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

Thursday, October 12, 2006

ONGOING STANDARDS AND RESEARCH DEVELOPMENT

Commencing at 8:32 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

MR. BOORD: Good morning. My name is Les Boord, and I would like to welcome all of you to this NIOSH/NPPTL public meeting.

It is certainly good to see all of you here today, and I hope that over the course of today's discussions and tomorrow's discussions that you gain a good understanding for the types of things and work that is performed at the NIOSH/NPPTL laboratory.

Most of you, I would assume, already have registered and have your information packet. And in the information packet, you have a copy of the agenda. And there are a few things I would like to note on the agenda a little bit later.

That's my next slide.

Before we get to that, I would like to point out that all of the presentations and posters that are discussed and presented today are being presented by staff, NIOSH staff. So it's people from NPPTL and NIOSH.

So for these presentations, there are no guest speakers or outside speakers, not that we don't want any, but the content of the presentations are strictly from NPPTL.

During the course of the presentations, what we will do is have the presentations at the conclusion of the discussion. Then we will have a question and answer session.

And for the question part of the program, we would appreciate it if the person who has a question would go to the microphone in the center of the room, announce your name, who you represent and then the question.

That way, I think everybody can get a -- will be able to hear and understand what's being asked and then certainly what the responses are.

I think at the manufacturers meeting we had yesterday, there was a little bit of difficulty with some of the questions because we didn't have that microphone.

So it would be appreciated if you could do that.

I would also point out that the meeting today is being recorded and transcribed. So there will be a recorded document for all the contents of the meeting today, including the questions and any discussions.

I will also point out that the meeting is being videotaped. And the purpose for videotaping the meeting is for NPPTL to look at the videotape as one of our outreach mechanisms.

So we want to capture some of the segments for the meeting and perhaps use it in future outreach activities.

I just wanted to point that out. The video recorder is in the back of the room.

Now to the agenda. Basically, the way the agenda is laid out, we have several categories of topics. The first session that we have this morning will be a research oriented poster session.

So during that presentation, or that series of presentations, the various researchers will be presenting a short discussion about their research activities and a poster that supports their

project.

And as you can see, the posters are located around the room. So first session will be the poster session.

Following that, we will have discussions on our standards development activities.

That begins at the 10:30 session this morning, and will actually extend throughout the afternoon, I think concluding at 3:30.

So our policy and standards development activities will be focused on, and there we will have presentations on the various projects that are occurring within our standards development.

To round out the day then, we will have a discussion on our quality performance initiatives, some of the things that the laboratory is doing to instill quality into our programs and processes.

Looking into the content of today's discussions, I think there are a few changes to the agenda that you have that I would like to point out.

The first one is on the poster sessions. The University of Maryland multifunction PAPR poster

will not be part of that presentation. The content of that information and project will be addressed in the policy and standards development discussions for the PAPR -- discussions later in the day.

The second change is the 1:15 sessions, policies and standards development sessions addressing the CWA live agent testing, CBRN and CBRN topics, that entire session will be switched for the 2:30 session, which is a policy and development standards topic on our Total Inward Leakage program, our quality assurance module and the administrative module.

And both of those have an allotment of about one hour for the presentation, so I think it's an even switch. And the reason for making that switch is we have a guest participant who has a -- is interested in the TIL program and the QA program and would like to see those, but he also has an early flight, so we are going to make that slight modification.

Then finishing out today, as I said, would be the quality performance discussions.

Tomorrow, we will resume the meeting with the discussions on research projects, and these research discussions will be presentations, presentations followed by the questions and discussions that -- parts of these presentations as well.

And then, we will also have a quality of science discussion at the end of the day tomorrow.

The meeting should wrap up on schedule, so I would anticipate that tomorrow early afternoon we should be wrapping up the meeting.

And, again, the objective of the meeting today for NIOSH/NPPTL is to provide program information to our customers and stakeholders.

We thought that this would be a good opportunity for us to share with you the types of things that we are doing, the projects that we are working on, and to create dialogue and hear different discussions and different points of view relative to those programs and projects.

And before we get into the technical discussion today, I would like to give you a brief

overview of NIOSH and NPPTL. I would like to give you a little information relative to the operational strategies that we have at the laboratory and then a brief discussion relative to the organizational structure, and more importantly, to set the stage for the different topics and activities within the laboratory and how they are -- which branches they occur in to give you a better understanding for the laboratory in general.

And I think most of you in the room are probably familiar the current paradigm for Occupational Safety and Health in the United States. And probably many of you have been working with it since the beginning.

But the current paradigm that we have was established with the Occupational Safety and Health Act of 1970. And that act was to assure safe and healthful working conditions for working men and women in the United States.

As part of that act, the Occupational Safety and Health agenda was really set up to be addressed with two arms within the federal

government.

And the first of those was the regulation and enforcement arm, which is the Department of Labor. And then within the Department of Labor, we have the Mine Safety and Health Administration, MSHA, and we have the Occupational Safety and Health Administration, OSHA.

And I think we have participants in the audience today, certainly from the OSHA side of that regulation and enforcement activity.

The parallel arm addressing occupational safety and health issues is the Research, Training, Prevention, and Recommendations arm. And that is located in the Department of Health and Human Services within the Center for Disease Control and operated by the National Institute for Occupational Safety and Health, NIOSH.

So when you look at NIOSH and the laboratory, our agency structure, as I have illustrated here, we are part of the Health and Human Services agency within the Center for Disease Control, National Institute for Occupational Safety

and Health. And we have the various divisions and laboratories that comprise the Institute.

And those divisions and laboratories are many, as you can see on this illustration. I believe there are 16 different laboratories and offices that comprise the Institute.

Some of them I'm sure you are familiar with. The Division of Respiratory Disease Studies, DRDS; Division of Safety Research, DSR; Health Effects Laboratory are located in Morgantown, West Virginia.

We have the Education and Information Division, EID; the Division of Applied Research, DART; Division of Surveillance Hazard Evaluation and Field Studies, DSHEFS; Office of Compensation Analysis and Support; Research to Practice -- Research to Practice, r2p. That's a theme that you will hear more and more throughout the day.

And those offices and laboratories for the Institute are located in Cincinnati.

Then we have the Spokane Research Laboratory on the right side of the column. We have

the Pittsburgh Research Laboratory with whom we share the campus in Bruceton, and we have the Office of Extramural Programs, which is located in Atlanta.

And then, of course, we have the Office of the Director for the Institute, which is located in Washington DC.

And at the meeting this morning, we are honored to have a representative, Mr. Frank Hearl, who is the Chief of Staff for the NIOSH Office of the Director. And I need to say that we are really pleased to have Frank at the meeting today.

So while he is the esteemed Chief of Staff for the Institute, Frank is really, I think for the laboratory, represents a little bit more. He helps us on many occasions to navigate through the systems and the processes that we need to deal with in order to accomplish the many things that we like to do.

So Frank is certainly a welcome guest for the public meeting today, and with that I would like to introduce Frank.

ADDRESS BY FRANK HEARL

MR. HEARL: Thank you, Les. You made me

sound a little bit like an expert, but I did stay at a Holiday Inn Express, so I guess that works.

I would like to bring you all greetings from our institute director, Dr. John Howard, who I'm sure would love to be here today but has some conflicting appointments.

And I want to give thanks to Les and the leadership team at NPPTL for putting together this stakeholder meeting and also to the speakers and poster presenters who you will be hearing from soon today who will be telling you a little bit about the research going on at the laboratory here and also the activities going on in the certification programs.

And also I would like to thank all those -- everyone else who helped organize the meeting here today.

I would like to kind of touch on three things in the few minutes that Les has given me to chat about NIOSH in general and to talk a little bit about one, NPPTL's important role it plays within NIOSH.

Second, I want to give you a little bit of insight into what NIOSH is doing to help improve our quality and relevance of our programs overall and our emphasis to improve and increase the impact that we actually have in the workplace.

First, talk about NPPTL. NPPTL is -- and its forerunner components -- have been critically important to NIOSH and to the American workers.

For over 35 years, they have helped to assure that U.S. workers receive quality, reliable protection from exposure to industrial toxic gases, vapors, and dust.

And recently, of course, the programs have expanded to include some new agents that we have had to deal with, the chemical warfare agents, through our CBRN program. And this is all very important to first responders and those involved in homeland security.

We have also been expanding our research here at the lab at NPPTL for dealing with emerging hazards that we are facing in these current days, things such as dealing with the unknowns of dealing

with things like nanomaterials and also the particular problem with dealing with infectious agents that we face from either natural or not so natural sources.

So NPPTL plays a critical and vital role within NIOSH, and it really does cut across all sectors of research that NIOSH has in its program portfolio, and so we really very much value the work done here.

In terms of overall NIOSH directions, one of the things that Dr. Howard, through his leadership, has done is to help us to direct our programs to try to improve our quality and relevance of our programs.

And what we recognize is that it's through outside independent external peer review that we really get the kind of feedback that we need to be able to better focus our programs, to redirect things and to give us some guidance for the future.

And in order to do that, what we have done is we have entered into a five-year agreement with the National Acadamies, through the National Academy

of Sciences and Institute of Occupational Medicine to review all of the various NIOSH program activities.

And we are doing this in basically reviewing 15 different program areas over five years through this agreement with the Academies.

The Academies have set up a framework committee that has established rules and procedures and are setting up independent committees that will look at each of the program areas, committees that have the particular expertise to be able to evaluate our programs for impact, relevance, quality, and future directions.

Now, you out there as stakeholders of NIOSH and NPPTL is one of the program areas -- or personal protective technology, which is predominately located here at NPPTL, is one of the areas that will be undergoing review by the National Academies.

And you may well be contacted by some staffers from the Academy or maybe even asked to come and present to them and let them know how the

programs from NIOSH have impacted you and the effects you have had and asking your opinions. So you may all be actually involved in this process.

The other thing that we have done is we have established an Office of Technology Transfer in Cincinnati and staffed it up over the last year to implement our research to practice, r2p, initiative.

One of things we recognize that NIOSH research -- if we just put it out as a journal article or as a NIOSH numbered publication, well, that's not a good enough end point.

What we really need to do is develop partnerships, formal and informal, to help diffuse the information that we have learned from our research, to make it effective and actually put to use in the workplace for the protection of U.S. workers.

And as part of this, we also recognize the need to involve our stakeholders on an up-front basis, that is, as we get into the program planning.

As each project is developed, we need to get input from you. And that's where meetings like

this really come in handy, to be able to get feedback to make sure that the things we are researching are going to be things that you will be able to put to use to help protect U.S. workers.

You can see this, and we have done this in a couple of ways. One, you know, this is the beginning of our second year of the National Occupational Research Agenda, NORA.

We completed the first ten years of the program, and the new ten years of the program just launched this year.

We held stakeholder meetings in 12 different cities in the last nine months or so, and we have taken input from over 1,500 people at those meetings, as well as we have created a website so that we can collect feedback through the web on all of the NIOSH program areas.

So we are looking for input, and we're listening.

So stakeholder meetings like this focused on a particular topic are also very useful to us.

And I want to conclude by thanking all of

you for taking your time to come to this meeting to learn about what is going on at the NPPTL and to maybe look for opportunities for partnership, to look for things that you can offer to us as helpful guidance and suggestions as you, stakeholders, give us feedback and input.

We very much want to hear from you, and we value your input a great deal. So it is very important that you come forward and speak, or give us the feedback at a later time through the email or through our website.

So thanks again, and I hope you have an enjoyable two-day meeting here and that you find it both interesting and productive.

Les.

CONTINUATION OF OPENING REMARKS

MR. BOORD: Thank you, Frank.

Just to touch bases a little bit on some of the things that Frank had mentioned in his words to you is relative to the NIOSH research program portfolio.

As Frank had mentioned, this year launched

the new leg of the NORA program, and that program is being designed around industry sectors and is really the leading edge of the entire NIOSH research portfolio.

So, as you can see in this illustration, we have the eight different industry sectors, agriculture, construction, healthcare, mining, manufacturing, services, transportation, and wholesale trade as the primary industry sectors geared for the NORA NIOSH research program portfolio.

In the second column on the slide, you see additional cross-sector programs. And these cross-sector programs are the types of initiatives and programs that the Institute has that really cut through the various industry sectors indicated on the left-hand column.

And it is interesting to note that about three-quarters of the way down the cross-sector programs, you see the personal protective technology cross-sector.

That cross-sector for the Institute is

being managed from the laboratory in Pittsburgh. And at tomorrow's discussions, the first discussion in the morning, we will tell you more about the work that's being done to develop that PPT cross-sector research program and portfolio.

Then in the far right column, we have the major emphasis areas for the Institute. The economic exposure assessment, engineering controls, and so on.

So with these three areas of focus, we have the entry sectors, the cross-sectors, and the emphasis areas. Those will be the road map from which the NIOSH research agenda is designed and implemented as we go forward.

And with that, what I would like to do now is talk a little bit more about some of the aspects for the laboratory, and the laboratory being NPPTL, which is located at the Bruceton research center.

Approximately 18 months ago in the laboratory, we introduced a program that we refer to as our APEX program, which is Achieving Performance Excellence.

And that initiative is basically what it implies. It is our program and our process to instill continuous improvement into the processes and operational aspects for the laboratory.

Our APEX program is patterned after the Malcolm Baldrige (phonetic) criteria comprising seven different categories. And those categories are leadership, strategic planning, customer market focus, measurement analysis, knowledge management, human resource focus, process management, and business results.

Within the laboratory, we have identified seven category teams with a leader for each of those teams to direct the activities and lead the activities in those specific areas.

One of the true benefits of this program is that it enables the laboratory to provide a focused strategic direction for the priorities for the laboratory.

And in that aspect, we have identified seven priorities for the laboratory. These are standards focus, personal protective technology

evaluations, science center of excellence, outreach, partnerships, human resource excellence, and achieving performance excellence in our APEX program.

A little bit of the detail behind each of these for the standards focus, the priority is to increase our focus and enhance the Laboratory's leadership role in the development of standards pertinent to work-related personal protective equipment.

Personal protective technology evaluations. Improve our technology evaluation and respirator certification processes.

Science Center of Excellence. Improve the quality, consistency, and dependability of the science delivered to our customers and stakeholders through a program of rigorous evaluation.

Outreach. Improve our communications with stakeholders and customers.

Partnerships. Increase quality and improve the effectiveness of partnerships with organizations in NIOSH-defined sectors, industry,

government, and academia.

Human resource excellence. Improve the management of our human resources.

And then, finally, achieving performance excellence to demonstrate performance excellence in all we do.

So I think within the content of those seven priorities, I think you are going to hear and see many themes that are going to be recurring over the next couple of days of presentations and activities within the laboratory.

Outreach. The meeting today is part of our outreach initiative. So it's very important to us that we stay focused on these seven priorities as we go forward to carry out our programs and projects.

What we have done within the laboratory is identify a value creation system. And this is a little bit of a complex illustration, but there are several key things I would like to point out.

As Frank mentioned, the outputs of any research program or activity are certainly

important, but that's not the end of the story. We need to have relevance and quality with those outputs.

So as we progress from the outputs delivered by the laboratory, we get into the world of intermediate outcomes, and the ultimate public benefit of those outcomes is to people who use personal protective equipment.

So we have this process of outputs and intermediate outcomes to achieve the public benefit.

In achieving that and in accomplishing that, we have many partners that we need to work with, our technology developers, the users, all the stakeholders in this room, regulators, our Congressional representatives, administrations, and state organizations.

And all of those stakeholders and other partnerships are helpful to us in achieving the outcomes and benefits that we ultimately want to achieve.

But they are also important aspects to provide input to this little -- this item here,

which is basically our surveillance and environmental assessment.

So while we are producing outputs, we are making them available to our stakeholders and customers and users, and we also have our receptors open because we want to have dialogue with the users and the stakeholders to learn more about the outputs that we have delivered and feed those into our assessment and surveillance activities.

It is also interesting to note that the intermediate outcomes aspect of our value creation system is also a key component because we recognize that a standard, a personal protective technology standard is recognized as an intermediate outcome.

So by identifying a standards focus for the laboratory, we are jump starting any of the programs that we undertake in the laboratory with a targeted intermediate outcome.

So at the inception of our programs, we like to have that intermediate outcome identified.

And I think as we go through the discussions in the poster sessions today and

tomorrow, you will see more and more of that connection towards standards.

The other thing that I would like to point out is the flow of this value creation system is pretty obvious if you follow the arrows.

The real challenge is then taking this information and factoring it and processing it through the inputs into new programs that the laboratory undertakes.

And for that, we have identified a strategic planning process. I think it is time that we talk about this process today because, as most of you know, the federal government operates on a fiscal calendar that ends September 30, begins October 1.

So today, being October, we are in the first month of the fiscal calendar year for 2007.

The process that we have identified here actually takes that surveillance and environmental assessment activity and addresses that in the early stages of this strategic planning process.

So, as you see on the flowchart here, we

have the environmental assessment occurring in the first fiscal quarter of the year.

So what we are in the process of doing with this, as one of our research activities and other activities identified here, is we are starting to build the input data that we will take into a summit meeting in the laboratory, occurring the beginning of next year, which will then be used to identify new programs, continuing programs, allocations of resources, and to eventually hone that down to an operating strategy for the next fiscal year.

So the process that we follow and will follow as we continue to develop the laboratory is as illustrated here.

So within the laboratory, how are we organized and structured?

Basically we have Office of the Director and three operating branches for the laboratory and various support activities for the branches that are housed in the Office of the Director.

We have a program manager component that

is -- crosses the boundaries of the individual branches, and we have several program manager positions that are aligned with the technologies of the laboratory, but also aligned with the industry sectors of the NIOSH NORA program.

We have technical support aspects, including our IT functions, our statistical analysis that are housed in the OD, but then provide support services to the various branches.

We have the Associate Director for Science, which is the driver for the quality initiatives for the laboratory.

The peer review and the review aspects that Frank mentioned, and the importance of those review processes for building quality into our program and building in the relevance are led through the Associate Director for Science.

Then we have the three operating branches for the laboratory, Technology Evaluation Branch, which is the home for respirator certification.

We have the Policy and Standards Development Branch, which is obviously the area

where we focus our standards development activities.

And then the third branch is our Technology Research Branch.

Over the course of today and tomorrow, you will hear about many of the programs, particularly in the Policy and Standards Branch and the Technology Research Branch.

The topics of respirator certification are fed by these other branches and were topics discussed at a manufacturers meeting yesterday.

I would like to talk a little bit about some of these major areas of operation for the laboratory.

The first is our quality performance initiatives. And, as I mentioned, this is led by the Associate Director for Science, Maryann D'Alessandro.

And during the course of the discussions at the end of today and tomorrow morning, we will hear more about some of our quality performance programs, our National Academy of Science involvement, which really ties into the programs

that Frank mentioned, but also expands that initiative very specifically for programs at the laboratory.

Our customer surveys. It is a very important part of our quality process to hear from our customers and know how what we are doing is being received and perceived.

And then the various committees and conferences that the laboratory participates in.

So as we go through the discussions today and tomorrow, we will learn more about that.

For the technology research, the branch chief for that is Ron Shaffer, who will be actually leading the discussions for the poster session and the research activities for the laboratory.

And the focus, the technological focus for our research activities is embodied in four different PPT areas. The first is sensor technologies, respiratory protection, ensembles, and then human performance.

And as we talk about our research programs, we will learn more about our activities in

each of those areas.

The Technology Evaluation Branch is led by Heinz Ahlers, the branch chief for that activity.

As I mentioned, this is the home for respirator certification and the audit. They are postcertification activities that take place.

Many of you are already familiar with our respirator certification program. Since the inception of the NIOSH respirator certification program, which goes back to the Occupational Safety and Health Act of 1970, there have been more than 8,500, probably closer to 9,000 approvals, respirator approvals that have been issued.

Those approvals had been issued to approximately 90 different manufacturers with more than 100 manufacturing sites located around the world.

So the respirator certification program has really been the cornerstone for the laboratory when NPPTL was established.

Some of the audit or postcertification programs that we conduct on a routine basis in the

branch is our certified product audits whereby we obtain and test and audit product, off-the-shelf commercial product.

We have a component for manufacturing site audits to audit the program quality for the various respirator manufacturers.

We have a certified product investigation program which conducts investigations into reported issues and occurrences with the use of a certified product.

We have our Firefighter Self-contained Breathing Apparatus Evaluation Program, which looks at evaluations of SCBA used within the fire service industry.

Then we finally have our long-term field evaluation program which primarily addresses self-contained self-rescuers, and this program goes back to the early days of the establishment with the U.S. Bureau of Mines.

Within our Policy and Standards Development Branch, Bill Hoffman is the branch chief. And many of the topics and projects that are

housed within that branch are CBRN respirator standards, our powered air purifying respirators, closed-circuit escape respirators, quality assurance provisions, and Total Inward Leakage. And most of those you will hear presentations on during the next two days.

So finally, the mission for the laboratory is to prevent work-related illness and injury by ensuring the development, certification, deployment, and use of personal protective equipment and fully integrated, intelligent ensembles. And the corollary to that mission is that we intend to accomplish this through the advancement and application of personal protective standards.

So that's a brief overview of the laboratory.

And since I am running over time, I will expeditiously try to get to the next part of our program.

And for that, I would like to introduce Dr. Ron Shaffer, who is the branch chief for our research branch. And Ron will direct and moderate

through the next part of the program, which is a poster session.

And he will key you in to the process of how we are going to conduct that part of the program.

Thank you.

FIVE-MINUTE PRESENTATIONS ON CURRENT NPPTL RESEARCH PROJECTS

INTRODUCTION BY RON SHAFFER

MR. SHAFFER: Thank you, Les.

Some of you that were here yesterday, there was a talk by Maryann D'Alessandro about the Customer and Market Focus Team and a survey that they did last year in conjunction with the Office of Personnel Management, where they contacted stakeholders, end users, and asked about -- various questions about NPPTL and its performance.

I think Maryann will have a talk about that actually at the end of the day today.

One of the questions on that survey was people were asked about their awareness of NPPTL research programs.

And it was surprising to me, we didn't get the kind of response that we thought we might get. Only 38 percent of manufacturers gave us a favorable response, and 56 percent of end users gave us a favorable response.

So as part of our outreach efforts to sort of improve the awareness of what we are doing in our research -- in terms of our research projects, trying to increase the transparency of the projects that we are doing, how we select the projects, and how we execute them and how we can get you involved, we are increasing our awareness in these areas.

And so, as part of that outreach effort, we are focusing on the research projects today. This is -- having this poster session this morning is just one step in that process. We are trying to improve our performance in that area.

So before I go into detail about the poster session itself, I wanted to give you a broad, you know, review from 10,000 feet of what we do in the research branch, and that will help set the stage for the research posters that we are going to

talk about next.

And I'll actually expand on this. I have another presentation tomorrow morning where I will expand on what we are doing in the branch a little bit more, so this is just a one-slide snapshot.

The branch, as the name implies, Research Branch, we are out on the leading edge of technology, so we are the ones that are assessing new technology and how it can affect personal protective equipment. We are developing new test methods where appropriate, and also helping to set performance criteria and assess new and emerging hazards.

And all of this is done within the context of supporting various standards, whether that be 42 CFR or an ASTM, and NFPA and ISO standard. And you will hear that through the various talks today, that every one of our projects, at least in one way or another, is involved or is -- the goal is to impact a standard or a guidance that NIOSH or CDC would put out.

The four research areas that the lab

focuses on are shown on this slide. Obviously respiratory protection is the bread and butter of the laboratory.

We also have a program in sensors and electronics. Primarily that's how they integrate with personal protective equipment and personal protective technologies.

To date, our sensor effort has really focused on end-of-service-life indicators.

The other areas are protective clothing and ensembles and human performance.

We strive to keep a diverse mix of projects in the branch. And so if you look at it from a budgetary standpoint, about 50 percent of our funds go in the area of respiratory protection, and 50 percent in clothing and ensembles.

And the way we do that is essentially since the sensor projects right now support primarily respiratory protection and our human performance, which is sort of measuring or assessing the burden imposed upon the wearer of personal protective clothing, all of those today are focused

primarily on clothing and ensembles.

So we try to maintain a 50/50 split of our research funds and our portfolio projects.

So within our portfolio, at any given time, we will range between 10 to 15 projects in the branch.

And, of course, those will be at various stages. Some of will be at the end of their lifetime where we are getting a significant number of outputs and impacting outcomes to new projects that are just in the sort of the brainstorming mode and getting input from stakeholders.

