, it is likely that the respirators will be useful for protecting workers.

Now I'm going to switch gears and talk about protective clothing.

Whereas we had a lot more data on the respirator side, we found a lot less information in the protective clothing. And, in fact, we found that there were no guidelines currently available to guide end users to select clothing or gloves for prevention of dermal exposure to nanomaterials.

There has been little data published on penetration. There is an ASTM standard that uses a 27 nanometer bacteriophage, and there is at least some data out there on larger particles.

We initiated a research study that actually looked at a broader set of issues on basically systems level aerosol testing for protective ensembles.

To that study, we have added some nanoparticle work. And Pengfei is the project officer for that.

I was at a recent conference just a couple of weeks ago, an elevated wind studies conference in September. I came across a number of military

reports that actually have studied particle penetration through clothing, which was something that we hadn't come across in our literature search.

The military studies are often buried in a government report that's very hard to find or in an obscure test method. But at the meeting, I did get some contacts, so we are in the process of gathering this new information.

But this slide just summarizes essentially some of the presentations that were at that conference, basically that aerosol penetration of permeable fabrics is also particle size dependent.

And the Battelle work in particular found that penetration was consistent with respirator filtration theory, although the penetration values were much larger because they are not designed to be respirator filter media, they find the most penetrating particle size and the very smallest particles, the nanoparticles, were captured much better than the larger particles.

What we have been focusing on at NPPTL is developing a passive aerosol sampler that would be

able to be placed on a person in a systems level test to measure particle penetration, something that would use minimal flow.

The feeling is that active sampling methods may overestimate particle penetration because you are adding an additional driving force. And our belief is that samplers should not disturb the PPE wearer environment.

So the concept that Pengfei and his team have come up with is to use a magnetic sampler, basically to use a very small magnet. And then use a challenge particle which has magnetic susceptibility. So that when it comes in proximity to the magnet, basically it becomes attracted and gets trapped in there.

So the idea is you don't apply an external sampling force, just enough force to get the particle to stick to the magnet so that, during handling, it would stay there.

And, you know, there is a number of advantages to this type of method. You know, certainly it would be inexpensive, and also a wide

range of particle sizes would be available if we used some iron oxide particles.

The detection would be accomplished, basically, you would take the magnet sampler out, take it back to a lab, use either a Colorimetric method or some other more sophisticated methods, SEMs or TEMs, or you can use some magnetic susceptibility.

I should say that this project was part of the project that went out for external peer review, and we are still responding to the some of the comments that -- that some of them did raise on some of the issues of the detection methods, and we are revising the proposal based on that.

Some preliminary data -- and I should point out this was collected before our aerosol lab was developed, so Pengfei did his best with the facilities in our clothing research labs.

You will see sort of a homemade aerosol test system that we built, and of course it has updated in the last year.

So this was some data from last year,

actually. This just shows the characterization of the passive aerosol sampler response. Basically, we filled this bag with an aerosol concentration just to see if the response of the sampler was proportional to concentration in the chamber.

We looked at two prototypes, and this is of the data that we got. You see that, yes, you do get a proportional response so that the more -- or the higher level of concentration of particles in that chamber, the more material is collected on the sampler.

It's not a -- the variation is more than what we would like to see, but we were happy to see that there was a proportional response. Certainly additional work is being done to validate this and to improve the method.

We also did an experiment that we actually tested the penetration through a swatch of fabric, in this case, a Nomex fabric. So we basically used an ASTM F-739. It's a vapor penetration cell. Put particles in the top half, put the fabric in the middle, and put the magnetic sampler at the bottom.

So there was an ambient condition, so we were not drawing the particles through the fabric sample. We used a prototype one for these measurements.

This is some the data that we got. This just shows the column on the -- the first column under the cell just shows type of fabric that was in the cell at that time. Nomex parafilm, which basically would be a blank. It would be nothing -- well, nothing would get through an opening, which would be everything should get through.

And so this is just some of the average numbers collected and the standard deviation and the number of experiments done.

We do agree that the variation is a little higher than what we would like to see. But as a proof of concept, we were encouraged that you could get a protection factor from a system, a crude setup like this. And it -- for a Nomex fabric such as this, we got a protection factor of six.

