NIOSH/NPPTL Public Meeting to Discuss CBRN and Quality Assurance

June 25, 2003 - 9:00 a.m.-4:15 p.m.
Hilton Garden Inn - Canonsburg, Pennsylvania
TRANSCRIPT LEGEND

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In the following transcript "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

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In the following transcript (inaudible) signifies speaker failure, usually failure to use a microphone.
UNKNOWN SPEAKER: If everyone . . . I guess everyone is
seated so sorry for the 5-minute delay, but we had a little
technical difficulties. What we'd like to do is start the,
start the meeting and to kick it off Rich Metzler is going to
give a few opening remarks.

RICHARD METZLER: Good morning and welcome. It's a
glorious day in western Pennsylvania. For those of you who
are familiar with the area know this is about the third day of
sunshine we had this year. Again, welcome ladies and gentle-
men and partners for improving occupational safety and health.
I am very pleased to see you here today and to welcome you.

I'd like to point out that there is a very diverse group
with us this morning: representatives from the manufacturing
community, the ISEA, private laboratories who perform tests of
personal protective equipment, instrument manufacturers, uni-
versities, and in particular I'd like to thank the emergency
responder groups, the IPP, the IFC, the NABSCA, the U.S.
capitol police, HAZMAT response teams. It's important that
your participation stay at a high level so that we can imple-
ment the best of standards to protect emergency responders.

The program that's hosting this meeting today is NIOSH's
National Personal Protective Technology Lab. We had our
genesis just a couple of years ago prior to 9/11 with a
guidance and a mandate from Congress asking that we focus our
attention on state-of-the-art personal protective technologies
for all workers but with a special emphasis and encouraging us
to work on those special needs of emergency responder com-

munities to terrorist events. The programs relating to self-
contained breathing apparatus for CBRN response, full
facepiece gas masks, the escape hood program are all part of
our special emphasis program. Before I begin additional

comments on where we had been and where we are going, I have

special announcement to make today. Recently we were able to

select our permanent management team and I'd like to announce

that Les Boord who has almost 30 years experience in occupa-
tional safety and health protective technology business and
was a senior vice-president with a major manufacturer is the
Deputy Director for the National Lab. Roland Berry Ann
sitting in the back here; Roland you want to stand up and let
everyone see you; Roland is selected as the Respirator Branch
Chief. Ron Shaffer right over here in the corner joins us

from Naval Research Lab and General Electric, Ron is a Ph.D.
analytical chemist who brings an expertise on CBRN standards
or sensor technologies. He will be leading our research
program in personal protective equipment.

I see a lot of familiar faces and partners in the audi-

ence here. Many of you have been with us since the early 1999
when we were trying to eek out enough budget to hold our first
workshop jointly with DoD and OSHA in Morgantown. This was
our first real introduction into chemical warfare agents and
protection needs of emergency responders against terrorist
threats. We held that meeting in March of '99. It had
131 attendees and 15 inches of snow outside at that meeting.
There's a book in the back of the room that described for us
as a first resource, the protection needs for emergency
responders. Our early efforts were aimed at identifying the
protection needs for the responder community and building
crucial partnerships. And our laboratory, by the way, is
founded on the philosophy that quality partnerships enhance
safety and health and we do these partnerships through
bringing funds in from critical partners and also putting
funds out to critical partners to help us do our work. And
during that process, we were able to learn that the critical
first needs of the emergency responder community was self-
contained breathing apparatus and full facepiece gas masks.
Again, I remember sitting in Chicago with Chief
John Ebersol and he asked me the question will self-contained
breathing apparatus protect fire fighters from chemical
warfare agent threats. I didn't know how to answer that
question. He kind of put me on the spot. You know SCBA are
not products used by the military so that they weren't
certified and constructed to protect against chemical warfare agent threats and NIOSH had no experience in the area. A lack of response lead John to say you should not put your head on a pillow and go to sleep at night until you have an appropriate standard to protect these emergency responders. And it seemed like it’s something we might have been able to do in 3 months, but in fact it took a couple of years to develop the appropriate standards for self-contained breathing apparatus.

These standard development activities are not the only activities that we as a new lab had been participating in. We sponsored a meeting in New York City following 9/11, that was in December, where we brought in actual responders from the Pentagon, the Oklahoma City disaster, and the World Trade Center disaster and learned from the emergency responder what they’re protective technologies needs were, how well did the equipment perform at that scene, and what they’re shortcomings and gaps in technologies were.

We’re also doing a study with RAN where they’re interviewing hundreds of emergency responders in all walks of life from that community to address what they’re personal protective technology needs are. And that really does expand it to HAZMAT workers, emergency medical workers, fire fighters, police officers, the full gamete of emergency responders.

We’re also developing and will have done by the end of this
fiscal year critical PPE guidelines for emergency responder
protective technologies during structural collapses.

This is not done alone and there are many partners we
have to thank. We did have many official partnerships
established. The National Institute for Standards Technology
has worked with us all along the way and in fact they along
with the Department of Justice really did provide the early
funding to initiate our programs and they continued funding in
part our work even through today. The SBCCOM, I'd like to
think of them as blood brothers . . . we're talking about in
the way of the standards for SCBA and gas masks could not have
been done without SBCCOM. We are one. OSHA, it's participa-
tion with us in providing us with advice and council and also
assuring that the standards that we develop can in fact be
implemented and enforced in the workplace. The NFPA, as a
private sector group, brings its body of standards in use with
our own new standards to ensure that we have a full range of
adequate protection. Not listed here are all of the user
groups, the fire chiefs, the fire fighters, the police, the
IAB, many organizations who have participated in every meeting
providing us with insights of what their needs are.

Today's meeting is going to discuss two important areas.
The first is the CBRN standards for air-purifying and self-
contained escape respirators. While the press and national
television media have not been putting a great deal of focus
on respiratory protection of late with one exception 20/20 had
a program last week in the shortfalls of gas masks protection
for first responders. The heat seems to be somewhat off in
this area but in fact with the introduction of these standards
we anticipate there will be a greater awareness and a greater
interest again in the coming weeks. There's also been a major
problem associated with the fact that there are so many prod-
ucts that can be purchased from a website where there has been
no standards used for designing and developing equipment to
provide adequate performance and many, many misrepresentations
of the equipment's capabilities.

The second part of this afternoon will address the
quality assurance module. A module in our terminology means a
set of standards for improving quality assurance in this case.
This is a module that we had to set aside while we responded
to 9/11 and the CBRN standards, but several things have hap-
pened that make the timing in introducing the concepts for
these upgraded standards the right time now, that is, ISO9000
recently came out with an upgrade and we see that as a very
improved set of quality standards. The respirator branch is
the cornerstone of a new national lab and it will and does
receive adequate funding from this new laboratory. We have
new experienced quality assurance staff who were trained,
educated, and have experience in the quality assurance
business and we have experience with using qualified labs in
the sense that SBCCOM labs have been qualified to our stan-
dards and actually using their standards and ours together.
And also we have an experience using private sector quality
auditors to supplement our own staff. All these things
collectively have given us a broader perspective to redefine
the concepts in the new quality standard.

And the last you'll hear from me is just a quick summary
of what we have done in the way of the CBRN standards. The
SCBA standards were implemented in December 2001. There are
3 manufacturers who hold approval on more than 12 models.
Additional applications are in-house as we are speaking and
nearing completion. The gas mask program was implemented in
March of 2003. There are five applications currently in-
house. Four of them passed the preliminary screening test
with sarin and mustard test, the system test that's done by
SBCCOM for us and we intend to finalize the escape APR stan-
dards by this October. We're optimistic that we'll be able to
even beat that date. And we've added to our agenda, not only
the APR part of it, but the self-contained portion of the
standards were integrated into the program. Next year we will
introduce the standards for power to air-purifying respirators
with other standards such as combination respirators, air
supplied, air purifying built into single products to come in later years.

I would encourage you to continue your high level of active participation at this meeting today, to get your comments into the docket office as it would be our intent to finalize these standards within the next 60 to 90 days. It’s a target that we think we could meet and are looking forward to finalizing these standards.

And with that, I’d like to introduce the Deputy Director for the National Personal Protective Technology Lab, Les Boord.