And so you will see today, we have got projects that are just starting this fiscal year as the ones that just finished in the last fiscal year.

And today -- within the research branch, I should say, we have 10 to 15 projects. That's only within this branch.

Obviously the policy and standards groups, on occasion where there's a specific need, they may delve into something may look a lot like research where it impacts a specific standard they are

working on, maybe because they have the right set of skills to do that project or there is some other reasons for doing it.

So today we are mostly focusing on just the -- at least this morning, just the projects in the research branch.

For a staff, we have about 20 people in the branch, and that includes the federal employees, senior research fellows that we get from the National Academy of Sciences, as well as contract staff in the laboratory.

With the summer students, you know, that may range up to 25 or so in the summer.

Our budget typically is in 2 to 4 million dollar range. Occasionally we will get some supplemental funds CDC or other organizations to conduct specific projects.

And in terms of the way we conduct our work, it's a mix of in-house work. We have research capabilities. We have got a brand new aerosol research lab that just came aboard last summer, and as well as sensor labs, physiology labs.

So we do the bulk of the work now in-house, but on occasion we go extramural and fund a contract with a university or an organization, another research organization as needed.

So that's a little bit about the lab -- or the branch itself.

I want to get into the poster session. Actually, we have 11 posters, not 10, and that actually covers about 12 projects. So for simplicity, we have actually -- where it makes sense, two projects may be on a single poster where they are closely aligned or related.

And one project actually has two posters because it has such interesting -- some new interesting results that we wanted to update. It didn't all fit conveniently on one poster board. So that's on two projects -- or two posters.

So these are a mix of ongoing projects: One new-start project for FY '07 as well as -- that had some significant interest, and we wanted to make sure it was presented today; and also one recently completed project is on the -- in the agenda here

this morning.

So the plan is to basically have each -- one of the authors, usually the primary or the lead author, is going to come up to the podium here, give a five-minute or less overview of their project, tell you where it is in the room. And they will give you a little bit of information about the purpose of the project and maybe some impact that they have had.

We are going to hold -- I'm going to ask that all questions be held until the end so that they can actually be part of the poster session.

Because after everybody has a chance to give you an introduction to their project and excite you about what they are doing, draw you back to their poster; the plan is for you to go there, mingle a little bit, and ask your questions one on one with them right at the poster where they may have some data that they can show you or additional discussion can follow up.

The posters will be on display until noon tomorrow, but the primary discussion points will be

during the breaks and maybe a little bit during lunchtime when people can get back from lunch and so on.

So, again, the poster session will go this morning until 10:30 or so when I think that the policy and standards discussion kicks off.

And I should mention that four of the projects will be discussed in more detail tomorrow, and I will mention those as we go through the poster session this morning.

And what I will be doing is I will be introducing each speaker. And as I am introducing them, they will come up to the front.

And I thought it was important that I give each person a nice bio because I think it would help as part of the exchanges, you have some discussions with people if you understood maybe their background and the types of projects they work on, what other standards committees they may support. So you will hear a little bit of a background for each person and sort of a -- to get to know us a little better on the research side.

Certainly the policy and standards guys, the certification branch have conducted, you know, numerous public meetings, and you may know them a lot better than you know the researchers. So this is sort of out there to get the awareness of what we are doing improved a little bit.

So with that, I will turn it over to the first poster that we are going to discuss this morning. And that is going -- the first speaker will be Jay Snyder.

Jay is an engineer at NPPTL. He has been here for five years now. He has been the primary person that's developed our sensor research program to where it is today.

Previously, Jay worked for MSHA for 30 years. He has a bachelor's degree in chemical engineering from WVU, a master's degree in occupational health from Pitt.

Obviously Jay is going to be very busy today. He has got three posters and a talk tomorrow. Very -- his projects have been very productive in getting a lot of information out, so

he has got a lot of things to mention to you today.

So with that, I will turn it over to Jay.

END-OF-SERVICE-LIFE SENSORS AND MODELS (POSTER)

MR. SNYDER: Well, I'm Jay Snyder, and I approved the content of that message.

Good morning, everyone.

I want to talk to you about NPPTL's end-of-service-life program today, and I have got three posters that cover that topic.

Early in NPPTL's history, a survey was commissioned, one in which the Bureau of Labor Statistics contacted users of personal protective equipment in the industrial sector and asked a variety of questions about how they use them.

And one of the interesting facts that came out of that survey was the fact that approximately 20 percent of the respondents said they left it up to the discretion of the employee as to when to change their respirator cartridge.

More recently, one of the organizations that we partnered with, the Organizational Resource Counselors, which represents a large segment of the

manufacturing companies in the U.S., posted some questions on their website.

And one of them which they asked their members to respond to was what improvements would you like to see in personal protective equipment. And you might guess that the answer would be reduced cost, more comfortable equipment, et cetera.

But, in fact, the by far largest response was end-of-service-life be associated with personal protective equipment.

So a couple of reasons why we have a personal protective program at NPPTL. We do think it's an important issue based on what our customers think.

It's been a two-pronged approach, a short-term and a long-term approach. The longer term approach, which we think is the ultimate solution, would be a sensor, an electronic sensor system be associated with personal protective equipment.

And our very first effort in this area would be to place sensors in respirators to provide

end-of-service-life information to the user.

Our initial effort involved getting involved with a manufacturer of sensors, Cyrano Sciences in Pasadena, California, which has now become part of Smiths Detection, a major DOD sensor contractor.

We tried to modify one of their off-the-shelf sensor systems to utilize it in the respirator cartridge system. It involved quite a bit of modification.

The picture you see on the screen on the left is their standard sensor system, which had 27 individual sensors on a chip on a rigid format.

And the conclusion from that work was the fact that there are a major number of problems to be addressed in this application.

For example, we found that temperature and humidity were significant barriers to implementing this device in the system.

The other interesting thing that came out of that was when they transferred their basic sensor system on a rigid format, which is what is shown

here, to a flexible format, which is what you need in a respirator cartridge, the amount of noise went up significantly.

So the bottom line was that we felt that that was not going to work as a final solution.

So we began a research program with Carnegie Mellon University here in Pittsburgh on developing a polythiophene-based chemical system. And we have been doing this jointly with the U.S. Air Force.

They have also been contributing this function under their multiuniversity research initiative work for Muriam (phonetic), which they have been providing funds for the basis research, and NIOSH has been providing support for the transfer and engineering aspects, moving that research into practice.

In support of that, we developed a cartridge simulator, which you see in the center of the picture. It's a diagram.

Up near the top, there's a red line. You will see that's a means of doing remote sampling

within the cartridge bed.

This entire area contains 50 milligrams of carbon, which, at the end of the red line, you can see a sensor that we would be placing inside the carbon bed.

This has given us an opportunity to collect and evaluate interesting, and in some cases unique, data from actual carbon bed applications.

The latest version of the sensor system, which is Generation 4, shown on the right, consists of a two and a half millimeter by two and a half millimeter silicone chip, which we have six spiral electrode sensors on polythiophene polymers inkjetted onto those sensors.

And this entire thing is then contained in a T-05 package, which is about a quarter of an inch in diameter. The T-05 package is a common electronics package that you would find in the electronics industry.

That entire thing will then be placed inside the cartridge bed. And it would then provide information feedback to the user about the condition

of the respirator cartridge.

So that's the summary of my two posters covering the sensor work. They are located on your right in the back of the room.

The first poster I described is a historical review of our sensor work. And the second one is a more in-depth, detailed look at our current efforts at Carnegie Mellon University.

The other area that we have been addressing end of service life through is our mathematical modeling systems.

And today we have developed three models to predict the service time for organic and inorganic respirator cartridges, purifying respirator cartridges.

The first model was Breakthrough you see on the screen. It was introduced in December of 2004, placed on the OSHA website. It's a downloadable program that you would download to your machine, run locally.

In its history, it has been downloaded over 5,000 times. There have been 10,000 visits to

the OSHA website to either ask questions or view a tutorial that also accompanies that program.

It is capable of calculating the service time for a single vapor with the effects of relative humidity.

A second model was produced, which we call GasRemove. It is for inorganic gases and vapors.

It has been completed. However, we did not release it to the public because we determined at about the time that we were ready to release it that data probably didn't exist with manufacturers that would need to be plugged into this model in order to make it useful.

So rather than cause irritation among users and manufacturers, we decided to refrain from releasing that.

In the meantime, we have been looking for some alternate forms of funding to actually do the work necessary to generate the data. If and when that happens, why, we will be releasing that model.

Finally, a model we are just about to release called MULTIVAPOR. It will replace

Breakthrough because it's capable of calculating a service time for organic vapor respirator cartridges based on five vapors as well as the effects of relative humidity.

And it will be somewhat different from Breakthrough in that it will be available in five versions. And the most significant difference there will be one Java-based version, which will permit it to run on any machine, not just a Windows-based machine, as Breakthrough was limited.

The other feature that that will provide will be a web-based version of this that you can go to the website and work with it interactively.

Any data that you would store or put into the system would stored locally in your system. So no need to worry about that information going somewhere that you can't control.

We expect to release this by the end of the year, and I hope that it will receive as good of a review as Breakthrough has.

So I'll be available at breaks throughout the day to talk in more detail about any of these

projects. If you would like to, please stop by.

MR. SHAFFER: Our next speaker is Sammy Rengasamy. Sammy has a Ph.D. in biochemistry. He has been with NPPTL five years now. Previous to that, he worked for five years with NIOSH down in Morgantown.

Sammy is a member of the ASTM E-56 committee on nanotechnology and the ISO TC-229 committee on nanotechnology, and is also a member of the American Industrial Hygiene Association.

So I will let -- Sammy is going to talk about a project. Actually, two of the collaborators from this project, which was just completed this past summer from Edgewood and Battelle are actually here. It's nice to see you.

Sammy.

RESPIRATOR FILTER PERFORMANCE AGAINST BIOLOGICAL AEROSOLS (POSTER)

MR. RENGASAMY: Thank you for your introduction.

I welcome you all. My name is Sammy Rengasamy, and I am going to talk to you on my

project, respirator protection against bioaerosols under high flow rate conditions.

Workers are expected to breathe at high flow rates under heavy workload conditions. And it is well known that high flow rates increase the penetration of particles through respirators.

So what happens to biological aerosols under heavy workload conditions? To address this question, we collaborated with the U.S. Army RDECOM laboratory and Battelle laboratory.

The experiments that are conducted are high flow rates ranging from 85 to 360 liters per minute under constant and cyclic flow conditions.

The bacterium called bacillus globigii, or BG, and the virus called MS2 were used in this study.

Aerosols of BG and MS2 were prepared, and penetration through NIOSH approved N95 and P100 filtering facepieces cartridges were measured.

And the sensors showed that the penetration of BG and the MS2 biological aerosols did not exceed the NIOSH approved levels, even at

the high flow rates at 360 liters per minute.

And, as you can see, we have gotten the report from the RDECOM and Battelle. And you can see the front page of the report in the corner of the poster.

If anyone needs the information, it is available to the public. And I will be happy to answer your questions during the break time.

Thank you.

MR. SNYDER: The next poster is entitled Respiratory Protection Research for Infection Control. It has a lot of authors involved in this one. It is going to be discussed today by Jon Szalajda.

Jon joined NPPTL NIOSH in 2001. Before that, he has 16 years experience with the U.S. Army where he was a team leader and system manager in respiratory protection devices.

Jon -- since he has been at NPPTL, Jon led the development of the CBRN standards. He has won a number of FEB, HHS, and NIOSH awards for that work on the CBRN standards.

He has a bachelor's degree in chemical engineering from Penn State, and a Master's degree from Pitt in systems engineering.

Today, Jon is the program manager for respiratory protection at the laboratory and is responsible for coordinating the respiratory protection work across all of the branches leading from research all the way through certification.

Jon.

RESPIRATOR PROTECTION RESEARCH FOR INFECTION CONTROL

(POSTER)

MR. SZALAJDA: Thank you, Ron.

It's always a challenge when you have the opportunity to talk at sessions like this to try to come up and think about what you want to say.

And one of the things that struck me this morning in listening to Les's and Frank Hearl's comments was the subject of the relevance, the relevance of the research that we are conducting.

And I thought that's a really good focus for this project that is currently being conducted in the technology research branch.

Because, when you think about it and you think about dealing with things such as an influenza pandemic, this is something that could theoretically touch everyone in this room, and not necessarily if you are a manufacturer.

But when you look at the things like a pandemic and how -- what we know about how these types of diseases are transmitted, you know, things that we can do from a public health standpoint to prevent those occurrences from happening I think are very important.

I think one of the nice things with my involvement with this project is the fact that we do have a multitalented, multifaceted team working on the project, between Sammy, who you just heard; Dr. Roberge; Ron, who will be the project officer for this effort; Evanly Vo; Dennis Viscusi; and Dr. Zhuang.

And everyone has brought different skills, different aspects to this project, which I think will ultimately make it a successful undertaking.

And this is one of the areas that we are

going to address in a little bit more detail tomorrow.

The poster is in the center of this -- of the room here on my left. And I welcome to have discussions with you regarding the contents of our research during the breaks today or at any time when you see me around the facility.

One of the things that is interesting with how -- the genesis of the project is that really the foundations and the seeds for ideas as far as what needed to be done began in a workshop that was conducted at CDC back in the early days of Fiscal Year 2005, which looked at respiratory protection needs for dealing with infectious aerosol substances.

And following that, you know, the incubation period starts, which is probably a bad term to use when you are thinking about flu.

But, you know, we started some internal brainstorming within the laboratory as far as what could be done, you know, with regard to projects that we could execute within our capabilities and

with our facilities to address some of these issues.

And around the beginning part of the calendar year, the early part of the Fiscal Year '06, CDC came out with an internal request for proposals to look at items where elements within CDC could conduct internal research to address different concerns regarding the influenza pandemic.

Ron led an effort to develop a proposal. We submitted it, and we received supplemental funding to conduct the program.

Along with this, or parallel with this -- and I think a lot of you are aware of it, this little -- the Department of Homeland -- or not Homeland. That's happens when you work in CBRN too long.

The Department of Health and Human Services issued a -- or consulted with the National Academies, and in particular the Institute of Medicine, to do an assessment. And that assessment was supposed to look at measures that would permit the reusability of filtering facepiece respirators.

I think, as most of the people involved in

the healthcare community and in the respirator manufacturing community know that CDC recommends the use of N95 filtering facepieces or higher as respiratory protection for influenza viruses and also other infectious aerosols.

The concern being that during a pandemic, there is going to be an increased reliance within the healthcare community as well as potentially by the general public to use the N95 filtering facepiece respirator.

One of the things that the IOM identified, which I thought was fairly significant, was the fact that during a pandemic, at least 90 million N95 type respirator -- filtering facepiece respirators could be used within the healthcare community. And that is independent of any requirements that may be used in other areas.

That's a significant number of systems.

But what our project is focusing on is it's addressing some of the recommendations that came out of the IOM report.

And if you are familiar with the IOM

report, one of the things that they identified as part of their evaluation was the fact that there really are no decon measures currently available that could be used on filtering facepiece respirators.

However, having said that, you know, their recommendation was -- and I know people will say, well, researchers always recommend additional research.

But in this area, one of the things that we felt was important to pick up and carry on was to look at this topic of decontamination, in potential -- in particular looking at the simple type methods that could be done in a healthcare setting that could potentially be used to decontaminate respirators and allow their reuse without compromising the respirator's integrity.

Another aspect of the work is understanding risks associated with the handling of respirators that may be have been exposed to a viral type agent. And those two things I'm going to talk about in a little more detail during the

presentations tomorrow morning.

The other portion of our research addresses the -- that addresses the IOM recommendations relates to the quantified benefit of annual fit testing.

And this is a proposed project which is currently not funded, but on our books for consideration, which would look at determining whether or not changes in anthropometrics result in changes of the fit of the respirator to the individual.

And also, this in conjunction with the benefits of annual fit testing.

You know, like anyone else, you know, as you get older, your facial dimensions change. You may get heavier. You may get thinner.

You know, those types of physical factors that address your anthropometrics as far as your -- your face could potentially impact the fit of the respirator to the individual. And that is another aspect of our program.

Again, I would encourage you to come and

discuss this with me at any point during the day today. There is -- various members of the group are present in the audience today, and we would be happy to discuss the project with you.

Thank you.

MR. SHAFFER: Our next poster that will be discussed is the Development of Computer-Aided Face-Fit Evaluation Methods. Sometimes we call this our anthropometrics program. And discussing that today will be Ziqing Zhuang.

And Ziqing has a very long bio. I will give you the shortened version of that. Ziqing joined NIOSH in 1996, and has been at NPPTL since 2001. He has a Ph.D. in industrial engineering, specializing in ergonomics from WVU.

Previously he was chairman of the AIHA Respiratory Protection Committee and is currently the past chairman of the committee.

He is on various ISO TC-94 SE15 respiratory protection committees. He is also the editor of the Journal of the International Society for Respiratory Protection.

His research papers have won a number of awards. I'm not going to go through all of them, but he has been nominated by NIOSH for -- twice for CDC Charles Shepard Science Awards and also has won three AIHA John White Best Paper awards.

So I'll turn it over to Ziqing.

DEVELOPMENT OF COMPUTER-AIDED FACE-FIT EVALUATION METHODS (POSTER)

MR. ZHUANG: Thank you, Ron.

Well, yeah, when we initiated this project, at that time, the military data was the only data available. And then when you look at military data, the data were collected on people they covered young. And then also back in the 60 as well.

And then when new personnel were recruited, they cover -- need to go through some restrictive criteria that, yeah, they may not represent the, yeah, the diversity that you see in the civilian population.

So -- and then also, over the last 30 years, the population demographics have changed a

lot.

And then also, over the years, I think, yeah, the earlier '70s, the Los Alamos Fit Test Panel was developed. There are a few scientific studies that look at the panel, and they found that the panel was, however not representative of the population and most of the people. I decide by then we have a significant portion of the subjects are outside the panel.

And so, you know, which we -- so we initiated the project. And in the words of our NPPTL former director, Rich Metzler, in the audience today, at that point he told me that like this kind of project is important. And it's like -- it's so important that like when you build a building on the sand versus you build a solid foundation and build a building on top of that.

So whatever NIOSH is doing or manufacturers are doing, like this have like information, very critical and very important.

So at that time, we set our goal to develop a database to collect data on respirator

user, their facial dimension. And then, yeah, use the information to develop fit test panels. And then also headforms for testing respirator and eye and face, like, protective device.

So what we need was, we created a database with like 3,397 subjects, and we also scanned one-fourth of the subjects.

And then at this point, we have developed two fit test panels. One is based on face length and face width, and the other one is based on ten facial dimensions, and we used principal component analysis approach.

And we also have laboratory study look at correlation between fit test and dimension and also did some review on those subjects as well.

And I also, yeah, was able to get seven of US manufacturer to fund a study in China to collect data from, yeah, Chinese worker. And that study has been completed, and we are doing data analysis right now.

And with the three-dimensional data, we were able to create our first generation of

headform, and now we are working on the second generation.

And as I am on various committee, and I was able to get input from the committee to help with the research.

So we expect the product to be used by the committee. And as we get a lot of people from them, and hopefully there will be, yeah, have good -- a lot of input on the standard. Thank you.

MR. SHAFFER: I forgot to mention that Ziqing will have a talk tomorrow where he will focus on one aspect of the project development of mid fit test panels.

Our next speaker is Angie Shepherd. Angie is the newest member of the research branch at NPPTL. She has been with us for about a year and a half now.

Her focus is protective clothing. She previously worked for Underwriters Laboratory, also in protective clothing. She has a bachelor's degree in chemical engineering and a bachelor's degree in textile chemistry from North Carolina State.

Recently, she won a number of -- two awards with the Pittsburgh Federal Executive Board. She was the rookie of the year and also -- the gold award for that one, and I think she got a bronze for the woman of the year the professional nonsupervisory category.

She's a member of five different NFPA Technical Committees and has been a task group leader or a task chairperson for CBRN issues in particular.

She is also member of the ASTM F23 committee on protective clothing and equipment.

And Angie is going to talk about her project, Improved Criteria for Emergency Medical Protective Clothing.

Her poster is over there with the nice display items.

IMPROVED CRITERIA FOR EMERGENCY MEDICAL PROTECTIVE CLOTHING (POSTER)

MS. SHEPERD: Thank you, Ron.

As Ron mentioned earlier, and you will actually hear over the next two days, we are doing a

lot of internal work on standards.

But this particular project actually is looking at helping an outside standards activity for the National Fire Protection Association.

As, Ron said, NFPA is the standard on protective clothing for emergency medical operations. It's currently in its 2003 edition.

And the standard is little different from some of the other standards. It actually has more of a menu approach. You can pick just a garment, just a single-use garment, just a glove, just a face protector. So it's not an ensemble standard.

The problem with that is, although it has had very, very good industry response, it has only been in certain categories, just as reusable garments. And there are a couple of certifications that exist currently for footwear.

But there are other areas, such as face protection and cleaning gloves, which actually have had little to no industry participation.

Why is this? A couple of different reasons.

Such items as cleaning gloves actually had mutually exclusive criteria in the standard, meaning nothing can be certified. You have tests that overlap one another. So if it passes one test, it automatically fails the other.

You also have other items that, once it passes a standard, the products that are a result of the standard actually don't meet the first responders' needs.

So even though you have certified products out there, nobody is wearing them, and nobody is buying them. So that does not make for a good standard either.

There are other categories, such as head protection and flammability as well as retroreflectivity that aren't currently covered by the standard, so it is something else we are looking to try to fill the gaps with.

And how we are doing this, we have partnered and actually have a contract with Mr. Jeff Stull with International Personnel Protection.

And we are looking -- the first thing we

did was we did a series of interviews with nine different departments ranging from your large metropolitan EMS departments, such as New York City, down to small ambulance services in Texas.

And what we learned from those interviews is which products were acceptable, which products were unacceptable, what they were using, what they weren't using, and why they were using the products they were using.

Gained a lot of good information from that. We selected the products that were going to be moved -- that we are going to move forward and test, both acceptable and unacceptable products.

And based on the test results that we get, we will be able to determine acceptable criteria and actually hand those over to the NFPA as recommendations and look to impact the 2008 edition of the standard.

So this is a really, really good example of how the work that we do at NPPTL actually can have a direct impact to the -- like the research practice that they mentioned earlier.

So -- and the other to mention with the standard, the NFPA 1999 is also one of the standards that's on the list for federal funding. So this is -- we have to see very, very good results from this project.

As well as my poster is over there on your left, and I have a significant number of samples. So please feel free to come and take a look at -- I have single-use garments. We will use different types of cleaning gloves. So I would love to hear your input on some of those.

Thank you.

MR. SHAFFER: Our next poster will be discussed by Pengfei Gao. Pengfei joined NIOSH in 1996 and worked in Morgantown down there, and in 2001 joined NPPTL.

Pengfei's background is in aerosol science and in protective clothing. He has a Ph.D. in environmental health science. He is a member of the AIHA Aerosol Technology and the Protective Clothing and Equipment Committees.

He is also a voting member for the ASTM

F-23 committee. He has been a certified industrial hygienist since 1999.

He has also won a number of awards, and most recently was awarded by the Pittsburgh Federal Executive Board the Outstanding Contribution to Science Gold Award.

Pengfei.

DECONTAMINATION STRATEGIES AND REUSABILITY OF CHEMICAL PROTECTIVE CLOTHING (POSTER)

MR. GAO: Thank you, Ron, for a wonderful introduction.

The title of my poster is the detox strategy and the reusability of CPC.

As we know, detox is a very important issue for the use of CPC. OSHA has the -- this is requirement for CPC decon, and it is a number of spindle (phonetic) and regulation. However, they don't tell you how the decon should be done.

So this project was to develop a -- test a method for CPC decon and to develop a methodology how you can evaluate decon efficacy, and then to provide you with a guideline for CPC requirement.

We selected seven most commonly used CPC material and the 12 of liquid chemical. The chemical was selected under the ASTM for a total of 26 materials and chemical combinations.

We used two decon method. One use heat, and the other one is water and detergent for comparison.

The exposure and the decon was repeat up to ten cycles, or until material fails. After that, we look for a change of chemical resistance and the degradation.

What we find, reuse -- multiple reuse of a CPC could be set for certain chemical/material combinations.

