

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.

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

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

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

15 And that list of topics is on the screen
16 now.

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

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

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

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

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

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

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

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

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

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

1 identified and named.

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

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

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

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

1 into the future.

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

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

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

22 Number four is to increase the research on

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

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

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

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

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

1 review. Some of the key dates are identified here
2 with the main and the most recent one being the June
3 25 meeting that the evaluation committee visited the
4 laboratory and presented the results of their
5 findings.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 Again, the date is March 3, 2009.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 If during the course of the day, if we

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

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

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

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

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

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

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

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

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

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

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

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

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

1 discussion with the stakeholders with regard to the
2 concepts, and then move those performance
3 requirements into the rulemaking process early in
4 2009.

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

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

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

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

1 are going to be discussing today.

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

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

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

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

22 And, again, these are ways to contact the

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

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

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

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

20 Actually, Bill, don't leave yet.

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

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

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

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

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

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

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

1 posters.

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

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

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

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

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

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

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

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

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

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

22 So after the NIOSH CBRN powered-air

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

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

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

12 Contained in Subpart Q are the optional
13 protection requirements for the CBRN and the high
14 heat and flame resistance performance requirements.
15 An SCBA will have to be able to meet the base
16 requirements in the subpart before it can be
17 certified for CBRN protection. As well, the SCBA
18 will have to meet the base requirements and the CBRN
19 requirements before it can be certified for high
20 heat and flame resistance protection.

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

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

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

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

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

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

5 As I said before, the optional CBRN
6 performance requirements are included in Subpart Q,
7 and it must be able to meet the base requirements of
8 8450 -- or sections 84-500 through Sections 84-520
9 before it can gain approval for CBRN protection.

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

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

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

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

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

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

14 The heat and flame resistance performance
15 requirements taken from sections from NFPA 1981 to
16 2007 version, include the peak exhalation and
17 inhalation pressures, component after-flame, and the
18 integrity of the unit to be worn or used as
19 specified in the users instructions, lens
20 obscuration and fabric heat and flame resistance.

21 We project the following milestones:

22 Complete the revised closed-circuit

1 self-contained breathing apparatus concept standard
2 based on feedback from this public meeting and
3 docket comments by October 2008. And we plan to
4 initiate the informal rulemaking process by December
5 2008.

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

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

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

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

1 We will reconvene in here at 10:30.

2 (A recess was taken to view the posters.)

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

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

9 Yes? Okay.

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

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

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

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

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

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

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

22 And if that's an issue that you would like

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

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

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

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

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

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

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

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

22 And, again, if you have any questions or,

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

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

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

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

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

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

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

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

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

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

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

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

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

16 Someone needs to be bold. Thank you.

17 MR. ANDERSON: Doug Anderson, BioMarine.

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

22 As a manufacturer, what this will do for

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

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

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

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

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

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

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

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

13 Thank you.

14 MR. SZALAJDA: Thank you.

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

1 topics going forward.

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

8 We also would like to see the flow rates
9 to be increased. So maybe you could add in another
10 flow rate level to go up to approximately 130 liters
11 per minute with cyclic inspiratory rates up to about
12 400 liters per minute as our peaks. We see a lot of
13 this in both the warfighter and in firefighters in
14 the tests that we have done.

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

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

1 trying to deal with.

2 MR. SZALAJDA: Thank you, Christina.

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

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

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

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

22 MR. SZALAJDA: Can you guys help on that

1 one?

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

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

6 MR. SELL: At each what temperatures?

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

11 This is on Table 7?

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

14 Right now, the requirement --

15 MR. PALYA: All right.

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

18 MR. SELL: Okay. At ambient temperature?

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

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

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

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

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

10 MR. PALYA: Yes.

11 MR. SELL: Okay. But not 507B?

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

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

18 MR. PALYA: No.

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

1 case.

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

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

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

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

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

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

21 MR. PALYA: Right.

22 MR. SELL: Okay. Thank you.

1 MR. SZALAJDA: Thank you, Bob.

2 Any other comments, questions at this
3 time?

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

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

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

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

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

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

8 And, you know, traditionally, you have
9 looked at respirators with regard to, This is a
10 15-minute unit. You know, This is a two-hour unit,
11 and what does that really mean? That people breathe
12 differently and, you know, one unit that might last
13 for 15 minutes for somebody might last five minutes
14 or 30 minutes. It depends on you how the individual
15 is breathing.

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

1 closed-circuit SCBA as well.