**LES BOORD:** Thank you. Perhaps first we ought to introduce the CBRN team which I’m sure everybody’s by now familiar with because they’re seated up here at the table. The first is John Szalajda, Frank Palya, everybody knows Rich, Mike Monahan, and a new member of the team is Mike Bergman who joined us several months ago and has been actively engaged in the process. Throughout the audience, there are several others who contributed significantly to the effort: Eddie Sinkule, in the back and I’m sure there are others: Roland Berry Ann. So I think everybody is pretty well known.

On the screen we have the agenda for today. I’m not going to walk through each element of the agenda. I think everybody can pretty much do that, but as Rich mentioned, the
focus and the primary objective of the meeting today is to
cover two major topics and two major project activities that
are being conducted within the laboratory. The first one is
the escape respirator standard and secondly is the QA module.
Hopefully the sun’s shining today for the first time or for
the second time or whatever it is for this year is a good omen
because we have a lot of information to cover and a lot of
technical details. Then tomorrow is equally an active day for
manufacturers and applicants to attend a workshop on the
certification process. So we have 2 pretty active days of
activities that I think will have an impact on the laboratory
and particularly on the respirator branch. So the agenda is
as illustrated. We are pretty intense with topics today going
into the afternoon until 4 o’clock.

The major focus of the discussions today on the escape
respirator is going to focus on really five different areas.
We don’t want to go back and rehash a lot of the information
that we’ve discussed previously in the April meeting that is
in the concept paper. What we’d really like to focus on is
the areas of work since the last meeting and plus some ancil-
larly things, but those areas really come down to the five
topics. One is breathing gas control which is the CO2/O2 con-
centrations. The second we want to talk about the description
of the categories: the general, the specific, and the high.
We want to spend some time on the LRPL. We've done quite a bit of work on the LRPL and that will be a topic of discussion today. Then we want to talk a little bit about the live agent testing and what has been done in the area of live agent testing since our last meeting in April. And then finally, an area of the standard development that we spent some time on in the last . . . since the last meeting is the testing sequence so I think the sequence in which all the requirements will be evaluated, the number of respirators, and so forth. So those are the areas that we really want to discuss in detail.

Also the surveys that you have in your information packet that you received from the meeting, one of the comments that we received from the meeting in April was that a lot of the background information that we presented is kind of redundant because we talk about it at each meeting and we do have a large percentage of the attendees to attend multiple meetings. So what we're going to do is we're going to abbreviate those discussions so we can really focus on the technical content.

Another area that we're going to do a little differently this afternoon in the afternoon session is that we've taken the opportunity to prepare all the comments that we've received during the course of the meetings through the dockets and sort of itemize them, tabulate them by topic area and we'd like to walk through those so you can sort of see how we man-
age and what we are doing to manage the comments and the
information that we get from the interchange and the inter-
active part of the discussions that we do have.

And then finally to round out the day, we have the dis-
cussions on the QA module which I think is also a refreshing
step in the program. I think most of the people in the
audience are familiar with the previous activities on the QA
module which we're all very good actions and activities.
There was a lot of work done in that program and basically
we're renewing that effort and would like to get everybody up
to speed at where it is and where it is going.

Just some of the logistics before we get into the dis-
cussions, I believe that everybody has used the sign-in sheets
at the registration. So if you haven't though, make sure you
do sign in so that we have an accurate list of the attendees.
The meeting is being recorded so you should be aware of that
and it is transcribed then for the docket. One of the activi-
ties this afternoon when we talk about the comments that we've
collected on the previous meetings, that's where some of those
come from, from the previous recordings and transcription.
The presentations that we do today will follow the agenda.
The agenda is kind of broad without the specific technical
requirements, but those discussions will follow the areas that
I mentioned just a little while ago. Following each discus-
sion we will have a question and answer period. Okay, so that
you have the opportunity to ask any questions or provide com-
ment or provide input relative to the topic that's been
discussed. To do that, we would like the individual person to
go to the center of the room to the microphone and then
announce their name, their organization, who they represent,
and then to make the comment into the microphone. Then
finally we have the information relative to the docket. Okay
so we actually have two docket numbers illustrated there: one
for the escape respirator of the CBRN escape respirator and
secondly for the QA module. So I think that information is
also provided and available in your packet along with the
other contact information.

So with that, we'll move into the overview discussion for
the CBRN escape respirator and while we're not going to go
back and rehash a lot of the background, I think it's very
important that everybody understands the goal which we're
trying to achieve. So I don't think we can have a meeting
without stating what the goal for the project is and that is
basically to develop an escape-only respirator to be used for
CBRN chemical, biological, radiological, nuclear inhalation
hazards in the event or the incident of a terrorist event and
it's intended for the general working population.
The escape respirator does represent what I consider to
be a very complex problem involving hazard analysis. To
really identify escape respirators and escape respiratory
protection, there needs to be some forethought behind what the
intentions are. Okay, what you intend to use it for, where
you're escaping from what you're escaping from where. Okay,
what's you're . . . perhaps what the threat level is for the
area, where the respirator would be deployed, whether it's in
areas where high concentrations could be considered or whether
it's in a low-threat area or you may have lower concentrations
to be concerned about. All these factors I think need to be
part of an assessment to determine what type of an escape
respirator is ideal for the situation, but then there's also a
wide variation of what those hazards and threats may be. As
we well know from previous efforts in our standards develop-
ment and in our APR. We have, our gas mask APR, we have the
hazards of chemical warfare environment. We have biological
hazards. We have toxic industrial material hazards. So we
have a wide variety of hazards that can be the threat and I
think also that the . . . an awareness is to the hazards that
are applicable to the particular area need to be a
consideration.

In addition to all that, we have multiple escape activi-
ties that can be taking place. So when we look at escape from
terrorism events, it is indeed a complex problem. We have a wide variety of hazards. Threat analysis can be site specific. As we said before, the hazards and the threats for one metropolitan area may be significantly different than they are from another depending on the industrial activities in an area or just the general proximity to perhaps military installations and so forth. So hazard/threat analysis can be site specific.

Escape strategies also can vary. Escape strategies are exit immediately or progress to designated areas. These factors, these threats, and the escape strategies they do have an impact on what the respirator is expected to be able to do. And as such, I think by virtue of that fact they have an impact on the standard that we ultimately develop for an escape respirator because if we have an escape scenario that has specific requirements. I think our standard that we ultimately end up with needs to be capable of being able to certify that, that respirator. For this reason, we segment the strategy for escape respirators into three categories which most of you're familiar with: the high category, the specific category, and we've renamed the bottom category there. I should have done these or mentioned these in reverse order, but the bottom category we're calling it a general category. When you look at the rough classifications of those
categories, we will start at the bottom here. With the general category, we’re talking about multi-hazard protections with chemical warfare agent capability. We move up to the specific. We’re now talking about that same general category with multi-hazard protection, CWA capability but then the ability to perhaps look at a specific threat from our list of 10 test agents. So it’s sort of the blanket from the general applied to the specific with the opportunity to focus on concentration on specific hazards. And then obviously the high category for oxygen-deficient environments or where you truly have a unknown situation. If you take those categories and then sort of designate them into the hazard description and respirator performance, then I think everybody’s familiar with this tabulation if you’ve followed the concept development for the escape respirator. But basically in going from the bottom up again in the general category, we’re looking at an air-purifying type of an escape respirator. The same for the specific category and the finally in that high category where we have the oxygen deficiency potential that’s where we really are looking for self-contained. And that’s the reason for expanding the scope of the escape respirator concept to include both the air-purifying type respirators as well as the self-contained.
Which gets us to the concept paper, again, most of you are familiar with the concept paper and the process that we've been using to develop the standard which basically is the concept paper. We first introduced the escape respirator concept paper last August where we identified the framework for the standard, a little bit about the categories and the general ideas of what types of requirements should be included. That has evolved through several iterations to the point where we have the June 15th edition of the concept paper which is going to form the basis for the meeting today. That concept paper is organized into two parts. The first part obviously addresses the air-purifying escape respirators and the second is the self-contained escape respirators.