We also find that if you wanted to evaluate a CPC decon efficacy, not only the change of chemical resistance should be investigated, but also the change in physical properties needed to investigate.

Some other outcomes of this project include the development of a computer program we call Permeation Calculator. It is only -- this is

the first screen of the program.

This program calculated all the permeation combination for ASTM standards F-739 and ISO standard 7529. And also, we develop a decon guideline. We -- a letter was published by AIHA last December.

My poster is located at the corner there. Please stop by, and I will be able to discuss with you for -- any questions you might have regarding this project.

Thank you.

MR. SHAFFER: The next poster will be discussed by Sammy Rengasamy, who I introduced previously.

While he is coming up, I will just mention that this is will be the subject of a longer presentation tomorrow that I will actually be giving, but Sammy is going to tell you a little bit about the poster that we have here today.

NANOTECHNOLOGY: PERFORMANCE OF PERSONAL PROTECTIVE EQUIPMENT (POSTER)

MR. RENGASAMY: Thank you, Ron.

This talk is going to be on the nanotechnology performance of personal protective equipment. And the co-authors are Dr. Pengfei Gao and Ron Shaffer.

I want to say we are living in a small world, but the nanotechnology is growing at a faster rate. Nanotechnology brings a lot of good things, but there are several concerns that have to be addressed.

And NIOSH, if you look at the center of the slide, NIOSH addresses these concerns. NIOSH addresses ten areas of nanotechnology issues by conducting research. One of them, you can see on the left, it is controls. These controls include engineering as well as personal protective equipment. That improves respirators, protective clothing, and other materials.

And Dr. Pengfei Gao, he is working on the protective clothing to look at the penetration of nanoparticles through the material, and I am looking at the penetration of nanoparticles through respirators.

Let me tell my story first.

There are lot of studies that look at the penetration of particles greater than 20 nanometers in size through respirators, but there is no information on the penetration of particles smaller than 20 nanometers through respirators.

So we wanted to look at the penetration of the smaller of these particles through respirators.

The contract was awarded to the University of Minnesota, and they did the work for us. And they -- the results from their study showed that the particles smaller than 20 nanometers, down to the size of 3 nanometers, they are captured well by the filter media. They used a filter media in this study.

Then we wanted to continue this study to look at the penetration of particles ranging from three to 400 nanometer size through NIOSH approved respirators.

So now we are doing this study in our laboratory at NPPTL, and we also want to look at the penetration of particles under a tight-fitting --

and also the leakage conditions using a mannequin head model.

And this we hope will give us a better information on the nanoparticle penetration through respirators and respirator protection for workers.

And I will be -- as you can see, some of our research has been incorporated in the NIOSH document entitled Approaches to Safe Nanotechnology, An Information Exchange with NIOSH. And this, you can get it from the web.

I would be happy to answer your questions at the poster session, and my poster is the second one from there.

Thank you.

MR. SHAFFER: I should mention that this was one of the posters, this has two projects on it. Also, there is a number of bullets and some discussion of the penetration through protective clothing that Pengfei Gao has led.

Both of those projects and some the preliminary results are discussed in the safe working practices document.

Like I said, I'll talk about this in more detail tomorrow, and I'll have a link to the website where you can download the report yourself.

The last speaker this morning is going to talk about two different projects, Dr. Jon Williams.

Jon joined NPPTL in 2003. Previously he worked at NASA where he directed one of the physiology labs there. He has a Ph.D. in physiology. He is currently the chair of the U.S. Tag (phonetic) PG-5 Human Factors Committee. And in 2004, Jon was the Pittsburgh Federal Executive Board Rookie of the Year.

So Jon will talk about two projects, physiological models and countermeasures, as well as the Project Heroes.

While Jon is getting untangled there, I will mention that Ray Roberge, who is our new medical doctor, who has been with the lab for about a year, was unable to attend today and tomorrow because they are actively doing testing in the lab, so I send his regards today.

PHYSIOLOGICAL MODELS AND COUNTERMEASURES (POSTER)

MR. WILLIAMS: Thanks, Ron.

One of the things that our laboratory is interested in is the physiological impact of wearing personal protective ensembles.

And you wear personal protective equipment and ensembles primarily because you are engaged in activity that exposes you to some external threat to your life or your health.

And unfortunately, those personal protective ensembles tend to be encapsulating. They are hot. They are heavy. Therefore, they impose a physiological burden on the wearer.

And our interest is how much of that burden is -- can be characterized, and what can we do about it.

And we also are interested in developing a model of that physiological burden that is predictive so that we don't necessarily always have to do testing. We can apply a model and get some idea of what the physiological burden will be when the person wears that particular ensemble.

We are also interested in how we can we alleviate that burden because a person has to wear -- if they are in a certain occupation, they have to wear their personal protective gear. That's not an option for them. They need the protection.

But in the case of, for instance, firefighters -- and I will show you another slide in a minute -- one of the biggest incidents of morbidity and mortality in firefighters is cardiovascular disease.

And thermal stress has been implicated as one of cluster of risk factors for the development of cardiovascular disease in firefighters, repeated high thermal stress.

And it isn't just coming from the incident -- high incident heat that you are exposed to when you go into a burning building, but it comes from the metabolic heat that a person generates because they are very active, and their muscles generate a lot of heat, but it cannot be transferred to the external environment as it normally is because they are encapsulated in this garment.

And so they tend to start getting a high thermal stress. And that, repeated over many years, can contribute to cardiovascular disease.

So one of the things we are interested in is the countermeasure to that. Well, the obvious thing is cooling them down, if possible.

And so my postdoctoral fellow, Dr. Itor Coca (phonetic), has a project that has been approved to look at cooling garments which take advantage of certain areas of the body where optimal cooling can take place.

You don't necessarily have to completely cover somebody's body with a cooling garment to get the appropriate amount of heat transfer out of their body. You need to take advantage of certain areas of the body where this optimal heat transfer can take place.

And that's why this cooling garment isn't completely encapsulating. It is simply taking advantage of head, forearms, chest, which are regions where a lot of heat transfer can take place.

The other thing is that you don't need to

cool somebody down maximally. You need to cool them down optimally.

The difference is is that if you cool them down maximally, then they tend to show warm blood, which tends to remain in their core, is not transferred to their peripheral vasculature in their skin. So that heat transfer, that warm blood does not transfer heat to the external garment.

One of the things that we are also interested in is providing -- in our models, providing a information to the ASTM standards, which will provide a guidance as to what type of physiological testing you need to do when you actually put somebody in a garment. What are the type of tests that you run?

So we supplied information to Angie Shepherd, who you heard speak a little bit ago, and she has been involved in developing this physiological test methodology for the ASTM groups. She has been pushing that through for the last year or so.

NEXT GENERATION STRUCTURAL FIREFIGHTING PPE ENSEMBLE

(PROJECT HEROES)

MR. WILLIAMS: The next project that I'm working on with everyone here is Project HEROES. And we are applying a lot of the physiological test methodology that I spoke of earlier to a project which involves looking at how a new firefighter prototype ensemble with some level of chemical and biological hazard protection affects a person when they wear it.

And I don't know if you can see from the picture, but if you look in this area here, you can see a little hose which takes -- is attached both to the mask, and then reroutes the exhaust air from the SCBA facepiece back into the garment.

And that does a couple of things. Number one, it presumably provides a certain amount of air flow through the upper part of the garment, which we are hoping will provide some level of cooling without the addition of a new garment or extra garment like the cooling garments I showed you earlier.

The other thing it does is that it can provide some degree of positive pressure, which limits total inward leakage, we think. So that that's another barrier to bad stuff getting into the garment and giving them a little more protection than they would have had before.

The other thing is that the company, Morning Pride, which manufactures the suit, has created novel seals between the wrist sleeve/glove interface and the pant leg and boot interface, along with some zippers and sealing -- a hood that actually seals around the facepiece. And all of these different -- right around here, kind of a baffle that goes around.

And all of these strategies are there to limit the firefighter's exposure to whatever is out there in the environment, whether it is a chemical or biological hazard.

The downside of that is that the more seals you put on somebody, the less you are able to transfer heat to the environment, and your core temperature goes up.

And so we are applying a lot of the physiological testing methodology that we have developed to studying how much that garment will actually either cool you through this novel hose arrangement by using the exhaust gases from the SCBA and blowing it back into the garment, how much that actually cools you, if it does at all, and what the heat stresses really are.

And so we are in the middle of this project right now. We conduct this particular project in an environmental chamber to control the environment. And we are comparing it to a standard ensemble which -- upon which this prototype has been built up.

This is a standard ensemble which serves as the platform that has been modified up to create this prototype.

So that's our big project that we are conducting right now, and I would be more than happy to discuss any of these projects or any aspect of them.

Our posters are located behind the screen

there to your right. Don't worry. I'll hand out money to convince you to come to these posters. Not really. I'm getting behind it.

But, in any case, I will be more than happy to discuss any of the aspects of the project at another point in the presentations here.

So thank you very much, and I hope to see you at the posters.

MR. SHAFFER: Okay. So that's the five-minute overviews of the various projects. Just a few closing remarks.

About the Project HEROES, obviously, if you have got physiology questions, Jon can tackle those.

Angie Shepherd has also been heavily involved in the project with a standards focus of various changes to some NFPA standards 1971, 1994. And she has been heavily involved in that aspect of HEROES, so that is part of the reason why those posters are back there, so they are close to Angie's poster as well. And Angie is going to discuss those topics if anyone is interested.

So if you haven't been to the laboratory in a couple of years, you will see some changes. We have got some new facilities in place. We have got a new aerosol research lab. Our anthropometrics lab is moved out of those tiny little buildings. We have got an entire -- Building 13, we have got the entire second floor which houses all of our respiratory protection research.

We have state-of-the-art physiology labs. We have got environmental chambers that we use for testing, in addition to the sensor labs and the labs that were there previously.

A protective clothing lab as well.

So if you haven't been to the labs, I encourage you. Give us a call. We will be happy to show you around and talk a little bit more about the projects.

So we are going to go on break now, which is open, obviously, for refreshments, restrooms, as well as for discussions at the various poster sessions. And we will reconvene at 10:30 with the discussion of the CBRN PAPR Step 2, Industrial PAPR.

(A recess was taken.)

MR. BOORD: I would like to start off by reversing an agenda adjustment that I announced earlier. And the adjustment is that there will be no changes to the afternoon sessions.

The original schedule for the CBRN PAPR standards development activities, the CWA live agent testing, CBRN hazard for first receivers, and the respirator standards will occur at 1:15. And the 2:30 session for Total Inward Leakage quality assurance module and administrative module will occur at 2:30.

So the agenda as you have it in your program is what we will adhere to. And sorry for any inconveniences that may have -- or confusion that may have caused.

To continue with our program today, I would like to introduce Bill Hoffman, who is the branch chief for our policy and standards development activities.

The next sessions, the industrial PAPR, the chemical warfare CBRN discussions, and the TIL

discussions later this afternoon are all part of the Policies and Standards Branch.

So I will turn it over to Bill.

INDUSTRIAL PAPR - CBRN PAPR STEP 2

MR. HOFFMAN: Okay. As all of you probably know, the CBRN Step 1 PAPR standard which was implemented by policy has gone into place. So we do now have a mechanism to approve CBRN PAPRs.

From this point forward, though, as Terry Thornton is going to discuss, all future changes to regulations or implementations will go through the rulemaking process. So it will be a lengthier but, I guess, more conclusive process in that everything will go through the proper steps to do that.

Terry is going to give the full presentation on the CBRN industrial PAPR standard, which we are going to be changing it from industrial PAPR to PAPR. Because when it goes through rulemaking, it will cover everything when we do that.

It's a rather lengthy presentation, but we are going to try -- we have tried to cover all of

the details.

So at this point in time, I'm going to turn it over the Terry. And following his presentation, we will go to lunch.

MR. THORNTON: All right. The quicker I can get done with this, the quicker we go eat. Wow. It did go pretty quick. We seem to be well into it by now.

Let me see if I can find the beginning of this. I hope there is no timer on this. I'm not sure why it has jumped over there.

As Bill said, my name is Terry Thornton. I'm a chemist. I work in the policy and standards. Many of you know me out there. I have been talking about CBRN for quite a while, especially the PAPR CBRN.

So today we are going to really kind of -- I've changed my focus a little bit. We are going to talk about the industrial PAPR.

As Bill pointed out, this may be a lengthy presentation because, you can imagine, industrial PAPR, or PAPR, covers a quite a bit, a little bit

more detail than we thought when we first jumped into it.

If you didn't get all of that...

I'm going to try to back that up somehow and slow that down. It would be nice to go through that presentation that fast.

But does somebody have a timer set up on this? We will try again.

This is a lot of fun, isn't it? Does anybody know how to stop this from taking place?

If we have any suggestions, please come forward now because I'm going to have to -- Jon to the rescue. If we can't fix it here in a minute, we will go through it a slide at a time.

All right. This makes it more exciting when things like this take place. Hopefully it won't do this anymore.

We also -- we have one thing that we have put out, that after this, we would go to lunch. I think that's incorrect. What we are going to do after this is Tim Rehak is going to stand up and talk to us about multifunction PAPR.

Once I get going here, this shouldn't take very long. I know that's hard to believe, but that may have taken my concentration away a little bit.

So I think I was introducing the industrial PAPR. Let me see if I can get back on track now.

The industrial PAPR concept is an actual project now, this year, in '07 for NPPTL. Before, it was something we were working on. Now it's an actual project. It has a can (phonetic) number. It has money to be involved to complete the project.

As you can see, this is what the project requires. It's really to put together everything for a PAPR to incorporate that into the 42 CFR.

We are going to look at it. Hopefully, we are going to pull in new technology and new requirements and put that all together.

Yes, it will go through formal rulemaking. That is one of the parts that will probably make it take a little longer than we have done prior. The formal rulemaking should be a very good thing for this.

I'll let you know that we are still using a concept process, and that's a process that we have used so far. We are going to continue that, even though we are going to do formal rulemaking. So the concept papers will go out. We will have public meetings. We will have manufacturer meetings. Maybe possibly 101 meetings. We will talk to user communities.

So we are still going to use that same process, and we'll use it to its fullest extent before we start the formal rulemaking.

So one of the things I want to bring out is we have a concept paper out there right now on the internet. It is dated September 19, and probably quite a few of you have already seen it, pulled it off, looked at it.

That concept paper is very fluid, and it keeps changing all the time. We have meetings in NPPTL between ourselves. Other manufacturers come -- or manufacturers come in, user communities.

So what you see there right on that date for September 19 is kind of like a snapshot of what

took place to that point.

So some of the things I will discuss in here are different from what's in that concept paper. And I'll try to point those out before I bring those up.

The docket comments, please use the docket comments and submit to the docket. You can see the number, 008. Put that on there whenever you are talking about the PAPR concept. It makes it get to the right place, and it's easier to find.

The computer is just not working for me today very well.

One of things I wanted to hit, kind of like Bill had spoken about, there was a little bit of confusion. I want to make sure we try to clear that up before we get started.

There has been a lot of talk about CBRN PAPR. We have done the CBRN PAPR Step 1. That's a statement of standard that's out there right now.

Some of the other terminology a lot of you have heard and may be confusing is CBRN PAPR Step 2 PAPR module, or PAPR standard, or PAPR concept. All

of those terminologies kind of get thrown in together.

This is what we are discussing here, and it will encompass all of the PAPR standard. When we are done, it will be a standard. For now, we are going to talk about it as a concept.

You also -- I slip up sometimes. I may use the word PAPR module or PAPR concept. We use those interchangeably. Once it is completed, it will be a PAPR standard.

So what we have presented in the past was -- this is kind of what we are looking at, how to redo this standard. We want it flexible enough to cover a potential wide range of applications.

We also wanted to have the flexibility to have specific tests associated specific applications. CBRN comes into mind, mining process.

One size fits all, the 42 CFR, is kind of quite old. But for the PAPR, it was a one-size-fits-all. We're not sure if that's really the best way to do it. So we think we have come up with a better way to have the standard laid out so

it's easier to look at, easier to understand.

All right. So for this PAPR concept consideration, we are going to cut it into two categories. The first will be a base requirement. This is just like it sounds. Base requirement would have -- all PAPRs would pass these base requirements.

That can be broken into the two subgroups, respiratory and nonrespiratory. The differences between respiratory and nonrespiratory, there is not a clear-cut line here. But that seems to be a very good way to distinguish some tests so that it's easier to look at the standard and read the standard once it is in place.

Use and application specific. Now, this is a little bit new to 42 CFR or to the way that NIOSH NPPTL has been doing testing. Usually we have had a standard.

This use and application specific gives us an area where we can have specific tests based on needs or a type of respirator.

So right now, what we have come up with

is -- that's a little out of place there. This is the listing that we have that would be under use or application specific.

Where it says CBRN responder, right underneath that, assesses new technology, that assesses new technology should be -- it got out of place. It's right here. It should be right under here. So it should read additional requirements to assess new technology. One of the confusions, I guess, when you transfer these things.

So the areas we have are CBRN responder, which we have been working one quite a bit.

You will see the law enforcement, clean room, hospital. Those are some of the areas, the specific-use applications. And then some of the others we will see on this slide are some of the additional tests that not all PAPRs would need to pass, but some PAPRs would be able to use that. So it would be almost like an option that you could have these additional tests performed.

We will kind of jump right into the meat of the story here. For the PAPR concept -- this has

been a big question that has come about. We have discussed it many times in NPPTL. Do all PAPRs need to be considered a positive pressure device?

Different opinions out there, but for right now, NPPTL is going to look at that. The answer to this is yes. We are going to look at them as a positive pressure device.

Now, exactly what does that mean? Kind of depends on who you are speaking to.

For a positive pressure device, we are going to have positive pressure inside the facepiece or inside the breathing zone while tested under NIOSH requirements.

So we can't -- we will look at it with a NIOSH test on a breathing headform with a breathing machine, specific tests, and see that it maintains positive pressure in there.

That's not to say that when a human puts the respirator on that he's going to be able to maintain positive pressure at all times while using a respirator.

And I think if anybody has used a

loose-fitting respirators, manufacturers, you know that as the user gets in there and starts moving his head and starts talking or doing hard work, extra hard work, that the positive pressure may not be there.

So when we say positive pressure device, that is going to be for NIOSH testing.

A couple of areas in here that you will see under the concept paper that talk about positive pressure test, and that's the low flow pressure indicator, power requirements, air flow determination, which is going to be some things we talk about, and then Total Inward Leakage. Those are areas where positive pressure will come into play.

As I said, we talk about air flow determination. Traditionally, under 42 CFR, we have two air flows, tight-fitting and loose-fitting.

Tight-fitting has 115 liters per minute. Loose-fitting has 170 liters per minute.

With new technology, we would like to be able to incorporate a little bit more expanse on the

PAPR and how they operate.

So if we look here, there is kind of three ways you can look at a PAPR operating. The first one is a single power blower unit. And a single power blower unit is kind of traditionally what's out there right now for a PAPR.

It has a blower. You turn it on. It goes up to an constant speed. You breathe in it. You use that flow.

Another thing that we have suggested by manufacturers and the user community is to have multiple blower speeds. All right. This would be a PAPR that is not just one setting. You could turn it to low. You could turn it to moderate. You could turn it high. So you would have the ability to change that setting, manually change that setting.

So some flows in there may be different for that.

The last way that we know that these types of units are out there is a breath response unit. And this is -- you can kind of look at it. It is

the same as a variable power blower unit, except it's not a manual switch that goes back and forth. It responds to the user and his breathing pattern.

So those are three kind of ways we can look at the PAPR that we are discussing here.

So the question is, what do we do with the flows? What type of flows are needed for these type of units?

It's also, we would like to do some performance type testing. So we would like to test these respirators as they are performing on a breathing machine, on a headform, actually breathing at some type of work rate.

So that's what we would like to do. Now, how are we going to establish what the minimum flows would be for those different work rates?

There are some questions there. And comments at end of the docket are going to be needed so that we can clarify this.

What we have right now, if we look at the tight-fitting, the three. We have low, moderate, and high. For a low tight-fitting, we would --

right now, it looks like there is no need for that. We wouldn't allow that.

If you had something that would be a low-flow tight-fitting, that would be probably an APR, not breath response, but breath assisted. So it would fall under an APR.

Now, this is a -- like I say, this is a concept. It's not completely finished. If there is docket comments that come in that suggest that we do have that, we can look at that.

For tight-fitting, look at the moderate, 115 liters a minute. That's an average air flow at 40 liters per minute breathing.

High looks like we would need somewhere around 250 liters per minute on an 86 liter a minute breathing machine.

If we look at loose, we have three flows there, also. We have 100, 170, and 370. Everybody is familiar with the 170. This 250 right here and this 370, those are numbers that are really under consideration. And we would like more docket comments on what those flows need to be, whether

those flows are too high or those flows are too low.

So that's some docket consideration that we would really like to see.

The other thing we have to keep in mind is the breath response units that we are looking at now, the ones that are currently on the market. They are very difficult to just measure the air flow.

All right. That doesn't mean all of them will be that way, but for right now, they are difficult to just turn them on and measure an air flow because they respond to the breathing pattern.

So what we have in the concept paper today is for a tight or loose-fitting or breath response unit, we would maintain positive pressure inside the facepiece.

And that would be inconsiderate of -- we would not consider needing a minimum air flow for that. We would just look to see on the breathing machine it maintains positive pressure inside the facepiece.

We can measure that average flow -- and I

think I have talked about that in prior meetings about how we can measure that average flow on that breathing machine. And we could use it in later testing if needed.

Another way that we have looked at this -- and this is not in your concept paper right now. This isn't -- what I'm going to talk about here is not discussed in the concept paper, the flows I had just mentioned, the minimum air flows are what is talked about in there.

The other way we can do this is to take all of the PAPRs and not require a minimum air flow, whether it be low, moderate, or high. We just would not require a specific minimum air flow.

We would hook it up and set it up just like we were looking for the breath response unit, put it on a headform, turn on the breathing machine, and see that it maintains positive pressure at that specified breathing rate.

These specified breathing rates, the 40 is traditional NIOSH. We have used that prior -- or we have used that in the past. You will remember that

as a Silverman Cam at 40 liters per minute minute volume. And that's 1.67 liters at 24 respirations per minute.

We have come up with a couple of more, and these go along with ISO, not directly with ISO, but we are more in line with ISO, looking at a low of 21 liters per minute minute volume and a high of 86 liters a minute.

Again, this is something that docket comments can come in, if you agree, disagree with these actual minute volumes or how we are setting up the liters and respirations per minute, we would like comments on that.

I covered two concepts there that we are looking at.

One of them is what's in that 19 September concept paper right now where we could actually measure flows for a constant flow type unit. We would measure, and there would be a minimum flow that it needed to pass.

Also with that, the breath response units would be tested differently, and they would just be

put on a headform and maintain positive pressure.

The other concept that I talked about, it is not requiring minimum air flows for any of the PAPRs and doing everything by positive pressure inside the facepiece.

Hopefully when the next concept paper comes out, both of those will be in there. Maybe they will be listed as an alternative. But we hope to get both of them in there so you will have more opportunity to read specifically on what we are looking at.

Jump to some of the other details of the concept, the PAPR concept. We will talk a little bit about battery life here and power requirements, specifically to battery life.

I think we have talked about this in past sessions, so we are looking at battery life at a minimum of two hours. Right now there is really no specified battery life except that you must pass the silica dust test, and that's a four-hour test.

Now we are looking at requiring a minimum of two hours, and you could advertise that in

increments of one hour at a time. So two, three, four hours.

Again, how are we going to measure this battery life? We are going to put it on a breathing machine on a headform. We are going to let it run at that breathing rate, or work rate, and see that during that time you have said that the battery will last, you maintain positive pressure inside the facepiece.

We have had a lot of comments and questions about alternative power sources besides a PAPR battery. Traditionally there is a battery there somewhere. You can plug into it, or it is internal into the system. You have rechargeable or nonrechargeable.

A lot of people have asked and said, why do you force us to use a battery when we are in a cab of a tractor, spraying pesticides. We have 24 volts or 48 volts, a 12-volt system right there. Why can't we plug into that?

So in this new PAPR concept, we are trying to incorporate an alternative or external power

supply, and you would be able to use that for tight-fitting or loose-fitting.

You see in red here some of the questions that we are asking. What type of power limitations should we have? Should we restrict it to a certain type of power, or should we leave that open for the market and let the market drive that power requirement?