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

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

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

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

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

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

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

5 Any other comments at this time?

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

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

10 I have got a question primarily about
11 84.511 capacity gauge minimum requirements. The
12 sentence here says: "Shall have accurate capacity
13 indicators."

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

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

1 those that fall on both sides of that. Okay?

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

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

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

12 You guys go ahead.

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

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

22 And in response to your other question, I

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

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

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

17 MR. SZALAJDA: Thank you, Nick.

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

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

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

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

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

14 And so with that.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 During this test, the unit is exposed to
8 95 degrees C for 15 minutes. Then it's brought out
9 of the oven and exposed to direct flame for 10
10 seconds. It is then raised 150 millimeters and
11 dropped.

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

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

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

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

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

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

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

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

7 And just like NFPA, you have exposure for
8 15 minutes to 95 degrees C. You have exposure to
9 direct flame for ten seconds. The unit is then
10 dropped from 150 millimeters.

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

14 If you could see in the top picture, you
15 have right here, above the right temple, they have a
16 2.5 millimeter tube put through there so it will
17 simulate an active leak in the unit.

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

20 Problem noted, none. Basically, the unit
21 met all of the requirements of EN137, Section
22 6.11.2.2, which is their flame engulfment test.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 Thank you. Typical disclaimer.

8 MR. ROUTE: Klaus Michael Route from
9 Draeger Safety.

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

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

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

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

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

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

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

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

19 MR. REHAK: Thank you.

20 MR. SZALAJDA: Thank you.

21 MR. REHAK: Any other questions or
22 comments?

1 MR. ANDERSON: Yeah. Doug Anderson,
2 BioMarine.

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

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

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

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

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

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

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

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

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

1 intended for direct immersion into fire, open flame.

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

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

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

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

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

10 Anything else? Any other comments at this
11 point?

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

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

18 (A luncheon recess was taken.)

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

1 morning for the closed-circuit SCBA.

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

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

15 Can you hear me?

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

22 We will also be updating the standard test

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

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

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

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

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

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

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

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

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

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

20 SPEAKER: Get closer to the microphone.

21 MR. PALCIC: Okay, Bill.

22 The temperature of the air produced by the

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

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

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

12 Continuing with base respiratory
13 requirements.

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

19 Carbon dioxide limit.

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

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

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

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

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

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

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

1 and a high work rate of 57 liters a minute with a
2 1.95 liter tidal volume at 29.1 respirations per
3 minute.

4 Base and non-respiratory requirements.

5 Required components:

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

10 The airtsource system consists of a
11 respiratory inlet, air supply valve or orifice, air
12 supply hose, detachable couplings, flexible
13 breathing tube harness, and a portable blower or air
14 compressor.

15 General construction shall meet the
16 requirements of Subpart G, general construction and
17 performance requirements, out of 42 CFR, Part 84.

18 And connections and couplings will require at least
19 two different motions for disconnection.

20 Continuing with base and nonrespiratory
21 requirements, harness tests.

22 The shoulder strap test was increased from

1 250 pounds to 300 pounds for 30 minutes. The belts
2 and rings increased from the 300 pounds to 500
3 pounds for 30 minutes. And the hose attachment to
4 the harness remains at 250 pounds.

5 Lifelines or the safety harnesses shall
6 meet applicable standards.

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

12 Once again, continuing with base
13 nonrespiratory requirements:

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

20 Noise level:

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

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

4 Failure Mode Effects Analysis -- hold on a
5 second.

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

10 Base requirements for supplied-air hose:

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

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

18 Okay. Base requirements for airsource
19 respirators only.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 Requirements for additional options.

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

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

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

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

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

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

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

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

10 The supplied-air respirator program
11 poster, a description of airline and airtsource
12 system posters, base requirements posters, including
13 respiratory, non-respiratory, and a dual topic
14 poster covering airtsource blower or air compressor
15 requirements, and air supply hose requirements.

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

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

22 Supplied-Air Respirator NIOSH Docket 083.

1 Written comments will be accepted through September
2 30 this year, and we encourage everyone to comment
3 for or against any of the new requirements or
4 existing requirements.