And rather than walk through the requirements in each of those sections or each of those parts of the standard, I'll just enumerate what the sections are and as the discussions progress today, we will focus a little deeper into some of these areas. But basically for part 1, we have the statement of the goal which we reviewed today. We have the description of the hazards categories. We have or section 3 addresses the respirator use, escape only. Section 4 addresses the gas-life testing, the 10 test representative agents, how they are applied to the general and the specific categories. Section 5 addresses the environmental conditioning, the environmental
extremes that the respirator is going to be exposed to.
Section 6 identifies performance requirements and here we’re
looking at like field of view and fogging and general
performance areas. Section 7 addresses design requirements
which for the escape respirator are not that extensive.
Basically, it’s a hood-type escape respirator and I think
that’s a good sign that the design-specific requirements are
not very extensive which means that the standard and the
evolution of the standard is very much oriented towards a
performance requirement. Finally, not finally, but section 8
addresses the applicable sections of 42CFR specifies the
appropriate sections there. Section 9 is service and main-
tenance. Section 10 is training. These areas require, as you
review the June 15th document, need to be some work done in
these areas, some additional effort spent and focusing on
those requirements, and finally, cautions, limitations, and
quality assurance requirements. So that’s the layout for
part 1 - air purifying.

The part 2 of the concept paper addresses the self-
contained escape respirator and there we have basically five
sections. The first section is a general description of the
standard and the description of it. Section 2 identifies the
requirements and what we do here is we identify a three-tier
requirement for the self-contained unit and those three tiers
are covered by Sections 3, 4, and 5 which basically are the first requirement is that it have a normal 42CFR approval as an escape self-contained escape respirator. The second tier of the requirement is section 4 which is what we’re calling the enhanced escape respirator requirements. These are the, this is the area of the concept where we introduce the environmental conditioning requirements for fogging, for field of view, and requirements that are enhanced beyond the normal requirements of 42CFR you have very applicable to escape respirators and escape respirators for CBRN requirements. And then finally section 5 is where we identify what the specific CBRN requirements are and those really come down to two primary requirements. The first one being the laboratory respirator protection level testing which will be a focus of the discussions today and then the chemical warfare live agent testing requirements for the escape respirator are also covered in section 5. And the content of each of these sections is identified in the June 15th edition of the concept paper and will be the topics of discussion today. And with that, I’ll turn it over to Mr. Szalajda.

JONATHAN SZALAJDA: Good morning. As Les has mentioned, we’re going to cover a couple things in little less detail and other areas, but we felt that there had been a few changes in regard to the gas-life test requirements and we wanted to make
sure that you were aware of those changes as well as the
things that we've been consistent with the chemical warfare
agent testing for the air-purifying respirators. Just a
little bit of background, I think a lot of people have seen
this chart in other forms before, but basically we performed a
comprehensive review of various toxic industrial material data
list as part of the standards development program and con-
sulted with several different Government agencies in an effort
to try to identify potential materials that could be iden-
tified as respirable hazards to individuals and then identify
protection necessary for providing respiratory protection.
But as going through this review, we established, the emphasis
was to establish a list of toxic industrial materials and
chemical warfare agents that proposed or that presented a
respirable hazard to the individual and along with that we
came up with a list of . . . it varies from time to time but
it . . . we came up with a list of 170 potential respirable
hazards that would need to be addressed as part of providing
protection for the user. In an effort to try to reduce the
number of tests that are needed for certification, we took a
look at the different materials and categorized them into
agent families with the intent of identifying a test
representative agent to be conducted as part of the certifica-
tion test for each of the identified families and the way that
we broke the classification down was to work through identifying the absorbents required to remove the hazard from the breathing zone of the respirator wearer.

Where we ultimately ended up and initially this was promoted as part of the gas mask standard, but the protections that we are providing or providing the gas mask standard as well as in the air-purifying escape respirator will protect against 139 potential respirable hazards. We ultimately ended up using vapor pressure as the single best indicator of the ability to bond the challenge agent against the carbon used in the filter. I think of note here and as far as the particulate family list includes a list of biological agents as well as radiological and nuclear agents that we've published in other forms. The complete list, the complete list of all these chemicals are available and on our website. If you go back to the initial June 2002 meeting, the list of chemicals is available on that site.

In terms of the actual gas-life testing requirements, there are a couple of factors that applicants should be aware of. One is the identifying the test duration for the equipment and the application that we've identified rating intervals or duration intervals in 15-minute increments and this will be specified by the applicant, the manufacturer, and we will conduct the tests in accordance with the breakthrough
or at the test challenges and the breakthroughs that we've identified to determine the capability of the item to meet that requirement. In terms of the actual test itself, we'll be conducting two tests: one at a lower humidity and one at a higher humidity at relatively room temperature with a 64-liter per minute flow rate and this is consistent with NIOSH's has historically done with the industrial respirator testing program. And also as a result of information that we've received to the docket, there appears to be a need or a concern over the capacity of these systems or any respirator system at a higher flow rate so we've included a panic demand requirement as part of the gas-life testing where we will expect the respirator to provide a minimum service life of 5 minutes when we test at a 100 liters per minute.

In defining the test challenges for the respirator that we ultimately ended up with a multiples of at least three times the ideal H (phonetically) in determining the test challenges. The breakthroughs that you see in the second column are either set at one-half the permissible exposure limit or at the American Industrial Hygiene Association's Emergency Response Planning Guidelines and what these guidelines are are the maximum concentration and air that individuals can be exposed to for up to 1 hour without experiencing or developing irreversible health effects. Really the
intent in trying to set these, the challenge and breakthrough up was to maintain a balance, a proper balance of requirements for the filter to ensure that we can cover a broad range of potential respirable hazards but yet still provide the adequate protection to the user to the worker to be able to exit from the site of an emergency where he would have to wear one of these devices. As Les had mentioned, I think the area which is new from the last time we were together in April was with regard to identifying specific requirements in response to some of the information and comments that we received through the docket and also from stakeholders that we felt it was important to delineate the requirements for the specific category that there was a need to provide some structure to identifying the test challenge requirements for the system where we ultimately ended up is that we took a look at air purifying, the gas mask standard and the test challenges for the air-purifying escape respirator are based on the require-ments on the gas mask standard. The only difference is in the breakthrough values that were set and the breakthroughs are consistent with what we set up in a specific category and the one point I did want to try and make clear in determining the specific category is that we felt based on the feedback we received and the discussions that we've had internally with the project team, we need to provide the general protection,
the across-the-board protection to the worker to the wearer of
the respirator in addressing all of the CBRN hazards that were
identified as part of the program and where we feel it's
advantageous with the specific category is that it gives the
leeway for the manufacturer for the applicant to go ahead and
identify certain chemicals that they may want to enhance to
provide additional protections whether it be ammonia or
formaldehyde or cyclohexane or a combination of where we can
enhance or manufacturer can enhance those certain test
representative agents to provide an additional capability and
that can be tailored towards a specific user community or a
specific user need.

We covered the benchmark testing. A lot of the benchmark
testing that we conducted in the April meeting and in summary
at least with the testing that was conducted, the benchmarking
of existing products performed fairly well. In terms of where
we saw shortfalls were in the areas of ammonia and nitrogen
dioxide and in part of addressing the ammonia concern we
looked at the, in setting up the original test matrix for the
benchmark testing, we used the initial concepts that we had
promoted for the test challenges and the test breakthroughs
which were more restrictive or more intense than what we
currently have specified. There may be some better per-
formance in with the commercially available products, but we
haven’t re-evaluated them at the existing breakthrough concentrations. With the nitrogen dioxide, we were originally sampling for NO and NO2 as is done with the gas mask standard, but we consulted with toxicologists within NIOSH to try and make a determination whether or not the amount of NO that would come through the filter media would present a hazard to the wearer then we were able to make a determination that the amount of NO that would come through the filter during the timeframe that the device would be worn would not be presenting a respirable hazard so we were only sampling for NO2 in that test and that may make a difference in the ultimate results. And again, this information, we do not have the charts for the April meeting up on the website yet. We’ll probably have them up at the same time that we get the charts up for today’s presentations on the site and the benchmark data will be available through the website.

To move to another topic in brief, we discussed the chemical warfare agent testing requirements at the April meeting for the air-purifying escape respirator. Those requirements have not changed. These are consistent with what was previously presented as well as what’s currently being done for the gas mask standard. And likewise this is still a requirement for the sulfur mustard test. And with that, I’ll
open up if there are any questions specific to the gas-life
requirements for the chemical warfare agent requirements.

