NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY

STAKEHOLDER MEETING

Wednesday, August 20, 2008

Commencing at 8:24 a.m. at the Sheraton Station Square, Pittsburgh, Pennsylvania.

MR. BOORD: Good morning, everyone, and I would like to welcome you to this NIOSH meeting, public meeting, stakeholder meeting on the NIOSH respirator standards development activities.

My name is Les Boord, and I'm the director for the NIOSH National Personal Protective Technology Laboratory.

And before we get into the meat of the discussions this morning on the various respirator standards and topical issues, I would like to just give you kind of a brief overview and an update of some of the more visible or important activities that are occurring within the laboratory and within the Institute.

And that list of topics is on the screen now.

I would like the briefly introduce you to the NIOSH director, talk a little bit about our PPT program evaluation activities, some of our policy and standards development branch activities, and then give you kind of a heads-up on some future things that the program is working on so you can

kind of note them for your calendar and future planning activities.

So to start with, I think probably most of you are probably aware of and familiar with the -- familiar with the activities relative to the NIOSH director, Dr. Jon Howard.

His term of duty as the NIOSH director expired on July 14, 2008. And the acting director who is taking over the reins of the Institute in the transitional period is Dr. Christine Branche. So her assignment as acting director of the Institute became effective actually on July 14, at about 5 p.m.

I don't know how many of you are familiar or have had some previous awareness of Dr. Branche, but her background and experience is certainly in the areas of occupational safety and health, as you can see on the overhead.

She actually joined NIOSH in July of 2007, so she has been on board with the Institute for about a year. Prior to that, her tenure with the government was with CDC at the various capacities

identified there. She was a director of the unintentional injury and prevention division. So she does have experience and background and awareness of the issues and the concerns of occupational safety and health.

During the time that she has spent with NIOSH, she has become familiar with the various NIOSH programs, including the Personal Protective Technology Program.

Her involvement has been to large degree in the evaluation activities for the various NIOSH programs being reviewed by the National Acadamies of Science, and I will speak a little bit more about that as one of the items to update you on.

So I think that we really look forward to a smooth and easy transition with Dr. Branche at the acting director position. Relative to the length of time that will be, it is really difficult to say recognizing that this is a change-in-administration-type year, so I think there's a number of things that need to come together in order for the permanent director to be

identified and named.

So speaking about the National Acadamies' activities, most of you are also probably aware that beginning 18 months ago, the Personal Protective Technology program for the Institute for NIOSH was preparing and underwent a very extensive evaluation by the National Academies of Science.

That evaluation was done at the request of NIOSH, and it was done for other programs within the Institute as well.

The reasons and the goals of that evaluation were basically to evaluate the various programs for the impact of the completed research that it has, the impact that it has had on the workplace, occupational safety and health, to evaluate the relevance of the research and activities that the programs were doing to make an assessment relative to whether the programs have a relevance to occupational safety and health.

And then, thirdly, to identify significant issues that each program is confronted with and should be important to the programs in going forward

into the future.

So for the National Academies of Science review of the Personal Protective Technology program, on June the 25th, we had a debriefing by the evaluation committee that studied our program. And that study that they performed was really and in-depth review of volumes of information that we had presented to the National Academy to review our activities.

And I think one of the important aspects of the report and the evaluation were the five recommendations that the evaluation committee made for the Personal Protective Technology program. And those are identified here. The first one is to implement and sustain a comprehensive national Personal Protective Technology program.

Number two was to establish Personal Protective Technology research, centers of excellence, and increase extramural Personal Protective Technology research. We will skip over number three.

Number four is to increase the research on

use and usability of Personal Protective Technology. And number five was to assess Personal Protective Technology use and effectiveness in the workplace using a lifecycle approach.

And then number three was a recommendation to enhance our respirator certification process. Now, behind each of these five recommendations, there are a number of subissues and recommendations that tie into the main recommendation.

And for that third recommendation, to enhance respirator certification, there was a clear message in there that we need to expedite revision of our regulations. And that is really the reason that we are here today, to talk about some of our activities to revise and propose technical concepts for respirator standards.

So I think the meeting that we are about to undergo really has a tie-in to the National Academy evaluation of our overall program.

That evaluation, as I said, actually spanned a period of about 18 months, 18 to 24 months, including the preparations and the actual

review. Some of the key dates are identified here with the main and the most recent one being the June 25 meeting that the evaluation committee visited the laboratory and presented the results of their findings.

That report that summarizes the activities can be found at the -- on the National Academy website. The link is through the NIOSH website, but you can get to the National Academy website and actually see a copy of that report to see some of the detail behind the evaluation.

So following that report, what is the program going to do?

And we have identified a series of activities that we are undertaking to actually address those recommendations that have been made by the evaluation committee.

The first one in the first step obviously is to really become familiar with the details of what the evaluation said.

And then secondly is to go through what we are calling an action planning process.

And we have kind of bracketed a six-week period beginning in the middle of August and extending through September where we have three teams that are looking at the action planning activities for the recommendations.

And we have kind of aggregated the recommendations. Recommendation 1 and 2 is one team. Recommendation 3 is a second team. And then Recommendations 4 and 5 is a third team.

So those teams are meeting to identify actions that the program needs to address to meet the recommendations.

Following that action planning, we will take the results of those teams and try to synthesize them into a total report for the program to take the activities and to carry the plan forward. That report will be submitted to the NIOSH Office of the Director in the December time frame.

So we anticipate that by the end of the year, we will have that package fairly complete.

Our Office of the Director will review it. Following the OD review, that report will then be

taken to the NIOSH Board of Scientific Councilors for review and action.

What we anticipate is the review by the Board of Scientific Councilors will occur in the first quarter of 2009. And following their review and input, the program and the action steps that we identified would then be part of the continuing activities for the laboratory and for the Personal Protective Technology program in the Institute.

So I think we have quite a challenge and quite a bit of work to do in compiling that action plan.

And I would encourage you to try to get to the National Academy report and to read about the evaluation and the recommendations that the committee has made.

The next thing I wanted to briefly talk about is the, not the development of respirator standards, but I think the development of our Policy and Standards Development Branch.

As I noted, one of the recommendations from the Academy was to expedite the revisions of

the regulations that we use to certify respirators. And we really have intensified that activity, even before that report was published.

Over the past year, we have actually increased the technical staff in our Policy and Standards Development activity from five to 13. So we have more than doubled the size of the staff that's addressing our standards and regulations.

And when we did that, the actual increase in staff was a combination of things.

It was primarily recruiting and recruiting people new to NIOSH, but I think one or two of those positions are also juggling around within the laboratory.

But in any event, I think an increase from five to 13 shows a real commitment and an initiative to increase and expedite the activity to develop respirator standards and regulations for our program.

Now, naturally the focus of those activities are 42 CFR, Part 84. And the approach that the program is taking is a strategy that was

adopted five, ten years ago. And that strategy is to basically break 42 CFR up into sections. And we refer to it as a modular approach.

And using that modular approach, addressing those various sections, we will go through a process of rulemaking.

So the activity that we use to actually develop and change the standards will be pretty prescriptive. And I think Jon, in his discussions a in a few minutes, he will elaborate a little bit more on that process.

The team, the Policy and Standards team, with that increase in focus and activity, has actually set a goal to complete development of two modules per year. And I think, again, in Jon's presentation, he will show you that we are on track do that.

In Jon's presentation, he will go into a little bit more detail relative to what rulemaking is, what modules are currently in the pipeline for the rulemaking process, and what modules are in the preparation stages.

So concerning some future activities that I think will be of interest to many of you to mark and note in your calendars, on November 6, the program is sponsoring what we refer to as a "No Fit Test Respirator Workshop."

The website link to the information about that website is identified on the slide. That workshop will be held at the Embassy Suites hotel near the Pittsburgh Airport. November 6, No Fit Test Respirator Workshop.

Then November 13 and 14 is another program that is of high interest to the Institute and has some tie in to the Personal Protective Technology program. And that's the NIOSH Direct-Reading Exposure Assessment Methods Workshop. That is November 13 and 14.

Again, the website link to the information concerning that workshop is on the screen.

That meeting will be held at the Hilton hotel -- Hilton Crystal City hotel in Washington DC.

Then a third activity is -- I think during the discussion today, Jon will identify that in the

November/December timeframe, there will be another respirator standards development stakeholder meeting. And that meeting will principally be focused on the powered air-purifying respirator technical concept development.

And then finally, we are going out a little ways. In March of 2009, we will be conducting a Personal Protective Technology stakeholder meeting that will embrace all of the research and activities of the Personal Protective Technology program for the Institute.

That meeting will actually be -- I think I have some actually more firm dates. The meeting is on March 3, 2009. And it will be at the Hyatt -- Hyatt Regency hotel adjacent to the airport. So that meeting will be really easy to get to for those who travel into Pittsburgh.

Again, the date is March 3, 2009.

So that really brings us down to the focus of today's meeting.

I think the agenda that we have put together is a good agenda. We are addressing two

technical concepts for respirator standards: The closed-circuit self-contained breathing apparatus, and the standard for our supplied-air respirators.

In addition to that, there are two topical issues that will be also discussed during the course of the meeting. That's the CBRN air-purifying respirator standard connecter, and a longstanding NIOSH prohibition for use of oxygen -- high oxygen concentration systems in a firefighting environment.

So I think we have really four interesting topics that we are going to try to shed some light on today during the presentations and the follow-through discussions.

The format for the meeting is a little bit different than some of the meetings we have done in the past in that it's going to be a blend of presentations and posters.

And we really want to try to facilitate and encourage discussion and input from the various participants at the meeting.

So with that, what I would like to do is turn the meeting over to Jon Szalajda who will kind

of get you up to speed with some of the logistics relative to the meeting, and launch the agenda.

So, again, welcome, everybody, to Pittsburgh and to the NIOSH meeting on respirator standards development. Thank you.

MR. SZALAJDA: And good morning, again. Again, I'm Jon Szalajda. Thank you for the introduction and comments, Les, on the program.

At least for moving forward this morning, I wanted to kind of go through the logistics and some of the administrative details for how we are going to try to organize the meeting today.

I think -- please keep in mind, though, as we go through the course of the day that the whole purpose of this session is to facilitate communication to get your feedback, you know, with regard to the topics at hand as well as your thoughts on how we can direct our work going forward in the future. And, again, this meeting is meant to be an information sharing type of session.

In terms of how we are going to run things today, I hope everyone -- when you came in, there is

a registration desk in the back. If you happened to sneak in without getting a badge, please go back and collect your badge and make sure that your information was registered as being an attendee at the meeting.

What we are doing with regard to what we are discussing -- excuse me, discussing today is that we are having the meeting transcribed, at least as far as what is being covered today, the presentations, any of the public comments that may be provided as well as questions and answers that we will take during this session.

We are not transcribing the poster sessions, but we will be trying to take notes and encourage people, you know, as the discussions go forward and talking about the different topical areas with the posters, that if you feel strongly about a position or you have a good idea, please, you know, feel free to come back up during the open comment period and restate your idea or your position on a particular topic during the open comment period.

We are going to follow the agenda that was provided when you came in and registered. As a stakeholder, you should have gotten a packet of information, which includes the presentations as well as the posters, or a smaller version of the posters today.

And making the posters in that size was a lit bit of a challenge. Some of the printing on the edges may have been condensed a little bit. But I think when you look at the content of any of the charts and the calculations and things of that nature, I think all of that came out fairly clear.

And this information, if you do want to get a different copy, we can make -- please let me know and/or let Tess or Judy know in the back, and we can make arrangements for you to get a larger -- or at least an 11-by-14 copy of the posters if you desire.

One of the other things to keep in mind is with the format that we are trying to follow today, it's a fallout of the March stakeholder meeting that we had this year where our researchers had the

opportunity to have poster discussions, and the stakeholders were able to have a little more intimate type of discussion with the NIOSH researchers on a variety of topics.

And that was very well received in the comments that we got in the survey following the meeting.

So we decided to try that, you know, for the discussions regarding standards. And so what we would like to you to do when we do the meeting survey today at the end of the day during the wrap up, if you can let us know what your thoughts were with regard to this type of approach.

You know, historically, if you have come to these meetings, we provide PowerPoint after PowerPoint. And usually by the middle of the afternoon, everyone is pretty well numb as a result of the approach and that approach in providing the information. But we would like to get your feedback with regard to this format.

And, again, during the question-and-answer period, we would like you to come up to the

microphone, state your name, who you are with, and then provide your comment.

Also, there is an opportunity during the public comment period for individuals to make presentations. So far, we have one presentation that's scheduled at the end of the day during the last topic area. And if there are any other presentations to be made, please let me know during the course of the day.

As far as the format, you will see a combination of presentations and posters and also the stakeholder comment sessions.

You know, with regard to the agenda, it's actually a pretty robust agenda, and we were a little concerned about trying to get everything done during the course of the day, but we will give it a shot.

I think when you see the time frames, the things to keep in mind are 9 o'clock, 11, 1, and 3, because that's when we will move to the next topic on the agenda.

If during the course of the day, if we

happen to finish one topic early, then we will take a break until the next time period when the next topic is slated for discussion.

I think when you look at the topics overall, it's a nice blend of, as Les had mentioned, of what we are doing with regard to standards development activities in terms of making changes to the federal regulation to reflect different performance requirements and different test methods to try to update the requirements that are indicated there.

And it also addresses areas where NIOSH has developed policy, you know, where we have identified specific areas that we felt important, either through establishing a prohibition, in the case of the oxygen-generating respirators, or in developing policy with regard to identifying performance criteria for the CBRN categories of respirators.

A little bit about standards. And part of the approach that we have taken with standards development is to use conceptual requirements or

conceptual papers to discuss our thought process and give the stakeholders an opportunity to provide us feedback prior to the initiation of informal rulemaking.

Once we get into the rulemaking type processes, things are a little more rigidly defined with regard to our interaction with stakeholders.

But by using meetings like the public meeting, posting our concept papers on the website for review, and soliciting stakeholder feedback, we think this will go a long way in terms of being able to shrink the timing or the time frames that are necessary for rulemaking, that if we are not solving or trying to address technical issues during the rulemaking cycle, but are just taking care of the administrative process, then we think the actual rulemaking will go a lot quicker.

In terms of where we are going, we have three items, three proposed changes to Part 84 in the rulemaking process that are in different aspects of agency review, either within the Department or within the Office of Management and Budget.

The key thing to keep in mind in here is once the rules leave the Department and go to OMB and go through the OMB review, then there will be a Federal Register notice that will be issued to advise the public that NIOSH is working on this proposed rule.

And once that Federal Register notice happens, we will notify people who are members of our listserve that this activity is underway, and there will be opportunities for stakeholders to participate at that time.

Items where we are looking to complete conceptual development in 2008 are the closed-circuit self-contained breathing apparatus, which we are going to discuss today. And we are looking towards taking that concept and developing the documentation and moving that into agency review before the end of the calendar year.

Powered air-purifying respirators are going to come along fairly quickly behind that.

The intent is to have a discussion like this in the early winter, to have one more

discussion with the stakeholders with regard to the concepts, and then move those performance requirements into the rulemaking process early in 2009.