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

8 And no questions until after the poster
9 session.

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

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

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

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

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

4 So with that, who wants to break the ice?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 The larger cylinder, you are going to have

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

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

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

19 Thank you.

20 MR. SZALAJDA: Thank you very much.

21 Any other comments? Don't be shy.

22 Thank you, Andy.

1 MR. CAPON: Andy Capon of Avon Protection
2 Systems.

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

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

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

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

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

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

7 Thank you, Jon.

8 MR. SZALAJDA: Thank you, Andy.

9 MR. COLTON: Craig Colton, 3M.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 I think they are still deciding.

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

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

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

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

1 following?

2 And that can be another one we can talk
3 about.

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

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

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

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

21 So I'm perplexed.

22 MR. SZALAJDA: Okay. I understand your

1 question now in that context.

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

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

13 Any other questions?

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

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

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

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

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

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

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

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

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

3 Thank you.

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

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

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

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

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

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

1 transfer and the alarm with that.

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

5 You know, if 20 percent -- and I asked
6 what was the rationale on the 20 percent, and
7 apparently that's a legacy carryover. But if it is
8 20 percent, then I think there should be an 80
9 percent alarm capacity, you know, where if you are
10 below 80 percent, it should alarm.

11 That's my comment here.

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

14 MR. SAVARIN: Mike Savarin, Sperian
15 Respiratory Protection.

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

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

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

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

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

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

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

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

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

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

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

22 That's it for now. Thank you.

1 MR. SZALAJDA: Thank you, Mike.

2 Anyone else?

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

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

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

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

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

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

5 And I think when you look at -- when Part
6 84 was incorporated, there were certain
7 accommodations that were addressed in terms of how
8 the standard was introduced and the acceptance of
9 material for certification.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 welcome comments related to the contents of the
2 proposal.

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

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

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

18 MR. ROBERTS: Mark Roberts from GMA
19 Technologies.

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

22 Recently, there has been a very high

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

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

9 MR. SZALAJDA: Well, I think with --

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

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

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

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

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

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

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

21 MR. SAVARIN: I'm sorry about this.

22 Can you please explain to us why toluene

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

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

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

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

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

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

1 the hose and getting into the air stream.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 And this standard was based off of DoD
2 requirements that were identified and used on the
3 M40 series of masks as well as the MCU-2P mask used
4 by the Air Force and Navy, and also met the
5 requirements, the European standards used for a
6 40-millimeter thread.

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

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

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

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

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

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

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

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

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

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

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

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

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

22 But with the evolution of the standard,

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

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

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

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

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

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

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

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

18 And respiratory protection for DoD is no
19 different.

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

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

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

11 I hope I got everything in the acronym
12 correct.

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

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

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

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

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

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

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

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

1 thread.

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

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

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

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

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

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

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

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

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

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

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

1 where we are with regard to the process.

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

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

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

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

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

1 can find it here on the screen.

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

11 MR. STEVENS: I have got people.

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

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

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

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

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

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

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

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

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

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

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

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

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

22 Currently, under 42 CFR, we meet the

1 performance requirements of Part 84, Subpart L.

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

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

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

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

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

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

1 demilitarization activities. That was not the case.

2 All of that has been resolved now.

3 10 through 12 July '08, I think Mr. Brice
4 was here. That's when he presented the letter from
5 the general. And he came back, and he threw me
6 under the bus, and I'm here now.

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

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

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

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

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

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

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

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

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

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

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

11 This mask, like I said, I think it's the
12 best mask we have ever had. I was in the Army for
13 25 years. I used the last two legacy masks, and I
14 have used this mask quite a bit, and there is a huge
15 difference.

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

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

1 and I think this is the best mask for them.

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

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

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

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

22 The troops with our legacy masks were

1 laying against trees, trying to get their breath.

2 It is a huge difference.

3 These are what the connectors look like.

4 You should be able to see the positive locking
5 mechanism there. It is about five locking points.

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

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

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

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

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

22 These are some of the people that are

1 working with us on this.

2 Any questions?

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

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

7 MR. SZALAJDA: Could you introduce
8 yourself?

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

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

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

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

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

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

12 It seems like the answer should be
13 obvious.

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

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

1 that's your purview, Operational Safety and Health.

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

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

11 That's the comments I had.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 facility commander there.

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

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

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

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

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

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

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

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

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

13 It does very well.

14 MR. SELL: Bob Sell with Draeger Safety.

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

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

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

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

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

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

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

22 I mean, some of the things that have been

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

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

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

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

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

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

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

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

15 MR. SAVARIN: Mike Savarin, Sperian
16 Respiratory Protection.

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

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

22 Is that true?

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

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

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

14 MR. SZALAJDA: Maybe I can --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 statement, that it's all done. Okay?