WILLIAM NEWCOMB: Bill Newcomb, North Safety Products, is
it the intention that these escape respirators could be
approved for specifics at a different time than general, for
instance, a 15-minute general, a 30-minute specific or vice
versa?

JONATHAN SZALAJDA: I think . . . I'm not sure I under-
stand your question. All the general requirements have to be
met for the, that the manufacturer specific either 15, 30, or
whatever identified rating period and that’s what will test
to. If you wanted to provide an enhanced capacity for the
general respirator, we would expect you to submit . . . if you
pick ammonia, you want to provide enhanced ammonia protection
that we would test at those specified concentrations for the
manufacturers, the applicants identified duration.

WILLIAM NEWCOMB: The question really . . . if you look
at the concentrations the contaminants, if you had a 30-minute
general, you would probably have a 15-minute specific on each
of the specifics.

JONATHAN SZALAJDA: Okay now I think I understand your
question now. We would probably have to evaluate that in
terms of the actual requirement if you wanted to specify that
you wanted to a joint approval as a general and a specific
application and then we would need to do the gas-life testing
for the specific requirement.

WILLIAM NEWCOMB: I just think it would be confusing to
the users.

JONATHAN SZALAJDA: Okay, that’s a good point.

UNKNOWN: If I understand your question, you’re talking
about the duration of use versus the general category and the
specific category so you may want to increase a specific
category but you’re saying would that change the timeframe if
you had enough capability in the cartridge to say 30 minutes
for a specific application and 15 minutes for a general. I
also think it would be very confusing to have different
timeframes on the cartridge and we will have a discussion
about it and invite your comments for the docket, but it does
seem like as though each application should be for a stan-
dardized timeframe. Users are not going to be standing around
thinking how long they have protection for one agent versus
the next one. They won’t know it’s there, but we would like
your comments for the docket and we will debate that in house.

Thanks.

MIKE KAY: Good morning. Mike Kay, Ocenco Incorporated.

42CFR allows for multiple durations below 15 minutes above
60 minutes. Why break these down into 15-minute increments?

What’s the rationale for that?
JONATHAN SZALAJDA: Part of our evaluation, we looked at that comment earlier. We really didn’t see that for this type of device not really knowing where the escape respirator could be used for a larger building, a multi-story building in a large complex in terms of the person escaping from a potential event having a specific time requirement to get from one spot to another. We didn’t really see it being advantageous to have a 3-, 5-, 8-minute interval for the (inaudible) capacity of the respirator and given the potential... one of the potential applications for use and not knowing exactly where the systems were going to be or going to be used or be placed that having that extra capacity we felt was important.

MIKE KAY: Well if it’s a CBRN event or a non-CBRN event, the user doesn’t know that they would purchase an apparatus of any duration. Again, why would a CBRN event require a 15-minute escape when a non-CBRN event may... you could have a 10-minute, 5-minute, you could have a greater than 60-minute respirator. You seem to draw a distinction between a CBRN and a non-CBRN event.

JONATHAN SZALAJDA: These respirators are designed in response to an event of terrorism. Now the intent is to provide protection for the workers in a terrorism event where a CBRN which could be a tech/bio/rad/nuke type of device could be used. I think if you were looking at taking the device and
having it approved for another application, an industrial-type
application, our existing NIOSH requirements in place to take
those devices for specific hazards and provide protection in
relation to where an event has been categorized but we’re
dealing in developing of the CBRN standard. We’re dealing
with unknown, uncontrolled, unquantified types of events where
we’re trying to develop a and provide a balance of capacity in
what the respirator can provide.

LARS RONNER: Lars Ronner from Sundstrom Safety, why is
not any requirement for carbon monoxide for specific category?

JONATHAN SZALAJDA: Oh thank you, that is a good point.

We, um, it didn’t, it wasn’t captured on the chart. There
will be a requirement for carbon monoxide identified. I think
it’s identified in the concept paper, but that will be an
option for the manufacturer to do to submit a piece of
equipment that provides carbon monoxide protection. That will
be included as part of the specific category.

BODO HEINS: Bodo Heins from Draeger, in your intro-
duction you showed that for the high category it has to be in
a self-contained breathing apparatus and for specific and
general air-purifying, what’s that mean that we cannot get
approved and unit oxygen supply for specific?

JONATHAN SZALAJDA: Well for the self-contained unit
which we’ll be addressing in greater detail this afternoon,
you know you’re dealing with a supplied area, some sort of oxygen source type system. There are no gas-life requirements associated with that. There’s no filter with those types of systems. What we’re looking at in terms of the higher concentrations are dealing and identifying the requirements are dealing with the potential of credible events that we identified as part of the SCBA program as with the initial modeling that we did in conjunction with the Army and identifying the tests that would be required for the system to resist the chemical warfare agent penetration and permeation and provide adequate protection for a person in a high concentration type environment.

WILLIAM NEWCOMB: Bill Newcomb, North Safety Products, when we’re talking about carbon monoxide as an option, carbon monoxide is usually associated with a product combustion. Yet the flammability requirements are not optional. Well I don’t think that an escape respirator should be made out of a flammable material. I’m wondering if the requirement that’s in there for flammability is a little stringent for the application. Not talking about is something that’s specifically designed for escape from a fire.

JONATHAN SZALAJDA: Thank you for bringing that point up too with the carbon monoxide requirement there’d also be a requirement if you choose to provide protection for carbon
monoxide, there's also a flammability requirement associated with that and for the flammability requirement we are using an existing EN standard. I believe it's EN136 to conduct that test. If there are alternate types of tests that we feel we should consider, we would welcome you know to bring those to our attention.

KAREN NELSON: Karen Nelson, Safety Matters Agent for the Phoenix Protective Hood, I wanted one question. Should the concept for the CBRN escape respirator standard contain any suggestions regarding weight and dimensions of this escape hood. Also, the 3,500 ppm carbon monoxide requirement, I'm, why did they find concentrations so high in something that could be like a 15-minute escape respirator. It takes, I mean that's, it just seems high to me. I've been in a lot of test chambers. It took us a long time to get it up to 1,200 ppm in a small room contained when we were monitoring it so I can't imagine if you were leaving an area where there was a carbon monoxide, a fire say that you would encounter concentrations that high.

JONATHAN SZALAJDA: Okay, thank you. I guess like with all the other requirements, we try to base the carbon monoxide challenge and the breakthroughs based on either a multiple of the ideal H (phonetically) or the permissible exposure level for the breakthrough or the Industrial Hygiene Association's
Emergency Response Planning Guidelines and we've tried to use those numbers consistently throughout the identification of the requirements for the testing and if we feel there are other values that are appropriate, we welcome your comments on that as well. I missed your first question.

**KAREN NELSON:** Regarding suggestions regarding size and dimension. I'm assuming that an escape respirator even though, of course you want CBRN capabilities that this would be something that we can use in a much more likely event that any civilian anywhere in the country would encounter a fire, an ammonia spill, or industrial accident.

**JONATHAN SZALAJDA:** Oh, okay I guess just for the docket in case anybody missed it. The comment is related to the size and weight of the units and it has been one of the considerations that we've been in considering or one of the topics that we've been considering as part of the evaluation of the standard and you know while we feel we're getting closer to having the goal, we haven't fully sat down and discussed size and weight considerations and we'll make a determination between now and the next release of the concept paper with that requirement.

**WILLIAM NEWCOMB:** Bill Newcomb again, I was looking at the June 15th draft where it indicates all specific and general hoods would be subjected to the flammability test whereas the
previous draft limited to those with carbon monoxide. So I'm a little confused with your answer to me.

**JONATHAN SZALAJDA:** Okay, the intent is if you have the carbon monoxide requirement, then we would do the flammability test for the air-purifying respirator.

**WILLIAM NEWCOMB:** Thank you. One of the, there is an EN standard for hoods, flammability as well that I wanted to point out. I'd also like to address the last commenter that the weight and size are market driven. If the product fits the panel that NIOSH is requiring it to fit, then it should let the market drive things like weight. Those are design constraints and not performance requirements. Thank you.