Along with that in 2009, we are looking to introduce by the end of the year the supplied-air respirators, which we are going to discuss for the first time this afternoon.

And always in the upcoming year, we are going to look at air-fed suits and developing performance requirements for air-fed suits where the suit acts as the respirator. And, again, as Les had mentioned, the intent is to go through by class of respirator and develop two modules a year.

A little bit has changed with regard to how we make the information available as well. You know, for this public meeting, we are using the NIOSH website, not the NPPTL website, as the venue for soliciting information.

You can go to that link that's provided on this slide, and you can get the draft concept papers that were issued for each of the four topics that we

are going to be discussing today.

Additionally, there is also a link on the NIOSH webpage that takes you to the docket, the NIOSH docket, which is the repository for all of the public comment that we receive on these topics.

And what our process is that we are currently going through is that probably within a couple of weeks' time, you will be able to go through the internet and be able to look at all of the docket submissions online, which is currently being developed by our offices in Cincinnati.

In the event that you want to look at something earlier, if there is a particular topic that interests you, you can always contact the docket office and request copies of the information that is submitted to the docket.

But, again, by making it web accessible, you know, here over the next few weeks, I think this will be a tool for stakeholders to help see what the information is that we are getting in a formal way and help you develop positions on topics as well.

And, again, these are ways to contact the

docket office. When you go through the agenda, you can either send it by mail, email, fax, or phone. And, again, all of this information is available in your slides on the various topics that we are going the discuss today.

And at least at this point, does anyone have any administrative questions about how we are going to proceed for the balance of the day?

And what we will do, at least in the plan is, for the closed-circuit SCBA and for the supplied-air respirators this afternoon, the primary project officer will provide a brief overview of the contents of what we are considering for the standards.

At the point where the project officer finishes the presentation, we will make a break. We will adjourn to the poster room next door. NIOSH staff will be available around the posters to have discussions with you on the content of the posters.

Actually, Bill, don't leave yet.

What I wanted to do is at least identify a couple of the newer staff that you may not be

familiar with, recent hires during the course of the year.

We have Bill King who is standing in the back of the room.

Jeff Palcic up here in the front, and Colleen Miller in -- somewhere towards the back. Rich Vojtko, and Gary Walbert. And these are recent hires that we brought in to NIOSH from the outside.

And we are very, very happy -- happy to have them on board. And so I would encourage you, they will all be in the poster room to say hello and introduce yourself to them because you will be seeing more of them over the years to come.

Okay. With that, what I would like to do is introduce Frank Palya to discuss the closed-circuit SCBA. And at the end of the Frank's presentation, we will break. We will move to the poster session. Please feel free to move around, ask questions.

During this first session, we will only be manning the closed-circuit SCBA posters. In the afternoon, we will only be manning the supplied-air

posters.

But everything will be there for your observation. We will reconvene in here at 10:30 for the comment period.

MR. PALYA: Good morning. Thank you for attending the NIOSH public meeting.

As Jon said, I'm going to present an overview of the proposed concept standard for the closed-circuit self-contained breathing apparatus.

I would like to touch upon some of the past efforts that was accomplished throughout the years.

Originally, NIOSH sought to develop and implement a standard for protection against chemical, biological radiological, and nuclear threats by using the policy method for the closed-circuit.

Originally, it was a two-tiered approach where we would -- the self-contained breathing apparatus would have to meet all of the requirements in 42 CFR and then meet a secondary set developed by policy to meet the CBRN threat requirements.

As you can see, we developed three concept standards in October of '04, June of '05, and November of '05.

And we held subsequent public meetings in December '04, July '05, and December '05. And the meetings, as you can see, were held within a month or two after the development of the concept standard.

Also, there was a technical meeting held at NPPTL mainly with personnel on a committee to develop a draft standard for the NFPA, the 1984, for the closed-circuit SCBA. So we got input from those people as well.

So we have been working on this for a while. So the current standard, what we have now, the May 2008 version, has evolved from many things, from the work over the years, the public comments that we received at the public meetings, the docket comments, the technical meetings, and a lot of the information was gained through the benchmark testing.

So after the NIOSH CBRN powered-air

purifying respirator was approved in October 2006, it was determined that all future standards shall be adopted by the informal rulemaking process. Thus, the closed-circuit fell into that category as well.

Currently, both the open circuit and the closed-circuit requirements are in Subpart H of 42 CFR, Part 84.

Now, what we are proposing is that the closed-circuit requirements will be removed from Subpart H and placed in a new subpart, and that will be Subpart Q.

Contained in Subpart Q are the optional protection requirements for the CBRN and the high heat and flame resistance performance requirements. An SCBA will have to be able to meet the base requirements in the subpart before it can be certified for CBRN protection. As well, the SCBA will have to meet the base requirements and the CBRN requirements before it can be certified for high heat and flame resistance protection.

The Subpart Q requires full facepiece only. Also, the facepiece lens system shall have to

meet the same field of view, the haze, the luminous transmittance, and abrasion resistance requirements as the NIOSH CBRN air purifying standard.

We also updated the breathing gas requirements as to the latest requirements in the United States pharmacopeia standards. We added the kerosene -- we added kerosene and toluene vapor challenge agents to test the breathing bag and other components for permeation and penetration resistance, as well as we kept the gasoline requirement.

The following performance requirements will have their test updated or replaced. The breathing resistance, valve leakage, gas flow, capacity rating, CO2, flow temperature operation, and the man tests.

Now, the proposed testing also includes the use of the automated breathing and metabolic simulator as well as the traditional human subject testing. We believe this is a more comprehensive testing method, and it tests the unit in the operational mode.

These tests will be conducted at a varying work rate. And additional proposed testings include capacity testing, performance testing, and wearability testing.

As I said before, the optional CBRN performance requirements are included in Subpart Q, and it must be able to meet the base requirements of 8450 -- or sections 84-500 through Sections 84-520 before it can gain approval for CBRN protection.

The testing includes the CBRN operational performance requirements which are different than the base operational performance requirements because it is based off of the NFPA requirements.

This also includes temperature extreme operational testing, environmental test requirements that include vibration, accelerated corrosion, blowing dust, communications, and the facepiece lens haze, luminous transmittance. This actual requirement is in the base requirements, so it's not part of the CBRN.

Also, the main one is the agent testing. The challenge and the times are the same as the open

circuit, but we developed at Edgewood a new breathing system that is more humanlike where it takes into account the humidity of a more human-like breath, the humidity, the CO2 content, the oxygen content because of the closed-circuit system. It is just not an air mover like the open circuit.

Also, the optional high heat and flame resistant performance requirements are included in Subpart Q.

These are again, optional. But, again, you must pass the base and the CBRN protection requirements before approval can be gained for the high heat and flame resistance.

The heat and flame resistance performance requirements taken from sections from NFPA 1981 to 2007 version, include the peak exhalation and inhalation pressures, component after-flame, and the integrity of the unit to be worn or used as specified in the users instructions, lens obscuration and fabric heat and flame resistance.

We project the following milestones:

Complete the revised closed-circuit

self-contained breathing apparatus concept standard based on feedback from this public meeting and docket comments by October 2008. And we plan to initiate the informal rulemaking process by December 2008.

These are the following posters that are on display in the room next door, and the NPPTL personnel who will be planning the posters. They will be available during the poster session to answer your questions.

However, as Jon mentioned before, we do encourage you to officially make comments during the proposed concept standard during the closed-circuit period or the comment period between 10:30 and 11 o'clock.

This completes my presentation, and thank you for your attention.

MR. SZALAJDA: At this point now, if we could have the NIOSH people go, you know, go next door. They will be manning the posters. And then you are free to come and see the posters as you see fit.

We will reconvene in here at 10:30.

(A recess was taken to view the posters.)

MR. SZALAJDA: Okay. Let's go ahead and get started. Let's go ahead and resume the program with the open comment period.

One of the things that we are going to try to do today as part of the dialogue -- can everybody hear me.

Yes? Okay.

One of the things that we are going to try to do as part of the dialogue is have the opportunity for individuals to provide comment as well as address any questions that you may have as a result of what you saw in the poster session and you may not have had a chance to ask the individuals at the different posters.

So what we are going to do for the closed-circuit SCBA as well as with the SAR this afternoon is that the people that manned the posters will be available for a brief panel discussion, which I will moderate during the next half hour or so.

A couple of things I guess in general I wanted to mention up front. We are going to have a survey, and I wanted to see who all has a survey form to fill out during the course of the day.

So I guess what we will do is Judy is going to come through the room. And if you can indicate whether you have a survey or not so you can get one and fill it out. Because we realize that some people may not be here in the after -- who are just coming for the closed-circuit technology and may not be here in the afternoon, and those types of considerations.

So we at least I wanted to you to have the opportunity to fill out the survey and turn it in if you are not going to be here for the whole meeting.

Another thing that came to my attention. I guess there a general question about whether parking tickets would be validated, and I think the answer to that is no.

So keep that in mind when you try to leave later on today.

And if that's an issue that you would like

us to think about for selection of the next venue, please indicate that on the form as well.

One other thing that I did want to bring up that someone brought to my attention during the meeting is that -- or during the poster session is that there were some difficulties, I think, for some individuals to find the concept papers for the standards development efforts.

And I think the challenge is it's a little -- what we did for this is a little different than what we have done in the past, if you have been familiar with the work we have done with the CBRN standards as well as some of the PAPR work where we have posted the standards on the NPPTL website.

But we are going to be going -- over the next year or so, we are going to be going through an evolution with how we present information on the web. And it's going to be more tied into going to the NIOSH site directly rather than going to the NPPTL site.

So for the next several iterations of standard development activities, we are going to be

making more and more use of going to the NIOSH site to get the information.

When you go to the draft document section for review, one of the guidelines that we have to meet is 508 compliance for American Disabilities Act. And one of the challenges when you do that, in preparation of the information, is trying to capture things like graphs and tables and things of that nature.

So the short-term solution to getting around that is that embedded in the general information pages that you can go to on the public review documents, or public review site. If you scroll about halfway down the page, you will find a link to a .pdf. And the .pdf is the concept paper for the closed-circuit SCBA or the concept paper for the supplied-air respirator. At least until we figure out how to get a little better, you know, in meeting the 508 compliance information, that's the tack that we are going to take in putting those products up for review.

And, again, if you have any questions or,

you know, when you get an announcement that things are out and available for public review and you can't find it, you know, please don't hesitate to call. Because I think with the all of the pages, there should be a point of contact that's identified. Or you can contact the docket office, and they would be happy to try to work with you to identify how to get to the information.

So with that, you know, keep in mind in going forward for formal submittal of comments to the docket, please reference No. 39A in your submittal, and that will get it into the right information pile.

And in looking -- and I just wanted to spend just a very few seconds on this for your information.

When we do these conceptual reviews and provide conceptual information and have a docket, all the information that we collect on these various -- while we are still in the concept development phase, all of the information that we collect will go into that docket. In this case, for

the closed-circuit SCBA, it will go into Docket 39. The A signifies that it's for this meeting.

When we get into the rulemaking process, this docket will be closed, and NIOSH will no longer accept comments to this particular docket. And what we will do is we will open up a new docket with a new docket number that will capture information related to the proposed rule.

And I think when you go through and you see how NIOSH is evolving the docket information, one of the approaches that we are going to take and what we have heard from stakeholders in the past is, well, what did do you with the information? What did you do with the comments that we provided to you from our organization?

And part of what we are going to do is provide a narrative to include with the docket to gave the stakeholders an indication of what we did with your comments.

And it may not be specific as far as, well, we received, you know, these comments from Individual A; and this is what we -- this is what we

did. But it might be more lumped in together that, you know, in general we received comments on work rates, and this is how we are addressing those comments.

So I know it's a little bit different than how we have done business in the past. And, again, if you have any issues, please contact us, you know, at NPPTL, and we will try to work you through the process.

So with that, at this point, what I would like to do is to open up the meeting for any comments from the attendees.

And if you could come to the microphone in the center, state your name, who you are with, and provide your comments.

Someone needs to be bold. Thank you.

MR. ANDERSON: Doug Anderson, BioMarine.

First I would like to say we are very excited by the change in these standards and happy that this is pulling NIOSH closer to European and ISO standards.

As a manufacturer, what this will do for

us is allow us to possibly make one unit that meets everything and make my life a little easier.

A couple of comments we have on the standards. One involves the gasoline, kerosene, and toluene exposure testing. We are not exactly sure why we need to go to this extent. And what we are afraid of is to pass that, plus agent testing, we are now coming into a very different chemical resistance problem with materials.

Materials that are good for agent permeability are not necessarily good for the gasoline, toluene, and kerosene. We would like to know exactly why those three were picked.

And I did have some discussions. I just wanted to bring that up here.

Our other issue that we have is -- it's been our experience that testing in both NIOSH and over in Europe that machine testing stresses out the respirator in a far greater and more difficult manner than man testing can possibly even achieve.

So we don't understand why we should continue man testing with this new standard.

Our main concern with the man testing when we come to NIOSH, that always seems to be our number one problem for scheduling with doctors, subjects. And it's always a concern of the manufacturer watching the subject trying to get through the man test, that if he can't, we have to start all over again.

We feel there really isn't any need for a man test other than probably just a generalized performance testing, not a full four-hour test. We feel that the machine test more than adequately tests the unit.

Thank you.

MR. SZALAJDA: Thank you.

I think when you look at the -- you know, again with the document as it currently exists, it is still fluid. So, you know, with getting the comments with regard to like the permeation testing as well as the consideration of excluding the man testing, I think it is important issues for us to consider at this time prior to the start of rulemaking so we can come to a consensus on those

topics going forward.

MS. BAXTER: I'm Christina Baxter from the Technical Support Working Group. And a couple of comments we have is, number one, we want to make sure the man test is still included so we have the cyclic flow rates that we see in a lot of our testing.

We also would like to see the flow rates to be increased. So maybe you could add in another flow rate level to go up to approximately 130 liters per minute with cyclic inspiratory rates up to about 400 liters per minute as our peaks. We see a lot of this in both the warfighter and in firefighters in the tests that we have done.

And we have done this tests at NAVAIR, replicated it up at DRDC in Canada as well as locations in the UK and Australia to show that we are definitely getting this kind of flow rates that are well above what we are testing at.

So the test right now is excellent for the industrial applications, but we would like to see a little higher for the other applications that we are

trying to deal with.

MR. SZALAJDA: Thank you, Christina.

I think one of the things that we are trying to be sensitive to, you know, with regard to the standards development as well as -- you know, a lot of work has been put in in the past few years with regard to work rates and trying to reflect that in, not only the ISO standards, but how we reflect that in updates to Part 84 as well. So we appreciate your comments on that.

MR. SELL: Hi, I'm Bob Sell with Draeger Safety.

I enjoyed the poster session, had a lot of my questions answered there. But a couple that I didn't have answered was concerning the visual field score test where you talk about in the document that all temperatures for which the device is intended to be used.

So during this test, do you intend to test at various temperatures, or just pick one temperature to test at?

MR. SZALAJDA: Can you guys help on that

one?

MR. SELL: That's Section 84-507B.