Type of connections is something a lot of people have worried about. Will a connection that we authorize actually fit into cigarette lighters or other things like that.

So one of things we want some comments on is the type of connection.

In the PAPR, as we look at tight-fitting PAPRs, they always have -- should have, may have an escape capacity to them.

If you have an external power supply, but you have to have an escape capacity, you are going to be required some type of battery. Probably a 15-minute emergency battery to be added on there. And that would need to be something that

automatically converts over, switches over to that battery so that you would not lose any kind of protection in there.

Another area that we have had a lot of comment on. I think we have tried to work on this in the past a little bit. And some units out there right now already have this type of indicator. It's a power indicator.

The user needs to know, as he looks down, he needs to know what his status is of his battery or his external power supply, if that's what he has on there. He needs to know how much he has approximately.

Now, I believe this needs to be a real-time measurement that specifically monitors and predicts information to that indicator, kind of like your cell phone.

When everybody opens up their cell phone, they see that little battery display up there. You can see it go up and down. And you know, when you open it up, you have a certain battery.

But then as you start using it, punching a

bunch of numbers, sending some emails, you start to use that battery a little quicker.

Well, that's what should be on a PAPR, I think. There should be some kind of indicator there that tells that user how much battery life he has left.

It also should alert him at the point where there's about 15 minutes left. Now, is 15 minutes the right number? Maybe. Maybe not.

We should be able to get some docket comments on that to see if that's a good number. But there should be something that alerts them that their battery is getting low and it is about to go away.

That should be able to take care of it, whether it's the lowest temperature or the highest temperature resistance.

If it's a feedback mechanism, it should be able to monitor that and predict that.

Now, again, when we do the test, we would do it specific to a breathing rate or work rate on a headform with a breathing machine. So in the test,

it would be very consistent. And we would be able to measure that 15 minutes or 30 minutes, whatever it comes out to be, to see that that alarm does go off, it does alert the user.

Low flow pressure indicator, we have had quite a few meetings on this. We went back and forth. The main thing you will see from the concept paper that you have right now, what is up here, is at all times, we use flow/pressure.

That indicator is just like I have said up here. It needs to be able to alert the user when this particular PAPR has insufficient power, whether that be flow or pressure, to maintain that protection inside the facepiece.

And so a low pressure alarm is what we look at in the laboratory because we can measure pressure much, much easier than I can measure flow inside of a PAPR, whether that be inside the facepiece.

If I'm measuring flow, you can measure that flow in the tube, in the facepiece. It just kind of gets convoluted on how exactly you would

measure that flow.

So measuring a pressure is much easier. You can put a pressure transducer in the breathing zone or anywhere else on the headform, and I can measure that pressure.

So an indicator needs to be there on the PAPR. It needs to be on all PAPRs. This would be another part of the base requirements. And it would measure and alert the user when the positive pressure is no longer there.

Now, the manufacturer can do that by flow if that's the way you want to do it. That's why it always says flow and pressure, flow/pressure.

We will go over a little bit to the respiratory inlet covering.

The main thing we are kind of bringing out here, which is new, would be lens must meet the ANSI standard for high impact. If they do not -- and this would be for all types of facepieces, whether it be loose-fitting or a tight-fitting, whether it be a permanent solid facepiece or eye lense covering, or whether it be a semiflexible or

completely flexible one.

It should either pass the high impact test or be prominently marked, Not Impact Resistant. This way the users could look at PAPRs and know that they have the impact resistance unless they specifically read that it does not have impact resistance. So that's something we are going to require.

A second here to catch up on my notes.

Service life testing. Here's another area that you can have a lot of fun when you go into meetings.

Not everyone agrees perfectly why service life testing is done in a certain way. So I'm going to kind of talk about a little bit what's in the concept paper first and the way it's laid out. And then I'm going to put in another concept that we were looking at as far as doing.

Service life, capacity testing, you are probably going to hear me use those interchangeably.

So the main thing for service life testing, when have you figured out what that

concentration is that we are going to test against and the time and the breakthrough, everybody is concerned about flow. This seems to be the point that we really need to look at a little bit with a little bit more detail, I think, is the best way to put that.

Again, if we look at these new types of PAPRs that are coming out, we have tight-fitting. We have loose-fitting. We are going to have different flow or breathing rates that they can have, a low, a moderate, and a high. We have breath response units. They all work a little bit different.

One of the things that I keep hearing is that a constant flow PAPR really responds to the breath of an individual user. All right.

And we have seen -- and I have showed this data -- if you put it on a breathing machine, even though it's constant flow, you turn it on. Yes, you do see a breathing pattern, all right. And it is consistent to what the breathing machine is doing.

But that works -- a constant flow usually

has a higher flow, even though it alternates up and down with the breathing, different from a breath-response unit. Remember, a breath-response unit is a unit that electronically controls that blower to slow it down and speed it up based on that user's breath, based on the response.

So they have a lower -- normally, they have a lower average flow based on a specific breathing rate, whether that be low, moderate, or high.

So for right now you can see that we would perform service life testing for a system based on this chart. Tight-fitting, moderate, traditional 115 liters per minute. Constant high flow, 270 liters a minute.

Again, this 270 and 325 is some numbers that we really need to look at and investigate. Docket comments would be very useful to see are they too high, too low. What do we need to do with them?

And this concept for breath response unit would be measured at a breathing rate, whatever the breathing rate is the manufacturer comes in with,

whether it is moderate, whether it is high.

If he says it can do high, then we would put it on at 86 liters a minute, and we would measure that breathing rate.

And for that system, we would use that average air flow that goes through there, that average minute volume, use that for testing of the canisters.

So in this, the breath response being a new type of unit, does work -- usually works more efficiently. I'm not going to say all of them are because I don't know what else is out there that somebody may be able to manufacture.

They usually work more efficiently with their air flow, and so we will probably be able to test those lower.

Go through this PAPR -- these are two -- actually, this slide and the next slide behind it, pretty busy slides, but I think everybody has seen these before.

I specifically marked these as nonCBRN. And the reason I wanted to do that is so you could

not get those confused with the ten TRAs that we use for CBRN.

CBRN still is that special application, and it will always continue to use the ten TRAs. We don't want to get that confused with this slide, which is for cartridges, and the slide for canisters.

Out of this PAPR concept, you will be able to come in, as you have done right now, and ask for ammonia protection and get just specifically ammonia protection, or any of the other gases that are listed on these charts.

For right now, these are the test concentrations, the breakthroughs, and those service times. All right? Don't get these confused with the CBRN, which has a service time of -- set up in capacities of 15-minute increments.

One of the things we are looking for here on this PAPR concept is an understanding if these chemicals are the right chemicals to have. Those are the protections that are really needed.

We are looking for docket comments, are

there additional gases that you would like to see that we run, that we have on this table so they are always there, people will be able to ask for.

You can see a lot of those have come from the TRAs used in CBRN, nitrogen dioxide. I think for there, we used the same type of breakthrough that we did for CBRN.

One of the things I want to point out, under the PAPR concept, we see organic vapor. Traditionally, organic vapor has been done with carbon tetrachloride. That was the organic vapor.

For this PAPR concept, we would like to step away from carbon tet -- many different reasons for that -- and go to cyclohexane. Now, we have already done that for CBRN, but for the PAPR concept, this industrial type PAPR also, we would like to go with cyclohexane.

I'm not sure what type of studies we are going to need to be able to go over there. I know there is some work being done in NPPTL about that. If you have specific comments, please send those into the docket.

PAPR concept, we are really looking at following along with what we did with CBRN and getting rid of the temperature and humidity equilibration for canisters and cartridges. And we would go to service life testing at high humidity and low humidity.

I'll go over this pretty quickly because, really, we haven't put it out yet in any kind of documentation where you could really see what we are looking at and see kind of how we have come up with this.

But an alternative concept to service life testing is to step away from kind of the traditional look that we have now, which is either a canister or a cartridge, and we would go to strictly a capacity testing.

And for this -- this is just a concept we are bringing out. We would like comments on it.

We would use one concentration for a chemical. We will take ammonia, for instance. We would use one concentration and one flow and test the capacity of that canister or cartridge, whatever

it is. And we would label those as some type of differentiation between them, whether it be a high capacity, low capacity, whether we keep it the terminology of canister or cartridge.

One thing we are concerned about is getting that -- if we go with this route, getting that confused with a Cap 1. So it would have to have some other type of terminology.

But this is an example of what we could come up with.

For ammonia, you would test everything at 2,500 PPM. We will say, for an air flow, 170 liters a minute. For a lower capacity, you would do that for 15 minutes. For a higher capacity, you would do that for 60 minutes.

Now, these times are just examples right now, 15 to 60 minutes. We could have more capacities, less capacities -- I guess you couldn't have less capacities, but you could have more capacities than that. You could work it in 30-minute increments.

So with some docket comments on these

times, that's something we would like to see.

Now, this is not laid out in the September 19 concept right now. Hopefully, in our next iteration of the concept paper, we will have this alternative out there. I'm hoping to write some other type of document, like a white paper, so we can show some calculations on what we have looked at.

Some other areas of the research that we are continuing in, as I mentioned, the organic vapor going to cyclohexane. Want to make sure we have the correct research done for that to prove that we can do that.

Acid gas, right now we do an acid gas for canisters only. We would like to see if those families of acid gas can be used with cartridges and canisters. We would like to expand that a little bit.

If you look at our CBRN and what we did with that for the APR, we really developed a lot of families there. So some other research needs to continue to see if we can carry on those families

from that CBRN and move that into PAPRs so that you wouldn't have to come in and do ammonia and methylamine. You would just do ammonia, and it would represent that base family.

So that's some research that we would like to continue to do. We are thinking about that. It's not in a concept right now.

Approval for tear gas. Quite a few people have asked for this. If you have a full-face tight-fitting respirator, would you need to perform the CS test and the CN test?

We think that we should be able to have it meet the cyclohexane, which would be the organic vapor and the P100 requirement, and that would be an approval for tear gas.

Carbon monoxide is listed in the concept paper. I'm not sure if there is really a demand for carbon monoxide testing against a PAPR. There doesn't seem to be a demand out there. We could take that out.

Any kind of comments you would like, please send those in.

Additional gases and vapors, you will see a large list of how that can be done, more detailed. The main thing to remember there is NIOSH still has a final authority when you come in and ask for an additional gas.

Failure mode and effects analysis is something that will be required. We will be covering this later on, probably not in this public meeting, but later public meetings. We are still developing that.

But it looks like for now, a PAPR submitted for certification will need an FMEA. These are the minimum requirements right now. Now those could change very much, and we really haven't decided exactly how we are going to require that.

I will go through some additional applications specific areas pretty quick.

The first one CBRN, everybody likes to talk about that. Tight-fitting 14G. It is going to really follow along with what we have done prior. The 10 TRAs with the DOP, LRPL, live agent testing, and durability conditioning for live agent.

Loose-fitting is going to follow the same thing. Now, remember, they are going to have to follow the base requirement, all of the power indicators, the air flow indicators or pressure indicators. They have to have all of that, and then this additional testing to get them a -- an LCBRN would be a loose-fitting CBRN responder. That would be the loose-fitting 23C.

Again, as you can see, it follows along with what we have done right, which is the 10 TRAs, the LRPL, the live agent testing.

LRPL, we are going to cover that a little bit later. Really, we should be able to drop LRPL and move towards TIL in the future. That concept is out there and is going to be discussed later on today. It does go through formal rulemaking.

We hope that also as we develop the TIL, we may be able to get rid of the isoamyl acetate testing. But that's still a concept out there.

Multifunction PAPR, Tim is going to get up and speak about that.

These are other application-specific

requirements that, if you look on that -- concept papers out there right now, there is no information about that. It says to be determined or to be written later on.

So what we would like is some more comments on what we could have underneath hospitals, clean rooms, for law enforcement, what kind of specific tests they would need for that.

Again, this is the docket comment number, 008. I hate to say it, but I would gladly answer any questions that you have.

No questions, even better.

Please turn that microphone on.

MR. METZLER: In a formal rulemaking process, the agency is required to provide an explanation, rationale for why comments were accepted or rejected for leading to the final standard.

How do you intend to handle comments that are being placed on the docket during this conceptual phase? Will they actually be accumulated and then just handled under the formal docket for

the rulemaking process?

MR. THORNTON: That's a very good question.

Can you tell us your name, when you come up to the mic, name and -- we want to make sure we know who was asking.

MR. METZLER: Rich Metzler with the SEA Group. It's a little more nervous on this side of microphone than up there.

MR. THORNTON: I'm sure it is.

That really wasn't for me. That was for our -- a person over here that's recording everything, so they know who it is.

I'm not sure how we intend to handle that, just don't know at this point either.

So we will address all comments -- really, I don't think we have come up with that question yet. How we are going to do that, I'm not sure, but all comments would be looked at for formal rulemaking.

MR. METZLER: I think the comments he presented today are an improvement over the

September 19 document that is posted. So, you know, I would encourage the update to be published as soon as possible.

And the last question is, do you intend to use the ISO work rates so that when some of your testing, where the manufacturer can submit an application where you define what work rate you want your respirator tested at, are you considering to use the new ISO work rates that are being developed under the physiology committee?

MR. THORNTON: I think -- we have three work rates, and ISO has eight or nine. So they have more detailed work rates than we do.

I think if we look at ours -- too close or too far away, the 21 for the low, the 40 for the moderate, and the 86 for the high is very similar to what ISO -- three of the standards ISO has right now.

But, you know, exactly how they match up, I'm not sure yet.

So, especially with the 21 and the 86, we would like comment on that. The 40 is kind of

locked in. NIOSH has used that traditionally for quite a while.

But the 21 and 86, we would be willing to look at ISO to see if we could match up with those.

MR. METZLER: All right. Thank you. Terry, you did a great job.

MR. THORNTON: Thank you.

MR. SZALAJDA: I wanted to add something on Rich's original question.

One of the things I think that we have tried to be sensitive to when you -- with the docket, dockets have been set up for CBRN primarily, at least as far as going through and assessing them as part of our process for making decisions on the performance requirements for the respirators.

I think the one thing that is advantageous that will come out with the rulemaking that, depending on how we resolve comments that are developed in the concept phase, that the user, the stakeholder community will still have the opportunity during the rulemaking phase, if there are elements of performance that you think we should

consider or did not consider as part of the process, that at that point in time, if you feel a comment that wasn't made or a comment that was made during the concept phase wasn't adequately addressed, you know, that type of issue could be resurrected and reissued as part of the formal comment phase.

MR. HEINS: It is Bodo Heins speaking from Draeger Safety in Germany.

I have problems in understanding your service life when it is tested against gases and vapors.

First thing you say that minimum requirement for PAPR is two hours. I think it is much too low because a PAPR will be used for a long-term usage, and two hours is nothing.

But even if you say then, at least the service time has to be two hours, how can the minimum requirement then be 24 minutes when the test -- the canister is tested?

MR. THORNTON: I think there is two different things that we are talking about, a battery life. And in that 19 September concept

paper, it may -- it is kind of confusing when you talk about service life.

What I would like to do is distinguish service life testing. That's for the canister specifically and how we do a minimum service life for that, distinguish that from the battery.

The battery would have a minimum two-hour battery life, and that would be two hours that would operate the PAPR.

And then separate from that is the canisters. And they are tested dependent upon the chemical, whether it is a canister or a cartridge. Some are 24, 12, 50 minutes, 60 minutes, so they have many variations. But that's chemical dependent.

I think switching out batteries is something that the user should be able to do regardless of what kind of service life there is for a canister. I think it would be very difficult to try to match up service life of canisters or cartridges specific to the operational life of the battery.

MR. HEINS: Two hours are nothing for batteries -- in our opinion, our opinion, the PAPR should last at least one shift, which is probably eight hours.

So, okay. My next question is if you are testing the breath control units with an average of the highest work flow rate, then I think it is a disadvantage for these units. Because these units are breath controlled to reduce the flow through the filter to increase the service lifetime.

And if you test some with a maximum average air flow, then it's not testing in accordance of the technique of this unit.

MR. THORNTON: That's a good comment. We will take that into consideration.

That is something that we need to look at.

MR. HEINS: Okay. That's it. Thank you.

MR. PFRIEM: There is nobody behind me, so that means I have all the time in the world; right?

MR. THORNTON: Well, we are going to get hungry soon.

MR. PFRIEM: The first question is, a lot

of the things that you presented weren't in the PAPR concept paper.

And if we want to comment on those alternatives, and slides weren't provided in the handouts, could we get a copy of your presentation so we can comment on your alternatives as well?

MR. THORNTON: Yeah. I'm not sure how quick we are going to be able to get that out.

MR. HOFFMAN: Yeah, we can do that. But they are also going to be on the web as well, the presentations. Because of the length of them and the number of slides, printing them out became --

MR. PFRIEM: So they will be posted on the web?

MR. HOFFMAN: Yes.

MR. PFRIEM: When?

MR. THORNTON: As soon as we can. I don't know how long it actually takes to do that.

We think within a week. Is that a fair assumption, Jon, within a week?

MR. HOFFMAN: Oh, yeah. It will probably be before that, but a week is --

MR. THORNTON: So they should be out there within a week. That's normally when they come in.

If we don't make it in a week, ten days, give us a little time to get it out there.

MR. HOFFMAN: Dale, while you're there, I want to point out, just in addressing that question, in your handout is a yellow sheet of paper that has all of the docket numbers on it.

And it is important that you get the correct docket number with the comment. Because what sometimes happens is the people that are categorizing look at the docket number rather than the text of the material, and your comment could get placed in the wrong docket. If that is the case, we may not see it. We may not know that it goes to ours.

Because if you look at the sheet, there is a whole lot of things going on, not all with NPPTL.

MR. PFRIEM: And most of the time I will run out of time, and you won't see it, so that's why I come up here and blab.

And then I guess there's a typo in a lot

of different places in the concept paper because I can't get past the fact that you guys want to allow a loose-fitter at a hundred liters per minute, but you are not allowing tight-fitter.

So I asked the question yesterday, why we are not preconditioning cans or units for loose-fitting hoods and helmets, and I didn't get a substantial answer.

So I ask this question. Why in the world would you guys put that out there?

MR. THORNTON: You mean to allow for a loose-fitting --

MR. PFRIEM: You are going to allow a loose-fitting helmet at a hundred liters per minute, but you are going to disallow a tight-fitter.

MR. THORNTON: You know, the tight-fitting -- there is kind of that minimum requirement for tight-fitting we looked at, which is the 115 liters per minute. That's what we have right now, and that seems to be a pretty good basis to put that on.

So allowing a low flow, or a low unit for

tight-fitting just does not seem to fit what we have right now.

Now, we are doing that for a loose-fitting yes, but we think that there is a need for that and a demand for that.

People who use a loose-fitting, users and manufacturers have come up and said that they use these in a setting where there is not strenuous work going on, not a large activity. They could be sitting still. They could be in some type of chair where they are in the cab of a vehicle.

So we thought that we could allow that and be able to do that.

Now, if the comments come in that says that's too low of a flow, should not be allowed, we will take that into consideration.

So we will have to look at that.

MR. HOFFMAN: There has been a lot of interest in the medical community to have a small battery, short-term filter, particulate filter only unit in loose-fitting, and we are trying to address those needs so that they don't have to carry a big

battery for something that may be a 15-minute procedure.

And like Terry pointed out, we are still looking into all of those things. And I don't think that we have actually said that we will not consider a tight-fitting, low flow, but there doesn't seem to be any need for it or any interest in it at this point. So we don't want to put things in there that will -- like a type A or type B supplied air respirator where nobody cares about them anymore, nobody will ever do anything with them.

MR. PFRIEM: Understand. And I can support the thought process, that it's -- it could be feasible as long as we have good fit testing protocols to allow for a hundred liter per minute unit on a loose-fitting.

But on the reverse side of that, I don't agree in the thought process, like you guys don't think that PAPRs, loose-fitting, are going to be handled delicately in the CBRN world where you don't think it is going to be needed on a tight-fitter.

So that's my thoughts.

MR. HOFFMAN: Why the conditioning for one versus the other.

MR. PFRIEM: He addressed that yesterday. I just don't happen to agree.

MR. THORNTON: I think we got that one.

MR. PFRIEM: Okay. And the maximum average flow rate, when you guys put this out to the next version, if you could define that a little bit more clearly as far as -- because it's maximum average flow rate as specified by the manufacturer. All right.

So then the manufacturer is going to have to, at least in my opinion, provide some data on how that maximum average flow rate was derived.

And then I'm thinking NIOSH should set some kind of protocol boundaries on how that -- how these things should be derived.

MR. THORNTON: Yeah, I think there may be a little confusion there.

I think when we are saying, let manufacturer specify that, they would specify one of those breathing rates, a low, a moderate, or a high.

And we would measure that average flow using that breathing --

MR. PFRIEM: Using the notated values?

MR. THORNTON: Yes.

MR. PFRIEM: So the terminology maximum average flow rate as specified by the manufacturer, I can ignore that?

MR. THORNTON: Whether it specifies the high or the low or the moderate.

MR. PFRIEM: Got it. Excellent.

MR. THORNTON: And then we would measure that.

That information, the next concept paper that comes out, I will try to get that information out there of how that measurement will be made.

MR. PFRIEM: Okay. And then, you know. You had two. You had an alternate in the way it is presented here, but I can't wrap my head around how you guys are normalizing pressure when you're shoving 250 liters a minute, you have got an 86 liter per minute breathing rate, quote unquote, okay, and you are trying to measure that flow.

MR. THORNTON: We are not going to measure flow. We are going to measure pressure.

MR. PFRIEM: But you said you are measuring flow in the concept paper.

MR. THORNTON: Yes. I tried to clarify that, that we are -- I'm not sure where it says we are going to measure -- we are going to measure pressure. That's going to be our measurement that we --

MR. PFRIEM: The alternate scheme, you were going to ensure that there was always positive pressure maintained.

But in the concept paper, the principal, you had positive pressure only for a variable for -- only for breath responsive PAPRs, but not for -- for nonbreath-responsive PAPRs, at least the protocol as I read it, is flow based.

MR. THORNTON: Yes. And we would measure average flow while it was on a breathing machine, whatever that was that the manufacturer came up with, whether they wanted a high, low, or moderate.

MR. PFRIEM: So you have got a breathing

machine working at 86. You have got a PAPR trying to push at 250. How are you normalizing?

MR. THORNTON: That's kind of a detailed answer, and we have talked about that in prior -- I can sit down with you and go over that, how we have done that and how we -- in fact, I think there is a draft standard test procedure out there that I could direct you to that shows how we have done those tests and how we take those measurements.

That should help us out quite a bit.

MR. PFRIEM: And we are getting to the end here.

MR. THORNTON: Good. Because we have got one more presentation before lunch.

MR. PFRIEM: On the LRPL, are you going to keep this same number of subjects, same number of samples as the APR STP protocol, because it's not specified in the paper.

MR. THORNTON: For the Step 2, or for the PAPR concept?

MR. PFRIEM: Yes.

MR. THORNTON: I'm not sure. I believe

for right now, yes, we would keep the same number, but we may need to re-evaluate that when we move that into TIL.

So right now, we don't have a specific answer for that except yes, that's what we are looking at, keeping the same amount. But that could change.

MR. PFRIEM: Okay. And then there was one more, if I can find it.

You are specifying two conditions for the end-of-service-life tests.

You're testing 25 and 85 percent RH, and then you say at two contamination levels, but you don't say what those contamination levels are.

So if I'm testing for a manufacturer ammonia service life, okay, and you have got it down 25 and 85 percent, but then you are saying, you know, two contamination levels.

What are the contamination levels?

MR. THORNTON: I will have to talk with you on that because I'm not sure what -- you will have to show me where that is in there.

That doesn't sound familiar.

MR. PFRIEM: And then Annex A for the FMEA that's referenced, but not here, is that going to be available? Or at least I couldn't find it.

MR. THORNTON: It will be -- I didn't know it wasn't out there, so, you know, we are going to have to get that appendix out there.

MR. PFRIEM: That's it. Thanks.

MR. THORNTON: Thank you.

MR. VANDERWOUDE: Brian VanDerWoude from Stryker Instruments.

My question is in regards to the filtration efficiencies that are presented as approvable in the draft standard.

You currently offer a P95 and a P100 equivalent for the powered -- for the PAPRs.

MR. THORNTON: Yes.

MR. VANDERWOUDE: I wonder why you don't offer an N95 equivalent.