This is data that is a little more current from the aerosol research lab. Pengfei has built a

system this summer that generates a monodisperse nanoaerosol stream. This just shows a photograph of that setup. The data in the lower half here is basically the particle size distribution from three different experiments.

And then this just shows the long-term stability of that aerosol stream. So the next set of experiments would be to take this aerosol stream and basically put fabric samples in sort of a wind tunnel type configuration, a miniature one, and then subject that particle stream to the fabrics and then detect what comes out on the other side.

So this is just some preliminary data that we have been collecting.

So I want to summarize the clothing results.

The prototype, based on magnetic sampling, does allow a minimal or sometimes we call it a zero flow collection of the iron oxide aerosols. We do get a proportional response, but we feel that additional characterization is necessary.

We think that it will be applicable for

bench scale fabric penetration. Its applicability has already been shown, but further development is underway.

And finally, we do need to incorporate and analyze the results from some of these military studies to update the NIOSH recommendations so that that additional information is available to a broader audience.

And with that, I will be happy to take any questions.

At this point, we will -- some extra slides. We turn it over to Jon Szalajda, who is going to talk about reusability of filtering facepiece respirators.

REUSABILITY OF FILTERING FACEPIECE RESPIRATORS

MR. SZALAJDA: At this point, you know, with everyone having the PowerPoints there, I wish there was some sort of reward I could give you all for hanging in there until the end. But unfortunately, I think the only reward I can give you is keeping my comments brief.

With that, we will move into the

presentation.

I think at least a little bit of information to keep in mind is that the planning efforts for our research program and the reusability and handling of filtering facepiece respirators started some time ago. And it has been a very, very dynamic type of road that we have been on.

I think a couple of things of note above and beyond what I had mentioned yesterday was the ILM report that the Department of Health and Human Services requested, you know, in trying to identify issues associated with the reuse of medical masks and N95 filtering facepiece respirators.

And this topic has also, believe it or not, gotten the interest of Congress. And if you go through the current appropriations language, you would see that the Senate is recommending that we do an evaluation of respirators for effectiveness against transmission of influenza and other pathogens.

So what really precipitated that ILM study, DHHS's request to the National Academies to

have the Institute of Medicine conduct this type of evaluation.

I think when you look at healthcare recommendations for respiratory protection, CDC recommends the use of NIOSH certified N95 filtering facepiece respirators or higher for dealing, at least as far as providing the minimum level of respiratory protection for healthcare workers dealing with the influenza viruses or other infectious aerosols.

And it's apparent that, you know, in the event of a pandemic, looking historically at other pandemics that have occurred in the past century, that healthcare workers and the general public will potentially have an increased reliance on these types of respirators for infection control.

What did the IOM tell us? Well, I think the one recommendation that a lot of people latched onto is there is no recommendation for decontamination. But, however, if you go through and you specifically look at the specific recommendations that the IOM put forward, they had

recommended a couple of things.

And few of the things we are addressing in this research program deal with the efficacy of decon methods that a hospital setting could use on respirators to decontaminate the filtering facepieces without causing a negative impact on the respirator integrity.

The other aspect of that is the handling aspect, and I think Ron had mentioned earlier today this is probably the last time that you will see the title of this project the way it is.

We will probably modify the title to reflect the handling aspect of the system as well because, you know, part of the issue is if you do have a filtering facepiece respirator that has been contaminated with a viral agent, you know, what happens with regard to the handling of that respirator, what types of controls need to be in place to avoid an individual from contacting the respirator and becoming contaminated that way.

Another aspect of that also is looking at the re-aerosolization of the viruses off of the

respirator itself.

And I think one of the things that's going to be important, an important product out of this research is that when you think of in general that hospitals tend to have lower concentration of particulates in their settings, and the reuse may be more dependent on the infection control procedures that we evaluate in this process than the actual decontamination proceedings themselves.

This is the fun part of the presentation, at least as far as how we are going to do the work. And I want to at least identify a couple of the key players that are going to be doing some of the initial tasks.

Dennis Viscusi is sitting up here in the front in the yellow shirt. He is going to be our task leader for task one, which is going to look at the effect of decon on filtering facepiece respirators' performance.