MR. PALYA: It will be tested at each of these temperatures, and then there will be a dwell period.

MR. SELL: At each what temperatures?

MR. PALYA: At the cold, the hot -- the cold temperature will be recommended by the manufacturer, operational. And then the hot, as it is indicated. And then the cold temperature shock.

This is on Table 7?

MR. SELL: No. Section 84-507B, not Table 7. And this is referring to the visual field score.

Right now, the requirement --

MR. PALYA: All right.

No. It's just going to be just tested at the regular ambient.

MR. SELL: Okay. At ambient temperature?

MR. PALYA: Right. For the visual acuity score.

MR. SELL: Under 84-507C, you are going down to a minus 21 degrees Celsius.

MR. PALYA: No, wait. I stand corrected on that.

That is going to be like the fogging test, that there will be -- it will be cold soaked, and then there will be a human subject test. And it will be worn, and then it will have the -- basically the same visual acuity or fogging test as the APR.

MR. SELL: Okay. That's under 507C, isn't it?

MR. PALYA: Yes.

MR. SELL: Okay. But not 507B?

MR. PALYA: Now, that one will be conducted at ambient. That's just a field of view.

MR. SELL: Okay. Now, when you are doing the test for 507C, are you going to be monitoring the subject's physical parameters, O2 and CO2, during that test?

MR. PALYA: No.

MR. SELL: Okay. One thing other I guess under the gasoline and toluene and kerosene test, I agree with Doug here that those are a lot of different tests that gasoline is probably your worst

case.

But for the test period, I think you are referring to twice the rated capacity? No. You are referring to -- what is it? Eight-hour tests.

Now, what we are suggesting is that you base it on twice the rated capacity or duration of the device to allow for shorter duration units, so a two-hour unit wouldn't have to go through the eight-hour test, whereas a four-hour unit would go through the eight-hour test.

MR. PALYA: Yeah. We were just working at -- looking at a workday, eight hours. And we were considering an eight-hour work shift.

MR. SELL: So then a two-hour unit would have a more stringent test?

MR. PALYA: No. We are looking at the permeation. We are just looking at the permeation of the materials.

MR. SELL: For one work shift period, eight hours?

MR. PALYA: Right.

MR. SELL: Okay. Thank you.

MR. SZALAJDA: Thank you, Bob.

Any other comments, questions at this time?

I think one of things that we are trying to do is take notes. You know, people are asking questions, and we are having a dialogue with the posters.

A couple of things I just wanted to mention that had come up during discussion that I just wanted to mention for the audience at hand because it has been an issue in the past.

One was the question regarding the availability of the chemical warfare agent simulant report. And I'm happy to report that by the end of this fiscal year, I expect it to be available through the NIOSH website.

You know, we have gone through -- it has been through all of the peer reviews. It has been approved by the NIOSH OD, and it is at the point now with the report that some typographical errors that were caught are being made -- are being made in the report. And that will be available here within the

near term for people to use to help assess their materials in designing respirators.

Another thing that -- a topic that had come up, and I didn't want to dwell on it. But one of the things I think you will see in going forward is the concept of using capacity with our closed-circuit types of technologies.

And, you know, traditionally, you have looked at respirators with regard to, This is a 15-minute unit. You know, This is a two-hour unit, and what does that really mean? That people breathe differently and, you know, one unit that might last for 15 minutes for somebody might last five minutes or 30 minutes. It depends on you how the individual is breathing.

I think that is going to be a little bit of a culture change for the community as we go forward in looking at these types of systems, but I do think that's something for everyone to be aware of as we go forward, that this is consistent with what was developed for the closed-circuit escape respirators, and it will be reflected with the

closed-circuit SCBA as well.

I see Dave Caretti would like to come to the microphone.

MR. CARETTI: Dave Caretti, Edgewood Chem/Bio Center.

I enjoyed the posters. They were informative, and I got my questions answered very well.

But just for clarification, when you are highlighting the ventilation rates that you are going to use, both in the standard closed-circuit requirements and then the CBRN, make sure you define whether you are talking about standard temperature and pressure conditions or atmospheric, or just make them all the same across the board to avoid confusion, especially since they use the same CO2 and O2 production and consumption rates.

And one other comment about the performance test sequence related to the wearability requirements. The work rate terms, you know, peak, high, and low, I think they really should reflect what's being used now for the ISO standards.

It would be a good reference, and it would be consistent across the board.

MR. SZALAJDA: Okay. Great. Thank you, Dave.

Any other comments at this time?

MR. LAMBERT: I'm Barnum Lambert from Environmental Support Systems.

I promised I wouldn't do this. I promised myself that. But here I am, so...

I have got a question primarily about 84.511 capacity gauge minimum requirements. The sentence here says: "Shall have accurate capacity indicators."

We are talking about a rebreather. This is a standard, and this particular clause comes straight out of the open-circuit systems where you can have something that measures the pressure in the cylinder and predict how much longer it will use.

But there's an ongoing argument in rebreathers that goes back 40 years. Should the scrubber last longer than the gas supply, or should the gas supply last longer than scrubber? There are

those that fall on both sides of that. Okay?

I don't know how you can get an accurate capacity indicator if the gas supply is longer than the scrubber or if the scrubber is longer than the gas supply, and particularly since you do not have a CO2 sensor of any type in these requirements.

I'm not sure it is possible to meet that requirement. Thank you.

MR. SZALAJDA: Thank, Barney. That is definitely something we will take under consideration.

You guys go ahead.

MR. KYRIAZI: Actually, it was much less complicated -- or intended to be much less complicated. It was simply supposed to reflect that pressure gauges in compressed oxygen apparatus, or whatever the compressed gas is in it, be accurate in its indicator.

We just didn't want to say duration, but it would probably be better to say they have to be accurate in their measurement of pressure.

And in response to your other question, I

think it is extremely important that the gas supply be higher than the capacity for CO -- I mean the CO2 absorption. I should say the opposite.

The CO2 absorption should be higher than the gas supply because you do not want the case where your pressure gauge says you have a thousand psi left, and your CO2 scrubber is already letting loose 10 percent CO2 because you do not have any -- well, your gauge of CO2 is just that, I feel bad and I feel like I'm not getting enough air or some vague symptoms of unease versus you can see precisely what's on the gauge.

You want the gauge to be the indicator of the remaining capacity of the apparatus, and it should be able to absorb CO2 at all times until the gauge is empty.

MR. SZALAJDA: Thank you, Nick.

And I think we are almost out of time for this portion of the program for today.

So, again, you know, I encourage you all to submit comments to the docket using this information, and the project personnel are free for

dialogue. So if you see them during the course of the day for any additional questions or comments you may have, please feel free to chat with them.

If you can give us about a minute to set up Tim Rehak's presentation, we will move into the NIOSH policy on oxygen prohibition for oxygen-generating respirators in heat -- or in flame and high heat environments.

I think with this topic, what we are going to do is there is no -- there was a poster, but immediately following Tim's presentation, we will open the floor for questions and comments at that time.

And so with that.

MR. REHAK: Good morning. My name is Tim Rehak. I'm with the Policy and Standards Development Branch. And I'm here today to talk about our testing, research, and work that we have done looking at what we call the NIOSH oxygen, or O2, prohibition.

To give you a little background, when we were developing the closed-circuit SCBA, developing

the module where we are at now, we looked at -- in putting firefighter protection requirements in there.

NIOSH currently has a prohibition where it prohibits entry into high radiant heat and open flame environments while wearing oxygen devices. But in the meetings we have had with manufacturers as well as firefighters, they asked us about the possibility of approval for these devices while fighting fires.

And also, when we are looking at it, many of these devices are approved for use in other countries.

So in January of this year, we put out a Federal Register notice, which is covered under Docket 123, where we requested stakeholder input on the current NIOSH policy or prohibition.

The current prohibition was established by NIOSH in 1985, and it reads as follows:

"Available information does not demonstrate to the satisfaction of NIOSH that positive-pressure closed-circuit self-contained

breathing apparatus which use a breathing gas of pure oxygen can be used during direct exposure to open flames and/or high radiant heat and assure the wearer's safety.

"Therefore, NIOSH has determined that until it can be demonstrated to the satisfaction of NIOSH that these devices can be worn under such conditions, it is prudent to presently limit the use of positive-pressure closed-circuit self-contained breathing apparatus which use pure oxygen breathing gas to mines and mining atmospheres which do not involve exposure to open flames or high radiant heat."

Okay, so basically what we did, initially we started conducting heat and flame tests. Currently, we have done testing. The first tests were conducted at Intertek -- and I'll review the results and everything that was done -- in June 8 in '05. Then we were invited over to Germany to witness their heat and flame test last July.

And then we conducted additional heat and flame tests at Intertek at March of this year.

And while it is not here and I don't have a final report from Intertek, we did conduct tests last week, which I'll share some of the results.

Okay. Additional testing that we conducted at Intertek in 2005, we basically followed the NFPA 1981 heat and flame test.

During this test, the unit is exposed to 95 degrees C for 15 minutes. Then it's brought out of the oven and exposed to direct flame for 10 seconds. It is then raised 150 millimeters and dropped.

The initial test we conducted with one unit each from two different manufacturers. And in these tests, we did not use live oxygen. We used a dummy cylinder. Initial tests, Intertek had some safety concerns, so that's why we did it this way.

Some of the problems noted. Results, we had afterflames for longer than the 2.2 seconds as required by NFPA in the hose, the harness, as well the facepiece hose connector.

A hole burnt through the hose. A hole burnt through the facepiece hose connector. We also

had -- a backpack fell off of one of the -- one of the backpacks fell off the mannequin. We had a bypass valve was fused shut on one of the units, and the oxygen bottle strap was burnt through on one of the units.

Then one thing I wanted to point out, while we conducted these tests, neither of the units that we tested were hardened by the manufacturer for the heat and flame test. So you have to take that in consideration.

Following these tests, we took the units back to our laboratory and conducted tests on our ABMS. After retrofitting the units, Unit 1, the results were no different from any untreated unit. The test was terminated at 240 minutes with the tank empty.

With Unit 2, there was no difference, again, from untreated units. And the test was terminated after 160 minutes with the bottle empty. The conclusion we reached from this is that the heat and flame treatment did not adversely affect the performance of the closed-circuit SCBAs.

Next, we were invited over to Germany to witness heat and flame tests over there. The treatment is very similar to NFPA 1981, and it is a treatment that they have for the Department 8 of the Association for the Promotion of German Fire Safety, covered under Guideline 0802.

And just like NFPA, you have exposure for 15 minutes to 95 degrees C. You have exposure to direct flame for ten seconds. The unit is then dropped from 150 millimeters.

The one difference between this test and the other tests, over in Germany, they simulate a leak.

If you could see in the top picture, you have right here, above the right temple, they have a 2.5 millimeter tube put through there so it will simulate an active leak in the unit.

In this test, we only tested equipment from one manufacturer.

Problem noted, none. Basically, the unit met all of the requirements of EN137, Section 6.11.2.2, which is their flame engulfment test.

And one thing to note from -- the difference between this and the test at Intertek, that the unit we tested was hardened for the heat and flame tests.

Next, after going through the safety people at Intertek, they did approve us doing follow-up tests with live oxygen at Intertek. This test is the same at 2005, except that the unit tests were conducted with live oxygen. And, again, we used equipment from two different manufacturers.

The results here, problems noted, both units did have an afterflame greater than 2.2 seconds, so it would have failed the NFPA 1981. But one unit was just over the 2.2 seconds.

The other unit did not function per manufacturer requirements after flame exposure. The sample had a small flame on the lower left side of the face mask. This caused a leak into the face mask which engulfed the unit into the flames during the post test airflow.

Follow-up tests, what I was saying, we did just do additional testing this past week or last

week. With this test, we used the unit from the manufacturer that had the unit that was engulfed into flames back in March.

The initial test, we did have the exact same results where the unit was engulfed in flames. But after reviewing the test, in between the tests, we noticed problems where it appeared that we had a leak of oxygen coming from the face shield which caused the fire.

So the second test -- and this was caused -- you had the straps that were connected to the face seal. And when you had the Nomex hood under, it forced the seal open where you had a major leak of oxygen into the environment there.

So basically with the next test we conducted, we did the same test. We changed the parts that were burnt in the initial test and made sure we conducted a leak test to make sure that there was no leaks, and we had positive results with that test.

Additional work that we have done: NIST, we had NIST do research for us. The objective of

the research that we had them do was to develop a computational fluid dynamics simulation of the outward leakage of the oxygen around the facepiece of a closed-circuit breathing device. And also to experimentally validate the simulation.

Our partner with this, this was done by the NIST Buildings and Fire Research Laboratory.

The conclusions that NIST reached, first, oxygen expelled through leak in a respirator is propelled away from the heed region through advection and dissipates through diffusion.

Second, risk of flammable mixture near the head is observed in a 10 percent propane environment. The thing to note is this is an extreme environment.

Three, in case of flammable environment, oxygen leak results in small fuel-lean region near the head.

Okay, finally, NIST Technical Note 1484 highlights their research. And the weblink for that is there on the slide, and it will be on your handout material if you wish to see it.

And also I was informed, while I haven't seen a copy of from it, I was alerted that NIST research paper is in the latest edition of the ISRP Journal.

Okay. Through the Federal Register notice that we put out this year, we are seeking stakeholder input on -- we would like to know what your opinion is on the current prohibition.

If you have any supporting data, whether to maintain, modify, rescind the current prohibition, we would like -- if you are willing to share that with us, we would like to see it.

Next, what, if any, additional research do you think NIOSH needs to do to support rescinding the prohibition.

And then also we are looking for partners if anyone is willing to participate in a collaborative agreement with us and what support you would be willing to give us and any other comments that you may have on this subject.

Finally, there's the docket information. Again, your comments, submit them to NIOSH 123. It

covers the prohibition. You could either mail it at the address listed there, send an email, fax, or phone.

Does anybody have any questions on the work that we have done? Your comments on the prohibition?

Thank you. Typical disclaimer.

MR. ROUTE: Klaus Michael Route from Draeger Safety.

We talked a lot about the NIST technical study, and we think there are physical effects. There is nothing to target against it because if you put oxygen into a hazardous, explosive environment, it could be possible that this -- it would be ignited when there is a source to ignite it.

So -- but our opinion still is that the best design for these long durations missions is still the closed-circuit device because it is designed to prevent gas leakages into the environment.

If it's fitted correctly, and your tests proved this, our set and the BioMarine sets that

were tested, if they are fitting correctly, you don't have any problem with it.

And for this, our proposal is to change from the prohibition to a limitation.

And like this -- when using closed-circuit positive-pressure breathing apparatus for extended duration and high radiant heat and exposed flames, it must be ensured that the equipment is fully tested and functional as required by the manufacturer, and that the wearer has a correctly fitted facepiece.

Failure to ensure the above may cause the equipment to support burning in and around any leaking area, including the head, facepiece, and the face.

So use these units, but use them correctly, and then you will have no problems with them. Thanks.

MR. REHAK: Thank you.

MR. SZALAJDA: Thank you.

MR. REHAK: Any other questions or comments?

MR. ANDERSON: Yeah. Doug Anderson, BioMarine.