MR. HOFFMAN: I'll comment on that one.

Actually, we are using the DOP for what we are calling the PAPR 95, but it's an instantaneous

DOP test. And the data we have shows that if you do it -- it's a 30-second test, because the DOP really doesn't have a degradating effect in that short of a time.

The 100 series is actually the full test with the full loading. And the interest seems to have been to this point that people only care about one or the other. There doesn't seem to be much need or interest of anything else we have like we do in the non-powered one.

That's not to say we won't consider them, but up until this point in time, there hasn't been any interest. We don't want to do the test at high flows with salt because it is just too hard to maintain and control the instrumentation.

MR. VANDERWOUDE: The concern is the, in the healthcare environment, the recommendation from CDC is often an N95 or better. And then the filtration media options are greater at that rating.

And that's our interest in pursuing the N95 option for a powered air respirator.

The other comment is in regards to

filtration -- or no, flow rate.

MR. THORNTON: I'm sorry. Can you say that again. Into --

MR. VANDERWOUDE: In regards to flow rates, our customers typically are asking for more flow rate than what would be covered underneath your standard, so a higher flow rate.

What you are saying about possibly not requiring a flow rate but only requiring positive pressure, I would be highly in favor of that so we could offer a higher air flow rate to our customers.

Since ultimately what matters is that there is positive pressure in, that their CO2 level is not excessive, and as long as you can keep the noise levels appropriately underneath your other requirements, the air flow rate is not significant.

MR. THORNTON: Very good. Thank you.

We have time for one more, and then we will to start this next presentation.

MR. SOLYNTJES: I hope this will be quick. Alan Solyntjes from 3M.

Can you comment on why you have limited

single level blowers, the single flow levels, to only the middle flow?

Why would there not be -- allow -- why would not allow a low flow single setting blower?

MR. THORNTON: Well, for tight-fitting, I think we have already had that discussion, whether we were going to look at that or not.

And I -- in the concept, as I think about that concept paper and the way it is written, we may have left out a single flow blower that just establishes a high as opposed to any of the other flows.

I think we do -- we are going to allow those. I just don't think it is written.

MR. SOLYNTJES: So a single flow, low flow loose-fitting might also be --

MR. THORNTON: Yes. Yeah.

MR. SOLYNTJES: Okay. Thank you.

MR. THORNTON: All right. If there is no other questions, thank you.

I'm going to present Tim Rehak. He is going to cover the multifunction PAPR and the

research that is going on with that.

MULTIFUNCTION POWERED AIR PURIFYING RESPIRATOR

MR. REHAK: Okay. Good morning. My name is Tim Rehak. I'm the project officer of the Multifunction Powered Air Purifying Respirator contract.

Okay. The goals of the contract are to develop new comprehensive test standards for hearing protection, head protection, eye protection along with respiratory protection for multifunction PAPRs.

Okay. This contract is funded by NPPTL. It's a multiyear contract that we have with the University of Maryland's Human Performance Laboratory.

The principal investigator for the contract for the University of Maryland is Dr. Art Johnson, and he has a long history of research in all wearability issues of respirators. And I guess the unique thing with his research is he takes a bioengineering approach to his projects.

This contract is -- MSHA is collaborating with us and our stakeholders besides the equipment

operators, is BCOA, the National Mining Association, along with the unions, the UMWA.

Okay, briefly, I'm going to go over a summary, after all of the testing and research that the University of Maryland has conducted for this contract.

Okay. First, they did testing on exercise performance while wearing a tight-fitting PAPR with limited air flow. Okay. For this testing, 16 subjects were tested at 80 to 85 percent of their VO2 max while wearing a tight-fitting PAPR.

And the power supply was changed to produce 100 percent, 94 percent, 66 percent, 30 percent and zero percent of a 110 liters per minute flow.

The results that they came up with, inadequate blower flow rate decreased performance time, facial cooling, and respirator comfort.

If you want more information on this research, it was published in the July 2005 issue of the Journal of Occupational and Environmental Hygiene.

The next testing they conducted was overbreathing a loose-fitting PAPR.

Here, 16 subjects were tested, again, at 80 to 85 percent of VO2 max while wearing a loose-fitting PAPR in a portable breathing chamber that they developed. That's it there.

All subjects exceeded the PAPR flow rate. 17 percent of the breathing volumes exceeded 1.4 liter dead volume that they measured inside the PAPR visor.

All instantaneous corrected flow rates were above 38 liters per minute. 30 percent were above 150 to 158 liter per minute range. And a small portion, approximately 1 percent of the flows, were in the 520 to 558 liters per minute range.

Again, this research has been published in the ISRP Journal, the spring/summer 2005 edition.

Inhalation flow rates during strenuous exercises, the subjects were measured under the following conditions:

Twenty-four were tested without a respirator at 80 to 85 percent VO2 max with a peak

inhalation flow rate of 379 liters per minute. Nine were tested without respirator at 100 percent VO2 max with a peak inhalation flow rate of 440 liters per minute.

Ten were tested while wearing a PAPR at 80 to 85 percent VO2 max with a peak inhalation flow rate of 679 liters per minute.

Conclusions they draw. A linear relationship was found between the peak flow rate and the average minute volume, which we began to use to produce peak flow rates expected at any given flow rate.

This research was published, again, in the ISRP journal, fall/winter 2005.

Okay. They did some testing that determined the effects of helmet weight on volume performance time at 80 to 85 percent of maximal aerobic capacity.

Ten subjects were tested with four helmets -- the weights are listed up there -- while walking on a treadmill to produce 80 to 85 percent of their VO2 max. The results that they came up

with show that the performance time in minutes was literally related to the helmet mass.

There's the equation right there. I'm not going to have to read it to you. And this research has been submitted to the Journal of Occupational and Environmental Hygiene, currently hasn't been published yet.

They also have been in a process -- I think this started well before our contract, but they are looking to develop a model to predict the physiological and performance features of respirator mask wear.

Currently, they are looking with the model to predict oxygen consumption, minute volume, and performance time. And right now, they are at the point where they are pretty accurate with the -- in predicting oxygen consumption and minute volume, but they still have some ongoing work that they are doing to improve the accuracy when trying to predict performance time.

And the goal, again, is to predict performance time and physiological responses for

respirators in the preprototype stage of development.

Okay. They have done testing on a correlation between personality type and performance time while wearing a respirator.

Here subjects perform at 80 to 85 percent VO2 max while wearing a modified M-40 respirator to create various inhalation resistance at 85 liters per minute, and all 31 subjects were tested using the Myers-Briggs type indicator and the State-Trait Anxiety Inventory.

The results that they came up with, when air intake resistant is the highest, sensing-intuition and thinking-knowing (sic) versus performance time was found to be statistically significant.

If you need more information on this, this has been published in the June 2006 edition of the Journal of Occupational and Environmental Hygiene.

They have been doing work on a flow visualization. First, on the loose-fitting PAPR. Two loose-fitting PAPRs were fitted on a headform

and connected to a breathing machine.

A modified portable breathing chamber contained all of the fog that was generated. And during the testing, the images were captured just using a basic video recorder.

The results that they came up with, about 1.4 liters of protective volume was observed to be inhaled before the fog was able to reach the mouth of the headform.

Items of interest that they came -- also noticed during the testing included that head tilt affects the protective volume that the PAPR provided. Also the racal fog was present inside the face shield at all times, even when there was no breathing.

And third, the fog reached the mouth quicker when you had a PAPR without a scarf. 1.2 liters of air was inhaled without a scarf compared to 1.4 liters when the PAPR had a scarf. And this testing has been submitted to the ISRP for publication.

Okay. Protective volume inside the

loose-fitting hood.

This was done in a full body chamber which they developed in their lab there. It was fabricated to test how much air must be inhaled before the fog reached the mouth with the blower off.

With the blower at 110 liters a minute, the breathing machine was set at 30 beats per minute, tidal volume, 2.21 liters. Total overbreathed volume was measured at about one liter, and no fog was evidenced.

The results they came up with was there was two liters of protective volume.

Okay. Also, flow visualization with the tight-fitting PAPRs. Here they tested two different tight-fitting PAPRs in a full body chamber.

They used a bronchoscope to observe when the fog was actually entering the mouth. And they broke down their videos, you know, frame by frame so they could tell it down to the second. And also they measured leak volumes.

The results showed that no fog was

visualized at the mouth, but they did detect leak volumes.

With the one unit, it was .26 to .28 liters, on or off. And with Unit B, it was .02 to .09 liters on, and .26 to .28 liters when the unit was off.

They also detected a possible leak. They weren't sure at the time from the face seal or the exhalation valve. And this research they have submitted to the Journal of Occupational Environmental Hygiene.

Since they discovered that there was some leakage here, they did some further testing to see if it was from the face seal or from the exhalation valve.

They discovered through testing that both face seals leaked approximately .05 liters.

Unit A, the exhalation valve closed within .16 seconds with about a hundredth of a liter of air entering only when the blower is overbreathed on this PAPR.

With the other PAPR, Unit B, the

exhalation valve open and closed three times throughout the entire breathing cycle.

They have conducted human testing of loose-fitting PAPRs in a full body chamber. So far, they tested 12 subjects to date.

The preliminary data that they came up with shows that from one to 1.3 liters needs to be inhaled before the fog would reach the mouth. And also that the pathways were similar with human testing as they were with -- while using the headform.

And finally the remaining work, they are doing work for us now to check or test on the CO2 buildup within the PAPRs, both loose-fitting and tight-fitting PAPRs.

They are going to do this work in the full body chamber. And the breathing machine's inhaled air will be instantaneously analyzed for CO2 concentration to determine actual overbreathing.

And, finally, all of this research and all of the reports, the testing that the University of Maryland did for us, it will be submitted to us in a

final report. We will have it peer reviewed, and it will be a NIOSH numbered document.

If there is any questions -- if not, we can go to lunch.

Okay. Thank you.

MR. BOORD: Okay. So we will break for lunch. And I think, according to the agenda, we will resume at 1:15.

So that leaves a little over an hour, about an hour and 25 minutes. Thank you.

(A luncheon recess was taken.)

MR. HOFFMAN: Okay. If we can get started. For the afternoon session, there's a lot of topics that we need to cover. And I did want to mention that for the policy and standards groups, there is a lot of areas we are working on, and some of those include guidance documents.

CBRN, we continue to develop and improve the test procedures and tweak things that we need in that area.

Combination units are going to be talked about, supplied air respirators, closed-circuit

SCBAs, closed-circuit escape respirators a little bit. We have talked about the PAPRs. Total Inward Leakage, QA and administrative module.

We are going to stay with the agenda. And the only difference in the agenda is a couple of the presenters are different so that we can give the speakers a rest so that the same person isn't speaking through the whole thing.

Without delaying the process any further, I would like to bring Frank Palya up who is going to give the first presentation on the Chemical Warfare Agent Simulant Project.

CHEMICAL WARFARE AGENT SIMULANT PROJECT

MR. PALYA: Thank you, Bill. And I would like to welcome you all to the NIOSH public meeting. I'm going to be discussing the Chemical Warfare Agent Simulant Project.

Back in April of 2001, when NIOSH said that they were going to use actual chemical warfare agents to do certification testing, the stakeholder community requested that we develop simulants so that the manufacturers could go ahead and do a lot

of their in-house testing without going -- and testing their products in-house.

Because a lot of this testing, the live agent testing is very expensive and requires a lot of lead time.

We partnered with NIST and RDECOM on this.

Most of the experiments were performed at Natick, and -- mainly the simulants were performed at Natick and Edgewood chemical biological center, and that's where the agent testing was done.

The project goals were to identify compounds to simulate the permeation effects of the GB and HD through elastomeric barrier materials. Also, the goal was to develop a standardized method that can be used by the stakeholders to measure simulant permeation times with the identical method that was employed with the HD and GB.

This would provide stakeholders with a readily accessible low cost screening method to evaluate their material, how it resisted agent permeation by testing it with simulants.

And this would also allow the stakeholders

to rank their materials. And then whatever materials performed best, then they could go ahead and perform actual live agent testing.

The accomplishments -- Phase 1 has been completed. And I would like to go ahead and discuss some of the accomplishments.

The accomplishments were that we obtained test data using the identical method. We tested -- gained information on the GB and HD, with the four simulants using three barrier materials. And these three barrier materials were silicon, EPDM, and butyl.

We also performed permeation tests and sorption tests. And we did find the four simulants that we felt that worked the best. And we found two for HD. That's the DCH and the CEPS. And for the GB, the DEMP and the DIMP.

We also developed a test method capable of testing liquid permeation resistance. It could test materials up to .7 centimeters thick, and it uses the Flooded Cell Technique. It is -- basically, it's not the whole cell is flooded, but it's just

the whole surface is covered and is challenged with simulant or agent.

This is a schematic of the permeation test system. It is pretty basic. This is the permeation cell that was developed at Natick. We came up with a new permeation cell, but everything else is pretty much standard equipment.

Again, that's a side view of the permeation cell.

As you can see, it's -- you have the sweep gas flow through there. That's the detector gas. This is the specimen. This is the film, the agent film, or the simulant film. A Teflon gasket, and then this screws on the top. And the agent is applied in this area right here from the top.

This is the actual picture of it with the various components.

Another accomplishment is that there was a journal article published in the Journal of Membrane Science in 2005. Also we produced a scientific document entitled Estimating Permeation Resistance of Nonporous Barrier Polymers to Sulfur Mustard and

Sarin Chemical Warfare Agents Using Liquid Simulants.

The document describes the rationale for the simulant and barrier materials selected. It contains 75 pages of detailed requirements needed to perform the test, including a test procedure. There's the test procedure, data analysis techniques, plots. Also a mechanical drawing is included in there, so respirator manufacturers could build it in their machine shop and use it.

So it does contain a lot of information in this report. This document will be published as an official NIOSH numbered document.

The status of this document is that it's in external review process. It already went through internal NIOSH review. The document was changed, substantially rewritten. And then it went through NIOSH OD review again, and it was rewritten.

So this document has come quite a long ways. So one of the last steps is to have it externally peer reviewed, and it's due back from the external peer review by the end of the month.

Hopefully it will be published as a NIOSH numbered document in '07, Fiscal Year '07. Then it will be released.

And this is another good example of research to application. There was a Phase 2 part of this project as well, and -- because we liked the results of Phase 1. So -- but we wanted to go ahead and expand this information, so we did this.

And part of their project, or Phase 2 project goals were to broaden the estimation and reliability of the simulant methodology by evaluating additional barrier materials, including thermoplastics.

Develop additional simulants if we felt that it needed to. Determine the quantitative relationship between the flooded cell technique and the conventional drop loading.

The conventional drop loading is the technique that is used currently by NIOSH when they are performing the agent testing, and that's ten grams per meter squared.

And also determine the sorption/desorption

characteristics and to correlate those with permeation results.

This information would be good for -- would assist in understanding the decontamination of PPE materials.

Also, we wanted to identify critical properties that control the permeation of G agents and mustard type agents through barrier materials and improve the capability to predict barrier material permeation just based off of certain chemical and physical characteristics of the material and the agent.

So if we got a broader understanding of the materials and what certain characteristics resist agent permeation, just by studying the material, you may have some idea what material would resist chemical agent permeation without going through testing, just from going ahead and doing the research and finding these certain characteristics.

The status of the project is that we have gone through a lot of screening. We have screened over ten candidate materials at one or more

thicknesses, and we selected these five right here.

But the trouble is a lot of these materials have such excellent permeation resistance that you just can't get any of the data from them. Because you want a material that will break in a reasonable amount of time, let's say between one and eight hours, and -- or you don't want it to break too soon, but you don't want it to break too long, because you need to get it in this one to eight-hour time frame.

So it has been quite a challenge to get the materials. You can only get them so thin. But these are the Phase 2 materials that we feel that we are going to go with.

A lot of the times, you can't get really get a lot of information from them because they are proprietary as well.

Also, there's -- some comparison testing has been completed. The flooded cell versus the conventional droplet contamination. We did that with DIMP and DCH on butyl.

And what we found, whether it was the

flooded cell or the droplet, basically has essentially the same breakthrough times.

Right now we have some interlab comparison tests set up to make sure that what work has been done with the simulant, what test results we got with the simulants will yield the same results in another lab. Basically a round robin test to ensure these results.

We also have some agent work scheduled for the ASTM neoprene. And also performed was 17 and sorption/desorption experiments completed for the simulants.

In summary, we developed a rapid relatively low-cost laboratory procedure that can be used by manufacturers to estimate chemical warfare agent permeation through candidate materials using simulants.

We identified the four simulants, and also we contributed to a peer review journal article in the Journal of Membrane Science. And then there's the NIOSH scientific information document developed, which is going through the external peer review

process.

So, again, we are expecting comments by the end of October, and we anticipate publication in fiscal year '07.

Thank you.

And I'll address some questions at this time, if there are any.

Okay. Thank you.

IDENTIFYING ALTERNATE LIVE AGENT TESTING LABORATORIES

MR. PALYA: Well, I'm going to continue on here. There is no use for introductions, so -- I'll get a drink of water, though.

I would like to discuss the efforts NIOSH NPPTL has been doing into identifying alternate laboratories for qualification to perform NIOSH chemical warfare agent testing for certification of CBRN respirators.

There has been some concern that there was -- we only have one lab, NIOSH only has one lab qualified to perform the live agent testing. So, you know, we started this project to go ahead and

find out, you know, find a different lab performance work.

So the live agent testing that we are performing, we only used two agents, and that's GB and HD.

And also the type of testing that these labs do is they test a NIOSH standard and test procedures development testing. They do CBRN certification testing, and then there is a manufacturing R & D testing program in place.

So when we go ahead and qualify these additional labs, there will be three types of tests being performed.

The benefits for funding another, an alternate lab is to expand the test capacity in case of a national emergency. The capability is needed to accommodate a surge in CBRN respirator applications, and increased lab availability for PPE manufacturers to perform their R & D testing for their product.

Again, we started this initiative in February 2006.

The goals of the project were to identify and qualify alternate laboratories that were capable of performing NIOSH LAT testing. Select alternate labs based on a stated criteria that we developed, not NPPTL developed.

This is to ensure that CBRN certification testing continues without interruption. So that was a high priority for us. And ensure that these labs are capable of performing NIOSH testing in accordance with our standard test procedures.

We contracted EG&G Technical Services, Incorporated to perform this work. And they also brought aboard a technical expert in chemical warfare agents from Georgia State University.

The work that -- the results of this work is that they identified two government-owned, government-operated labs. And these labs were surveyed. That was Dugway Proving Ground and Pine Bluff Arsenal in Arkansas.

And they also found that there is five contractor-owned, contractor-operated labs. And they were also surveyed.

EG&G went out and physically visited these laboratories, and they had a series of questions to ask. And they evaluated them based on this criteria that we established.

And these are the five contractor labs contractor-owned, contractor-operated labs that were surveyed.

The selection criteria for the candidate labs was -- this pertained to the contractor-owned, contractor-operated labs, was if they had a bailment agreement in place. That was a very important aspect of it.

This bailment incorporates such documents as Army Reg 50-6, AR 385, AR 190-59 -- most of these documents that I'm reading here pertains to chemical surety, chemical security, chemical safety.

In one way or the other, all of these things that are listed below, the training, the PPE, the inspection, accountability, decon, disposal, medical surveillance, storage, you name it. It's all addressed within these documents and then within this bailment agreement.

And this bailment agreement is negotiated with the Army. So if they cannot fulfill and meet the Army regs, there is no bailment agreement issued.

The selection criteria that we felt, NPPTL felt was important, was that if we went to these contractor-owned, contractor-operated labs, does the bailment agreement allow for NIOSH LAT testing, testing of nonDOD products.

And the products that NIOSH gets certified are considered nonDOD products, not directly defense, Department of Defense related.

The bailment -- within the bailment agreements, there are limitations on the amount of agents stored on site. Basically, is there an adequate supply of agent for NIOSH testing. Do they have quality assurance to ensure that the agents, this GB and HD, meet the purity requirements that we are currently using of the CASARM agent.

Because just agent is not agent. There is a lot of purity in agents, or impurities in agents, depending -- especially if it is weapons grade,

depending if it's stored in an artillery round or a rocket or bulk.

So as they are stored there and, over time, they get these impurities. And these impurities cause the agents to behave different and therefore affecting the permeation rates.

So we have to ensure that we have good agent and there's consistency so there's consistency amongst our tests.

Looking at the lifecycle costs, obviously, the convenience of the laboratory. The location for delivery of the agent for NIOSH and PPE manufacturers to visit.

So is it convenient for NIOSH and PPE manufacturers to visit, or is it very difficult? So that was a criteria we looked at.

And of course, does the laboratory have the capability to meet the demand to develop alternate tests.

Because such as these -- the tests that were coming through for -- during policy development. So we are always doing a lot of

development tests as we are developing our standards.

So just not certification, but additional alternate tests that NIOSH may require of them.

The projected milestones, the status of the project is the draft is -- the draft report is being written right now, and it will be sent to NPPTL.

We are going to evaluate it, and then we will send this report back out to the laboratories to ensure that they -- what's in the report is accurate and so there is no disagreement.

And then the report -- after the comment period, the report will be revised and then provided to NIOSH NPPTL management to make a decision whether to activate the alternate lab. And, if so, which lab.

And that concludes my presentation on the alternate lab.

And any questions at this time? Okay. thank you.

MR. HOFFMAN: You have got one.

MR. PALYA: Oh. Oh, geez, Dale.

MR. PFRIEM: 17025 wasn't listed. Can I assume it's among one of the criteria?

MR. PALYA: Dale, would you stand up to the mic, please?

MR. PFRIEM: Dale Pfriem, ICS Labs.

MR. POA: Is that on?

MR. PFRIEM: Dale Pfriem, ICS Labs.

Was 17025 one of the criteria?

You didn't note it.

MR. PALYA: You mean was it a DA PAN (phonetic)?

MR. PFRIEM: No. Accreditation to the ISO model.

MR. PALYA: No.

MR. PFRIEM: Why not?

You guys don't think that's important? I don't know.

MR. PALYA: Well --

MR. PFRIEM: Is a surety license all that counts?

MR. PALYA: No. That's not all that

counts.

But, I mean, again, we are going to go ahead -- there is quality assurance in there. Okay. I mean, we did have some quality assurance provisions, and that was part of the survey. We are going to go through the survey and see what they have.

MR. PFRIEM: Will you require a 17025?

MR. PALYA: Not at this time.

I would think -- I don't know. We are going to go ahead there and go look at -- investigate it further.

MR. PFRIEM: All right.

MR. PALYA: But thank you for a point well noted on that.

MR. SZALAJDA: That's a good comment, Dale.

I think the one thing we need to keep in mind is really the intent of the study up front was to look and see if it was even possible to go and use an alternate lab and try to identify the issues associated that.

I think any implementation on the way forward, obviously we are going to look at accreditations and things like that, at least as far trying to make sure that when we, if an alternate lab is established, that, you know, we are getting repeatable, reproducible type results independent of which lab the testing they go to.

So that's a good comment.

MR. PFRIEM: Thanks, Jon.

CBRN HAZARD ASSESSMENT OF FIRST RECEIVERS IN MEDICAL FACILITIES

MR. PALYA: Okay. This is the last presentation I have, so -- I'm going to present another project we were performing here, and that's the hazard assessment of First Receivers in medical facilities responding to CBRN terrorist events.

Some of the issues that came up is what degree of individual protection is required for First Receivers in emergency departments in response to a CBRN terrorist attack.

Also, what is the extent of the secondary hazard that it will be in the ED.

So we need to find this out before we go ahead and develop our standards or, you know -- so it would assist in our standards development.

The definitions of the First Receivers are emergency physicians, emergency nurses, patient care associates, clerical staff, hospital cleaning staff, and security staff.

The secondary hazard would be the residual contamination from the chemical or biological agent on the clothing or the bodies of the casualty coming into the ED.

This is the definition of the First Receivers in the OSHA best practice document. And it basically says the same as the definition that I used.

Some background is that the chemical warfare agents and biological agents are orders of magnitude more toxic than Toxic Industrial Chemicals. First Receivers have suffered in the past in previous CBRN terrorist events, such as in Tokyo and Matsumoto incidents.

The potential of contamination hazards

that might be encountered by the First Receiver have not been determined yet. So we know that, and that's the whole purpose of this hazard analysis, is to determine what has -- what is the concentration level that can happen inside the emergency department.