And as part of that task, we are going to be looking at things, doing things, the base types of research activities that you would expect in any

type of study. You know, we are going to do a literature survey looking at trying to identify decontamination methods that could potentially be used against filtering facepiece respirators.

And in particular, I then think when you think about the materials of construction that roll into the fabrication of these types of systems, we are going to try to focus our literature survey to look at decon methods that may have been developed that specifically look at those materials.

We are also going to do some screening studies as part of this evaluation. Initially we are going to try to identify potentially up to 10 different types of decontamination methods for consideration and look at doing some initial screenings with N95 respirators and P100 respirators under two different conditions, either, you know, maybe depending on the type of decontamination, but maybe things along the lines of sprays or soaking the respirator in the solution and then determining any degradation in the filtration performance of the respirator.

Once we go through that initial screening, then we are going to go and expand and do some additional studies looking at a broader population of filtering facepiece respirators.

We are going to add surgical masks/N95 type systems. And we are also going to look at filtering facepiece respirators that possess some type of antiviral sterilization types of capabilities that are integrated into the respirator itself.

When you look at task two, the intent is to develop a standard test procedure, a reproducible test procedure that can quantify decontamination effectiveness. That effort is going to be led by Evanly Vo, who is sitting in the back of the room.

And the intent here is to look at developing a generic methodology that could be applied to any type of decontamination agent that could be used in the decontamination of a filtering facepiece respirator.

We are intending with this effort to collaborate with the ASTM F-23 committee to help us

with the development of that methodology.

Task three is going to address the concerns, the infection control procedure concerns about the survivability of a virus on the -- virus simulant on the filtering facepiece respirator where we are going to contaminate filtering facepiece respirators under controlled conditions and see what happens.

You know, it might be the case that in a contaminated respirator, if it's left alone for a day or two days, that may be enough to allow the reuse of that type of system.

Task four, the re-aerosolization, is going to be conducted on a contract that we have with the Battelle Columbus Laboratories, and this is -- we selected Battelle to do this work.

They had done initial studies for us using -- on re-aerosolization of virus particles, and we felt that the contract with Battelle was a good fit to conduct this effort for us.

When you look at the task and our relationships, the task five and six are really

dependent on the outcomes of one and two.

And one of the things that I think it's important to note when you are looking at the potential of developing a method, I mean, from our perspective, this project will still be a success even if the end result is there is no decon method that can be used to decontaminate, effectively decontaminate a filtering facepiece respirator.

You know, the one thing that we have noted and the IOM noted as part of the research was there really is a lack of research in this area.

And we are hopeful that by going through, you know, the comprehensive screening effort that we will be able to make a determination whether or not there are methods that could be used and then take them to fruition.

If not, then that's good information to have that can be relayed to the stakeholder community as a whole.

The other aspect to keep in mind, too, with this process is, this is really a respirator shortage emergency type of situation.

We don't anticipate, you know, any guidelines, at least as far as the methods are concerned, being implemented and put into practice unless there is an actual pandemic where there are respirator shortages in place. You know, this is not something to, you know, circumvent existing recommendations for disposal of contaminated respirators.

Again, it is addressing an emergency, you know, type of situation where there could be a respirator shortage.

But just to kind of finish the effort with the slides, in task five, we are going to take the results of task one and task two and take the method that was developed in task two, look at the promising characteristics identified -- or promising decontamination methods that were identified in task one, marry those two things together and see what happens.

Another product of task five is going to be when you look at the types of systems that have the antiviral capabilities, we are going to evaluate

in task five what the reactive by-products are of those types of systems, whether or not when you -- excuse me -- whether or not there are any by-products that we should be concerned about coming through the respirator into the breathing zone for people that are wearing those types of systems.

Task six ties things together. Once you have a decontaminated respirator, how does that affect -- how does any changes in the integrity affect the fit of the respirator to the individual. And this will all be tied up at some point in a nice final report which could be used to generate guidance documents for the stakeholder community.

One thing that some of you I know have noted that's in -- been recently published in the Federal Register notice is an announcement where we are looking to try to identify some of these antiviral technologies to consider as part of the candidate respirators that we are going to evaluate in the various tasks.