I think that was a good statement. BioMarine stands behind that as well, although we would like to also just say that we are a little nervous in that we are not sure exactly how firefighters would use this. And if they are always used to doing things one way and you got to do it another way, we are introducing possible danger here.

We think maybe the limitations should also be a little stronger and perhaps say that these units would be suitable for exposure to open flame and high radiant heat, but not be suitable for flame immersion to try and discourage people from putting on a closed-circuit unit and running into a burning house or something like that.

MR. REHAK: So you are looking more to amend the existing as opposed to rescind it completely?

MR. ANDERSON: It has been our experience that this whole issue has been mainly miners who go

down in mine rescue situations and have to fight a fire, and somebody is pointing out that NIOSH has this -- MSHA has this prohibition.

I don't really think that there's a lot of people, at least in North America, firefighters that are looking to use closed-circuit respirators to go in and fight a house fire.

So I don't -- I guess what I'm trying to say is our main thing is with mine rescue. It isn't so much with firefighting, and we don't feel the firefighting in North America will be a significant contributor to closed-circuit apparatus.

But we just want to make sure that, you know, nobody tries to run into a burning building with a -- because if the guy gets hit in the side of the face with a facepiece in a closed circuit, and that comes off, it is going to start jetting oxygen out of it. And he is not only putting himself at risk, he also could put other people at risk with that cylinder jetting oxygen into a burning area.

So we feel maybe the rescission could occur, but with a limitation that it's not really

intended for direct immersion into fire, open flame.

MR. REHAK: Okay. Thank you for your comment.

MR. SZALAJDA: And thank you for the comments as well, especially, you know, regarding changing the limitation.

I think the one thing that we really want to try to encourage, especially from the user community as far as, you know, getting input from our stakeholders, from the people that would actually use these types of devices and where they are used.

And I think one example we had talked about earlier was, you know, people that are familiar with the fire a few years ago in Baltimore in the railway tunnel, you know, that the responders that dealt with that event could not use the open-circuit technology because they could not get deep enough into the tunnel before they had to come back because of the limitations of the open-circuit device, and they ended up using closed-circuit technology.

And, you know, again, in trying to be responsive to things that we have heard, you know, informally, you know, regarding potential applications of this device, we are trying -- again, you know, we appreciate the comments that we have and anything that, you know, you may be able to do to stimulate comments from the user community to support the rescission or maintain the rescission or modify it, we would appreciate that.

Anything else? Any other comments at this point?

Well, the good news for you is that you can have extended time for lunch today.

But we will start promptly at 1 o'clock with the supplied-air respirator, so please make sure you are back for 1 o'clock, and we will resume the program then.

(A luncheon recess was taken.)

MR. SZALAJDA: We are going to go ahead and resume the program with the supplied-air respirator standard. And, again, we are going to follow the same type of format that we used this

morning for the closed-circuit SCBA.

The lead project officer, Jeff Palcic, will go through an overview of what is in the conceptual standard. At the point at the end of the Jeff's presentation, we will break -- we will adjourn to the poster room, and we will remain in the poster room until 2:30. At 2:30, we will reconvene in this room for questions and answers as well as the public comment period.

MR. PALCIC: All right. NIOSH has initiated a program to update 42 CFR, Part 84, Subpart J for supplied-air respirators. I'll be focusing primarily on the changes to the standard requirements that are being added.

Can you hear me?

The technical actions required to complete the SAR draft standard include continuing internal technical reviews, posting the revised draft standard on the NIOSH web for public comment, and reviewing additional docket comments and revising the draft as required.

We will also be updating the standard test

procedures which will include eliminating obsolete procedures, modifying existing procedures, and developing new procedures to test to the new performance requirements.

Finally, we will be evaluating, acquiring, and securing test capabilities, which will include the evaluation of the current test capabilities with regard to the new standards. We will also be purchasing new test equipment and conducting validation testing to the new performance requirements.

Subpart J will remain -- I'm sorry. The SAR will remain in Subpart J of 42 CFR. The subpart will contain optional requirements for both IDLH and CBRN applications. And the SAR will continue to meet the requirements of Subparts A through G of 42 CFR, Part 84.

We have established two types of supplied-air respirators, airline and airsource.

An airline type respirator consists of an air line, respiratory inlet covering, and a coupling for connection to Grade D or better breathing gas.

An airsource type respirator consists of a portable blower or air compressor, air supply line, respiratory inlet covering, and is certified as a complete system.

Proposed technical updates for Subpart J. These are base respiratory requirements. Airline type changes. We have eliminated Type A, AE, B, and BE. We have redesignated Type C and CE as airline type. And we have eliminated the demand-type apparatus.

Airline breathing air requirements, they have remained unchanged. We have updated the CGA G-7.1 reference.

Airsource breathing air supply requirements, blowers or compressors for airsource SAR shall be equipped with a CO alarm to warn user if the CO concentration and the breathing gas climbs above 10 ppm.

Can't hear me? Can you hear me, Bill?

SPEAKER: Get closer to the microphone.

MR. PALCIC: Okay, Bill.

The temperature of the air produced by the

blower or air compressor cannot exceed 6 degrees Celsius above ambient as measured at the respiratory inlet covering.

Airsource systems must maintain positive pressure in the respiratory inlet covering's breathing zone with the system in the most flow-restrictive configuration at the manufacturer's highest specified work rate.

And finally, a 95 percent efficient filter or better will be required between blower or air compressor and the respiratory inlet covering.

Continuing with base respiratory requirements.

Exhalation valve leakage, dry exhalation valves, and valve seats will still be subjected to suction of 25 millimeters, but the leakage between the valve and valve seat cannot exceed 15 milliliters per minute. The old requirement was 30.

Carbon dioxide limit.

This requirement has been included to ensure that the level of CO2 in the breathing zone is acceptable prior to human subject testing.

The human subject testing was included to determine the carbon dioxide and oxygen levels in the breathing zone during tests performed with the subjects standing and walking at 3 and a half miles an hour.

Finally, the fit testing will be accomplished through the LRPL test.

Once again, continuing with the base respiratory requirements. Work rates.

Manufacturers will specify the work rate for which their system is to be approved. Their system must maintain positive pressure in the breathing zone during both inhalation and exhalation at the specified work rate.

This will replace the current flow rates of 115 and 170 liters a minute for tight and loose-fitting respiratory inlet coverings.

The approved NIOSH work rates are a low work rate of 25 liters a minute with a 1.3 liter tidal volume, and 19.2 respirations per minute. A moderate work rate of 40 liters a minute, a 1.67 liter tidal volume at 24 respirations per minute;

and a high work rate of 57 liters a minute with a 1.95 liter tidal volume at 29.1 respirations per minute.

Base and non-respiratory requirements. Required components:

An airline system consists of a respiratory inlet covering, air supply valve or orifice, air supply hose, detachable couplings, flexible breathing tube, and a harness.

The airsource system consists of a respiratory inlet, air supply valve or orifice, air supply hose, detachable couplings, flexible breathing tube harness, and a portable blower or air compressor.

General construction shall meet the requirements of Subpart G, general construction and performance requirements, out of 42 CFR, Part 84. And connections and couplings will require at least two different motions for disconnection.

Continuing with base and nonrespiratory requirements, harness tests.

The shoulder strap test was increased from

250 pounds to 300 pounds for 30 minutes. The belts and rings increased from the 300 pounds to 500 pounds for 30 minutes. And the hose attachment to the harness remains at 250 pounds.

Lifelines or the safety harnesses shall meet applicable standards.

The total length of hose for approval in its heaviest configuration shall permit dragging over a concrete floor without compromising the harness or exerting force on the respiratory inlet covering.

Once again, continuing with base nonrespiratory requirements:

Visors and lenses, all lenses of respiratory inlet coverings shall be designed and constructed to be impact penetration resistant in accordance with ANSI Z87.1-2003, or the lenses shall be prominently and permanently labeled to indicate that they are not impact resistance.

Noise level:

Noise levels generated by the respirator during normal operation shall be measured at the

maximum air flow attainable within pressure and hose length requirements. It must be less than 80 decibels in both ear canals.

Failure Mode Effects Analysis -- hold on a second.

Manufacturers shall demonstrate that reliability is assessed and controlled within their quality assurance plan by conducting a system FMEA on their device or component.

Base requirements for supplied-air hose:

Hose length. The hose length limitation of 300 feet has been eliminated, and the hose length will now be manufacturer specified.

Hose permeation. In addition to the gasoline permeation test, we are proposing the addition of permeation tests for kerosene and toluene.

Okay. Base requirements for airsource respirators only.

Portability is defined as any system capable of being carried to the work location by two users with a hundred pound maximum, including

accessories, or manually rolled to the work location using a cart-mounted system with a 300-pound maximum, including accessories.

Performance evaluation, the blower or compressor will be required to go undergo a performance evaluation by operating for eight hours a day for a total of 15 days with a maximum length of hose and maximum number of users for the approval is sought.

Continuing with the base requirements for airsource respirators only. Noise level must be less than or equal to 85 decibels at any point within a three-foot diameter circle around the blower or air compressor.

Temperature. Any system component exceeding 60 degrees Celsius shall be guarded against user contact.

Multiple user systems will offer a maximum of three users. Each air hose will be connected directly to a manifold at the portable blower or air compressor. It will be designed so that air does not backflow from one line to another.

Each line must also flow properly, regardless of occurrences in other lines.

All right. Enhanced combination SAR, SCBA requirements for IDLH atmospheres.

Escape cylinder, airline and airsource combination SAR will incorporate a five- or ten-minute duration SCBA escape air cylinder.

A 15-minute or longer duration SCBA air cylinder will allow for 20 percent of its capacity to be used for entry.

These systems must automatically switch from supplied air to the air cylinder if the air supply line becomes disconnected, severed, or can no longer supply breathing air.

At that point, an alarm will notify the user when the system is on cylinder air. It can be an audible alarm, mechanical, or an indicator visible to the wearer.

And finally, these systems require a tight fitting full facepiece.

Continuing with enhanced combination SAR/SCBA requirements. Visors and lenses. We have

added the haze, luminous transmittance, and abrasion tests. We have also added the low temperature fogging test.

And for communication, we have added the Modified Rhyme Test.

Enhanced requirements for optional CBRN protection. They must meet -- they must first meet the base and combination SAR/SCBA requirements.

They must provide a 15 minute or longer duration escape air cylinder. Once again, the system must automatically switch from supplied air to the air cylinder if the supply line becomes disconnected, severed, or no longer can supply breathing air.

And at that point, an alarm will notify the user when the system is on cylinder air.

Criteria which have been established for CBRN/SCBA respirators will be applied to combination SAR/SCBA systems, such as requiring tight fitting full facepiece, durability conditioning, and agent testing.

Requirements for additional options.

Hydration. Drink tube valve and valve seats shall not exceed 30 milliliters per minute of leakage at a 75 millimeter vacuum.

Pneumatic tool take-off. Airline and airsource respirators equipped with a pneumatic tool take-off manifold must have a check valve and filter at the take-off point to prevent any backflow or contamination to the respirator.

Also, the respirator must maintain positive pressure in the breathing zone at the manufacturer's highest specified work rate, regardless of occurrence in the pneumatic tool line, such as blockage or free flow.

Standard test procedures. We will be developing new standard test procedures or deriving them from existing procedures for other respiratory protective devices. We will also be updating existing SAR procedures to test to the new performance requirements.

Finally, we will eliminate the obsolete procedures due to changes in the performance requirements and evaluation methods.

Project timeline. In July of this year, we posted the SAR concept standard on the NIOSH web.

Comments from this meeting and the docket comments, we plan to revise the standard in October and repost an updated SAR concept standard on the web in December of this year.

The poster session will follow this presentation. The posters will be organized in the following manner:

The supplied-air respirator program poster, a description of airline and airsource system posters, base requirements posters, including respiratory, non-respiratory, and a dual topic poster covering airsource blower or air compressor requirements, and air supply hose requirements.

Also enhanced requirements posters for both culmination SAR/SCBA and CBRN. And another dual topic reference poster for work rate and escape cylinder capacity.

Finally, the final reference poster will be for standard test procedures.

Supplied-Air Respirator NIOSH Docket 083.

Written comments will be accepted through September 30 this year, and we encourage everyone to comment for or against any of the new requirements or existing requirements.

So if there's something that you like, comment. If there's something you don't like, comment. Thanks.

And no questions until after the poster session.

MR. SZALAJDA: At this point, if the NIOSH folks could go next door, and then we will reconvene in the poster area and be back here at 2:30.

(A recess was taken while a poster session commenced.)

MR. SZALAJDA: Okay. Let's go ahead and reconvene at this point and go through any comments as well as questions regarding the poster discussion for the supplied-air respirators.

You know, again, I think just in general, I think this is a very good opportunity to make your points known. And I would encourage you, depending on the interactions you had in the poster session,

to reiterate any comments or, you know, possibly, you know, repeat back to us what you think you heard us say with regard to the concepts at hand.

So with that, who wants to break the ice?

MR. BARD: Good afternoon. Brent Bard with Supplied Air Monitoring Systems.

I want to start off by saying that I'm glad to see the opening and discussion on SAR apparatus. I believe that it is probably the workhorse of industry that's been neglected to a great extent in the past, and I applaud the fact that you are looking at making some changes.

From the poster session, some of the items that drew my attention started off with, I believe, that you need to look at allowing the approval of the air source and configuration of the air source separate from the apparatus that it is going to be used in or used with.

I think that NIOSH needs to consider making that a separate piece of equipment that is rated on delivery rates, number of users, air quality that it's able to produce.

And that once you identify what it is that your system will do, it can be used with whatever NIOSH approved SAR system that you want because manufacturers typically are not making those air delivery systems. It is a different entity that does it.

So I think that it is one of the things that you need to address.

I think when it comes to the testing requirements on the harnesses, I think that you need to look at the integration of fall arrest because you will find that a lot of the SARs are now currently being used with fall arrest.

I think you need to look at adopting some sort of interpretation or, much like the air source, that will allow you to use an improved harness that meets an ANSI standard with an approved NIOSH SAR unit.

I think that also, when it comes to the communication requirements, the communication requirements should be identified as being in an IDLH environment as being intrinsically safe. I

think that you also need to identify what class of intrinsic safety the unit has to have.

I would suggest that the concept of component testing and certification case really does have some merit. And as I think everyone here is aware of, it's very common for one manufacturer's air line to be used with another manufacturer's apparatus. And I really think that there should be something that would acknowledge that because that is industry practice.

I think as well that the concept of allowing a pneumatic tool to be operated off of an air source is a bad decision. I think that the requirements of operating tools or air tools needs to be from an separate identifiable source.

You need to realize that if it is an IDLH environment, maybe you don't want great volumes of the air being dumped into that environment. You may want to have that air tool run off of nitrogen in case of some pyrophoric issues.

I basically would also just like to address the issue of hydration. And I think it's

important to realize that -- and I heard from several people why they feel that the inclusion of a hydration tube is a good idea and that you have been asked for it and the requirement of it.

But by the same token, OSHA requires that workers not eat or drink in an unsafe environment. And I believe that the proper place for workers to get hydration is in a proper rest area and facility, and that they take time away from the work activities to get properly hydrated so that they can continue working.