This effort was performed primarily by OptiMetrics, and this is through a NIOSH collaboration with the U.S. Army Research Development and Engineering Command.

The contract was let through the Army because they have a task order contract with OptiMetrics to do this type of work, and it was funded by NIST and the Department of Homeland Security.

The object is was to identify potential CB hazards inside a typical emergency medical facility.

Estimate the levels of potential vapor concentration to enable development of the standards for NIOSH CBRN nontight-fitting PAPRs and other appropriate standards for clothing, PPE clothing.

Also, the objective was to use sound

rationale and assumptions based on previous studies, published documents, mathematical modeling, to obtain estimated hazard concentrations within the emergency departments.

There is an infinite amount of scenarios that one could have, and, therefore, yielding an infinite amount of concentrations. So, therefore, we had to make some -- what we felt were sound assumptions, and go with those and model with those assumptions.

The first one was that the medical facility is not the primary point of attack. It's not ground zero. The contamination source is from the incoming victims.

We selected nine chemicals to model, and these nine chemicals were from the NIOSH list of chemicals used to when we developed our CBRN APR standards. And we felt that -- they were from the TICs. Well, seven were TICs. Two were CWAs.

But the seven TICs that we developed, we felt that they were going to be the most likely to be encountered. And we also based that on toxicity

as well.

And the seven TICs were ammonia, chlorine, formaldehyde, nitrogen dioxide, phosgene, phosphine, and sulfuric acid.

And the two CWAs are GB and HD.

So once we developed what chemicals would probably potentially be used in a terrorist event, we said, Okay, now, first you have a develop a hot zone contamination level.

So we looked at the various hot zones, and there was -- one venue would be a meeting room with 350 people in it. And we felt one liter of CW chemical. That's reasonable.

There's an auditorium venue, a theater with 800 people. One and four liters of chemical warfare agent.

Airport concourse, 300 occupants at various amounts of chemical agent.

But we decided to use the auditorium/theater and with a -- for the TICs, a 50 gallon of initial explosion at Ground Zero.

So this contamination would explode,

contaminate the people in the room. And then these people would be eventually sent to the hospital.

So it would be 50 gallons for a TIC, or one and four liters for a chemical warfare agent.

There was many aspects of it. One of them that was characteristic was the agent to explosive ratio. So there was five parts agent, one part explosive.

And basically this yielded a very fine aerosol, which meant there was high vapor, and the high vapor would be disseminated or placed on the -- deposited on the victims in the room.

So there was high vapor deposited on the victim's clothing or on the skin, and another assumption was there was a ten minutes elapsed time from the explosion until when the victims entered the ED.

Yeah, that sounds pretty short, but we were -- most of all -- on this study, we tended to overestimate the hazard rather than underestimate the hazard.

Also on the hot zone decon device

modeling, used to Non-Uniform Simple Surface Evaporation model. And basically what this model does is it gives you certain fractions for liquid, fractions for a pool, and fractions for the vapor.

Again, liquid deposited on the victims and vapor were observed on the victims and on their clothing.

And this also -- the end of that model was used to go ahead and determine a concentration when this explosive, this 50 gallon of TIC exploded or this one to four liters of chemical warfare agent exploded.

So this was, first of all, exploded. The end of that model was used to generate the concentration of the hazard. Then they are eventually deposited onto the victim.

Then at the hospital, we also took this into consideration. There are four different types of scenarios.

A lot of people would say, Aw, geez, if you go ahead and decon everybody, there is no -- they won't need any PPE. Or we are going to assume

that everybody who comes into the hospital has been a hundred percent thoroughly decontaminated.

Well, some people -- some experts say, yes, that may happen. But others say, you know, there is still potential that people still can get through the wire and get through the security system and enter the hospital contaminated.

So we looked at these four scenarios here, and we decided to go with Event Scenario No. 4 because it was the most severe, where mass casualties would arrive at the hospital, no time for decontamination. The hospital staff really had no time to implement their decon protocols, or -- so that's the case -- that's the scenario we went with.

And then, again, you have to model, with the end of that model again. Because now the source is not a 55-gallon drum blown up in the hot zone. It's the incoming victims into the hospital.

So we, again, we used InDeVap in the ED and the decontamination scenarios used were no doffing at all, no doffing, no decon. Doffing with 10 percent, 25, 50, and 90 efficacy of the

decontamination at the emergency department.

So this kind of gives us a range when we were running our models.

We also looked at the air changes per hour. You know, power on, six to eight air changes per hour. Power off is .3 air changes per hour.

Then we conducted surveys at five different hospitals and did some research to find out the average size individual treatment room and the center console area.

And these volumes of the rooms, the 1,500 for the individual treatment room, was using the modeling. So was the center console area at, you know, 27,040 cubic feet. So all of these parameters had to be established and be placed into the model.

These were the five hospitals visited, and these hospitals also were surveyed. Their HVAC systems were surveyed. Their operating procedures. Their room sizes. So we did evaluate five different hospitals.

This is just photos of some of the hospitals' individual rooms. We have all seen them.

And then, now, the results determined the following: The peak hazard concentrations for the individual treatment room, the center console area, the patient bubble in the individual treatment room, the patient bubble in the console area.

And you probably want -- the patient bubble was just the volume around an individual victim and where this individual victim would be off casting the TIC or CWA.

This is a typical decay chart of a victim, the decayment into an ED after being exposed to 50 gallons of chlorine.

Under the different conditions, as you can see, small room average, small room peak, large room. For this particular case, there was no reduction due to doffing or decon. Again, 50 gallons of chlorine exploded with a 5 to 1 burster round.

But as you can see, it is a high concentration. Then, as time progresses, it will -- it decays, as in all cases. But this -- a lot of it depends on the vapor pressure, just different

conditions.

And from our hazard analysis, this is what we, for the TIC estimated concentrations, we go up to the highest of 41 under this condition, no doffing, no decon. At 41.8 milligrams per meter cubed.

Now, that's the peak concentrations. But, again, as that chart, as I showed you before, it will decay over time. And that was in the peak patient bubble.

This is for the chemical warfare agent. In the no-doff worst-case condition is in the no-doffing no-decon scenario, and for GB at one liter. And that was at .9 milligrams per meter cubed.

And this concludes my presentation of hazard assessment.

The biological -- this -- the first half, we just hit all of the chemical, the TICs and the CWAs. Next year, we are going to go and do one for biological as well.

So at this time, I will take your

questions.

MR. PITTS: Sam Pitts, United States Marine Corps ChemBio Incident Response Force.

Frank, just a technical comment. We might steer you towards considering the wisdom of doing decontamination perhaps outside of the hospital facility.

For some of the more persistent agents, if you get them in the interior of the hospital, they could be extremely problematic, especially if you consider some of the emerging threats that we are looking as well as the some the more persistent agents.

That's the comment.

Question. You didn't look at any radiological contamination from either fallout, rainout, or RDD isotopes of any kind?

MR. PALYA: No, sir. We were just concentrating -- this, again, the first half dealt with mainly the chemicals. And now, we are going to go look at the biological.

But maybe it is worth mentioning, as we go

through the biological, being particulates, versus -- we may want to look at that and see some of these isotopes.

I'll talk to my partners on this, and maybe we could, you know, look at it and see how we would approach this.

I mean, we really never thought much of it.

MR. PITTS: You might also suggest -- like with the clean up after the anthrax in the Senate office buildings, we had to actually remove like carpeting, tile, ceiling tiles, furniture, to get them down to background levels, safe background levels.

If you bring it inside of a hospital, you may compel the hospital staff to perform their operations in an elevated PPE, which we would also suggest is really not a cerebral approach to utilize in a hospital, respectfully.

MR. PALYA: Yes.

Again, we looked at this because there was -- a lot of the people felt that maybe PPE

wasn't used and needed in hospitals because all of the decon was going to be performed outside.

Maybe, but maybe not.

The University of Maryland hospital down in Baltimore relies on the Baltimore Fire Department to go ahead and perform their decon. So they really don't have a lot of decon set up in place, in the area. We are going to have the fire department.

But by the time the fire department deploys and gets set up, Lord only knows how much time is going to elapse.

Now, for instance, Shadyside Hospital in Pittsburgh, they have got a real decon, nice decon system in place where they just lock down and direct people to go.

What you think would be lights, if you look up, as soon as you walk into Shadyside Hospital are showerheads. And then they just shower everybody, and that's their decon method.

So some hospitals are better than others as far as decon, but it depends. We can't make that assumption that everybody is going to be clean when

they enter through the emergency department.

MR. PITTS: I guess that's the point we are trying to make. You need to keep the contamination outside of the hospital facility to the greatest extent possible.

Once it gets inside, you may shut that facility down, and it would be combat noneffective for your purposes.

MR. PALYA: Yes, sir. That's what the -- the priorities are protect the facility, protect the clinical staff, and then save the patient.

So that's how they do it. But you're right. Go ahead and keep the hospital clean because if that's contaminated, the whole hospital is ineffective. The same with the staff.

MR. PITTS: A question on the civil live agent test facilities.

Are they -- are the facilities, the chamber, the restricted are where they do their testing, are they of equal or similar dimensions, Frank, or are they vastly different?

Could we test a vehicle in one, or are we

talking about small items in testing live agents in the civil facilities?

MR. PALYA: That would be just respirator components, that type of thing.

MR. PITTS: Small PPE items?

MR. PALYA: Yeah, right, that would meet NIOSH's needs.

MR. PITTS: Got you. Thank you.

MR. PALYA: All right. You're welcome.

Any other questions? Okay, thank you.

CBRN RESPIRATOR STANDARDS DEVELOPMENT

CLOSED-CIRCUIT SCBA

MR. REHAK: Okay, good afternoon. I'm back again. My name is Tim Rehak, and I'm going to talk about the benchmark testing for CBRN hardened closed-circuit SCBAs.

Okay, previously, at past public meetings, we talked about the benchmark testing that was done prior, and that included the LRPL, the heat and flame testing, the salt fog test, and the sand and dust testing.

With the past heat and flame resistant

testing, just a quick review of that.

The procedures we followed were from Section 8.11.5 of NFPA 1981. Here, the unit was exposed to 95 degrees C for 15 minutes. Then it was exposed to direct flame contact for ten seconds, raised to 150 millimeters, and dropped freely.

And with this test, though, the only exception from the NFPA standards that we did, live oxygen cylinder wasn't used.

And the problems that we noted in these tests were afterflame beyond 2.2 seconds at -- on some of the hoses, the harnesses, the facepiece hose connector.

And with one of our test units, the backpack fell off of the mannequin.

Now, follow-up testing, what we plan to do is basically follow the same procedures as before, except this time, we got Intertek agree to do the tests with a live oxygen cylinder.

Basically, the status where we are at right now is modified flame resistant closed-circuit SCBAs were obtained from two different

manufacturers, and we already processed the requisitions for Intertek to do the testing for us. And they also -- well, let me back up a little bit.

In order to do the testing, I guess their safety director required the people doing the tests that they have some kind for safety barrier up just in case since we are using live oxygen cylinders.

So basically, we have a requisition in place for them to design and build a safety barrier so that they can conduct these tests for us.

And basically right now, the latest I heard, they are in the process of buying their safety barrier. So we hope to have this testing done sometime we are projecting in the middle of December or early in January.

Other testing, benchmark testing we did was the vibration endurance.

The procedures we followed here was NFPA 1981 Section 8.3.5.3, the second edition.

The tests for this was conducted by the U.S. Army Research Development and Engineering Command. And for this, two units were tested, one

each from two different manufacturers.

The results that we obtained, both closed-circuit SCBA showed signs of external wear. And one of them, two latching mechanisms became disconnected. And with one of them, one internal fitting was fractured.

The conclusions that we reached from this testing, one system passed the follow-up operational test when run on the ABMS. And the other unit required -- excuse me -- replacement of the fractured fitting before passing the follow-up operational tests.

We also did environmental temperature operational tests.

First, we did a hot test at 71 degrees. This was done with two units. And one thing I would like to note is the closed-circuit SCBAs were not rated for this requirement.

For this test, both units were hot soaked for 12 hours at the 71 degrees C. Operational tests were then conducted, and the testing was stopped when the CO2 level rose above 4 percent.

The results: Unit A reached 191 minutes. Unit B made it to 11 minutes.

Continuing on with the environmental operational performance tests, we did cold tests at minus 30 degrees C with two units, again, noting that the units were not rated for this requirement.

Both units were cold soaked for 12 hours, and the same operational tests were run with the same limits for CO2 when we would stop the tests.

And for this, the results were Unit A reached 7 minutes, while Unit B made it to 84 minutes.

The chemical agent permeation and penetration resistance against HD and GB, the closed system -- what we are planning on doing is the closed-circuit SCBAs will be held to the same performance requirements as the open-circuit units.

We are currently working to develop a system that can simulate the CO2 and humidity so that we could activate the closed-circuit SCBAs without requiring us to use an ABMS.

This will help us to control test costs,

eliminate the need for a walk-in test hood, and to minimize decon exposure risks.

We are not -- we don't plan on doing benchmark testing on accelerated corrosion resistance.

The particulate resistance, the facepiece lens haze, luminous transmission, and abrasion resistance, or with the communication performance requirement or vibration endurance.

This is because of the testing will be conducted in accordance with NIOSH standard test procedures that will be based on NFPA 1981 standard, the 2002 edition. And our rationale for doing this is that NIOSH STPs can be updated to reflect the latest changes to the NFPA standard.

Remaining benchmark testing that we plan to do, again, we are going to do the heat and flame resistance with the live oxygen cylinder and the chemical agent permeation and penetration resistance.

Any questions? All right.

CBRN RESPIRATOR STANDARDS DEVELOPMENT

COMBINATION UNITS

MR. SZALAJDA: I think you're all either too satisfied from having lunch or looking forward to the break. So my comments and Bill's comments are going to be brief with regard to the last two items.

The recent -- or the latest notice that we put out last week released the first concept paper for the CBRN combination units.

And what we are doing -- and it's sort of doing back to the same story you have heard from us for the past several years regarding CBRN respirators, is that everything is built on three tiers of requirements: 42 CFR Part 84; consensus standards, whether national or international standards; and also special CBRN requirements.

Combination units are going to be no different than the procedures that have been followed in the past.

The comment has been made -- Bill Hoffman had made a comment earlier today that going forward, all of the standards are going to be done using --

the CBRN standards are going to be done using rulemaking procedures.

I think in terms of our process for going through the initial phases of the development, we are still going to continue the use of concept paper to share the information with you regarding what we are currently thinking with regard to the performance requirements for the system.

I think the one thing to note with how we have developed the standards in the past with policy in our regulatory authorities versus going through the rulemaking is that essentially we have followed the spirit of rulemaking in what we have done with policy, that we have had a dialogue. We have had comments, opened up the requirements for stakeholder review.

And feedback, listened to that feedback, and made decisions like would be done in rulemaking, whether we agreed, you know, with comments that came from the stakeholders, or if we disagreed, and at least were able to rationalize why we chose to disagree with the stakeholder comments.

I think when you see, as we go forward with the closed-circuit SCBA, the combination units and the supplied air respirators, that even though we are going to be going into a formal review process review, a review and comment process with rulemaking, that the spirit of what we have done in policy is still going to continue with regard to the types of dialogue that we have had in the past with stakeholders regarding CBRN.

With the development of the combination units, a couple of things have come into mind. And from my perspective, I'm probably wrong because I'm wrong pretty often, at least my wife tells me so.

I think this is -- from a technical standpoint, this is going to be one of the easier standards that we develop. I think most of the concerns and what we are going to be looking for feedback going forward are going to be related to operational types of scenarios.

When you think about closed -- how you select a respirator and how it is used in the workplace, you may make definition decisions on are

you in an IDLH environment. Are you not in an IDLH environment. What types of protection characteristics does the respirator need to provide, you know, to the wearer in going into a certain environment.

You know, in the past, NIOSH, in the process of certifying respirators, if we were to get a combination unit, the type of approval you get is at the lowest level of protection. So if you did have a combination SCBA PAPR, SCBA APR, you would get a 14G approval for a gas mask.

I think in going forward, one of the things that we need to consider and where we need to get stakeholder feedback is how we approve -- or your recommendations on how we consider these types of systems in going forward as far as the approval process.

I think in general, though, when you look at the types of requirements that we are looking at, some of the considerations are related to how we test the units. And I think the types of things that indicate, or at least we indicated so far, I

think -- or at least to us were readily apparent as far as considerations for general requirements.

I think the one thing of note, when you look at the PAPR, is we want to make sure that there still is a degree of protection available for the user. If you had a combination SCBA PAPR, that you would still have a degree of protection if the PAPR or the blower component were to stop working in operation.

Some of the specific things that we have thought about. One is having some sort of indicator for SCBA versus air purifying types of operations. And I know the question is going is come up, Well, what kind of indicator?

Well, we are looking for you to tell us that. I think some of the things that we thought of, very simply, an indicator can be a switch that is on the respirator which takes a device from a supplied air mode to an air purifying mode.

That can be -- that could be the indicator because the operator would have to manually make the change from one side to another, or you could have

something more elegant, like a heads-up display or some other type of indicator that could be considered in the operation.

One thing to note as we go forward in our considerations for testing is that we expect, when you look at the SCBA combination with an air purifying respirator, when we do a test, it is going to be done in the most stringent testing or conditioning applicable to either combination.

What that means -- I guess, for an example that we kick around, is when you look at the SCBA, the SCBA has a cold temperature requirement as part of the process.

Well, your air purifying system is going to have to meet that requirement as well because of how the system is going to be evaluated.

As far as CBRN performance, you know, we are looking at established criteria. We are really not planning on inventing anything new at this point. The requirements, performance requirements will be based on what has already been identified for either the SCBA, the APR, or the PAPR.

And we do have a special docket to collect comments regarding combination units at 082.

I think one thing I did want to bring up with regard to the combination units, you know, we have taken a very focused approach with regard to the developments for this type of respirator in looking at open-circuit SCBAs plus an air purifying type element.

And you could look and say, Well, there's lots of other examples that could be done. You could have a closed-circuit SCBAs with air purifying. You could have, you know, lots of things that we probably haven't even considered yet.

But at least as far as right now, trying to respond to what we have seen in the industry and what we have seen in the stakeholder communities, that is there a focus on having the availability of these types of respirators in the near term.

And the focus for the standard, for this standard initially, is to look at that combination.

So with that, does anybody have any questions?

MR. METZLER: Rich Metzler of the SEA Group.

Did you intend to publish a schedule for the modules that you are going to be working on?

MR. SZALAJDA: Yeah. The question was if we intend on publishing a schedule and going forward.

I think, at this point, one of the things that we are doing is looking at the -- and Bill can correct me if I'm speaking out of turn for the branch.

But I think we are looking at prioritizing the different modules that we are working between things that -- or making changes in the near term to Part 84 along with the CBRN type of activities going forward.

I think that's one of the things, at least as far as the branch will have to determine, you know, the types of schedules because we are limited with the resources, you know, that are available. And depending on what the priorities are in the organization, you know, other things will be

promoted quicker than others.

MR. METZLER: And last, I have a comment.

I agree with Dale Pfreim's comments, that there seems to be little justification for having differences in the environmental testing for loose-fitting PAPR versus tight-fitting PAPRs.

In a formal rulemaking process, I would expect you would have to provide a more detailed rationale in why that decision was made.

Also, I have noticed in Tim's presentation, you're not applying abrasion resistance to the lenses on those closed-circuit self-contained breathing apparatus, or at least it appeared that way to me. And it is required in the full facepiece CBRN APRs.

MR. PALYA: That would be under 1981 --

MR. SZALAJDA: Turn it on, Frank.

Well, while Frank is turning the microphone on, I think, just to address the topic that -- regarding loose-fitting versus tight-fitting PAPRs.

At this point, you know, we made a

determination as part of the standards development process for the PAPRs, at least as far as how to -- Step 1, how to expeditiously bring the standard to bear.

One of the things that -- and it was a very specific tightrope that we had to follow in looking at the performance requirements for the PAPRs, whether -- when you have the needs of the emergency responder on one side where PAPRs could be used in the same scenarios as air purifying respirators as gas masks versus scenarios where PAPRs are used in an emergency department or, you know, medical type applications where their needs may be different.

I think, as you may have seen, with -- or picked up with Frank's presentation on the health hazard assessment for the work that's being done by OptiMetrics, the performance requirements for the what the hospital workers need are going to be less than what is expected for somebody actually working at the site.

So we made a decision based on, you know,

that type of analysis to go ahead and look and make a determination where we could go without doing the conditioning for the loose-fitting PAPRs because we do not see those types of systems being used where the tight-fitting were.

MR. METZLER: You are going to have cautions, limitations, and restrictions of use to prevent the use of those loose-fitting PAPRs other than for that specific application.

MR. SZALAJDA: I appreciate your comment. I think that's part of what we tried to address.

And part of it is going to get into the relationship between the manufacturer and the user community, as least as far as how these types of products are marketed.

And I think the one thing to keep in mind -- and there is a caution and limitation in the PAPR, the Step 1 PAPR standard, which says, you know, you should not be using the loose-fitting types of system where escape is possible.

I forget the actual number on the -- or the letters on the cautions and limitation.

And again, it needs to get into, you know, the types of -- the types of decisions that are made by the users in buying these types of products.

I mean, you should not be wearing a loose-fitting type of respirator if you're working where you need to have an escape capability.

MR. PALYA: Okay, Rich. On that abrasion resistance, there is an abrasion resistance requirement on that closed-circuit. And that goes -- a lot of those durability requirements go back to 1981. So that's pulled from the 1981 standard.

MR. REHAK: We're not going to do the benchmark testing on those units because we have 1981.

MR. SZALAJDA: We will take a couple more questions, and then we will let Bill go ahead and proceed.

MR. HEWITT: Don Hewitt. Just a quick question with regard to the combination unit.

Since the intended use of this thing, particularly for emergency responders, is this

notion of being able to conserve the supplied air, you know, while using the PAPR, and the transition is likely between IDLH and non-IDLH environments, one of the questions I have heard from a number of responders is, I know there is supposed to be a switch so you could tell which mode it's in.

The question is, has any consideration been given in the requirement to mandating some warning in the device for the transition to IDLH, some sensor, so that somebody can say, You're running on the PAPR. And, gee, it has changed.

Because the fear is, of course, that the person is going to wander into an IDLH environment and may not have a handy sensor to look at.

Is there any consideration, or are they just going to do a caution limitation and say don't do that.

MR. SZALAJDA: That's a very good comment. And I think that's somewhere -- you have touched on an area where we are looking to get feedback back from the community with regard to what that type of requirement should be, you know.

Because, again, you know, it is sort of, you know, with the system it's how complicated to you want to make the design.

In one of the things that -- you know, at least as far as the indicator, our initial cut in looking at it was, Well, simply put, you can have a indicator that says it is either, you know, supplied air or it's air purified. You're in one or the other mode.

When you start getting into details as far as where you should be and in what mode, that's I think where the toughest part of this standard is going to be, is in that classification as far as addressing, you know, the types of approvals that we give -- we give to the respirator. Then, in turn, how people actually use it.

MR. HEWITT: We will try to get you some feedback from responders.

MR. SZALAJDA: That would be great. Thank you.

MR. PITTS: Sam Pitts, United States Marine Corps Chem/Bio Incident Response Force.

Jon, very similar to what Don said, we are very intrigued by these combination units, but we have some questions, like in the gating mechanism that separates one tidal volume or plenum, you know, from the other.

We are also a little curious about, if we were to use the PAPR first on an entry and then go in a, say, an enclosed space and utilized bottled air. And then, say, we ran out of air, and we are coming back through decontamination and want to go back on the PAPR or be compelled to go back on the PAPR, how are you going to determine the usable life that's left on that canister, and has it reached saturation?

And have you thought about the, even with filters that are somewhat saturated, the tranquil migration of the contaminant through the filter bed in nonuse, how -- we are not smart enough to know the answers, at the risk of exposing my Cro-Magnon genetic material.

MR. SZALAJDA: On that question, Sam, I don't think you have to apologize because we don't

have the short answer for you yet either.

I think that's part of the consideration for us in looking at the requirements is, you know, not knowing where the system may be going, what happens.

And just a hypothetical, what happens if you have a SCBA PAPR, and you go and use it in a firefighting type operation, and you are on the bottle there. What effect does the heat and the products of combustion have on the filters?

We don't have that answer yet. And hopefully, as the requirement develops over the next several months, we will be able to start putting some flesh to the performance requirements for those type of considerations.