And this is a hierarchy of how we are going to make a selection on the types of

respirators that are going to be used in the system.

The first emphasis is going to be looking at existing products that are currently in the work force that meet and conform to NIOSH part 84 requirements.

Then we will go from there, looking at products that may be in the loop to be certified or products that come from manufacturers that have existing NIOSH certifications for other types of respirators.

But we also wanted to leave the announcement open enough that, if there was a novel technology that's currently being explored in the industry that could have a widespread application, we wanted to be able to address that as part of the study.

At this point, if you are interested in participating, all you need to do -- I'm the contact point in the Federal Register. All you need to do is send me an email or a letter just identifying your interest in participating or having your products being considered as part of the process.

We are not looking for hardware or anything else at this time. We are just looking to identify interest in the project. And then we will go through this hierarchy of consideration that was in the Federal Register notice, at least as far as to select potential candidates for inclusion in the project.

One thing I did forget to mention, I was talking about the research, the research itself.

We are in the process of developing a proposal. We have developed a proposal that we are going to use to execute the various tasks in the study.

Right now, we have gone through an internal review of the proposal within NPPTL. Dr. D'Alessandro has gone out looking for external peer reviewers looking for a combination of manufacturer industry representatives, academia, and stakeholders to review the proposal and give us suggestions and critique the work that we wanted to execute.

What I would suggest was, depending on

where you are in those different categories, ISEA and IAHA, the Industrial Hygiene Association, have the lead, at least in terms of identifying potential proposal evaluators.

So if you are interested in being part of the evaluation process, I would suggest you could talk to Dr. D'Alessandro or talk to your contacts at those organizations to indicate your interest in being involved.

The schedule, at least as far as how it is currently laid out, is resource driven. I mean based on the existing workloads within the branch and the other activities going on and the amount of resources that were identified by CDC to conduct the program, we have laid out a schedule to bring the project to fruition.

Where do we expect to end up with outcomes for this project? I think there's three different -- there is three specific areas where I think we are going to expand the knowledge base in these areas.

One is the performance data on the

filtering facepiece respirators that incorporate decontamination capabilities. Now, these are relatively new products to the market.

We would like to expand our knowledge base on them as far as their effectiveness and as far as any issues that may be associated with the use of those types of respirators.

Also, depending on how the project goes, there is a consideration for making modifications to what CDC currently recommends for reusability of filtering facepiece respirators.

And ultimately the product will come up with an output that can be used or can be established and documented in an ASTM procedure where others in industry or academia can go out and do their own studies to look at decontamination effectiveness on filtering facepieces with other agents.

Now, when you look at how we are conducting the program, we are going to be using a viral simulant which will hopefully replicate or represent, you know, animal viruses and is based on

existing research that's been done.

But that's not to say that there isn't an opportunity for work in other laboratories to look at other types of viruses and other types of settings to implement this procedure to develop knowledge and use that knowledge to protect workers.

So with that, I would be happy to take any questions.

MR. BERGMAN: Excuse me. Mike Bergman, the SEA Group.

Jon, thank you very much for your presentation, and it is a very important study that you are undertaking.

I would like to ask that you also consider looking at elastomeric half-masks with mechanical P100 filters as a complement to your study in that that type of system will also be a protective measure in the event of a pandemic influenza.

Thank you.

MR. SZALAJDA: Thank you, Mike.

I think that's a good consideration. You know, when you look at the CDC recommendations of

using an N-95 or higher, you know, half-mask respirators are used within the various settings, and that could be a good consideration for us to consider.

MR. GREEN: Larry Green, Syntech International.

And I was wondering about the studies regarding PAPRs for that. We have a lot of customers that -- in the health care that want to go to the even higher levels of protection and use PAPRs to get the reduced CO2 loadings for those critical personnels.

And I'm sure they would like to -- this -- all of this study is very closely related to what our customers are telling us that they want to see.

MR. SZALAJDA: Okay. That's a good comment as well. Thank you.

I guess, again, when you look at the initial approach to the project, we are closely following the recommendations from the IOM looking at the filtering facepiece respirators, but that's not say that eventually a project could evolve to

look at other categories.