And I think that the last comment that I wanted to make was that when it comes to the escape cylinders, I believe that the very word "escape" means that you are planning to get out of the area. I don't think that we want to encourage people to have more available air to stay in that area longer.

I think that the larger the cylinder, the harder it is to get into what is the North American standard on, for examples, in refineries and vessels, which is an 18-inch manway.

The larger cylinder, you are going to have

the individuals taking it off and passing it in after they have entered and having to do the same to get out. And in an emergency, I just think you are asking for a catastrophe.

I also think that you should never allow an entrance -- to use an egress system for entry. I just -- it's wrong. You know. That's why they call it escape or egress.

I think that you would be better off to look at including the option of another connection so that you would have a larger air source outside of the work area because you have to have a man watch attending this worker anyways, that you would pass in an approved air line which would go to this larger approved air supply that would allow the person to egress and -- or if he is trapped, give you a longer period of time to figure out what you need to do.

Thank you.

MR. SZALAJDA: Thank you very much.

Any other comments? Don't be shy.

Thank you, Andy.

MR. CAPON: Andy Capon of Avon Protection Systems.

Dave Caretti and I tossed up whether he or I would say the same thing as was said this morning with regard to nomenclature.

We do feel that it would be extremely valuable if you could begin to follow the ISO nomenclature that is being developed for the ISO standards. I know you yourselves have been working very hard on the definitions document on that.

Whether we call it a compressed airline tube, a compressed airline hose, a breathing hose, a breathing tube, whether you need a different definition for it, a pipe that takes air at atmospheric pressure versus a pipe that takes air at greater than atmospheric pressure could be useful.

And I think you would find a lot of those definitions are already sorted out in ISO, and it would be useful for all of us to follow.

We were also talking about, where possible, to harmonize some of the requirements with ISO as they come along so that as the standards

develop and as the manufacturers start to make equipment to those standards, there aren't very many changes that need to be made between an apparatus now or in the next few years than in a year or two after that, when we will see the ISO standards being published.

Thank you, Jon.

MR. SZALAJDA: Thank you, Andy.

MR. COLTON: Craig Colton, 3M.

I was wondering if NIOSH could provide their rationale for the LRPL values that were selected and -- the different values.

MR. SZALAJDA: Do you guys want to take a crack at that, or do you want me to?

Well, I think in general, I guess philosophically, let me start on that, and I'll let the guys bail me out when we get there.

But I think people recognize that we are looking to move towards establishing, you know, some sort of inward leakage testing for respirators.

And part of the thought process there was, you know, in looking at the existing technologies

where we have used the technologies for the CBRN applications as well as, you know, how people test respirators in development right now.

And at least that was the approach in looking at the LRPL type of testing using corn oil because it is a very proven, very repeatable-type method that has been used for several years on a variety of topics.

And in the selection -- in the selection -- I don't have the numbers in front of me.

But with the selection of the criteria, I think part of it was driven by, you know, where the respirator is going to be used, you know. And along with that, the higher LRPL values associated with entry types of operations and dealing -- possibly dealing with unknown, uncharacterized types of hazards, so it would necessitate a higher respiratory protection level value.

And then looking back, you know, basing the other values, looking -- depending on where the systems may be used.

You guys want to help me out there or...

I think I will just, you know, fill the dead space.

But with the -- you know, again, it is sort of -- again, when you look at where we are going, and I think in part I might be getting a little bit ahead of the wrap up that I was going to give later, we are moving, in terms of the standards -- with the standards development efforts, looking at identifying inward leakage testing for the remaining classes of respirators.

We do have a proposed rule going through the systems on filtering facepieces and half-mask respirators. And then the next step is to address the remaining classes of respirators.

And, you know, at least we want -- knowing that that is going to come down the road later, we want to at least start integrating that type of thought process into the standards development effort now for the other types of respirators that we are going to be developing for the PAPR, for the closed-circuit SCBA, for the SAR.

So I think you are going to see that common thread of having an LRPL value and going forward until a rule is promulgated in the future that addresses inward leakage for the remaining classes of respirators.

I think they are still deciding.

MR. COLTON: I don't disagree with the idea of doing the LRPL test, you know, and the technology you are using.

I just found the values that were chosen at least interesting and why. Because like for loose-fit -- I mean, you mentioned about where they would be used as sort of dictating the number.

So that sort of implies to me that, you know, with a protection factor, a device that would maybe be used in a higher concentration has a higher APF, might have a hirer LRPL, if I interpreted what you said correctly.

But then when it looks at the loose-fitting respiratory inlet coverings, there are some of those that have the -- at least with OSHA -- so the one question, I guess, is whose APFs are you

following?

And that can be another one we can talk about.

MR. SZALAJDA: That's another question; right.

MR. COLTON: But, you know, working off of the NIOSH one, there is hoods and helmets that have the same protection factor, or can have the same protection factor, as the tight-fitting full facepiece, but yet the values are different.

And then in that, you have loose-fitting facepieces with hoods and helmets and then tight-fitting half-mask, which are the same as the hoods and helmets, but, yet, they have got a different APF.

So I envision those as -- I see four different areas where they could be used at different -- going to different areas, to use your words, or trying to use those words, but, yet, I only see two values, so I don't know.

So I'm perplexed.

MR. SZALAJDA: Okay. I understand your

question now in that context.

And I think one of the things, since it is a concept paper, if you have some suggestions as far as what you think we should do in that area, that would be helpful.

You know, again, it is kind of -- the nice thing about, you know, having to use the concept paper, it is dynamic at this point. So I think when you see the next iteration, we will take your comment in context and look at the values in relationship to the different types of head covering that may be used.

Any other questions?

I think one thing I just wanted to touch on, just while you are coming up to the microphone, one of the other things -- and just to reiterate what Andy said with regard to the terminology and what we call things.

And I think it's one of the things, as we learn more in sticking our feet into the standards development process and looking at a lot of the other efforts that are going on, you know, within

the community for standards development of trying to make sure we are using, you know, familiar terms, because I have been in this business for a while, and I still call things what I call them when I worked for the Army 20 years ago.

So, you know -- and I get corrected by my guys; Well, that's not really what you mean. You mean this.

So it is a very -- terminology is a very important thing for us to keep in consideration.

MR. BARD: Brent Bard, Supplied Air Monitoring Systems.

I also just want to point out from the one poster that I had asked about the work rates and the flow that was being delivered. I also think that you need to look at the pressure that that flow needs to be delivered at.

And additionally, I also think that you need to consider when you are doing the CO2 dead space testing, that if you improve the system to work at these flows, then you also need to do that CO2 dead space testing at those flows.

Because if you are not, you are not getting a true representation of what is going on.

Thank you.

MR. SZALAJDA: Thank you. Good comment. Thank you.

I have got the process working now. That's good.

MR. SMITH: Chris Smith, U.S. Navy.

First I want to say something positive. The Navy uses combination SAR/SCBAs, and we currently use one that you have to manually open. So I do like the idea of the automatic transfer switch.

One thing I did see that was missing, and I mentioned this in the meeting -- in the session over there.

But, you know, for 15 -- for the entry and escape devices that have to have 15 or minutes longer of air, said you could enter, but you can't use more than 20 percent of your air. I didn't see anything mentioned about a low pressure alarm, only the automatic transfer alarm, again, the automatic

transfer and the alarm with that.

But I think there needs to be a separate alarm requirement to let the user know that they don't have enough air to enter a space.

You know, if 20 percent -- and I asked what was the rationale on the 20 percent, and apparently that's a legacy carryover. But if it is 20 percent, then I think there should be an 80 percent alarm capacity, you know, where if you are below 80 percent, it should alarm.

That's my comment here.

MR. SZALAJDA: All right. Thank you, Chris.

MR. SAVARIN: Mike Savarin, Sperian Respiratory Protection.

The first thing I want to say is there has been a significant gap in having these airsource devices qualified, approved, recognized as performing.

So certainly, I think it is extremely encouraging that NIOSH is trying to look at a way of incorporating that in some way into the program.

I'm one of those people, too, who supports the fact -- the approach that we should look at it as a separate thing and approve it separately and maybe look at the things -- we talked about this in the room, so this is just going formally, if you see what I mean -- talking about categorizing the pumps, for example, and categorizing those based on either flow or work rate so that they can go inline with respirator systems.

Right now, the way the proposal stands is a big drain on restricting market opportunities and competition. The default test paradigm that is currently being, you know, in process at NIOSH, means that there's an awful lot of time that goes by with each subsequent submittal. And every pump that came along, you would have to do another one.

And I think from the manufacturer's viewpoint, this is completely unacceptable.

The time frames that are involved in this kind of thing and the multiple submittals that would have to keep going in, I don't think is something that the community, the marketing community really,

you know, the manufacturers really want to go ahead with.

But I think we could support a separate type of proposal where we look at the pump separately.

Notwithstanding issues about confusing work rates and work flows with an air flow rate, we have something that says that currently it's 115, 170. The new proposals seem to indicate that the 40 liter a minute volume is in some way equivalent to the 170, and then there is this higher 57. But the implication of from reading it makes it look as if the flows and everything are not equivalent, and are lower.

So I do think that we do need to agree on the way to describe it and the way to make this information very clear to people who have taken 20 years to understand that there were two rates -- two flows, that is, not even rates, just two flows.

There are a number of things. I think I'm going to stop there, actually.

That's it for now. Thank you.

MR. SZALAJDA: Thank you, Mike.

Anyone else?

MR. SAVARIN: I should mention -- excuse me.

The current system is that we have SARs that are approved and can be used with anything you want to use them with. Of course, that's what you are trying to address.

What do you do about the products that are already out there if you put this in? Do we have a grandfathering period where those products go away or how do you intend to address the fact that there are units out there that are going to be continued to be supported, probably for many years by the existing customer base?

MR. SZALAJDA: Yeah. Thanks, Mike. I'll try to take a shot at that one.

I think part of the approach is when you look at the -- that we will need and we will develop an implementation strategy for all of the classes of respirators, acknowledging the fact that there is certified equipment and how do we address the

introduction of new equipment to a different standard conceivably, you know, with significantly different performance characteristics than what has already been approved.

And I think when you look at -- when Part 84 was incorporated, there were certain accommodations that were addressed in terms of how the standard was introduced and the acceptance of material for certification.

And I think we would look at that, and probably when we have the next SAR public meeting next year, we will introduce an idea for how we are going to introduce the standard into practice.

And, again, I think in general you can kind of anticipate that there will be a certain grandfathering period, you know, while NIOSH accepts material and goes through the certification process, you know, to allow and still support product that was submitted and approved under the previous standard.

But that's still all subject to development and clarification as we go forward, but

I think you can anticipate that there will be a period of time where all of the equipment with be grandfathered in.

MR. SAVARIN: In addition -- thank you for the answer, by the way, Jon.

I'm not entirely clear why we have to limit the number of users for the device.

We are already saying there should be positive pressure inside the device. I understand that we are trying to come up with some kind of arbitrary measure for saying this is a portable unit, and this isn't. And that raised quite a lot of discussion back there, actually.

People using what everybody would consider to be a portable device, but tacking it onto the back of a truck.

You know, how do you define that system? How do you test it? Away from actually a compressor that is so large -- you know, it seems as if we try to concentrate on the weight of the devices and what people can generally be viewed as movable by two people.

And there was an issue with that, too, with people who have pacemakers. We won't go into that right now.

But if we could focus more on the weight of the device as opposed to the number of users, we don't want to restrict design and development for people who can actually design systems that will work for four users, for example.

MR. SZALAJDA: Thank you for that comment as well, Mike.

I think, again, the one thing that's nice about -- with the concept paper, it at least gives you our thought process for where we are in terms of the development.

And if there are things that you think we should consider as part of the evolution of the concept, I think is appropriate to go ahead and bring those up at this point.

And, again, it is, you know, with -- please keep in mind with the concept paper, at this point, nothing is completely etched in stone until we actually go into the rulemaking process. So we

welcome comments related to the contents of the proposal.

I think just philosophically, when you look at defining the performance requirements, I think it gets back to the comments that we made about terminology and definitions.

At least at some point with the common -- identifying common terms, we know part of going along with that is backing up those definitions with, you know, the explanation and whether it's a two-man -- you know, like the definition of portable, you know, in providing the clarification in the standard, you know, what we meant by portable. So that's something that we will continue to look at as we go forward.

And I think, since it is 2:57, I will take one more set of comments, if anybody has any.

MR. ROBERTS: Mark Roberts from GMA Technologies.

My question on the toxic industrial chemicals related to this specification.

Recently, there has been a very high

requirement noticed by DoD as far as NFPA, NIJ, and other groups for toxic industrial chemicals for both CBRN and other type of requirements if it's used in an industrial setting.

Has there been any thought or push for this standard to add any toxic industrial chemicals through either the CBRN or the base requirements at all?

MR. SZALAJDA: Well, I think with --

MR. ROBERTS: And that's -- and just to go on more about that. I'm talking more about the system wide, not just the one respirator filtration unit, but the entire system, whether it be the mask, the hose, everything all through together.

MR. SZALAJDA: Okay. I think part of what we are trying to do when you look at the development of the requirements, is we are really trying to use tiers of requirements in development of the standards.

You know, we will identify base requirements that all systems, SARs, closed-circuit, PAPRs, what you may have that have to meet. But

then be able to add tiers of protection on top of that.

And at least at this point, to specifically answer your question, I think when you look at the systems level type testing, the consideration there that pops to mind is the CBRN testing that, you know, if you had an SAR that you wanted to get a CBRN approval for, that would go through the systems type test that we do with our partners at ECBC with the challenge against the chemical warfare agents.

At this point, if you look at some of the other tests that we are doing with the toluene and the kerosene and gasoline with regard to evaluating some the components, if you think there are some other things that we should be considering as part of the development process, then we would be happy to take those on as well.

All right. With that, it's 2:59, and I think -- oh. Go ahead.

MR. SAVARIN: I'm sorry about this.

Can you please explain to us why toluene

and gasoline -- kerosene are being added to this, please, to this particular one?

MR. VOJTKO: These two materials were being added as analogs to specific workplace hazards.

The kerosene is considered analogous to jet fuel, same boiling range, maybe some different additives, but same general chemical structure of the boiling range of a distilled hydrocarbon.

And the toluene was considered as a one-component analog for paint thinners, for a paint shop type environment.

This is what we -- what we ended up with at the time that this draft was issued. We are certainly considering other combinations for that.

Now, ketones are a possibility with the toluene. We felt that the -- at the time, at least, that the aromatic hydrocarbon was possibly the most aggressive thing over the longest period of time because it is probably less volatile and would -- if a hose was dragged across that, for instance, have a greater chance of migration of the material through

the hose and getting into the air stream.

MR. SZALAJDA: Okay. All right. Thank you guys for -- I'm sorry. Go ahead, Jeff. I'll give you a minute.

MR. PALCIC: We appreciate the comments, and I hope that everyone reads the standard and gives us additional comments in the docket. So for those of you that haven't read the standard, please do and give us some additional comments.