Any comments or suggestions of things that you think are important, you know, with regard to the performance, you know, just keep our dialogue going, and we would be happy to --

MR. PITTS: Some of us were postulating that perhaps we could start, you know, with the PAPR and go up to bottled air, but not the other way as a

training or an operational concept of employment.

MR. SZALAJDA: That's a definite possibility.

Again, I think it gets into -- with this system, I think the big challenge for us is going to be, not necessarily the performance. Because I think between all of the standards that we have developed, we will be able to come up with a good cache of performance requirements, but operationally how is it going to be used.

And I think that's the tougher question that we are going to have to answer, you know, in the time to come.

MR. PITTS: We are thinking along the same lines, then. Thank you.

CBRN RESPIRATOR STANDARDS DEVELOPMENT

SUPPLIED-AIR RESPIRATOR

MR. HOFFMAN: Okay. The last one we are going to talk about before the break is the conceptual requirements for an airline respirator, actually, a Type C or Type CE. And those terms may now be obsolete since Type A and Type B, don't seem

to be much need or call for those anymore.

The initial concepts that we are considering for a supplied air respirator would be that we would use existing criteria from 42 CFR Part 84, consensus standards, and the CBRN statement of standard.

And the supplied air respirator CBRN standard, again, will be developed using a rulemaking process, as would everything else from this point forward.

At the present time, we are looking at a supplied air respirator since it would be used for CBRN type of environment to include a 15-minute open-circuit escape cylinder. It's an airline respirator that has an escape bottle in the event, obviously, that if something happens to the air supply.

Requirements from 42 CFR -- and, again, this is in its very early stages.

We would look at the appropriate requirements from Subpart J, which include also Subparts A, B, C, D, E, F, and G, which are the

general requirements that we apply to all respirators. Those are the things from Part 84.

Requirements from consensus standards, we would look at some of the things that most people are already familiar with from the CBRN standards, durability, the low temperature, the lens materials, and the things that you can see on the screen picture here as well.

So, again, it's a compilation of things that have been done to date.

The CBRN specific requirements, of course, we are looking at an open-circuit SCBA, and we would also be looking at the CBRN APR statements of standards to pick up on things that we have already done before.

So we are not looking at it so much as anything brand new in the area of CBRN requirements, but adopting what we have used in some of the other ones in applying it to a supplied air respirator. That's a very brief presentation. We have just started on this.

Again, this has a different docket number

on the yellow handout sheet that's in your packet, that you will find this listed. And it is Docket No. 83.

I do want to comment that a couple of questions we would expect to see, that we have been asked many times, is would there be a provision for the takeoff for the operation of a pneumatic tool.

If I'm going in with an airline respirator into some type of an environment, the reason I'm not doing that and not using an SCBA is I may be in there for some period of time.

If I'm going in there for some period of time, I have got a job to do. And it may be using a cutoff tool, an air drill, or something like that. Would we have provisions for that?

Also, would we consider changes for hose lengths or hose length connections, what would they would have to be, could you use a longer length than we presently require. Could you use different lengths, or how would they be adaptable, things that we really haven't thought about yet, but things that we would be looking for your input on, is there a

need for that.

I know I can think of one specific example. Terry Cloonan, when we were at the World Trade Center, people wanted to go in with airline respirators with a 5 or 600 feet of hose so they could go in there and spend a little bit of time and look. And they wanted it -- they wished such a system was available that was NIOSH approved, which, of course, back then, it wasn't.

A very brief overview. Are there any questions specific to the airline at this time?

Okay. What I would like to do is, if we could, we are running a little bit behind schedule. Take our break, but hold it to about ten minutes. So if people could be back at about a quarter to 3, that would be great, and we could try to catch back up.

Thank you.

(A recess was taken.)

MR. BOORD: If we can take our seats, we will continue with the program.

Okay. Before we -- before we begin with

the next discussions, I would like to request that everybody look into their information packet. And in your packet, you will find two different customer satisfaction surveys.

And what I would ask you to do is if you look at the bottom left-hand corner of the survey, you will see the date.

One is for today's meeting, and one is for tomorrow's. So October 12 and October 13.

The final presentation after we have the discussions on the Total Inward Leakage and the quality assurance provisions, the final presentation we have today will be addressing our -- some of our quality initiatives in our work with the National Academies and our work with the OPM and the surveys that we have been performing.

This survey that you have in your packet, it is important to us to retrieve the information.

So I'm going to ask the next presenters to wait two minutes. And I would hope that during that next two minutes, you would look through the customer satisfaction form dated October 12 and

share with us your opinions of the presentations and the discussions that you have heard today.

Following the presentation -- Maryann, will it be your presentation they will be collected, or during?

MS. D'ALESSANDRO: During.

MR. BOORD: Okay. So during the last presentation, we will come around to collect the surveys.

So I would appreciate it if you could take the next two minutes and fill that out.

Thank you.

(There was a pause in the proceedings while the attendees filled out their surveys.)

MR. HOFFMAN: The last group of presentations today will be the Total Inward Leakage program that Bill Newcomb is going to present. The Quality Assurance module, which Bill Newcomb along with Dr. Doug Landsittel will present information.

And then what is called on the agenda the administration module, but really which has evolved into the certification fees module, which will be

presented by Heinz Ahlers.

So, Bill, if you want to step up.

TOTAL INWARD LEAKAGE PROGRAM

MR. NEWCOMB: Thank you.

The Total Inward Leakage program has been around for a couple of years, but for those who may not remember, I'll give you a little bit of background.

When NIOSH was established, Schedule 21C had an isoamyl acetate test. Prior to that, Schedules 21A and 21B had coal dust tests for fitting of respirators.

With the 21C, there were some configuration issues in the fact that isoamyl acetate fit testing needs an organic vapor removal mechanism, and most particulate respirators do not have that type of mechanism. So they had to be altered in order to be tested.

When 42 CFR Part 84 was promulgated in 1995, the isoamyl acetate test was eliminated for particulate respirators, although it still remained as a qualitative fit test for other types of

respirators.

One of the impetus for not having a fit test was the fact that OSHA still required an individual fit test of a respirator before it would be used.

So it was felt that, even though NIOSH did not have a fitting test as part of certification, that any respirators that did not fit well would be not used in the marketplace because of the requirement for individual fit testing.

In 2000 -- I believe it was 2003 it was actually published, but the respirator usage in private firms, 2001, suggested that 53 percent of the respondents were actually doing fit testing.

And this number, I believe was greatly exaggerated because of the fact that there seemed to be some confusion in the answers between fit testing and fit checking, or what is termed today user seal check.

At the OSHA public hearings for the changes to 1910 134, the -- when the table of assigned protection factors was first introduced,

there was some concern over protection factors that were given to some of the respirators.

And at that time, NIOSH committed to putting -- to adding certification tests for fitting of respirators.

So consistent with NIOSH's modular approach, the standards to be developed would be for half-mask respirators for particulates, including filtering facepieces, and that would be done first. Then the regulations would be modified to include those tests.

After that, other types of respirators, full facepieces, hoods, and helmets would be addressed.

Again, one of the criteria that we set upon for the TIL testing for the whole program is that it would not be a substitute for the OSHA mandated individual fit test. Because the only method of assessing individual fit is a fit test.

Furthermore, no respirator can be certified to fit. The respirators would be quantified, or evaluated, to show that they could

give fit to a certain population.

The Total Inward Leakage program was broken up into three phases. The first one was a conceptual development phase. The second was to establish a test facility, conduct the actual benchmark testing, and establish the criteria concepts.

Phase 3 was to finalize the requirements and the implementation plan.

Now, the guidance for establishing the certification criteria were set upon back in, I believe, 2004. And they would not be based on the OSHA APS. We did not want to be influenced by the current regulations for fit testing. But they would be based on actual fit test results. Also, that it would be inappropriate to use previously obtained data for several reasons.

We would conduct benchmark testing on state-of-the-art respirators within the class, and we would use the entire panel for TIL evaluation.

For the half-mask project, the following test method characteristics were compared:

The ability to use -- to be measured, regardless of the air purifying element; knowing that they are all particulates, but some would be N99. Some would be P100. Others might be N95s.

That it have the required sensitivity for the desired results; the ability to give fairly accurate and reproducible results; the ability to do the test exercises without disturbing the fit of the respirator; ease of duplication within the labs; cost of the equipment; need for a test chamber; and ease of preparation, clean up, et cetera.

We came up to the conclusion that the best choice for measuring half-mask respirator Total Inward Leakage would be the PortaCount Plus with a companion in a direct reading mode.

And the most reproducible exercises were those found in the OSHA fit test protocol with some minor modifications.

NIOSH embarked on a project which you have probably heard about several times to look at the fit test panels that were in use. And at the time that we started this program, there were two panels

from Los Alamos' national laboratory that went back quite a ways. One was a half-mask panel that used lip length and face length. And the other was a full face panel that used face width and face length.

It was determined that those panels did not represent the public at large as the respirator users of today. And, furthermore, when some of the results of the tests of the studies were evaluated, it was felt that lip length was not a good indicator in fit of respirators.

So we came up with a further -- or so should I say Dr. Zhuang came up a new bivariant fit test panel with the face length and face width, which essentially moved up and to the left of the old panel.

It seems that the faces in the general population seemed to be longer and wider than they were in the -- from the anthropometrics that we used to establish the Los Alamos panel.

The matrix is broken up into ten boxes with 25 members in the boxes. And you can see that

Panel 4 has five members, and Panel 7 has four members, and the rest of them have 2.

This is to replicate the approximate percentages of the population of respirator wearers that fall in those categories.

We conducted the benchmark testing over the last year. We tested 57 filtering facepiece respirators, 43 elastomeric half-mask respirators and one quarter-mask respirator.

Again, 25 subjects across the board, three donnings per subject, which gave a total of 8,250 data points.

To summarize where we are today, Phase 2 is complete. The study was designed to assess the overall capabilities of individual respirators.

The benchmark data was derived by testing across a complete panel regardless of respirator size designation and, therefore, does not represent actual field use.

One of the reasons we did this is that there are respirators that appear to be one size, or medium, that don't necessarily fit the people in the

center medium size of the panel.

The ones that are marked small don't necessarily fit the best on the small. And the ones that are marked large don't necessarily fit best on the large.

And I think I this has to do with the fact there is no standard for what a small is, or what a medium is, or what a large is.

So we wanted to see the capability of the respirators to fit a segment of the population, so we tested across the whole panel with every respirator, regardless of whether it was marked small, medium, or large.

The data was being analyzed in several ways, and no conclusions have been reached concerning the proposed requirements for certification.

There is a NIOSH docket -- it is the TIL Docket 036, and you also have the standard NIOSH disclaimer here.

Because we have a preponderance of data, we have asked Dr. Doug Landsittel, who is a

statistician and senior fellow with NIOSH to look at the data and try to make some sense out of it. I'm glad he's got to do it instead of me.

And he is going to come up now and tell you some of the areas that we are looking at to try to come up with some criteria for certification.

TIL CRITERIA DEVELOPMENT

MR. LANDSITTEL: Thank you. Thanks, Bill.

So this is the outline here of what I was going to discuss. The focus will be on statistically related issues.

And the two main considerations I'll focus on within that context are definition of a performance criteria and strategy for subject selection.

For each of the possible approaches as far as subject selection, I will look at the strengths and limitations.

And then Bill already talked a little bit about the existing data collection. I'll mention that again briefly, and that will lead into different statistical considerations for different

performance criteria.

And then I will conclude by summarizing our current progress and corresponding challenges and also look at the subsequent impact of results in terms of practical implementation of the eventual criteria.

So, as far as definition of performance criteria, there's two main approaches that we could pursue. And I'll mostly focus on this first one here, which is probably a bit more intuitive.

One is to require a fraction of the subjects to meet a particular penetration cutoff.

So we have three unknowns in that scenario: What the cutoff penetration would be that is deemed acceptable; the fraction of subjects that need to meet that cutoff; and what an adequate sample size would be for making statistically defensible statements in formulating a criteria.

The second type of approach would be similar thing, but a little bit different called a tolerance limit where we have a certain percentage of subjects within an acceptable range, a percent

confidence that the actual population or percent is within that range, and then an adequate sample size, again, for having adequate statistical precision.

Now I'm going to go into a little bit more detail as far as the strategies for subject selection and just outline potential avenues here.

One potential avenue would be testing every respirator on every subject, similar to the existing data that Bill described.

The second approach might be specifying a restricted range of face sizes for a given size respirator.

And then third would be for models with sizing of the same model, only require the subject pass through one size, which I will go into a little more detail to appropriately distinguish between that second and third bullet.

As far as the idea of testing every respirator on every subject, that would be where you would randomly select a certain number of subjects for each respirator. And then based on the NPPTL or some other panel, select the specified number of

subjects, regardless of the respirator sizing.

As far as strengths and limitations, obviously this would be the most straightforward approach, but would be limiting for respirators that were designed for specific face sizes.

So I mention this approach here for completeness of the discussion and because it's our existing data that is collected, but is not being considered for the final criteria.

The second approach would be specifying a restricted range of face sizes. So based on a respirator size, then you would restrict a selection of the sample to a certain subset of face sizes and then randomly select that specified number of subjects for a given respirator.

This requires a definition of how respirator sizes specifically relate to, say, cells of the NPPTL panel or some other categorization that you might pick.

And in this case, it becomes pretty complex because your choice of panel and how you define what's a, say, small, medium, or large

becomes critical in formulating the final criteria.

In some ways, I think this is an intuitive way to go about it, but actually in terms of practical implementation becomes very complex with a lot of statistical questions related to it.

So as far as current analysis ongoing, we are currently working on assessing the relationship between size of the respirator and face dimensions and how they jointly relate to respirator fit.

Now, the third strategy requires a little more explanation, is required given subject pass for only one size.

So the approach here would be to consider a family of respirators as a whole, say, small, medium, and large, and then randomly select a given number of subjects for each respirator, but then have some more flexible approach to determine which subject is assigned to a given respirator.

So rather than a priority, say, that sells one, two, and three of the panel, or small, et cetera, have some flexibility, whether it is on the part of the manufacturer or some other approach, to

important to note that those 25 subjects are actually sampled from a pool of 87 total used across all of those tests.

And, again, there was a fixed number of subjects per NPPTL panel as -- per panel cell, I should say, as explained in the last talk meant to be representative of the population but irrelevant to the respirator size.

And so the point I want to get to as far as the existing data collection is there are two main concerns that we are working on addressing.

One is the criteria feasibility. So if you pick a particular cutoff for acceptable penetration, how feasible is that really going to be in practice, and what is the relationship between face dimensions and model size and how do they jointly relate to the model fit.

You will be quizzed on this next slide later.

This is just meant to be an illustration. I don't want to dwell on this too much, but I didn't really -- and here is where I have to get out the

pointer here.

I didn't really have room to put it, but you have face width across the X-axis and face length here. I'm going to hit Bill's head on the way here. Length and width. I'm not nearly coordinated enough to do it on that one. You are going to have to look over there.

So we have -- what this represents here is the cells are labeled for the NPPTL cells of the tables described before, or panel.

That's at Cell 1, 2, 3, 4, et cetera. The numbers below the cell right there, those numerical values, as explained in the title, are mean penetrations by NPPTL cell.

And I just took one example here of medium size elastomeric models. And not all of them are quite this complicated of a result, but this is actually fairly similar.

So all I was doing is summarizing collapsing over a number of different models that fit into, say, medium size elastomeric models, how does the average penetration look by different face

sizes.

And what the different colored rectangles and circles represent here is areas of the facial dimensions where there were no statistical differences.

So, for instance, between Cells 6 and Cell 10, they are both in the black circle, so there is no significant difference.

The largest rectangle is this red rectangle, which is like a maze trying to follow it, but there is no statistical difference between those. On the other hand, so two is statistically different from the ones not within the blue rectangle.

So my point here is to underscore something that Bill has said in the last discussion was that it doesn't work out to a real clear picture, at least at this point.

And we are in the process of kind of reanalyzing this data in ways I will explain here in a minute. But there is not a real clear picture of well, here is where the medium size fits. Here is

where the small size fits, et cetera.

Okay. So what are the statistical considerations that we are trying to take into consideration?

Well, for a different option, I'm referring to that first type of formulation that I discussed where you require a certain fraction of the subjects to be below a certain cutoff penetration value.

We have to evaluate -- if we say that we determine the penetration either a-priori from our existing data, or we look at different options for a specific penetration cutoff, once you specify a penetration cutoff, then you have to decide, Well, what percentage of the subjects do we need to meet that penetration cutoff and what's the -- what's a sufficient sample size.

So that's one issue. And I will talk about that one a little bit more in a minute.

Another issue that I'm not really going to talk about that we are still in the process of getting into is the analysis across multiple

measurements.

The respirator is donned three times per subject, and each of those, you have multiple tasks. Currently, the penetration values as we are analyzing them are just averages across those.

And one underlying factor or overriding factor here I want to mention is that we are not trying to look at the statistical issues in isolation, but rather considering them jointly with scientific considerations and feasibility considerations.

So let me talk a little bit about statistical properties at different criteria. So again, we are saying we have a specific penetration cutoff value, and we want to look at the first -- we will forget sample size. We will say a required percentage of subjects needing to meet that cutoff.

What do I mean by -- so what we are looking at is we are looking at -- we want to look at a choice that has, quote, good statistical properties.

So what do I mean by good statistical

properties? Well, let me explain that via a couple of illustrative examples.

In one scenario, let's say we have a model that hypothetically we know to pass or meet that penetration cutoff very high percentage -- for a very high percentage of the population.

If we make that assumption, then we would want to see a very high probability that it meets that specified percentage of the given sample size with high probability, or a high percentage of the times.

On the other hand, if we specify a model or look at one that only passes the cutoff for a low percentage of the population, we would want to see a high probability it fails to meet that specified percent of the given sample size.

So let me get a little more specific in terms of the data we have.

Here is one example. We looked at the requirement of what would happen if we required 24 out of 25 to meet a given cutoff value. And this tends to lead to less optimal statistical

properties.

And basically I think the explanation here intuitively is we are just very close to a threshold there of having to pass for every single person.

A respirator model truly meets the cutoff for 96 percent of the population. And one of these symbols got changed. That is actually supposed to be an arrow there, but I think you can follow along.

Turns out that if you make the assumption -- I'm not talking about an actual respirator in practice, just doing calculations where we make that assumption -- it turns out with this cutoff of 24 out of 25, that, in fact, under that assumption, the respirator that works for 96 percent of the population would fail that test over 25 percent of the time.

So that seemed like a less optimal result.

Let's take another example. If we require only 15 out of 25, or 60 percent of the sample to meet the cutoff, this also tends to lead to less optimal statistical properties.

And in an example -- we did a lot of

calculations with this, but you take an example, the model that truly meets the cutoff for 60 percent of the population, in fact, it will fail this test on average about 40 percent of the time, or over a large number of trials, 40 percent of the time.

So that also did not seem optimal.

On the other hand, if we pick a cutoff for a percentage of the pop -- a fraction of the sample that's somewhere in between there, say 20 out of 25, we get better statistical properties. A respirator model that truly meets the cutoff over.90 percent of the time will almost always pass that criteria. A respirator that truly meets the cutoff less than 60 percent of the time will almost always fail that test.

So what I hope to accomplish with this slide is just to give you an illustration of some of the specific statistics that we are looking into to try to systematically judge a criteria.

What about sample size? Well, if we increase it to 50 per test instead of 25, which I used in the previous slide, that improved some

statistical properties, but not quite across the board.

For instance, if you are given a respirator that truly meets the penetration cutoff over 90 percent of the time, using that requirement of 20 out of 25, I say it would almost always pass. It is around 97 percent of the time.

If we move the sample size up to 50, it gets a little better. It is closer to a hundred percent.

Given a respirator that truly meets the penetration cutoff -- and I apologize. It got moved down a little bit here.

The respirator truly meets that 96 percent of the time, if we use this cutoff of 24 out of 25, this respirator will pass -- this is the one I said would fail over a quarter of the time. That translates to pass over 73 percent of the time.

And the last one you probably can't read, but if you have a requirement of 48 out of 50, it gets a little worse with that sample size. The respirator would only pass under 70 percent of the

tests.

So, again, just more considerations that we have to systematically account for.

So let me start summarizing here and try to bring it to conclusion. So we are looking at statistical assessment of sample sizes and percentage of the sample required to pass for the given criteria. And we have completed some of these analyses.

I briefly mentioned a few bullets, but we have a lot more output than that for a couple of selected sample sizes and a wide range of required percentages needed to meet that cutoff.

So currently what we need to do is assess other variations on this and also look at where I described the tolerance limit approach, which may have some drawbacks or benefits, but also address that type of approach in the same way.

As far as determining the appropriate penetration cutoff -- and I haven't really shown any results here because they are still ongoing, but we have completed some analyses to assess feasibility

across different types of respirators and model sizes for different face dimensions.

But we are currently reanalyzing respirator fit relative to the face size and respirator size. And considering the issue of what I'm calling finite sampling -- in other words, you will recall I said for this data we currently have, it was 25 subjects testing on each respirator.

But that's only 25 each time selected out of 87, so it brings up some intricate statistical issues for which we are using a model called repeated measure analysis model to look at that data currently.

As far as analysis of individual versus average penetration values, as I mentioned, we have donning-to-donning and task-to-task variability. We have not gone very far in terms of addressing that issue. But that's another issue that we have to take into consideration.

Determination of an optimal strategy for subject selection and testing, this actually turns out to be a very complex and integral part of the

criteria, as I hope I have tried to at least illustrate to some degree.

And just to remind you, we have those three possible approaches, looking at every subject, every size. Which, again, we are not -- I mentioned for sake of completeness of discussion, but not concerned for the criteria.

Second option, where you define sizing a-priori with a set panel and size definition. And thirdly, considering size with more a flexible approach.

So we are currently doing analyses to address each of those two considerations.

So finally, I'm going to conclude by saying a few statements about the impact that subsequent results might have.

Certainly, each model and size is to be tested on -- that should say at least 25 subjects. We are still looking at the appropriate number of subjects and the statistical approach for specifying the criteria. Those are still under analysis.

The strategy for subject selection and

testing, this is unlikely really to affect the total number of subjects being tested, but rather how those subjects might be divided between different sizes when you have different sizes of a given model.

And then as far as complexity of the analysis and any timeline issues in criteria development, that's highly dependent on the subject selection where that second approach is the most complex approach.

And as I just hit the final thank you slide here, I want to say that what I hope to kind of clarify through this discussion is that we are trying to comprehensively look at both statistical issues intertwined with feasibility and scientific considerations in a very systematic manner moving toward formulating the final criteria.

So I will be happy to take and/or defer any questions you might have.

MR. NEWCOMB: Before we get to questions, there's one thing I would like to say that I didn't in my presentation.

The last time we had this discussion, I told the manufacturers that they would be able to see the data after the public meeting. And we will be making individual manufacturer's raw data available to any manufacturer that would like to see how his respirator did in the benchmark testing, knowing that there's really no criteria yet, but at least you can see the numbers that we got.

And, unfortunately, I'm going out of town for almost a month, and I won't be available until December. But any manufacturer that does want to come in and review his data is welcome to do so at this point. Thank you.

MR. SAVARIN: Mike Savarin, Bullard Company.

It seems a lot of effort is being expended in trying to statistically analyze fit to data, come up with models, kind of play around with the whole thing. And I think that was a -- I think it is a valiant effort to see -- get an insight into some of the complexities surrounding what on the face of it looks a relatively simple thing to do, come up with

a map on how to award pass and fail criteria.

Some time ago, a detailed study was performed by an Asian gentleman at NIOSH, whose name escapes me. It wasn't Ziqing, was it, yeah, Ziqing Zhuang, who looked at the face panels in great detail looking at modernizing today.

It has been a great deal of time since we have sort of seen the full outcome of this. I understand it was supposed to be under peer review.

Assuming that that study is relevant, it would appear to me that the best thing to do would be to somehow break that study up statistically divided by the demographics and try and assign face sizes in accordance with that panel.

That seems to me much more straightforward than trying to fit this thing that you are doing right now.

MR. LANDSITTEL: Well, let me make a few comments. I think you are referring to the PCA panel with the principal components, and that is nearing completion of review.

There was some switching of the National

Acadamies' review, so it got pushed back a little out of our control. But that is nearing completion of review. The review has not been finished.