**JONATHAN SZALAJDA:** Okay Rich?

**RICHARD METZLER:** Rich Metzler, NIOSH, I do want to respond to the size issue. Size is more important and some of it does need to be in the form of the standard and you did mention testing or passing the fit test. In our benchmark testing, we found that some of the respirators that we tested and we tested only three of what we thought were the best among those on the market from three reputable companies and what we found out was size does matter. Some of the neck dams do choke individuals. Some of the size of the hoods do not allow for the internal nose cup to properly be seated on a face. Size matters and it will end up in our standard.
JAY PARKER: Jay Parker with the Bullard Company just to amplify what Bill was saying. I also think we should use the EN standard for hoods for flammability which I did mention back in the April meeting. It's EN 270. Also on the service life testing, you know that can be affected by breathing back through the filter or cartridge. Is there a requirement to have inhalation and exhalation valves on these units because some of them may have integral type?

JONATHAN SZALAJDA: Yeah, there's a breathing resistance requirement in the concept paper for both inhalation and exhalation.

JAY PARKER: But that doesn't mean . . .

JONATHAN SZALAJDA: That doesn't require a valve, right

JAY PARKER: So there could be a unit that doesn't have exhalation or inhalation valve?

JONATHAN SZALAJDA: Right. Having a valve isn't required.

JAY PARKER: Thank you.

LARS RONNER: Lars Ronner, Sundstrom Safety, again.

Talking about the flammability tests, the European standard 136 contains two flammability tests. One test with a single burner with at 800 °C; six-burner test at 950 °C. The only reason for the six-burner test is that the fact the full-face mask are used together with an SCBA breathing apparatus.
Could you explain the reason to have a six-burner at 800 °C which do not exist in the European standards?

JONATHAN SZALAJDA: Yeah, I guess the one thing that I don’t know if it came out in the concept paper, we were looking at doing a single-burner test not a six-burner.

LARS RONNER: You’re talking about a single burner?

JONATHAN SZALAJDA: Yes.

LARS RONNER: Thanks.

JONATHAN SZALAJDA: I’m glad I got the ball rolling this morning.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA, (inaudible) sizes, couldn’t sizes be dealt with through the test panel so it doesn’t have to be sizes saying it has to be this size or this size? It is spread over a test panel which means you take away the size restrictions.

LES BOORD: If I could, I think the issue on sizing and so forth perhaps gets into our next discussion. So maybe we could sort of defer that a little bit.

UNKNOWN SPEAKER: I want to make a comment on the inhalation and exhalation valve. While the concept paper itself doesn’t specify the need for either of the two valves, it is very much performance driven which will become obvious when we start talking about the breathing gas control. Okay,
I mean it is, the factors are breathing gas control and then obviously resistance.

BODO HEINS: Bodo Heins from Draeger, when I read the new draft and came to the part 2, I got the impression that the hood connector for the respirators only required for the height category. Is it right or I guess a hood required for the whole escape?

JONATHAN SZALAJDA: Yeah, there's a hood required for each class of respirator, but the air-purifying is self contained.

LES BOORD: The next area that we want to talk about is the LRPL, laboratory respiratory protection level, requirement and Mike Bergman is going to present to you some of the details of the work that has been done in this area since our last meeting in April, but before we get into those details, I'd like to just go over a few things relative to the requirement. In my estimation and I think I probably mentioned this at the April meeting. I think that the LRPL is probably the most difficult part of the escape respirator standard and the reason is that we're talking about defining and applying anthropometrics data from anthropometrics that really has not been brought together in a requirement criteria previously. So we're looking about identifying the anthropometrics that are critical and of important to ensuring that you have a hood
that is properly fits, properly fits the test subject. So we’re talking about the parameters, the anthropometric parameters of certainly head size, neck size, circumference of the neck, but in addition we find a lot of variation in the escape respirators. Some of them have inner masks, so the inner mask needs to be considered which means you need to somehow factor in the face length and face width which we’re all familiar with from our previous work with the Los Alamos panel and full facepiece respirator fit testing, but the difficulty is that on a hood, you have all these things at one time. You can have an inner mask, so face length/face width are important, but you have a hood so that the neck circumference is important, but by the same token, the hood needs to go over the head. So you have this inner play of all these different variables and dimensions that come into the equation here for trying to determine how we can properly evaluate hoods and sizes of hoods. So I think it’s very complex. Some of the information that you’re going to see today will sort of identify to you the logic and the thought process that we’ve applied to come to the concept that’s identified in the June 15th addition of the panel. One of the key things that we found in our testing in our breathing gas testing, the two kind of merge here, okay is as Rich mentioned, we found a lot of human interface issues, let’s say, associated with using
hood-type escape respirators and those issues those human
interface issues are indeed and can be and appear to be size
dependent. So we have the aspects of tightness on the neck,
fitting over the head, fitting a nose cup to the facepiece,
and how that's done effectively. Our directions and our
concepts are in the June 15th concept paper where we identify a
test panel. The test panel does I think for the first time
actually try to take, it does take a step to identify criteria
for small, medium, and large and also a tool or mechanism for
relating the parameters (face length, face width to neck
circumference) and how we are proposing to approach that and
evaluating hoods. So with that, I'd like Mike to come to the
microphone and Mike's going to walk through some of the
analysis that he's done that's been used to construct the
concept the way it's identified in the June 15th paper.

MIKE BERGMAN: Thank you and I'd like to start out by
thanking our partners at SBCCOM for their help and their
consultation on this concept and also like to thank the panel
members here and others in NIOSH who have helped with this
concept.

The purpose of the LRPL is to establish a bench-mark for
performance in the laboratory for protection. It's not
intended as an indication of protection for an actual escape
scenario. The challenge we're up against here is that the
data on actually fitting hoods and response to anthropometric
data is limited and again we're trying to bring together
all of these anthropometric parameters (head circumference,
neck circumference, face length and width). We still require
a review of the data on the distribution of population in
response with these parameters. The (inaudible) the challenge
aerosol criteria remains the same. It's a 20 to 40 milligram
per cubic meter corn oil aerosol challenge with a .4 to
.6 micrometer mesh median aerodynamic diameter. We believe
that the option for multiple hood sizes is important for the
user to select the best fitting hood and we've seen that the
problems with the human interface if the neck seal is too
tight, it's uncomfortable. Also the inability to fit the head
through the neck seal and we want to ensure that if the unit
has an inner nose cup that it fits properly and also if
there's an interior head harness, it's important that it fits
correctly to ensure that there's a proper fitting of a nose
cup or interface cup seal. And the one-size-fits-all option
is also available.

The anthropometric parameters that are considered in this
concept are the neck circumference, head circumference, face
length and as an addition now the face width. There are two
LRPL values: the breathing zone LRPL which will remain at
2,000 and now the addition of the under-the-hood LRPL which is
simple location under the hood but outside of the breathing
zone and I'll get to the rationale for that. We believe that
the 2,000 LRPL and the breathing zone is consistent with the
current hood technology and I have some data from SBCCOM that
will show that it's possible.

What you see here is a chart of six hoods labeled A
through F. This is LRPL testing from SBCCOM. What's impor-
tant here is the past percent at 2,000 which is a cell in the
first row. That indicates the percentage of trials for each
hood that is at least 2,000. It could be 2,000 or greater.
What you see here from these 6 hoods there is only 1 that had
a past percent of 2,000 that is greater than 95% although
there are 4 hoods that are in the low 80s and approaching 95%
so we see that it is possible.

The rationale for the under-the-hood LRPL is we want to
protect users from an impairment of the vision due to expo-
sure. It is based on a percutaneous ECT50, an effective dose
for GB and with that effective dose it is possible to have a
slight reduction in vision, eye injury, and the pupils react-
ing weakly to light.

Further discussion on that, it is based on the percuta-
neous limits for GB. The LCT50 of 10,000 which is the median
lethal dosage and the ECT50 of 1,200 CT which where a user
could experience mild visual effects and so we come up with a
15 by dividing the outside CT of 10,000 which is the challenge CT by 1,200 CT and we arrive at approximately 15. We multiply that by a safety factor and arrive at 150. The rationale for the size ranges come from a published study in the Department of Defense Military Handbook. The author is Gordon and it is a 1988 Anthropometric Survey of U.S. Army Personnel. The ranges from that set of data covered the 5th percentile through the 95th percentiles for both men and women. That is for head circumference and neck circumference. For size in the face length and width, that's adopted from the Los Alamos panel which is also the criteria that we have for the CBRN, SCBA, and air-purifying standards that are currently passed.