MR. SZALAJDA: I think at least at this point, we will move on to the last item on the agenda, which is the CBRN APR mechanical connector.

Just to wrap up the SAR, for formal comments, please reference Docket No. 83 in anything you may submit to the docket office.

At least -- this presentation that I'm going to deliver is a recap of what I provided to the Interagency Board for Equipment Interoperability and Standardization back in July.

And we are going to cover a couple of topics at least as far as a request we received from one of our partners and stakeholders with regard to

a performance requirement that was identified in the CBRN APR statement of standard, which specifies a single 40-millimeter screw-in thread as a mandatory performance requirement for that type of system.

And at least in going through the discussion, I wanted to spend a couple of minutes talking about the development of the standard and why that requirement was identified.

And the request that we received from DOD to modify -- or to attempt to address an area of concern that DoD had with regard to that requirement.

And when you look at the generation of standards, I think you can get a feeling that there is two methods in how we identify performance requirements for the respirator.

One is the statutory authorities that we have in 42 CFR, Part 84 which identify performance requirements for various classes of respirators.

Along with that, in Part 84, there are policy provisions which allow NIOSH to identify additional tests to provide a capability for

establishing protections where Part 84 does not currently have an identified requirement.

And because of the events that happened with -- in 2001 with 9/11, NIOSH undertook a program which used these policy provisions to allow us to expeditiously develop a series of standards for certain classes of respirators for self-contained breathing apparatus, gas masks, air-purifying respirators, escape respirators, and powered air-purifying respirators, to use these policy provisions to identify performance requirements for these types of respirators to provide chemical, biological, radiological, and nuclear protections for responders that may be dealing with these hazards at these types of events.

Following the development of the standards for the PAPR, organizationally, the department made a decision that all future CBRN standards were going to be promulgated using rulemaking processes.

And I think what you have seen with the discussions that we have had in the past with the industrial powered air-purifying respirator standard

that we are working on as well as the closed-circuit SCBA and supplied-air respirators that we have discussed today, there are provisions for CBRN -- or for testing against CBRN as enhanced requirements for those types of devices.

A little bit about why the 40-millimeter thread came into existence.

One of the -- some very strong feedback that we received following 9/11 was that responders, emergency responders wanted to have canister interoperability where, in the event of an emergency, that you could take a facepiece from Manufacturer A, and you didn't have any more of Manufacturer A's canisters on site, but you had Manufacturer B's canisters on site, that you could put those two systems together in the event of an emergency to allow operations to continue.

And based on a lot of dialogue that had happened in the 2001, 2002, 2003 time frame, we developed a performance requirement that identified a single mechanical connector for use on the CBRN APR.

And this standard was based off of DoD requirements that were identified and used on the M40 series of masks as well as the MCU-2P mask used by the Air Force and Navy, and also met the requirements, the European standards used for a 40-millimeter thread.

And in looking at the development of the -- just to give you a perspective on the importance of the canister, you know, reinforcing what the user community was looking for, part of that discussion that we heard was not just, you know, we wanted a 40-millimeter thread, but we also wanted a system that provided a wide range of protections, you know, that when a responder went to an event, he didn't want to have to know, I need to dig through my cache of equipment and get, you know, Canister A or Canister B or look for something that you know, is out of an assortment of canisters.

But they wanted one system which would provide protection against a maximum number of threads, to include toxic industrial chemicals and chemical warfare agents.

So we went through a hazard analysis process as part of the standards development to try to quantify and identify the testing parameters associated with that type of system.

And along with that, we included, you know, in partnership with working with other organizations like the NFPA, the Department of Defense, Environmental Protection Agency, to try to look at the thousands of chemicals, you know, and other toxic industrial materials that are available in the system and try to boil that down into some sort of manageable identified range of hazards that we could address in terms of developing a standard.

They also included chemical warfare agents. And so from that standpoint, in going through the hazard analysis process, we were able to reduce that list of thousands potential things down to 139 TICs and TIMs, which we felt were viable respiratory hazards that responders may see in dealing with a terrorist event.

And how we did that in terms of the standard was to break down the hazards into

families, which included organic vapors, acid gases, base gases, and particulates, and in particular, radiological, nuclear, and biological particulates that a responder may need to deal with a particular event. And this also included the chemical warfare agents.

So at the end of the day, the standard was released in 2003. And since then, you know, there are -- multiple manufacturers have gotten NIOSH certification on multiple models of the CBRN APR.

And we have also -- we have also been able to provide, through the standard, the capability of for the responders to have multiple protections from one system. You know, that when they do respond, or would need to respond to a terrorist event, that we have provided a requirement or a design requirement that identified the maximum number of protections that technologically manufacturers can meet and addressing the -- in addressing the potential hazards.

One thing I did want to add -- and we are planning on developing a report to address this --

is that when we developed the standard, we took a leap of faith with the identification of the TRAs, that we had good, you know, good minds thinking good thoughts with regard to the classification of the hazards and for the family, but we didn't have -- necessarily have a lot of data to say, you know, that, yes, that is -- that TRA is appropriate, and by testing against that particular TRA, it will protect against those other hazards.

And over the past couple of years, under contract with an organization, we have accomplished that testing. And one of things I'm glad to report is that the testing shows that, you know, our hypothesis was correct in that by testing those TRAs, you do get the protections against those other chemicals that are on the list.

And I think as we go forward over the next year or so, we will be generating some reports in the literature and making that available to the stakeholders to, you know, make that fact well known.

But with the evolution of the standard,

you know, part of the decision making that you have to go -- and I think you can appreciate with the development of the standard is sometimes you can't always address the needs of all the stakeholders.

And one of the things that -- the issues we had dealt with in regard to the development of the CBRN APR standard was the fact that, while responders, the responder community was very adamant in their support of interoperability or maintaining an interoperability feature for the canister, we also had other stakeholders who said, you know what? Interoperability really isn't that good of an idea.

You know, when you look historically at the certification of respirators and the fact that respirators are certified as a system, you know, what does that really mean, and is this going to create more problems than you may be solving by having that feature in there?

But, again, you know, at the end of the day, when you develop standards, you know, while we try to do things and develop consensus, at the end of the day, you know, NIOSH is going to make a

decision on what the content of the standard is going to be.

And that's what we will develop and we will put through based on trying to look at all of the needs of all of the stakeholders and making a decision on what the requirements of the standards should be.

But, you know, once you get into practice, you know, we need to be attentive and also to have some consideration for the application and how this affects other applications that may be used by stakeholders.

And some of the discussions that we have had over the past few years with DoD is where Department of Defense is looking to comply with one of their instructions where they want to comply with OSHA standards for workplace applications.

And respiratory protection for DoD is no different.

And so from that standpoint, this chart is probably a little hard to see, but DoD brought to our attention that, with the development of their

new protective mask which is being deployed for the military services as well as being used for DoD installations both, you know, CONUS and internationally, that they would like to use the JSGPM to support not only the warfighter, but also the DoD civilian workforce on installations and other sites worldwide.

And we received a letter from General Reeves, who is the Joint Program Executive Officer for Chemical and Biological Defense.

I hope I got everything in the acronym correct.

But at least as far as for us to take a look at the potential of a modification or a request to consider allowing an alternative design for DoD specific applications to the statement of standard.

And there's a couple of things I think to keep in mind along with that when you look at the request, and is that DoD is looking at this request for their applications.

This is not necessarily a product that they envision seeing migrating into the workforce,

but this was something that they would be able to get -- to move towards getting a NIOSH certification of their product to allow them to meet the intent of the DoD directive.

You know, and along with that, you know, when you look at some of the logistics considerations, you know, with the DoD train, if they come to a site, they are going to bring their stuff with them. They are not going to be looking to tap into the logistics training of a particular response.

And in general, though, by looking at trying to come through an avenue of allowing them to proceed and obtain a NIOSH certification that meets the intent of the DoD instruction as well as compliance with OSHA that they are trying to achieve.

So back in the July time frame, we issued a Federal Register notice which asked for the following things:

One was opinions on the design requirement for the mechanical connector using the 40-millimeter

thread.

Another was what kind of rationale do our stakeholders to have to maintain the current design requirement.

Also, any data that may support the addition of an alternate connector design for the DoD application.

And also, any alternative approaches or ideas that people may have with regard to the connector and other ways that we may be able to solve and address this issue.

And what has been interesting, you know with many -- and of all of the dockets that we have had over the past several years while I have been employed with NIOSH, this has by far been the most active docket.

And it's interesting because I think when you look at the perspective of the situation, whether you're pro or con, the argument is still always interoperability.

And those who are in favor of allowing an exemption or proceeding with some sort of process to

allow DoD to use an alternative design, use interoperability as an argument. And those who don't think it is such a good idea use interoperability as an argument.

So from a design standpoint, it is interesting to see that common thread between the two perspectives.

What we are doing today is -- part of our answer back to General Reeves' letter was to state -- was to indicate that when we developed the standard, initially we developed it in partnership, in forums such as this where we solicited our stakeholders' feedback with regard to the content of the standard.

And as such, you know, now that one of our stakeholders has an issue, we felt it was important go back in partnership to our stakeholders and say, we have -- there is an issue associated. Let's try to do some fact finding and go back and come up with a solution that addresses, you know, all of the stakeholders' concerns.

And at least at this point, I think that's

where we are with regard to the process.

You know, with the docket -- the docket will be open through I believe it is October 16 to continue to receive comments.

You know, and at this point, you know, from my perspective, we are still in an information gathering stage for this issue, that we are trying to get the opinions of all of the parties that are involved, you know, with regard to developing a path forward.

And, you know, our hope is that at the end of the day, you know, we will be able to come up, you know, with a solution that maintains the integrity of what the responder community is looking for, but also allow some avenues for DoD to achieve, you know, their objectives as well.

So with that, what I would like to do is -- we will take a minute to get set up.

We have one presentation from Mr. Mike Stevens, who is the Joint Program Manager for Individual Protection under the JPOCBD. And he is going to provide a presentation for us on -- if I

can find it here on the screen.

He is going to provide a presentation for us on the DoD perspective on this topic. And then once he has completed his presentation, there are some other representatives from DoD are going to be participating in a panel discussion, and we will see -- you know, we will take any questions, you know, regarding the JSGPM and the DoD requests. And we will open it up for comments after Mike's presentation.

MR. STEVENS: I have got people.

I would like to thank everybody for still being here. I think I'm the last thing between you and hitting the road and some of that traffic I saw on the way in yesterday.

Like I said, I do have some people here. I have Mr. Chris Ezelle. He is my senior analyst.

I have Mr. Andy Capon. He is from Avon, the manufacturer of the mask for us. Andy serves a dual purpose here. I'm from the South, so he is the translator if you should not understand what it is I'm telling you here.

I have got Randy Lampson. He has been with us about the longest. So when you start seeing my timelines and how long some of this has been going on, I have got Randy here to hopefully be able to answer your questions.

And I have got Mr. Kevin Puckace. He is my senior test officer.

One of the things that I have noticed today -- I have had people coming up to me since I got here. And one of the things I have heard more than once is I think it was a little bit of a perception problem.

What we are asking for here is just inside DoD. We are not asking for this to go outside of the DoD. And Jon has kind of went over that already, but I want to make sure everybody understands that, that we are talking DoD here.

All of my operators, as you can see, are DoD and civilian military first responder personnel. Operations, non-military unique, we are talking such as what happened at the Senate office building where we had to send people out there.

Logistics, I had some questions about logistics. We would, as Jon said, have our own train. We will take care of all logistics to support the mask.

As you know, JSGPM at this time does not support the current 3.1 interoperability.

There is a perception out there that right now with our legacy items, that we do have the interoperability standard. That is not the case. We do not have it. We do not have it with our legacy items either. So going to the bayonet mount does not take us out of standard.

JSGPM and CBRN certification, you can see the breathing resistance with the JSGPM. And later, I'm going to show you a little presentation that shows you a little bit about JSGPM because I'm sure there are some people here that haven't seen it and don't know the difference and why we did what we did.

But as you can see, the breathing resistance there is much lower.

Currently, under 42 CFR, we meet the

performance requirements of Part 84, Subpart L.

Organic vapors, at this time, we have not done that testing, but we believe it has a high probably of meeting that.

We have been doing this for a long time. We started in March 2004.

And, as you can see, we met with NIOSH. We discussed the possible certification at that time. I believe we also had our -- from the Army, ECBC was hear. The Air Force IP office. The Navy IP office, and NIOSH were present when this started in 2004.

And as you can see, we continued to meet throughout. And you go to the next slide, in 2005, we met with OSHA in DC. After that, we went to the Deputy Undersecretary of Defense.

There's a big gap there between July 2005 and November 2006. It took them quite a while to draft the policy memo.

Once the policy memo was drafted, it went up to Deputy Assistant Secretary of the Army. The policy was interpreted as a memo to include

demilitarization activities. That was not the case.

All of that has been resolved now.

10 through 12 July '08, I think Mr. Brice was here. That's when he presented the letter from the general. And he came back, and he threw me under the bus, and I'm here now.

So he said that I should have any problem from here on out with getting this through, so he is waiting to hear how I do today.

We had a telecon on the 19th of August with NIOSH, and we worked out some issues there. And, like I said, that's why we are here today.

Now, I'm going to give you just a quick overview of the JSGPM for those people that have not seen it before or do not know what it is or why we would go to the bayonet mount dual filters.

This program has been going on for quite a while, as you can see. Milestone Zero was in January 1987. We had a Milestone 1 in '98, requirements document approved in September '98. Critical design review was in April 2003. I know back in November 2001, we actually had an EUTNE at

Camp Lejeune, North Carolina with pretty much a set design of how the JSGPM was going to be.

We will be giving this mask to 2.2 million warfighters. We have already started to field this mask in the Republic of Korea to the Air Force, and we are fielding it now in Turkey to the Air Force only.

JSGPM is a very revolutionary advancement in protective mask technology for us. We have done some work lately in TICs and TIMs because that has become a very big area of concern with us with what has happened in Iraq. And as attacks happen, they come back to us very quickly wanting to know how it is that we are going to react to that and what our mask will do.

This is a breakdown of what it looks like. There are a lot less parts to this mask also than the legacy masks that we had before.

Major features, it's a new head harness. It has like a skullcap in the back of it that the troops seem to like quite a bit. One of major items that everyone likes with this mask is the visor.

They can see a lot better. And of course, I have already mentioned the breathing resistance.

Here's a comparison. Some of you have probably seen the C-50. It takes a 40-millimeter thread. But as you can see from the C-50, the mask, while it still has the same face blank and visor of the JSGPM, it has the one filter hanging off the side. It's a much bigger profile, and your whole -- you are kind of tilted at a cant when you wear it. It's not balanced, as the JSGPM is.

This mask, like I said, I think it's the best mask we have ever had. I was in the Army for 25 years. I used the last two legacy masks, and I have used this mask quite a bit, and there is a huge difference.

It's the first thing we hear from the troops when they put it on, and we have had lots of troops wear this mask. We have tested this mask more than I think any other piece of equipment we have ever had.

I currently have three children all serving in the U.S. forces. Two of them are OCONUS,

and I think this is the best mask for them.