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

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

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

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

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

1 that.

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

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

9 MR. SAVARIN: I think it does.

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

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

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

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

1 have to have a different one for them.

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

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

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

13 MR. SAVARIN: Okay, thank you.

14 MR. ALBERTI: Gordon Alberti again with
15 the Navy.

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

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

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

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

10 MR. ALBERTI: Got it.

11 MR. STEVENS: Thanks, Gordon.

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

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

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

1 standard?

2 MS. STAUBS: Correct. Has that been
3 considered?

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

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

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

13 MS. STAUBS: If it passed performance
14 requirements?

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

17 MS. STAUBS: Okay, thank you.

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

1 there.

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

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

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

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

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

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

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

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

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

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

17 MR. STEVENS: Thank you.

18 MR. SZALAJDA: Any other comments?
19 Questions?

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

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

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

9 Edna.

10 MS. DEMEDEIROS: Edna DeMedeiros, North by
11 Honeywell.

12 I just want to clarify this.

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

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

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

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

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

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

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

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

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

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

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

3 MR. STEVENS: That is correct.

4 MR. SZALAJDA: Yes.

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

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

13 Do you agree with that?

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

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

22 We had a difficult time due to the

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

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

7 MR. SZALAJDA: That's a good observation.

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

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

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

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

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

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

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

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

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

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

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

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

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

8 So the thought is by going through forums
9 like this and revisiting it with stakeholders, if we
10 are going to try to do something to change the
11 standard, you know, we are going to have to try to
12 get everything decided up front before we were to go
13 through the process.

14 You know, again maybe at the end of the
15 day we don't change the standard, and there's
16 another option to be able to address the DoD's
17 issues. But at least at this point, we are still
18 trying to work through, you know, looking at all of
19 the options and looking at what everyone's concerns
20 are. So at some point in the next couple of months,
21 we can look at the information and, you know, look
22 at options and decide how to go forward.

1 MS. FEINER: Lynn Fiener, North by
2 Honeywell.

3 First, I want to say that is a
4 nice-looking respirator, and I appreciate keeping
5 our troops safe. But I'm still trying to wrap my
6 head around, my hands around the whole who the
7 target audience for this respirator is beyond the
8 military.

9 And you said it is for the military, and
10 then it is for also the civilians working at
11 military sites. So that means that is not just the
12 military, and what's to prevent a contractor from
13 using that mask at nonmilitary locations?

14 And you are saying you are going to
15 control how you get it into the market for the
16 military, but how are the contractors going to get
17 it?

18 And so I'm back to what exactly are you
19 proposing in the change to the standard?

20 Are you just proposing just this mask, or
21 are you opening it up to any type of dual
22 connectors? Are you changing the standard?

1 I'm just trying to understand exactly what
2 you're trying to do.

3 MR. STEVENS: I'm proposing the JSGPM and
4 the JSGPM only.

5 I'm not sure which contractors you are
6 talking about getting their hands on my mask --

7 MS. FEINER: Anybody on any military site.

8 MR. STEVENS: Well, the only people that
9 will be issued this mask are military and DoD
10 civilians.

11 Now, you might think that's kind of hard,
12 but let me tell you something that happened to me
13 about a month ago.

14 I get a phone call from General Reeves,
15 and somebody has sold a MCU2P on Ebay. One MCU2P
16 somewhere in the world, somebody has sold on Ebay,
17 and he knows it. And I have got to find him the
18 serial number who the troop was that took it and
19 sold and -- everything about that mask.

20 So I can tell you right now, we do track
21 our equipment, and we know where it is.

22 And as I said, it's for troops and DoD

1 civilians only.

2 MR. SZALAJDA: And let me just supplement
3 something that Mike said regarding my previous life
4 when I was the system manager for the M40.

5 Unless things have substantially changed,
6 you know, until all of the DoD's needs are met, the
7 2.2 million plus needs are met, they won't allow the
8 mold that are used in production to be used to make
9 anything else.

10 You know, when we went through the process
11 with the M40, there's a lot of interest in foreign
12 military sales, sales to, you know, the police
13 department, sales to others, you know, regarding the
14 product.

15 But because of the limitations of the
16 contract, until all of the DoD assets were met, you
17 know, that production line was not allowed to be
18 deviated to make any other products for sale to
19 anyone else other than the Department of Defense
20 needs.