This is from the Gordon study of military personnel and what I have here is a chart with the 5th, 50th, and 95th percentiles for men and women with their neck circumference and head circumference. This is a graph of the percentiles of neck circumference and what we see here is an overlap of the ranges for the medium size hood of neck circumference range for the women and the men. For the head circumference, we are currently only looking at the large head size which is from the 50th through the 95th percentile of men which also covers the top of the population for the women. This is the subject matrix that we have arrived at the columns, small, medium, and large. If, for example, it's a three-size model, the small
size would have to meet all the criteria for the small column, the medium size for the medium column, and the large for the large column. If it's a one-size-fits-all model, it would have to meet separately the criteria for the small and the medium and the large. For selecting the panel, it's possible that, for example, cell A for the small that is face length and face width, if you select subjects for that cell and those subjects also meet the criteria for the neck circumference for the small cell C, you can use those subjects simultaneously tested for the criteria of that cell. And again, for the head circumference, currently we're not looking at the criteria for the small and the medium sizes. There's a change in this slide from what's printed in the handout of the concept and that is in cell H, the large circumference, the change is now 568 millimeters. It was 569 and the reason for changing that is to include from the 50th percentile man head circumference at 568.

Here's an example of the requirements for simultaneously including subjects. If it's a large hood, for example, and there are no overlapping parameters for those subjects, you would have a total for the large size 31 subjects. That's 11 subjects from the face length and width cell, 10 from the head circumference cell, and another 10 from the neck circumference cell. If you select your 11 subjects for the
face length and width cell and if 10 of those subjects also
meet their requirements for head circumference, they can be
tested simultaneously with those same subjects, but if they do
not meet the requirements for cell I for neck circumference,
you would have to recruit 10 more subjects for that cell.

And we now have a slide here. It's a chart of the mini-
mum and maximum subject requirements, subjects required for
testing. If it's a, for example, three-size unit (small,
medium, or large), then you would have to find subjects for
those cells. If it's a one-size-fits-all unit, then you'd
have a minimum and maximum subject number as well. That's all
and we will welcome your comments and questions.

WILLIAM NEWCOMB: Bill Newcomb, North Safety, how does
NIOSH intend to address the subjective things like the fact
that the neck seal is choking someone?

LES BOORD: Good question, what we intend to do is
introduce a practical performance requirement that will be
part of the evaluation of the respirators and the issues that
we'll talk about a little bit later that became significantly
important in our testing will be used to evaluate and estab-
lish those practical performance evaluations.

WILLIAM NEWCOMB: Thank you.
GÖRAN BERNDTSSON: Göran Berndtsson from SEA, did I understand you right? We’re talking about three sizes only?

LES BOORD: We have the ability with the anthropometric panel that we’ve identified. We segmented it into three sizes, correct.

GÖRAN BERNDTSSON: We, as you know, we’re working a lot on this particular part in the eye system*, but then, of course, you have the same problem in the United States as we have in the world. We will have a big mixture of Asian and other types of ethnic groups and they could have big heads and small noses so big heads and small faces and this is a . . . I would assume that you would like to have three sizes on the hood and the neck. That where you have three sizes on the inner masks so you can go up to six and nine sizes.

LES BOORD: Well there are three . . . You have that capability within the panel that we’ve identified because you do have the face width and face length considered but then you also have the uniquely or you have the neck diameter as well as the head circumference to consider into the equation as well. The problem and the problem that we see is that we’re talking in some cases it’s like apples and oranges. You don’t know the relationship between this and this so our approach is that you do see and you do expect that there will be overlap
between those, but we don’t expect it 100% of the time. And in those cases, then you need . . . according to the concept that we’ve identified, you need to uniquely look at those parameters that don’t overlap.

GÖRAN BERNDTSSON: Just for your information, we got hold of a publication that was done by the U.K. government who has actually a very comprehensive face sizes, neck sizes, head sizes on the very broad population taken out from the number of surveys around the world. May be we should have a look at that.

LES BOORD: Yes, we would certainly be interested in looking at that anthropometric data. Thank you.

RICH STEIN: Rich Stein from QPS, I have a question about the protection factor of 2,000. For example, you showed that six hoods had been tested and that one barely made the 95th percentile level. Has anyone done any testing on repeat of those hoods because there was wide variation and person-to-person protection factor testing? One of the things that I’m concerned about at 2,000 is that’s about as high a number as I’ve ever seen on any product anywhere. The military which has five sizes and a very limited sized population has a 1,667 and one of the things from a practical matter is that you could pass the test today. Let’s say you had 20 subjects and you tested that same 20 subjects 6 months later on a QA audit
and one of them fails which is not unusual because they can
either pass or fail it at 2,000 on any given day and now
you’ve got units in the field and what do you do about that?

LES BOORD: So, well . . .

RICH STEIN: Let me just continue, Les, a second. One of
the things that you showed here is why you’ve had a PF
requirement of 150 in the hood and you showed you wanted a
certain margin of safety what at 10,000 CT, etc. Have you got
a slide equivalent to that showing where you found and what
was the rationale for the 2,000?

LES BOORD: First of all the 2,000 is the same level of
protection that we’ve identified or the same level of per-
formance that we’ve identified in the full facepiece gas mask
analysis and that analysis does have a rationale that produces
the 2,000 number, okay, and it’s based on a number of dif-
ferent variables and I can get that information for you, but
secondly, I wanted to comment on the data that was illustrated
relative to the testing that’s been performed and the level of
protection the 2,000 performance level for the ABC whatever it
was, 6 different respirators. The thing that you need to keep
in mind there is that those respirators were not necessarily
designed, at least not to my knowledge, designed against a
specific-size criteria. What we’ve done in our concept is
defined requirements for what those size criteria would be.
The fact that one indicated a greater than 2,000, 95.7, I think, greater than 2,000 was a design that was covering the range, okay. I think when you focus on size, if your seal is indeed achieved by the neck dam. I think when you focus on size, the design capability is there to achieve the numbers.

MARY TOWNSEND: I'm Mary Townsend. I'm adjunct at the University of Pittsburgh and I have a comment related to this man's comment about the general population and that is did you inquire whether the National Center for Health Statistics in Haines, the National Health and Nutrition Examination Survey that was conducted across the entire U.S. population, sampled heavily Caucasian, Hispanic, African-American, did they do this kind? They measured lots of things. I know lung function I'm especially familiar with, but did they measure head size and things like that. It was just in the late, early nineties I think.

LES BOORD: To answer your question, I cannot answer it specifically relative to the cite of reference that you made, but I can answer in general that we did research potential sources for the anthropometric data because we were very keen on trying to find what the variables were and really what we wanted to try to do was connect them. We wanted to try to find out perhaps what those relationships were and we have been unable to do that to our satisfaction at this point.
MARY TOWNSEND: I'll check and see whether any . . .

LES BOORD: That would be great.

MARY TOWNSEND: I forgot about that too.

LES BOORD: And anybody, we would certainly welcome any anthropometric information that is available to make that known to us. Any other questions?

So you can see my opening remarks. They say that the LRPL is I think one of the most difficult and challenging aspects of the escape respirator standard because, just because of these variables and the lack of scientific information, technical information, connecting and establishing those relationships. We have done, as you've seen, quite a bit of work to analyze existing data and try to form it into an approach to define a requirement. We are obviously breaking new ground in defining the panel and in defining the way the panel will be applied to testing a performance requirement.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA again, last question, are you going to adjust the sizes in the heads of smart man to accommodate these different neck sizes and so forth.

LES BOORD: Good question, but the smart man, you need to keep in mind that the smart man testing requirement is focused on a different performance. When we do the smart man testing,
we're not looking at the seal of the respirator or the inner face between the respirator and the mannequin. We're looking at the performance of the respirator and the functioning of the materials in that chemical warfare environment.

GÖRAN BERNDTSSON: That's true, but it's relied on the inner mask sealing on the face. If you have a bit of leakage on the inner mask on the smart man, you will create a negative pressure inside the hood and if you don't have a good tight seal around your neck, you will have leakage into the hood then. That's not because it doesn't work too well, yes, but it always doesn't work on the smart man.

LES BOORD: And that is as well a good comment, but the smart . . . and to perhaps take it another step, I think the smart man is available in multiple sizes. There are small, medium, and large smart man for that type of situation. That I need to defer to our SBCCOM partners including the net.

Yes.