I feel very -- that it's a very capable mask, and it will that protect them to what they need to do.

As you can see from protection, quantity, mission performance, logistics supportability, it's a very good mask. And we have reduced the cost, which could save us about $30 million based on the lifecycle cost of the mask right now.

Dual filter approach. What the dual filter approach provides us is more ergonomic weight distribution. It reduces neck strain, and it lowers the breathing resistance.

While testing this mask at the different military facilities that we went to, we tested it side by side with some of our legacy masks. One of the things we noticed was that when we would stop from road marches or any other type of activities that we were doing, the troops with the JSGPM on were up. They were playing around. They were wrestling, all kind of things.

The troops with our legacy masks were

laying against trees, trying to get their breath. It is a huge difference.

These are what the connectors look like. You should be able to see the positive locking mechanism there. It is about five locking points.

Field of view. Field of view enables better target detection. We have had improved hit probability when we have taken this mask to the range and compared it against the legacy items.

As I said before, the improved breathing resistance. The troops really love this mask.

We have great communications that is interoperable with all of our systems.

Sighting interface, it has reduced the eye relief, enables the warfighters to use a lot of the targeting systems that we had problems with before.

The troops, as you can see some of their statements down there. It's just helping them quite a bit. Whereas before, they would have to cant their rifles like this to acquire a target, now they can fire as they normally would without a mask.

These are some of the people that are

working with us on this.

Any questions?

MR. ALBERTI: I don't have any questions for these guys. I know what they think.

I'm looking at this thing from the Interagency Board --

MR. SZALAJDA: Could you introduce yourself?

MR. ALBERTI: I'm sorry. I'm Gordon Alberti with the Navy.

I'm looking at this position paper on this docket number from the Interagency Board that you mentioned, back in June.

And it seems like there's either confusion or -- like you talk about the perspective about what DoD is asking for.

They make made some comments in here like the consensus opinion of the IAB committees and subgroups is that the safety and operational enhancement claims of the new bayonet lug are not sufficient to subordinate equipment interoperability.

It's almost as if they think that DoD is saying, This design is better so you should go to it too, or something like that.

And that's not the case. The case is that this design is out there. It exists, and it is going to be out there in the millions. And the only question is, does 70 to 100,000 people that work on DoD installations, who are they interoperable with? You know, the other ten organizations on the installation or firefighters, FBI, police? Whatever.

It seems like the answer should be obvious.

And I don't know where the IAB was going with this, but they made other comments that they needed to see more data and information to show that this respirator may offer some useful benefit to the civilian responder and military community.

The data is out there. This thing has been tested and tested. The user community has accepted it. They are going to use it. It's just a matter of is it safe to use for the civilians. And

that's your purview, Operational Safety and Health.

Is it going to damage these people, or is it going to jeopardize occupational and safety and health of these people that work on DoD installations by them not having interchangeable canisters with civilian agencies.

I mean, that's question we got to look at, not does this thing do a good job because that's not an issue. And that will be settled anyway through NIOSH certification of the mask.

That's the comments I had.

MR. SZALAJDA: Yeah, actually, those are some very good points.

And I think when you look at the development, NIOSH is not involved with the DoD process as far as for warfighting applications. But you are absolutely right when you look at it from the standpoint of population that is supporting, you know, occupational-safety-and-health type considerations in installations. That's an area, if it's desired to have compliance with the, you know, having a respiratory protection program as

administered or identified by OSHA, that identifies a need for using NIOSH certified equipment.

And I think when you look at it and with the amount of testing that has been done, you know, I think the issue again, it comes back to the argument of interoperability.

There is no question, at least as far as within the DoD train, you know, DoD will be able to take care of its own. The area of concern is when -- what happens in the situation -- and we will pick on Baltimore for an example.

You know, if there is some sort of terrorism event in Baltimore, and CBIRF responds and maybe APG responds to the event, and they show up with the JSGPM.

Well, what happens in the situation if they did not have a NIOSH certification for that respirator? I mean, are they going to be told to -- by the incident commander to go away, are they going to be allowed to work?

And I think -- and Mike can correct me if I'm wrong, but I think that's the crux of what we

are trying to look at in addressing this comment as far as the, you know, the evolution of trying to come up with a solution to deal with that type of scenario.

You know, with looking at the operation within the DoD control, you know, that's DoD's business.

But just when you get into that scenario where, you know, you may have the fire department and police department of Baltimore showing up with, you know, CBRN-approved respirators with a single-canister thread, those have a NIOSH certification. Somebody comes up from CBIRF with a JSGPM, they don't have a NIOSH certification. What happens?

And that's the issue that we are trying to I guess anticipate and identify and take care of it before some sort of event like that actually occurs.

MR. STEVENS: That is correct. But we also have trouble on our facilities sometimes because some of the DoD civilians are in unions and organizations like that, and it's up to normally the

facility commander there.

But we are not always allowed to use our DoD-approved respirators for the civilians there. So that's another reason that we need to do this.

MR. FURGESON: Jim Furgeson with Air Techniques. I think one other scenario which I have heard is military people involved in an operational use, having nothing to do with a city, per se, but coming across TICs or TIMs as a result of occupying foreign lands.

What do you do in a situation like that where they have the JSGPM, and they come across TICs and TIMs?

MR. STEVENS: Jim, currently -- well, I would say for the last year and a half, going on two years now, we have been looking at TICs and TIMs.

We have a major member on the TIC/TIM task force, Dr. Karen McGrady, that works out of my office.

We have put together a plan with the TIC/TIM task force. We have prioritized all TICs and TIMs. We have looked at that -- at a different

approach as far as the likelihood, the ones that would cause us the most problems, the delivery systems.

I could go on and on about that. It doesn't really have a lot to do with this, but the thing is we have done a lot of testing in that area.

We know what our mask can do right now, and we kind of call it -- after we went back and did that and then I guess looked at the NIOSH -- what NIOSH says it should do, I think at 15 minutes, we actually call it a super APR now because it does very well.

It does very well.

MR. SELL: Bob Sell with Draeger Safety.

Seeing that the DoD and the NIOSH and a bunch of agencies have been talking about this for some time now, what is NIOSH's concept or plan on how to implement something like this if this should go through?

MR. SZALAJDA: Well, I guess the short answer to that, Bob, right now is we are developing -- or going to develop the plan based on

the feedback that we get from this forum as well as the comments that we get through the docket.

I didn't really want to try to get into the potential or at least what we have kicked around internally, at least as far as, you know, potential solutions to the problem, you know, in this forum.

But, you know, I think there are some things that we have had discussions with DoD about as recently as yesterday with regard to possibly just looking at just getting an industrial certification for the JSGPM and not necessarily getting a CBRN certification.

Because, again, part of it goes into how the system -- where the system is going to be used. And, you know, God forbid that, you know, there is a terrorism event. But if you are in Fort Riley, Kansas, how important is saying that my mask is NIOSH certified versus my mask is NIOSH CBRN certified?

That's the aspects that we would have to work through.

I mean, some of the things that have been

kicked around or, you know, Well, what if we modified the standard to allow an adapter instead of -- you know, an adapter with a 40-millimeter thread instead of -- that would connect to the bayonet-type thing.

So at this point, there is really nothing concrete. We are still in the process of generating ideas.

I think as far as moving forward, the short-term plan is that, you know, the docket will be open for another seven weeks. We will see -- we will continue to get comments. You know, we will see what type of feedback we get from the stakeholders.

Mike is going to go make a presentation at the next IAB meeting, you know, which I think is going to be very similar to the presentation that was made today, you know, at least with regard to provide some clarification to their position.

I think, in retrospect, one of the things that, you know, if we could do differently, you know, with regard to the presentation that I made to

the IAB, it might have been important to have Mike make a presentation at the same time. Whether that would have changed their perspective on the issue, that's still to be determined.

But I think it's just a question of getting the information out regarding what they are looking for. And they are looking for something that supplements the standard for their applications.

And this point, we are still in a fact finding mode to try to get information for us to make a decision and recommend a plan that we can review again with the stakeholders to let you know, This is the way that we going to proceed.

MR. SAVARIN: Mike Savarin, Sperian Respiratory Protection.

As it is late in the afternoon, it could just be that I lost track.

I was under the impression that the topic of discussion was to discuss the DoD's requirement to have this alternate connector.

Is that true?

MR. SZALAJDA: I think that's what we just did.

MR. SAVARIN: Okay. But at some point earlier on in the presentation, there was some information that was quickly skimmed over which basically said that -- it said two things.

It said that the device was -- that it met, you know, NIOSH 42 CFR, Part 84. And then later on in a table, it said, Well, actually, it didn't really meet the OV characteristic part, but that there was good confidence that it would probably meet it. So I was confused as to what that was all about.

MR. SZALAJDA: Maybe I can --

MR. SAVARIN: And then there was another reference just now to, Oh, well, yes, and we will probably find some way of integrating it into the industrial chemical, so that suddenly we are in this other field.

You know, just clarify for me, please, what is it exactly we are talking about and what exactly are you trying to do? Thanks.

MR. SZALAJDA: Well, I don't want to speak for Mike, and he can kick me if I'm speaking out of turn.

I think as a manufacturer, you can appreciate, you know, any time that you want to come in for NIOSH certification, you are going to do pretesting to assure that, before you submit something for NIOSH, that your device will meet the requirements of the regulation.

And the information that we have done -- we have done a lot of work with the DoD regarding testing of the JSGPM.

And, you know, like any type of manufacturer, they are doing pretesting as well. So if there is an opportunity to go another path, there's pretesting to supplement or support a certification.

The C50 product that Mike showed in the presentation, that is NIOSH certified. The JSGPM is not at this point.

So the plan is -- or at least the plan in going forward is, in order to be able to allow the

DoD to get a NIOSH certification to be able to use these respirators, you know, either on a routine or on an emergency basis, what's the best way forward for them to address this issue.

MR. SAVARIN: Basically to get this respirator into the market, but it's not ready yet.

MR. SZALAJDA: But part of what they are -- and that's part of something that we need to look at from the standpoint of the certification, is part of what DoD wants to do is use it for DoD applications.

However, having said that, part of what we need to look at from the aspect of NIOSH is we don't regulate where the respirators are used.

You submit to us a respirator. We certify it against the performance requirements, and you, as a manufacturer, sell it wherever you want saying that NIOSH has evaluated the respirator to meet these requirements.

Now, the challenge for us at this point is, as I see it for NIOSH, is we have never really done a niche certification.

I mean, CBRN was kind of a movement in that direction because there was a particular threat for a particular group, you know, responders, in dealing with these type of events. So we evolved the CBRN standards to address that hazard for responders.

And at this point, when you look at historically how we develop and approve respirators, we don't identify this -- I mean, granted when you look -- it is a philosophical discussion on my part.

But when you look at respirators like the N95, you think, Oh, well they use that in health care. If you look at the closed-circuit escape respirators, Oh, well, they use that in mining.

But we don't approve them that way. We approve them against a certain set of performance criteria. And then, you know, the market determines where -- the market and the users determine where those products are used.

So part of the concern that I have personally is, Well, if you get a NIOSH certification on this product, you know, there is

nothing to preclude the manufacturer from going out and selling that somewhere else.

And that's an issue that we would have to work through, you know, at least as far as, you know, accepting or identifying a certification criteria for an alternate connecting configuration.

MR. STEVENS: I would like to add to it.

Of course NIOSH has to be concerned with what happens if they do something like that.

But you asked what I want. I want to be able for my soldiers, airmen, Marines, to use that mask right alongside with my DoD civilians. That's all I'm asking here. That's what I want to happen.

And I'm sorry if I moved too fast through the information, and it may have been a little confusing to you. But Jon was right on what he was telling you there as far as the filters. We have tested the filters. We know what they will do.

We also have an XM60 filter right now. We know what it will do.

But until we get a type classification on that, I can't -- you know, I cannot make that

statement, that it's all done. Okay?

MR. SAVARIN: Whilst it's true that a product is placed for certification, and then it is approved to set of criteria, and then it can go anywhere it wants to go, the whole idea actually is that it self-regulates itself into certain markets. That is what happens and has always happened.

And a lot of that is down to the particular criteria that we are actually evaluating it against so that it does appear in a particular marketplace. So actually, although we don't really do that, actually, we do.

So that the thing here is, What's the big problem with -- what is it that's the biggest conflict with what you are trying to do into the market that we are in right now? What is it that you are most concerned about?

MR. STEVENS: Well, as far as the market as you speak of it, I'm not. Reason being, I'm the lifecycle manager for that piece of equipment.

No one can buy a JSGPM unless they get it from me. Okay? That's the only place they can get

that.

Now, my manufacturer can go out and make a civilian version and try to sell that civilian version if he wants to. But JSGPM military mask, no one can buy that unless they buy it from me. And I'm going to control where that mask goes.

I'm not sure if that answers your entire question.

MR. SAVARIN: I think it does.

What is it that you are asking as feedback from this group?

MR. STEVENS: Well, I guess what we are asking from the group is do they really have a problem with us being able to put our DoD civilians in the same masks that our troops are in?

They work side by side. I have gate guards, and they have to wear a NIOSH-approved respirator with a 40-millimeter thread right now. And my soldiers are standing next to them, and they are wearing a JSGPM with a bayonet.

So now, with your tax dollars, I have to -- I have to take care of two supply trains. I

have to have a different one for them.

There is also a perception problem there, big perception problem.

The troop goes, Why is he wearing that? Is his mask better than mine? And the civilian does the same thing. So they are protecting the troop; they are giving him this great mask. From what I've heard, it's a great mask. Why don't I have that?

So there's a lot of perception problems there. And we have been doing through that for years with the -- when we had the 40 and the MCU2P out there.

MR. SAVARIN: Okay, thank you.

MR. ALBERTI: Gordon Alberti again with the Navy.

Just a quick comment. You're worried about what a NIOSH certification would mean to the rest of the world as far as Avon's product is concerned. And you just want your civilians to be able to wear the thing.

Now, DoD has an exemption for military -- I don't know the exact wording. Military specific

operating -- military unique operations. Can you just broaden that to DoD operations? Solve your problem, solve your problem? And let Andy worry about how he is going to sell it to the rest of the world because I don't care about that.

MR. STEVENS: I would like for it to be that easy, but when we are dealing with DoD facilities at different places, they have unions, and they have regulations, and it's not that easy.

MR. ALBERTI: Got it.

MR. STEVENS: Thanks, Gordon.

MS. STAUBS: Hi. It's Amy Staubs from Scott. I have a quick question about consideration being given to NATO military masks that may employ the same type of connection that are fielded elsewhere.

Would NIOSH consider evaluating those to the same level of performance, I suppose, as we are looking for the JSGPM?

MR. SZALAJDA: I think what you are asking is if we get an application from somebody for another military mask, if we would certify it to the

standard?

MS. STAUBS: Correct. Has that been considered?

MR. SZALAJDA: I think we would do that if someone were to come in with an application that met the criteria, then we would evaluate the product against the standard.

MS. STAUBS: What about for commercial masks that may have a CBRN level of performance with a bayonet style fitting. Is that --

MR. SZALAJDA: Then it wouldn't meet the requirement.

MS. STAUBS: If it passed performance requirements?