21 And what Mike said is true, I mean,
22 similarly, we had issues in working with what Mike

1 termed the legacy masks, which are the M40s and the
2 MCU2Ps. And part of the issues that we saw
3 historically with the DoD products were when the
4 Army or the other services would dispose of the
5 masks, at lot of the DRMOs, which were the Defense
6 Reutilization Material Organizations, would take
7 things that were not longer worthy for use by the
8 Army, but they would turn around and take it from
9 the disposal site and sell.

10 So a lot of old M-17 types of the masks
11 ended up in the hands of police forces and others
12 around the country which were no longer, you know,
13 applicable or valid for use, you know, by the
14 military.

15 But yet, they had trickled down and were
16 being used in civilian applications. So of the
17 mechanisms that DoD put into place was to not allow
18 sales of these types of systems in going out, you
19 know, for use by the general public.

20 MR. METZLER: Hi, Jon. Rich Metzler
21 representing myself.

22 I wonder if the wrong question is being

1 asked of the public.

2 And it seems like the appropriate question
3 would be, Should NIOSH be approving
4 application-specific respirators.

5 Years ago we had the mining industry and
6 mining unions coming to us at NIOSH requesting a
7 special approval on a multifunction PAPR which did
8 not meet 42 CFR 84 requirements.

9 So it seems to me there may be a need for
10 application-specific certifications. And the
11 question might ought to be whether NIOSH should have
12 the authority through some sort of new subpart to
13 approve site-specific or application-specific
14 products.

15 MR. SZALAJDA: I think that's a good
16 comment, Rich. And that's -- you know, I don't know
17 if Les is ready to take on that mission yet or not,
18 but I think that is something worthy to consider.

19 MS. RICHARDSON: Hi. I'm Irene Richardson
20 with the U.S. Army Center for Health Promotion and
21 Preventive Medicine.

22 And just a general comment of how

1 important it is to us to really have a military mask
2 that is NIOSH approved.

3 Because every day we receive phone calls
4 and emails from both DoD civilians and from soldiers
5 and other military members that are deployed around
6 the world and in the United States.

7 They are involved in situations that are
8 not considered military unique. We had people
9 responding to Hurricane Katrina. We had people
10 responding to the 9/11 attacks, both the World Trade
11 Center and the Pentagon, that were in that same
12 situation where you had military showing up with a
13 military mask that was not NIOSH approved.

14 Therefore, the civilian first responder incident
15 commander was saying, Well, what we are supposed to
16 do with these people because they are not OSHA
17 compliant because they don't have a NIOSH-approved
18 respirator.

19 Likewise, a situation with some of our
20 troops that are overseas right now. They are doing
21 operations that are not military unique.

22 They are converting an old warehouse into

1 housing for troops that are over there because it's
2 better than living in a tent, and it might provide
3 some better protection in the event of some kind of
4 an attack.

5 They are dealing with, Lord knows,
6 lead-based paint, asbestos. There's old chemicals
7 that have been left behind. I mean, they are
8 painting things. They have having to respond to IED
9 attacks with chemicals that are considered toxic
10 industrial chemicals, but not chemical warfare
11 agents.

12 What do we do in this situation? How do
13 we advise them? If we had one mask that would
14 satisfy both requirements, it would be a godsend.

15 Just a comment. Thank you.

16 MR. SZALAJDA: We have four minutes left
17 in this topic area. So if anyone else would like to
18 add anything at this time, it's the right time to
19 ask your question or make your comment.

20 I think what we would like to do, first, I
21 would like to thank Mike for coming up as well as
22 his entourage.

1 I think it was important in terms of, you
2 know, developing the standards and partnership to
3 allow the partners an opportunity to speak and state
4 their positions. So thank you very much.

5 What I would like to do before I jump into
6 the wrap-up is I hope everyone received a survey.
7 So I would like you to take two minutes to go
8 through and fill out the survey. A lot of it is
9 just circle the answer.

10 We would also be really interested in
11 getting your perspective on the format of the
12 meeting. So if you can fill out the survey and pass
13 them to the center aisle. And Tess is going to walk
14 through the aisle and collect them in two minutes.

15 Okay. At least at this point, let's go
16 ahead -- I would like to go ahead and try to wrap up
17 the meeting.

18 You know, first of all, I would like to
19 thank everybody for their participation. I think it
20 was very informative for us, and I hope it was
21 informative for you as well with regard the topics
22 that we discussed today.

1 And I think it gives you a level of the
2 depth and the breadth of what we are trying to do
3 within the policy and standards development
4 organization.