UNKNOWN ZONG: This is (inaudible) Zong from NIOSH also. I just want to let everyone here know that our project is going well. We have measure almost like 4,000 worker rates so far by (inaudible) height and weight and lately we also had another dimension to measure the neck size. Also as soon as I let them know that, we need to consider that dimension, but we do have the head circumferences and the other things that I
mentioned so our data correction is expected to finish by the
end of the month and then we'll look at the data, analyze the
data so by that time if we see, yes, a significant differences
we'll revise the panel and we'll incorporate that into the new
standard.

LES BOORD: Thank you Dr. (inaudible). I forgot to
mention that we have been working with Dr. Z in establishing
the parameters that we talked about today. Just one other
thing I would like to, two things that I would like to cover.
One I'd like to backtrack a little bit, back to the comment of
size and practical performance. I think you can see the
direction that we're going. Okay, we do see that the sizing
of the respirator and the human interface is an important
criteria and we need to be able to address that, but secondly
I would like to talk about the size and weight in terms of
perhaps the package and the envelope and that's where I think
that . . . So I think that we have two different topics on
size and weight and I think the size and weight can't fall
into the design requirement as opposed to a performance
requirement, okay, of the package and I think in my opening
remarks as I mentioned, the design requirements that we have
identified thus far are kind of minor or kind of minimal not
minor but minimal and I think that's probably good because
that indicates we're achieving the performance that we want or
the operation we want through performance requirements. With
that, we’re going to . . . we’re running a little bit behind,
but we’re going to take a 15-minute break.
Okay, if we’re ready to resume . . . Continuing on with
the requirements and the areas of the requirements that we’ve
looked at since the April meeting gets us to the topic of
breathing gas control and to start this discussion what I’d
like to say is that the definition that’s in the June 15th
concept paper is actually a little confusing because it’s the
blend of two previous, two previous contests and it wasn’t
quite, it didn’t come out quite the way we wanted it to in the
June 15th edition. So what I want to do at the beginning here
is identify what that requirement is and then I want to talk
to you a little bit about how we get to the point to identify
that requirement and then we’ll take some questions.
But basically the concept for breathing gas control and
we’re talking about carbon dioxide and oxygen in the breathing
zone for the respirator. The concept requirement is that for
carbon dioxide to maximum average inhaled concentration of
2¼%. The 2¼% is actually a 42 CFR, Part 84 requirement iden-
tified for self-contained breathing apparatus so that is the
maximum and actually it’s a sliding scale. If you’re familiar
with 42 CFR, it depends on the duration of the device. I
think for less than 30 minutes it’s 2¼%. For 30 minutes to
60 minutes, I believe it's 2% and then it continuously changes with the duration of the unit. That is the requirement that we are invoking for or attempting to use for CO2 so the maximum is 2½%. The oxygen the minimum inhaled oxygen concentration is 19½% and again that's identified in 42 CFR, Part 84. The way we intend on establishing conformance with that requirement is through human subject testing. Okay, so to establish and evaluate CO2 and O2 breathing gas performance, we will test it using human subjects. The criteria will be is that we will have two different weight categories that we look at: first one greater than or equal to 80 kilograms and then less than or equal to 60 kilograms. And the test subjects will wear the respirator for the duration, rate of duration of the unit and we'll have three levels of activities: standing, walking at 2.5 miles per hour on a treadmill, and walking at 3.5 miles per hour on the treadmill. That's the requirement the way it will be editorially revised in the next edition of the concept.

Now, how did we get there? In the last meeting in April, we reported on testing that we've done relative to evaluating breathing gas control. The bench-mark testing that we discussed I think to some degree at that meeting was the bench-mark testing involving a metabolic simulator and this testing involved the escape respirators, various escape respirators at
six different work rates as illustrated in the overhead there.

We had a low work rate of established at approximately
.5 liters per minute oxygen consumption and then varying at
half liter increments, oxygen consumption up to the high work
rate of 3 liters per minute oxygen consumption. Again, the
bench-mark testing was performed on commercially available
escape sets. We performed multiple metabolic simulator tests
using each respirator and the results of those tests were that
we observed carbon dioxide levels that exceeded 4%. That was
common. In fact we had levels I think that went as high as
perhaps 8%. On the oxygen concentrations, we likewise mea-
sured levels of oxygen that were considerably less than 19.5%.
I think in some instances it even went down to under 10%. So
when we looked at the metabolic simulator data, we obviously
had some concerns relative to what the requirements should be
and what was the best way to achieve and establish conformance
with those requirements. So what we did was we embarked on
the second part of that bench-mark testing which is what we
called human subject tests. And to do that we performed human
subject testing using seven different test subjects: four
men, three women and we had the tests performed at the work
rates, three work rates: standing, treadmill 2.5, and
treadmill at 3.5 miles per hour. The results of this testing
were that we saw carbon dioxide levels as high as 5.5% and
that would be a maximum average inhaled carbon dioxide concentra-
tion and we saw oxygen concentrations that were down as low
as 14.8% minimum average inhaled concentration. Now both of
these values obviously exceed what the requirements that we
have identified from 42 CFR and that we used for other testing
of other respirators so both exceed those requirements. But
the question is: what’s the physiological consequences?
The next chart that you see is going to be overpowering
for you, okay, but there’s help. The chart that’s on the
bulletin board is what this is replicated from and the key
values there, basically, this, to break this down a little
bit, this shows test results from three different respirators
using seven different test subjects at the three levels of
work that we discussed. The areas highlighted in the blue are
the areas where we experienced and had actual measurements
that were reflective of the numbers that I mentioned: 5.5%
CO2 and 14% oxygen. So I don’t want to go into the chart
during this discussion because I can’t read it. So I’m sure
you can’t read it, but it is on the poster illustrated in the
corner of the room and I think during the breaks Mike will be
available and will be available to answer any questions that
you may have relative to that.
Other observations that we had during the bench-mark
testing and as I think was already mentioned, we did observe a
number of human factors, human subject interface issues and these were, ranged throughout the comments that are identified here. We had quite a few comments relative to the degree of tightness of the neck seal. Hooded respirators primarily achieved a seal using a elastic neck membrane. Types of comments we had: neck constriction, sensation of strangulation. And in some instances, we had people who just couldn't complete testing because of that. Other instances we had: people that had negative reactions to wearing and breathing through mouth bits and mouth pieces and interfaces between the breathing zone and the mouth and some individuals expelled mouth bits and so forth. In still other test subjects had difficulties donning the respirator, actually being able to physically open the neck seal, the neck dam, and stretch it over the head. So these are the types of requirements that we observed during the testing illustrated on the poster and these will be factored into practical performance evaluations for the escape respirators. So at that point, basically, we've dropped back to the 42 CFR criteria for carbon dioxide as I stated at the beginning. We will set the CO2 requirements at 2.5% maximum and with a sliding scale so if it's a long duration unit, the CO2 will go and follow the tabulation that's identified 42 CFR and the oxygen concentrations at
1289 19.5%. At this point, I think we can open it up for any
discussions.

1291 **GÖRAN BERNDTSSON:** Göran Berndtsson from SEA, I don't
1292 know if I misunderstood or was asleep here, but you said
1293 you’re going to test over 80 kilo and under 60 and you
1294 classified that as two classes. What do you for the people
1295 between 60 and 80?

1296 **LES BOORD:** What we’ve observed in the testing? We
1297 actually have, the situation that you have relative to mea-
1298 suring the CO2 and the O2 is the ventilation rate. Okay, and
1299 where you have a particular problem is where you have a low
1300 ventilation rate so you have a low breathing exchange and the
1301 relationship that has with the dead volume of the mask, okay,
1302 and typically that low ventilation rate, you’re going to
1303 experience with a light weight individual, okay, in the stand-
1304 ing conditions. So that’s why we wanted to capture per-
1305 formance at that level. You have the other end of the extreme
1306 where you have a high ventilation rate where you have a large
1307 individual who’s breathing heavy, okay, who perhaps has a
1308 different phenomenon that’s occurring relative to CO2 reten-
1309 tion in the respirator and displacement of the oxygen. So
1310 those, the testing that we have performed actually indicates
1311 that those two extremes are the most interesting areas.
GÖRAN BERNDTSSON: But, wouldn't that be three classes then? What I don't understand is over 80, below 60, and then between 60 and 80.