MR. SELL: Bob Sell, Draeger Safety.

This is a kind of a two-person question by another member of the audience, but will you evaluate the effect on the electrostatic charge on some of these filtering facepieces after the decontamination?

MR. SZALAJDA: Well, the approach that we currently have defined is to look at doing the particulate challenges using sodium chloride that is currently done, you know, for the certification of filtering facepiece respirators.

So we will look at the contamination -- we'll do the contamination/decontamination, and then measure the filtration efficiency following that, and then make a determination of the delta between the untested -- or the unchallenged filtering facepiece and then the challenged.

Great. Well, thank you very much.

I guess what I would like to do before -- while Les is in the process of coming up, somewhere in your pamphlet, there is another survey to be

filled out.

And if you can take 30 seconds and fill that out and start filling that out while Les is doing his concluding remarks, I don't think he will mind.

Thank you very much.

MR. SHAFFER: Let's thank Jon for his talk.

CLOSING REMARKS

MR. BOORD: Jon, thanks for that last comment. That was the first thing on my list.

So, yes, if you could fill out the customer satisfaction surveys, we would greatly appreciate that.

And, again, remember that the lower left-hand corner has the date. There were two surveys; one for yesterday and one for today. So if you do that, we would greatly appreciate it.

And keeping true to schedule, we promised to conclude by 11:30, so after I take my one hour, we will be...

So I just have a few closing comments.

First of all, we certainly want to thank all of you for attending this meeting. We hope that the information that's been presented can be of some use to you, and we also hope that the result of the discussions and presentations have given you a greater awareness and understanding for, first of all, NIOSH, the institute, and some of the future directions and activities for the institute relative to the sector based program portfolio; the role that NPPTL has within the institute, and some of our programs and projects; and our operational strategies and focus for the laboratory.

And then, finally, the concepts and the ideas that we have and are building for the greater picture of the personal protective technology cross-sector for the institute.

The programs and the projects that we presented yesterday and today are a really good representation of the activities at the laboratory, but that's not everything.

There are projects and programs that have not been discussed during this meeting, but I think

they do give a very good cross-section of our activities.

I would encourage you to periodically visit our website for updates on various concept papers, concept -- standards development concept updates, and for other information relative to our research programs and ongoing activities.

You are certainly welcomed and encouraged to make contact with any of the researchers, program managers, or others from within the laboratory to share your ideas.

Yesterday, during the discussions, we mentioned the dockets. And I think in your information package, you have the listing of all of the open dockets that we have for the laboratory.

And there will be additional docket numbers added for the PPT cross-sector and perhaps for some of our ongoing research activities.

So, again, I would encourage you to visit our website to stay familiar with our programs.

And, finally, I would just like to mention that, from our perspective, I think the meeting has

been very useful.

It is always good for us to -- you know, it is good to go through the motions to say you have outreach. It's good to get out there and try to do things.

But I think that for me, it has really been a very good experience to have the opportunity to share with you the things we are doing and to have the side bar conversations and discussions to further facilitate the information exchange.

I would look to trying to do a similar type meeting on an annual basis. I think, as I explained yesterday, our systematic way for strategically moving the organization forward is based on the federal fiscal year.

We go through our systematic strategic planning, and we kick off the year in the first of October. And if there changes made to our programs, new programs added, that's the time when it really takes effect.

So I think there would be benefit to having a similar meeting to this on an annual basis

to keep you informed of what we are doing, of our new programs, and our activities.

So your customer satisfaction surveys are very important to help us make that decision.

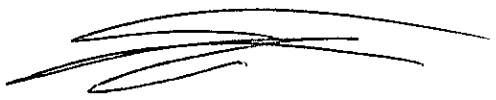
With that, I think we can adjourn this meeting. And, again, thank you for your time and your attention and your ideas.

Thank you.

(Whereupon, the proceedings in the above-captioned matter were concluded at 11:33 a.m.)

CERTIFICATE OF REPORTER

I, Joseph A. Inabnet, do hereby certify that the transcript of the foregoing proceedings was taken by me in Stenotype and thereafter reduced to typewriting under my supervision; that said transcript is a true record of the proceedings; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.



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