MR. SZALAJDA: It wouldn't meet the requirement.

MS. STAUBS: Okay, thank you.

MR. SZALAJDA: Again, it gets back to the issue is, and as we have seen with this product, you know, the issue is because of the need for interoperability, as was identified by the responders, you know, the 40-millimeter threads

there.

And right now, if you were to submit for something for CBRN certification and you don't have a 40-millimeter thread, it's not going to be certified.

MR. STEVENS: A lot of this is about the soldier, the Marine, and all of our warfighters in the field.

When I showed you that chart there about the differences, it's really -- that's what it gets down to.

I mean, we need to make them as effective and efficient as we possibly can. And to do that, we had to go to this design. Some of our allies are designing masks. Some of them already have. And they have gone to the two-filter design, also.

For us to be able to do our mission, we need this mask and we need this design.

MR. BARD: Brent Bard, Applied Air Monitoring Systems.

In theory, you have a unique situation. Personally, I don't see how there is any issue with

you trying to submit a product for evaluation by NIOSH for an approval that would allow you to meet your unique situation of controlling your costs and outfitting all of your -- let's call them workers -- with the same piece of personal protective equipment.

It makes solid sense as a business case. It makes solid sense as a training issue. And, quite frankly, if it ends up being out in the market because it is a better mousetrap, well, that's a completely separate issue.

I don't think that that's what you are here to ask about, and I would think that you would have everyone's support if it's going to give you a tool that better protects, in your opinions, your fighters and your civilian workers.

MR. STEVENS: Thank you.

MR. SZALAJDA: Any other comments? Questions?

And, again, I think you can appreciate, you know, even on paper, it seems to be a -- it shouldn't be that hard to solve.

But, unfortunately, when you go to put the concept into practice, you know, because of the nature of the business that we are in, you know, we do have considerations to take into effect.

So, again, you know, I encourage you to, if you have ideas or something that we haven't talked about for us to consider, to please submit something to the docket.

Edna.

MS. DEMEDEIROS: Edna DeMedeiros, North by Honeywell.

I just want to clarify this.

What you're asking for is you're asking to modify the current CBRN APR standard to include this connector, just this connector?

MR. STEVENS: Do you want to touch that or not?

MS. DEMEDEIROS: You want a dual-cartridge design so you don't have interchangeability -- but I mean, is that the question?

MR. STEVENS: Well, no. I guess what we are asking for is -- I hate to use the word

alternate standard. You stated it well the other day. I'm looking for it right now.

What we are asking for is to be able to -- oh, supplemental. We are asking for supplemental standard for DoD only.

MS. DEMEDEIROS: But for a CBRN APR, so would your TC number be the same? And -- I'm just asking. All right. Because you will be modifying the standards; correct?

MR. SZALAJDA: Well, from the administrative standpoint, you know, at least as far as if something like that were to take place, I'm not sure how we would do it in terms of our nomenclature for the approval number.

MS. DEMEDEIROS: Because I have just never seen a standard modified after it's been promulgated and it's out there and we are making product to it, and so that's what I'm asking.

Basically you are asking for an approval for a CBRN APR respirator that doesn't have -- doesn't allow interchangeability. It would just be for DoD, but it will be a dual-canister respirator.

So it would be totally different than everything that has been approved so far.

MR. STEVENS: That is correct.

MR. SZALAJDA: Yes.

MS. DEMEDEIROS: And through -- and you are not exactly sure how you are going to be able to do it --

MR. STEVENS: Well, you saw the -- when I started going through the chronological order. I think they started this in 2004, and we have been digging along now for over four years. And I think we have a plan now.

Do you agree with that?

I think we have a plan on how we do it. Is it -- it's been very hard to accomplish.

MS. DEMEDEIROS: But just from a manufacturer's perspective, I think we are all looking at -- I don't know if everyone agrees or disagrees, but I'm mean, I'm looking at it, okay, we came out with a product, and we have a difficult time because of interoperability.

We had a difficult time due to the

interoperability portions, and now that would not be part of it for your approval, even though it would have the same TC number.

And so it's going to look -- from a TC number perspective, it looks identical. Yet when you look at the two masks, they look very different.

MR. SZALAJDA: That's a good observation.

Again, it kind of gets into developing the plan forward, you know. When you look at options, it's kind of -- we have the existing products against the existing standards.

MS. DEMEDEIROS: My recommendation would be to write another standard for this application. I mean, if that's what you are trying to achieve is NIOSH certification.

MR. SZALAJDA: Actually, that's a good -- actually, I think that was one of the things we considered early on, you know, in the process, but it's sort of the Pandora's box at this point.

When you look at the traditional NIOSH role, everything is developed or approved against a certain set of criteria. And when we discussed this

with legal, it's sort of a, Where do you draw the line at this point?

Okay. Now, you did this for DoD. Okay, say three months from now the health care comes in and say, We want our own standard for this type of respirator. You did it for them; why can't you do it for us?

It gets into the point of where do you draw the line.

MS. DEMEDEIROS: That's where you get legal involved and get a decision.

MR. SZALAJDA: But it's a good point.

And saying with Mike, you know, at the end of the day, we are going to come up with some sort of plan. Because obviously, you know, DoD is not -- I mean, they developed -- they have spent millions of dollars. They have developed this product.

The troops are going to get it. They want to use it at the installation. We are going to work together to try to come up with some sort of defined position to try to move forward through our process.

You know, I think the kind of -- at this

point, when you look -- and I kind of alluded to it, and I think Frank did as well with his presentation this morning, you know, our instructions from the department were pretty clear, you know, at least as far as making changes to the standard that, you know, we are not -- for CBRN-type applications going forward, we are using rulemaking.

So the thought is by going through forums like this and revisiting it with stakeholders, if we are going to try to do something to change the standard, you know, we are going to have to try to get everything decided up front before we were to go through the process.

You know, again maybe at the end of the day we don't change the standard, and there's another option to be able to address the DoD's issues. But at least at this point, we are still trying to work through, you know, looking at all of the options and looking at what everyone's concerns are. So at some point in the next couple of months, we can look at the information and, you know, look at options and decide how to go forward.

MS. FEINER: Lynn Fiener, North by Honeywell.

First, I want to say that is a nice-looking respirator, and I appreciate keeping our troops safe. But I'm still trying to wrap my head around, my hands around the whole who the target audience for this respirator is beyond the military.

And you said it is for the military and then it is for also the civilians working at military sites. So that means that is not just the military, and what's to prevent a contractor from using that mask at nonmilitary locations?

And you are saying you are going to control how you get it into the market for the military, but how are the contractors going to get it?

And so I'm back to what exactly are you proposing in the change to the standard?

Are you just proposing just this mask, or are you opening it up to any type of dual connectors? Are you changing the standard?

I'm just trying to understand exactly what you're trying to do.

MR. STEVENS: I'm proposing the JSGPM and the JSGPM only.

I'm not sure which contractors you are talking about getting their hands on my mask --

MS. FEINER: Anybody on any military site.

MR. STEVENS: Well, the only people that will be issued this mask are military and DoD civilians.

Now, you might think that's kind of hard, but let me tell you something that happened to me about a month ago.

I get a phone call from General Reeves, and somebody has sold a MCU2P on Ebay. One MCU2P somewhere in the world, somebody has sold on Ebay, and he knows it. And I have got to find him the serial number who the troop was that took it and sold and -- everything about that mask.

So I can tell you right now, we do track our equipment, and we know where it is.

And as I said, it's for troops and DoD

civilians only.

MR. SZALAJDA: And let me just supplement something that Mike said regarding my previous life when I was the system manager for the M40.

Unless things have substantially changed, you know, until all of the DoD's needs are met, the 2.2 million plus needs are met, they won't allow the mold that are used in production to be used to make anything else.

You know, when we went through the process with the M40, there's a lot of interest in foreign military sales, sales to, you know, the police department, sales to others, you know, regarding the product.

But because of the limitations of the contract, until all of the DoD assets were met, you know, that production line was not allowed to be deviated to make any other products for sale to anyone else other than the Department of Defense needs.

And what Mike said is true, I mean, similarly, we had issues in working with what Mike

termed the legacy masks, which are the M40s and the MCU2Ps. And part of the issues that we saw historically with the DoD products were when the Army or the other services would dispose of the masks, at lot of the DRMOs, which were the Defense Reutilization Material Organizations, would take things that were not longer worthy for use by the Army, but they would turn around and take it from the disposal site and sell.

So a lot of old M-17 types of the masks ended up in the hands of police forces and others around the country which were no longer, you know, applicable or valid for use, you know, by the military.

But yet, they had trickled down and were being used in civilian applications. So of the mechanisms that DoD put into place was to not allow sales of these types of systems in going out, you know, for use by the general public.

MR. METZLER: Hi, Jon. Rich Metzler representing myself.

I wonder if the wrong question is being

asked of the public.

And it seems like the appropriate question would be, Should NIOSH be approving application-specific respirators.

Years ago we had the mining industry and mining unions coming to us at NIOSH requesting a special approval on a multifunction PAPR which did not meet 42 CFR 84 requirements.

So it seems to me there may be a need for application-specific certifications. And the question might ought to be whether NIOSH should have the authority through some sort of new subpart to approve site-specific or application-specific products.

MR. SZALAJDA: I think that's a good comment, Rich. And that's -- you know, I don't know if Les is ready to take on that mission yet or not, but I think that is something worthy to consider.

MS. RICHARDSON: Hi. I'm Irene Richardson with the U.S. Army Center for Health Promotion and Preventive Medicine.

And just a general comment of how

important it is to us to really have a military mask that is NIOSH approved.

Because every day we receive phone calls and emails from both DoD civilians and from soldiers and other military members that are deployed around the world and in the United States.

They are involved in situations that are not considered military unique. We had people responding to Hurricane Katrina. We had people responding to the 9/11 attacks, both the World Trade Center and the Pentagon, that were in that same situation where you had military showing up with a military mask that was not NIOSH approved. Therefore, the civilian first responder incident commander was saying, Well, what we are supposed to do with these people because they are not OSHA compliant because they don't have a NIOSH-approved respirator.

Likewise, a situation with some of our troops that are overseas right now. They are doing operations that are not military unique.

They are converting an old warehouse into

housing for troops that are over there because it's better than living in a tent, and it might provide some better protection in the event of some kind of an attack.

They are dealing with, Lord knows, lead-based paint, asbestos. There's old chemicals that have been left behind. I mean, they are painting things. They have having to respond to IED attacks with chemicals that are considered toxic industrial chemicals, but not chemical warfare agents.

What do we do in this situation? How do we advise them? If we had one mask that would satisfy both requirements, it would be a godsend.

Just a comment. Thank you.

MR. SZALAJDA: We have four minutes left in this topic area. So if anyone else would like to add anything at this time, it's the right time to ask your question or make your comment.

I think what we would like to do, first, I would like to thank Mike for coming up as well as his entourage.

I think it was important in terms of, you know, developing the standards and partnership to allow the partners an opportunity to speak and state their positions. So thank you very much.

What I would like to do before I jump into the wrap-up is I hope everyone received a survey. So I would like you to take two minutes to go through and fill out the survey. A lot of it is just circle the answer.

We would also be really interested in getting your perspective on the format of the meeting. So if you can fill out the survey and pass them to the center aisle. And Tess is going to walk through the aisle and collect them in two minutes.

Okay. At least at this point, let's go ahead -- I would like to go ahead and try to wrap up the meeting.

You know, first of all, I would like to thank everybody for their participation. I think it was very informative for us, and I hope it was informative for you as well with regard the topics that we discussed today.

And I think it gives you a level of the depth and the breadth of what we are trying to do within the policy and standards development organization.

I wanted to spend at least a minute or two talking about timelines, which is a topic that I had heard in discussion during the course of the day.

And I think what you can expect with regard to our activity is that, in general, you are probably going to see us take anywhere from 12 to 18 months to develop a concept from the point of the concept initiation to the point where we think we are in a position to be able to initiate the rulemaking process.

So I think from that standpoint, we have indicated that at least for the closed-circuit SCBA, we see the concept phase closing out at the end of this year. So you can anticipate the rulemaking process will start on that around the holiday times.

And then at some point during 2009, you will see a Federal Register notice indicating that NIOSH is proceeding on a rule for that system.

You know, likewise, you know, we are looking at having a November/December timeframe meeting to discuss PAPR, which, if you have been involved with the process, you know we have been working on for several years, and we think we are relatively close to completing that effort.

And, again, following that meeting, early in 2009, we will close the concept development portion, move that into rulemaking.

With SAR, this is the first time we have discussed SAR in public, and I think we have got a lot of good feedback with regard to the session today with regard to the content of the standard, where you think that we are on track with identification, the requirements, as well as areas where you think we can improve of modify what we have identified.

But, again, you know, looking forward, you know, 12 to 18 months from now, you are going to see is SAR moving into rulemaking. And then following up with air-fed suits.

And I hope by the time we get together in

during the early winter, we will be able to add other items to this list to give you an indication of where you think we are going with the regard to the rulemaking processes for our equipment.

Again, for the closed-circuit docket, 39A, as the docket office receives comments, they will be become visible through the web.

You will also be able to go to the docket. If they not visible on the web, you will be able to go to the docket office and request copies of the submittals.

And, again, I think the closing date for the information that we discussed today as well as the concept paper that's posted on the web is the end of September.

Likewise for the work on the re-evaluation of the oxygen prohibition for the use of oxygen-generating devices. The open comment period on that will also close at the end of September.

We hope to be able to get a lot of feedback on this area. From the industry side, the stakeholders have been very active with regard to

working with us and letting us know with regard to the testing and, the developmental type testing that has been doing at different laboratories. We really like to hear from the user community.

And if you can encourage users that may have an interest in this type of device to please, you know, get in contact with us with regard to the re-evaluation of this prohibition.

You know, with supplied air, again, the docket on this closes September 30th. And, again, I wanted to reiterate on this, when you go to the web page -- you know, I think we will all gain familiarity with it. If you scroll halfway down through the description of the standard work, there's a .pdf file in the middle that contains the statement of standard.

And, again, we look forward to receiving additional feedback above and beyond what we received today.

And this noncontroversial topic regarding the CBRN APR mechanical connector, I think, you know, simplistically, you would think this is a

no-brainer to fix. Unfortunately, when you -- like anything else, when you start working on something and you start getting into the nuances and administrative controls that are in place, the answer is not always so straightforward.

And I think with regard to some of the comments that people made today, I think there is some maybe innovative avenues that we can take to try to come up with a solution that meets one stakeholder's needs without invalidating the needs of the other stakeholders that have voiced their opinion as well.

So we look forward to continuing to receive comments on this. And I believe based on what we have heard and discussions that we have, we will probably revisit this in one of the next public meetings to come to let you know what our plan is going to be in going forward.

And I'm sure Mike Stevens and I will get to know each other a lot better over the next several months.

With that, I believe I'm finished.

Again, thank you very much for your; participation. I hope it was as informative and worthwhile for you guys as it was for us, and we look forward to seeing you at future NIOSH events.

(Whereupon, the meeting was concluded at 4:24 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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Joseph A. Inabnet

Court Reporter