So certainly comments that we get back or a review of that would be relevant, but it doesn't -- I don't think that -- that's one issue related to the criteria development, but I don't think that -- and I'm not sure, to be honest, how to provide a concise answer to that. But I don't think that that just answers the question.

It provides an interesting look at the these joint relationships between different ways to categorize face dimension and the fit, but there are still other, you know, other issues in relation to how you formulate the criteria. And it's not clear that you necessarily want to have everything hinging on one panel, although it is certainly useful to, you know, have the panels to evaluate the question.

MR. BOORD: Mike, I think if you're asking if the analysis that we are doing is utilizing the latest NIOSH research for an anthropometric panel, the answer is yes.

So the data and the analysis that is being applied that Doug is using for his statistical approach is indeed that panel.

One of the questions that we are confronted with going forward is whether that becomes the bivariate panel that Dr. Ziqing Zhuang had developed, or do we go down a different road, which is to use the PCA panel.

So the bottom line, though, is it's the latest anthropometrics.

MR. SAVARIN: Okay. I'm trying to -- after what we saw, I wasn't clear that the new assessment or conceptual analysis was going to generate anything better, actually.

MR. BOORD: Well, we are using the most current anthropometric data.

MR. METZLER: Rich Metzler of the SEA Group.

I was wondering, you didn't mention this in your analysis, but are you looking at the data to determine whether there is a difference in the fitting characteristics of elastomeric half-mask and

filtering facepiece mask?

MR. LANDSITTEL: Yeah. Certainly almost all of the analyses we do is stratified by that factor. And it's not -- we are not just kind of lumping those in together.

I don't think the focus has really been to try to differentiate between the fit of those, but that's certainly, you know, part of the analysis.

MR. METZLER: I wonder will you eventually draft and produce a report on this, and will that work be peer reviewed?

MR. BOORD: Absolutely.

MR. METZLER: Because everyone is wanting that data, all of the data, not just the small subsets of the individual manufacturers.

Do you plan to implement this through policy, or is this going to be another module that will go through formal rulemaking?

MR. BOORD: The plan will be to implement the entire program through rulemaking.

MR. METZLER: Thank you.

MR. PFRIEM: Dale Pfriem, ICS

Laboratories. Question for Bill.

Bill, when this work was originally presented a few years back by Dr. Z, there was some lively discussion, if we should have stable concentrations in a test chamber, et cetera. You know, I think you remember those.

In your latest data sets, what was the challenge concentration? Was it controlled?

MR. NEWCOMB: We had, I believe, four sodium chloride generators in the lab space, and we did have a minimum background concentration.

I don't remember exactly what it was right now. We didn't control the upper limit, but we did control the minimal -- minimum concentration of background.

MR. PFRIEM: And then, that said, going forward, what are your thoughts about upper and lower bounds and uses of a chamber under controlled environmental circumstances?

MR. NEWCOMB: I don't think that -- at least I haven't seen that a higher concentration because of the protection factors are so low is

going to make much difference, but we do need a minimal concentration.

MR. PFRIEM: So you guys will at least establish a minimum?

MR. NEWCOMB: Yes.

MR. PFRIEM: Will you specify a chamber and ambient temperature and humidity concerns?

MR. NEWCOMB: Most likely.

MR. PFRIEM: Thank you.

QUALITY ASSURANCE MODULE

MR. NEWCOMB: I told you I was glad that I wasn't doing the statistics. Now you know why.

Quality assurance module. Something you probably haven't heard about in a while. It hasn't been forgotten. A little history on it.

A relatively new project. It has been under discussion since 1995. There was a manufacturers meeting in 2000, two public meetings in 2000, and two public meetings in 2003 where it was discussed.

The difference between today's discussion and those discussions is that at the time we first

started talking about this, it was a combination administrative module and quality assurance module.

And the administrative module has things like fees involved in it. And all manufacturers around the table, around the room know that we are still working with 1970 fees in the testing that is done at NIOSH.

It's actually the best buy there is in the United States, I believe, right now for test time.

And the administrative module we are going forward with as well, but we felt it was better to separate the administrative and the quality assurance provisions.

The status of the quality assurance module at this point in time is that the concept of the proposed modifications to 42 CFR Part 84 have been written and the preamble that is necessary to go forward with a notice of proposal also had been written, and it's ready for internal review.

What's in the concept?

Well, the first thing is it's a paradigm shift from manufacturers' benefit to consumers'

benefit.

What I mean by this is the original way that 42 CFR 84 was written, it was based upon the manufacturer not making bad product.

What we, and what the consumers, want is something that looks at the consumer's chance of getting a bad product, putting the emphasis on the consumer's benefit rather than manufacturer's benefit.

There is a mandatory quality management system requirement, a clarification of the audit procedures. As most of you know, there have been some policy letters and so forth on the audit procedures and how they pertain to the manufacturer and to manufacturing entities that are controlled by the manufacturer, and also the method of getting product for auditing.

There are some modifications to the application procedure, and there will be a codified procedure for the use of external auditors. Right now, again, under policy, NIOSH is using external auditors, but this will be written into the code.

One of the major changes is quality assurance requirements rather than quality control procedures. Back in 1970, when this was first written, people didn't talk about quality assurance. They talked about quality control. And for those of you that worked with it, there is a difference.

There is also a procedure for revocation of approval for QA deficiencies, clarification wording on that. Also a clarification of the procedures for changing ownership.

Back when the regulation was written, there wasn't a lot of larger companies gobbling up smaller companies. And there has been an awful lot of consolidation in the respirator manufacturing business over the last few years, and there is not always the best notification to NIOSH of the change in ownership, the change in quality assurance plans, and the change in management philosophies. So we want to make the code clearer in that respect.

There is also modifications to the quality control plan content that's required to be given to NIOSH in the application. Further, there is

replacing of the classification of defects with a critical-to-quality characteristics concept.

We don't like to see defects, so why classify them. So we are looking at, again, changing the way we look at that.

Replacing mandatory sampling plans. If any of you are involved in that today, you know that there are certain AQLs that are called out for different characteristics, and you have to go to a military handbook and see how many products have to be sampled.

What we are going to do is allow flexible plans suited to manufacturing entities. If you have statistical process control, you will probably have to do less sampling. There will be rewards for having good programs.

If you have a poor program, you will probably find that you have to do a lot more sampling with the new requirements than was done with the old program and, thus, an impetus to improve the quality procedures.

There is also clarification of a procedure

for reporting consumer and user complaints.

Right now, if you have ISO 9000, there's a requirement in there that you have a procedure, but obviously there is nothing in that requirement that says you have to notify NIOSH and that you have correspond with NIOSH about the way you are handling that procedure.

Again, this will be added to the proposed requirements.

Also one of the issues that some of our auditors have come across -- and I won't say it is in all manufacturing facilities, but some -- where they look for records, and they find that the records have -- are no longer available.

We have put into this a requirement that the records be kept for -- the quality records be kept as long as the expected life of the product.

What's next? Well, the first thing we have to do is a NIOSH NPPTL internal review, which has been quasi underway, a complete NIOSH review.

The NIOSH OD has given us a hand in preparing this, so I don't foresee any big issues

there.

Obviously then CDC has to review it, HHS has to review it. OMP has to review it, and then finally it has to be published as a notice of proposed rule in the Federal Register.

We are looking at a timeline which would -- some of my font has changed. The Federal Register notice in the old system, before I got this elongated screen, said it was going to be approximately last May -- next May, rather.

So that May that you see over there on the far right, it should be above the Federal Register notice.

That gives approximately a month for the approvals. Some of them may take less time than that. Some of them may take more time than that. Hopefully there won't be a lot of changes in it, and we will see a proposed rule on the street by the middle of next year.

Thank you very much. I would like to entertain any questions.

Must have been a quality presentation.

Thank you.

ADMINISTRATIVE MODULE

MR. AHLERS: This was supposed to be one slide. Here we go. We don't need those. We will go through it quickly to talk about money.

Okay, very simple slide.

As Bill mentioned, the NIOSH fees have been in place since approximately 1970. The only changes that have taken place to date have involved the CBRN testing.

NIOSH desperately needs to update our fees because of the cost of running the laboratory and the costs that we are incurring in having a certain number of tests done on site by contractors.

And every time you pay us for a test that we have to have the contractors do, we lose a great deal of money.

And I'm sure that that troubles you all greatly, but it does trouble my boss, and it is part of my performance plan. So we have to do something about the approval fees.

You have this yellow sheet of the

certification dockets that have been opened, and you can add on to there, there is a new docket, No. 092, on certification fees.

And we are very much interested in your comments on certification fees because we are busily putting together how much it costs us to operate the tests.

You know, we can do that. We can break it into what it costs us to pay the contractors, what it costs us to run the labs, what it costs to run our own people. But what we don't know about is what the impact of our fee increases have on you.

And we are very interested in knowing that because it is probably highly unlikely that at any point in time we are going to pass on all of costs that there are associated with the tests to the manufacturers. Unless you sit back and don't offer any comments whatsoever on the fee schedule, we would assume that maybe you would like to see that happen.

So we are very open because, you know, we realize with the cost of development of different

kinds of respirators, the testing fees can become, you know, very prohibitive when you have a customer base of a thousand or two thousand people for a given type of respirator.

So we are interested in that type of information and what you see as things you can tolerate in those kinds of areas, and we would be very happy to entertain those in that docket.

So, again, it is 092, and it's certification fees.

We will be moving forward with gathering our data, and we will hopefully be able to have that available to put up on the web. It's something like an ANPR (phonetic) sometime in the next 60 days we are guessing, in a draft kind of format.

This would be precede as a formal rulemaking. Actually, it's an informal rulemaking, but it would go through all of the rulemaking steps, so there would be the same things.

Why it is split off in the QA module is hopefully this will would move forward somewhat more swiftly because all of those steps and through CDC

and the rest of the federal government tend to be a little quicker when it looks like money coming into the federal government.

So if you have any questions, I would be glad to try and answer them at this point. Otherwise I would encourage you to get your comments in.

Thank you.

And then Les Boord, save Bill jumping up.

MR. BOORD: Okay. For our final discussion today, I would like to talk about some of the quality initiatives that we have in the laboratory.

And that discussion will be led by our associate director for science, Dr. D'Alessandro. So Maryann.

SCIENTIFIC EXCELLENCE FOCUS

MS. D'ALESSANDRO: You can start finishing your surveys while I get my presentation up.

Just saw the whole thing, so...

Thanks, Les.

I'm going to focus on the scientific

excellence focus at NPPTL, which primarily focuses on quality performance initiatives which are described in three categories, evaluations, customer and market knowledge, and customer relationships and satisfaction.

Under evaluations, one key component of evaluations which helps us to emphasize our quality, relevance, and impact of everything we are doing in NPPTL is our National Academies involvement in NPPTL, and I will get into that on the next slide.

Another area is the scientific information product review.

We have a very rigorous process for evaluating all of our activities to include project proposals, protocols, specific investigations that are conducted in the lab, manuscript reviews, as well as scientific information products such as those that Frank Palya discussed, and other information products that are being developed in the lab.

The logos that you see on the right are those specific organizations who have a regular

involvement in our peer review processes.

The National Academies in the highest level reviews that we have, the AIHA, ISEA, and OSHA are always solicited to participate in our reviews, and then those -- that text across the bottom are the various agencies that we do solicit depending on what the review is and what expertise is needed in the review.

NIOSH has required peer review in all of the activities that are conducted. And what we are transitioning to is all of our research activities being peer reviewed, and then those research activities feeding into our standards and certification activities.

We are beginning to benchmark with other agencies, and I won't get into that today, but that's a process we are just initiating at this time.

In the customer and market knowledge and customer relationships and satisfaction area, the bottom logo there, the Office of Personnel Management is the agency who is assisting us with

those activities.

And OPM was the agency selected because they have a very high level of expertise in organizational psychology in their agency. They have developed surveys that are used government wide.

And that was the reason that we selected that, so we could also benchmark ourselves with other government agencies who take their surveys and also use them with their organizational psychology expertise.

The public meetings and feedback, the surveys that you are preparing for us today determine how well we did with these type of events.

Customer satisfaction groups, I'll get into that. And then with customer relationships and satisfaction, customer satisfaction surveys, I will discuss. And then direct customer involvement is something that NIOSH has done for a long time, and we continue to do.

With the National Academies involvement in NPPTL, one activity is -- I will start with the

fourth bullet there, the fourth dash, and that's what Frank Hearl from NIOSH OD discussed today.

That's the National Academies evaluation of various activities. And that's something that we at NPPTL did not initiate. That's something that was initiated NIOSH wide to evaluate all activities in the various sector groups in NIOSH and also cross-sectors for which PPT is one of those cross-sectors and will be evaluated next June.

And our evidence package will go in for evaluation in Spring 2007.

We are currently submitting names to the National Academies to participate in that review. And if any of you do have names for consideration, we welcome you to provide those names to us to forward on to the National Academies.

Now back to the first three bullets. Those three dashes are initiatives that NPPTL has proactively initiated in order to improve upon what we are doing in the lab.

The first is the committee on PPE for the work force. That activity was initiated

approximately two years ago, and the contract was finalized with the National Academies a year ago.

And the committee formed, and we had three open meetings in Fiscal Year '06. And the next meeting is scheduled for October 23 and 24th in Washington DC at the National Academies.

That committee is comprised of a number of experts in PPT, in standards development organizations, academia, various government agencies, and also some experts who are outside of the PPE and PPT field in order to have a fresh perspective and perhaps provide us information on what the PPE needs are in the nation from those who have not been involved.

And something, the first two meetings were really -- we really got them up to speed with what we were doing in the lab and what NIOSH is doing and where we are heading and what our strategic planning process is.

And then by the third meeting, they were really able to provide us some advice. And the main advice that came out of that committee this past

year was that there a need to really understand what the PPE needs are if there were an influenza pandemic, not only for the work force, but also for PPE for the general public.

So we are going to be conducting a workshop through them around February 2007 time frame. And the focus will be PPE during an influenza pandemic focusing on research standards, certification, and testing directions in those areas.

The FDA will be involved in this. OSHA will be involved. NIOSH. Perhaps EPA. A lot of government agencies and as many standards development organizations as will participate as well, and other government agencies.

The second and the third bullets are two other activities that we initiated in NPPTL. And those activities, the first one is what one of the members, Mike Savarin, brought up earlier, and that was the anthropometric survey of respirator panel modification.

These two, the second and the third bullet

are two activities in NPPTL we thought warranted the highest level of scientific review because of the impact they are going to have, not only on all of the activities we are doing in NPPTL, but on the manufacturers and on the users of PPE as well.

So the National Academies is in the process of reviewing, or has completed the review of that survey of the results that came out of that survey, the conclusions that were drawn, and how that data is planning to be used in the future.

The report was actually due to us in June, but that committee was hijacked by the Department of Health and Human Services.

And that report that you see there in green is what came out of that, and that was the committee on the development of reusable face masks for use during an influenza pandemic.

That came out in March, or April time frame, and our researchers are actually using the results from that committee report in the future activities, as is shown in one of the posters and the discussion this morning.

So that report is now is due this month, but it may be delayed. It is currently in the review process.

National Academies also has their own review process as well.

It also important to note with this committee, that there is some very -- some names you will probably recognize on that committee. Alan Hack (phonetic), for one, who was involved in the development of the LANL panel was on that committee. Lisa Bruso (phonetic), who is a leading researcher at the University of Minnesota. Howard Cohen, who has been involved in standards development for respiratory protection for a long time.

So there are some very key personnel involved who are assisting us in making these decisions and will help us move forward with where we should be going in those activities and will also lead into the future standards and certification as well.

The review of the BLS survey for respirator use in private sector firms, we also had

them evaluate. And the reason for this is because our surveillance information is what we use -- another part of what we use to determine what we should be doing in research areas, standards areas, and certification.

And that study was formulated internally with NIOSH personnel and Bureau of Labor Statistics Personnel.

I'm not sure how much of the outside use there was in developing that survey. So we thought it warranted a National Academies review to help us in formulating future surveillance initiatives in helping us see how we should conduct our activities in the future.

There were three open meetings conducted for that activity in 2006, and that report is due this month as well.

The next area of our quality initiatives is in our customer satisfaction surveys. Again, we have an interagency agreement with Office of Personnel Management to assist us in developing the survey.

And also we have a customer and market focus team within NPPTL that consists of members of the Office of the Director and each of the various branches who has put together various NPPTL specific questions in addition to the OPM core customer satisfaction items that they use for all of their surveys that are administered.

The survey was pilot tested in October 2005, obtained OMB approval for distribution in December 2005. And we administered it online in December 2005.

The customer base that we use, we separated our customers into two groups, manufacturers and users of PPE. And users also were a little bit broader than just users of PPE. We also included academia in there and others who have signed up for our list serve.

We began analyzing the results from that, the survey in -- from January to April time frame, began acting on the results in April. We are continuing to do that in monitoring and evaluating our progress.

The survey that was conducted utilizes nine service dimensions that you see listed here on the left in the yellow rectangles.

And the results from the survey are posted on our website. And to get specific details on what exactly those dimensions mean, you can go to the website. And they are all defined on there on the final report of the results.

These nine dimensions are the nine core dimensions that OPM uses in their surveys. And, again, the reason we used those is so we can benchmark with other agencies.

In addition, we had NPPTL specific items that we put within each of those dimensions that were not OPM specific questions. And our hope is that, again, there is a -- should be a circle there.

That has disappeared in the middle. And what that says is customer satisfaction is what we are hoping to obtain, and then the outcomes would be the rectangles that you have on the right.

This is a summary of the results. We had a 30 percent return rate for both the users and the

manufacturer's surveys, responses from 185 users and 75 manufacturers.

While OPM did indicate that this is a reasonable number, there is definitely room for improvement. And we are hoping the next time the survey is conducted, that we can get a better return rate.

Now I'm just going to summarize some of the results from both the manufacturer and the user survey. And the results are color coded with blue, green, yellow, and red codes.

I'm happy to report you will not see any red. We did not have anything in the critical range when it came to the results, but we did have some marginals. And the marginals are where we have begun to focus.

In the user survey, the marginal results were in the recovery area. And so that is where we decided to focus. And most of the other results were pretty good.

Quality and tangibles. Quality, the users said that the quality of our products was very good,

and I think that's a reflection on our certification activities and the products that manufacturers develop.

The other areas in green are areas we could work on for the users, but we are focusing on the recovery area. And that is how we respond to issues that users raise and how we address the concerns that they have in what we are doing.

This is the benchmark data provided from OPM, and it shows -- it is -- I misspoke yesterday. I said it was 1,200 surveys the government conducted. It is actually a hundred surveys that OPM -- approximately a hundred surveys OPM has conducted.

And it is important to note that other government agencies who have used this survey have used other government customers. We are the first ones to take this outside of government personnel to our customers. You are not government employees or other government representatives. This is the first time that has been done.

As you see, the blue is the high benchmark

area, and the red is the low. And the green circles in the center are where we fell for each of those areas. And you can see that we are above average in all of them. And, again, the recovery is where we are the lowest.

For the manufacturers, the issues were in recovery, timeliness, quality, and choice that needed the most help.

Choice, there isn't much we can do about that. There is nowhere else that manufacturers can go. But we can focus on the quality, timeliness, and recovery. And that is where we are focusing our activities.

Again, looking at the benchmark data, though, it is nice to note that we are above average in all of those areas as well. But, again, the recovery, timeliness, and quality are low, and choice.

This dimension profile shows you a comparison between the manufacturers and the user data. And you can see most of them track closely together, but there are some, like quality.

Manufacturers rated us low in quality. And the users rated us high.

And, of course, the manufacturers had different products. There were different reasons for their ratings than the users.

And also in the -- the other difference is in the timeliness area. The users rated us higher there than the manufacturers did.

So now that we have the survey results, where do we go from here?

Now, I guess there are three particular benefits to us in having these survey results.

One is that they will validate that what we are doing are the correct things that we should be doing. And, secondly, it will resolve other -- the areas, perhaps where we thought we should be working, but really the surveys and customer satisfaction groups are showing that we should not be working in those areas. So we can resolve those issues.

And another way it helps us is in helping us when we have these, the second bullet, the

customer satisfaction groups.

At these customer satisfaction groups, something that has come out of those is something that in some cases did not come up in the survey and something we weren't working on in the first place.

So there are three ways that these activities are helping us.

What we are doing now in response to the survey is the next step is we are working on the low hanging fruit in most of the branch activities, to address those issues that came up in the surveys. And, secondly, we are creating customer satisfaction groups.

And in the customer satisfaction groups, it will benefit our customers by keeping them satisfied on an ongoing basis and providing them an easy way to voice complaints and concerns and seek more information.

For us, it will provide a resource for direct customer contact and give us direct feedback into what we are doing and allow us to have regular input in keeping up with the changing PPE market.

Today we have conducted two customer satisfaction groups. The first group was conducted in April 2006 with manufacturers.

And it is important to note that we do not solicit manufacturers. We solicit organizations. And those logos to the right there are the organizations we solicited.

For the manufacturers, we solicited ISEA, SEDA, and a Canadian group. And then for our second group, the fire services, we were focusing -- in the customer groups for users, we are focusing on the fire services first since that's most of our research activities, certification, and standards activities has focused in that area of late. So that's where we decided to focus first.

We had one fire services group in September, and we solicited Pennsylvania Region 13 for that group. The next group is scheduled for this month in Arlington, and we have solicited IFF and International Association of Fire Chiefs for that group.

We have three meetings that will be

scheduled in 2007.

We will have another meeting with the manufacturers, since that is something we always have to continue to improve in the certification and evaluation and standards activities and research.

And we also have one with health care because of the emerging needs, especially in the pandemic influenza areas.

And then in manufacturing as well because of the respiratory protection issues in manufacturing, and the needs there. And we are still soliciting organizations for those three groups.

The actions that we are addressing to address the user issues focus on recovery, reliability, access, and on research updates.

Recovery is focusing on -- we are holding the focus groups to see exactly what are the issues that the users have with the recovery issues that came out of the survey.

It wasn't clear to us exactly what those issues are, so the focus groups are the next step to

improve upon the issues that came up there.

And we are beginning to develop another approach for improving the methods for handling requests for additional information.

And reliability, we are improving on our review processes, as I mentioned earlier, primarily our peer review processes and getting the National Academies involved in what we are doing.

And we are involving stakeholders up front in our research activities, standards and certification evaluation activities as well.

With access, we are exploring other potential avenues for disseminating our information. We are trying to post all of the contractor reports that we have coming through the lab. We are videotaping this public meeting today and seeing if there is anything we can do with that videotape, perhaps somehow put some of that on our website.

And also we are trying to disseminate our findings as quickly as possible.

Something that came out of the survey is the need to provide research updates. That's one

reason why the activities were presented today and the posters presented as well.

And also we are focusing on one research activity monthly and providing updates on our list serve in e-news as well. And there are e-news -- e-news is the NIOSH tool for providing information on what NIOSH doing.

And there are sign-up forms on the side of the room and at the registration table at the -- outside the room to sign up for e-news.

And, again, updating research activities at public meetings.

The manufacturers heard yesterday all of the quality, timeliness, and recovery issues that are being focused on in the certification and evaluation activities.

And our next steps are to continue to act on the results, monitor and evaluate our progress. And we intend to conduct our second NPPTL customer satisfaction survey for both manufacturers and PPE users at around the March time frame next year.

At this time, I'll entertain any

questions.

Thank you. And if you could please just pass your surveys to the center of the room before you leave, we would awe appreciate that.

Do you have any closing remarks?

MR. BOORD: Okay. Thank you Maryann.

I thank all of you for your attention today and for participating in our public meeting.

I hope that, as a result of the discussions that we have had today, that you have a greater appreciation and understanding of some of the activities of the laboratory, some of the programs that we have in our policy and standards branch, the research activities of the research branch, and certainly the certification activities.

For tomorrow's meeting, we will follow the agenda that you have in your information packets. So the meeting will start at 8:30, and we should finish and adjourn the meeting by 11:30.

I would request that you be here promptly so we can start at 8:30.

Again, thank you for your attention. And

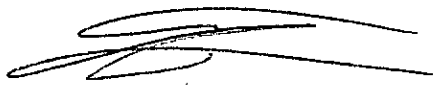
if there is any questions or discussions that any of you want to have on a continuing basis with any of presenters, we are certainly available to do that.

Thank you.

(Whereupon, the proceedings in the above matter were concluded at 4:18 p.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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