5 I wanted to spend at least a minute or two
6 talking about timelines, which is a topic that I had
7 heard in discussion during the course of the day.

8 And I think what you can expect with
9 regard to our activity is that, in general, you are
10 probably going to see us take anywhere from 12 to 18
11 months to develop a concept from the point of the
12 concept initiation to the point where we think we
13 are in a position to be able to initiate the
14 rulemaking process.

15 So I think from that standpoint, we have
16 indicated that at least for the closed-circuit SCBA,
17 we see the concept phase closing out at the end of
18 this year. So you can anticipate the rulemaking
19 process will start on that around the holiday times.

20 And then at some point during 2009, you
21 will see a Federal Register notice indicating that
22 NIOSH is proceeding on a rule for that system.

1 You know, likewise, you know, we are
2 looking at having a November/December timeframe
3 meeting to discuss PAPER, which, if you have been
4 involved with the process, you know we have been
5 working on for several years, and we think we are
6 relatively close to completing that effort.

7 And, again, following that meeting, early
8 in 2009, we will close the concept development
9 portion, move that into rulemaking.

10 With SAR, this is the first time we have
11 discussed SAR in public, and I think we have got a
12 lot of good feedback with regard to the session
13 today with regard to the content of the standard,
14 where you think that we are on track with
15 identification, the requirements, as well as areas
16 where you think we can improve or modify what we
17 have identified.

18 But, again, you know, looking forward, you
19 know, 12 to 18 months from now, you are going to see
20 is SAR moving into rulemaking. And then following
21 up with air-fed suits.

22 And I hope by the time we get together in

1 during the early winter, we will be able to add
2 other items to this list to give you an indication
3 of where you think we are going with the regard to
4 the rulemaking processes for our equipment.

5 Again, for the closed-circuit docket, 39A,
6 as the docket office receives comments, they will be
7 become visible through the web.

8 You will also be able to go to the docket.
9 If they not visible on the web, you will be able to
10 go to the docket office and request copies of the
11 submittals.

12 And, again, I think the closing date for
13 the information that we discussed today as well as
14 the concept paper that's posted on the web is the
15 end of September.

16 Likewise for the work on the re-evaluation
17 of the oxygen prohibition for the use of
18 oxygen-generating devices. The open comment period
19 on that will also close at the end of September.

20 We hope to be able to get a lot of
21 feedback on this area. From the industry side, the
22 stakeholders have been very active with regard to

1 working with us and letting us know with regard to
2 the testing and, the developmental type testing that
3 has been doing at different laboratories. We really
4 like to hear from the user community.

5 And if you can encourage users that may
6 have an interest in this type of device to please,
7 you know, get in contact with us with regard to the
8 re-evaluation of this prohibition.

9 You know, with supplied air, again, the
10 docket on this closes September 30th. And, again, I
11 wanted to reiterate on this, when you go to the web
12 page -- you know, I think we will all gain
13 familiarity with it. If you scroll halfway down
14 through the description of the standard work,
15 there's a .pdf file in the middle that contains the
16 statement of standard.

17 And, again, we look forward to receiving
18 additional feedback above and beyond what we
19 received today.

20 And this noncontroversial topic regarding
21 the CBRN APR mechanical connector, I think, you
22 know, simplistically, you would think this is a

1 no-brainer to fix. Unfortunately, when you -- like
2 anything else, when you start working on something
3 and you start getting into the nuances and
4 administrative controls that are in place, the
5 answer is not always so straightforward.

6 And I think with regard to some of the
7 comments that people made today, I think there is
8 some maybe innovative avenues that we can take to
9 try to come up with a solution that meets one
10 stakeholder's needs without invalidating the needs
11 of the other stakeholders that have voiced their
12 opinion as well.

13 So we look forward to continuing to
14 receive comments on this. And I believe based on
15 what we have heard and discussions that we have, we
16 will probably revisit this in one of the next public
17 meetings to come to let you know what our plan is
18 going to be in going forward.

19 And I'm sure Mike Stevens and I will get
20 to know each other a lot better over the next
21 several months.

22 With that, I believe I'm finished.

1 Again, thank you very much for your;
2 participation. I hope it was as informative and
3 worthwhile for you guys as it was for us, and we
4 look forward to seeing you at future NIOSH events.

5 (Whereupon, the meeting was concluded at
6 4:24 p.m.)

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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.

Joseph A. Inabnet

Court Reporter