LES BOORD: Yeah, but you only, I think when you capture the performance at those two, at the two ends, then I think the in-between is going to be in line with those worse-case scenarios.

GÖRAN BERNDTSSON: Okay. The other question is that you showed a slide with oxygen uptake and there was five, six, seven classes. Can you put that slide up again please?

LES BOORD: Now those were for the metabolic simulator.

GÖRAN BERNDTSSON: Ah.

LES BOORD: Those were tests that were performed on a machine, machine tests.

GÖRAN BERNDTSSON: Are you going to test those . . .

LES BOORD: No. No. This was part of the, this was part of the bench-mark testing that we did to, in the development process and the process of developing our requirement the first thing we did was look at machine testing using a meta-bolic simulator operating at these ventilation rates. Now the reality is that if you look at the breathing rates that we’ve or the work levels that we’ve established for the requirements standing on a light individual less than 60 kilograms, you’re probably going to be in the .5 per minute consumption rate.
GORAN BERNDTSSON: Oh, maybe, but the, what we are doing, what we’re doing in ISO, you are measuring this, you put body weight and we’re using an ISO standard for, which is based on height of the person and starting at 1.7 as the standard ISO person male and 1.6 as an ISO woman I think and from there you can then scale it up and down because the metabolic rate is related back to your body, square meter surface area of your body, and then you can that way very easily don the different liters of oxygen required for doing this workload. So just an advice that may be don’t using kilos may be using sizes and refer it back to ISO standard, it would be much easier as times moves on to have the same kind of starting references.

LES BOORD: Thank you.

JAY PARKER: Jay Parker with the Bullard Company, Les I didn’t hear a reason why you removed the metabolic simulator testing. Wasn’t that in the last draft?

LES BOORD: Yeah.

JAY PARKER: I guess it has been removed?

LES BOORD: Yeah, it has. Actually we’re relying on the human subject testing and the reason that we’ve decided to go that way is when we went through our bench-mark testing, the first phase was machine testing. Second test, second phase was the human subject testing and what we’ve found was that the low ventilation rates, we really didn’t get 100% tracking.
Okay, in other words, human subject testing the values that we were obtaining for CO2 and O2 were not identical with the types of results we were getting on the simulator. So rather than trying to identify a machine requirement, okay, that would be equivalent to the human requirement, our decision was to use the human subject testing. That's the proof. The machine test would be an approximation.

**MICHAEL KAY:** Mike Kay from Occeno, getting back to the ABMS and the human subject testing, at the public meeting regarding the SCSR rewrite of 42 CFR, the concept in that was to go to ABMS testing to get away from the inherent problems with human subject testing. Now the pendulum seems to have swung back the other way.

**LES BOORD:** I think that, first of all, I can't speak on behalf of the SCSR, but I think that with the bench-mark testing that we've observed, that there are appropriate tests at this time that can be done using the simulator and the tests that perhaps aren't quite there yet. We think that there would be additional work required to actually tune and to develop a protocol that would be appropriate to use a machine test for the certification requirement, for this certification requirement.

**RICH STEIN:** Rich Stein, QPS, Les, let me see if I understand correctly. If we make a submittal, is the first thing
you’re going to do is run a bench test to prequalify or you’re just going to jump in to human test on this or how are you going to run this?

LES BOORD: Yes, actually there is no machine test, no bench test relative to CO2/O2 that the criteria will be established using the human subject testing.

RICH STEIN: Okay, so you’re just going to run into that and put it on a human subject on a unit that comes in?

LES BOORD: Yes and the test sequence will be identified actually in one of the next discussions what the overall test sequence is.

Any questions? Okay with that we’ll go to the next topic.

FRANK PALLYA: Good morning, my name is Frank Palya from NIOSH and I’m going to discuss the test methods and required quantity of the escape units that are required to complete the NIOSH certification of the CBRN air-purifying escape respirator. This chart is the summarization of the test categories, the quantity of escape units that are required for each of the test categories, and the test sequence within each test category. Each column is a test category and it identifies the test sequence: the top being the very first test and the bottom being the very last test within each of them. As you can see, there’s the resistance in breathing gas and human
factors and service life. There’s no sequence to the ones right here, but basically it just starts at the top within each column and then goes down.

I want to discuss each one of those columns. First being the resistance and breathing gas, from that we’ll initially, a total quantity of 12 is required and 3 will be used for inhalation resistance and 3 will be used for exhalation resistance and now 12 will be used for the breathing gas concentrations. If you take note, the same respirators will be used for all the tests. In other words, there’s three respirators that were used in the inhalation/exhalation will also be used in the breathing concentration. The reason for that was we’re trying to conserve on the number of respirators required from the manufacturers. Again, as Les previously discussed, there will be 12 required for the breathing testing. Each one of these units which will be the human subject testing will only be used once by the human subjects for personal hygiene reasons.

For the human factors, the total quantity of 3 to 9 is required for this series of testing. This is size dependent. If there’s one size, then three are required. If there are three sizes, then nine will be required for this particular series of tests. First it’ll be the field of view test conducted. We’ll use the STP CBRN 0312 and that is the same
standard test procedure that is used for the gas mask air-
purifying gas mask.

The next step would be the fogging and 3 to 9 will be
used in that particular test. This is a new STP 0321. It
varies from the gas mask fogging test in that you’ll enter,
you’ll don the respirator in ambient conditions and then enter
into a hot environment, a hot environment being 90 degrees
Fahrenheit at 60% relative humidity and then go through a
series of visual acuity tests and then another set of respira-
tors, you’ll don in ambient conditions and then you’ll enter
into cold condition of minus 13 degrees Fahrenheit.

And then the final test in this series is the flame and
heat resistance. No human subjects required for this par-
ticular one, but it will be in the equipment in accordance

The next series I want to discuss is the gas service
life. Thirty respirators are required for this particular
test. Three respirators will be tested against each of the
gases, each of the ten gases; however, before they’ll be
tested for the gas service life, they’ll be subject to the
hot-temperature storage, the low-temperature storage,
humidity, transportation vibration testing, and then the drop
test. These tests are pretty similar to the gas mask CBRN gas
mask requirement; however, take note at the high-temperature
storage. It'll be at a constant temperature for 5 weeks as opposed to the (inaudible) test required under the CBRN gas mask standard. After they go through all these series of durability testing, then they'll be tested for service life at 100 liters per minute at 50% relative humidity in the challenge.

The next is the service gas life rated at 64 liters per minute; 60 respirators are required for this. Again, they'll be subjected to the same durability testing. The durability testing is the same throughout all these tests categories: same hot temperature, low temperature, humidity, transportation drop. Six gases, six respirator units will be tested for gas. Again there are 10 gases. They'll be 3 at 25% relative humidity and 3 at 80% relative humidity for 10 gases at 64 liters per minute.

For the permeation and penetration testing, six respirators are required. However, initially there will be two respirators that will not be subjected to the durability testing. They are considered pre-qualifiers and they'll be subjected to the initial or one will be tested for GB and one will be tested for HD. Again, these are pre-qualifiers. Two of them will not be subjected to the durability testing. Once they pass their pre-qualifications, the four will go through the high temperature, low temperature, humidity, transporta-
tion, and drop and then they'll be tested and challenged with
the two against sarin vapor and two against sulfur mustard HD
liquid and vapor. This was at the (inaudible) discussed
previously.

For the filter particulate efficiency, 20 respirators are
required for this test. Again, they'll be subjected to the
durability test and the filter efficiency will be tested,
challenged, tested in accordance with the outlined in 42 CFR.

And last is the laboratory/respiratory protection level
testing. A quantity of 30 to 65 tests or respirators are
required for this particular test. Again, when using human
subjects, respirator will only be used once for hygiene
purposes. The donning procedure is still being developed and
the LRPL test is similar to the STP 0352. This 0352 initially
was planned to be a generic test to test all of the, to test
all the classes of respirators: the SCBA, the air-purifying
respirators, the escapes. However, I think that we're going
to have to make some modifications to this because of the
donning procedures and different probes so, but all in all,
it's very similar to the self-contained breathing apparatus
standard test procedure that we currently use now to test LRPL
test. And at this time, just any questions? Okay, thank you.

UNKNOWN SPEAKER: I have a question here. On that test
protocol, may be I'm not up to date, but the test protocol,
the procedures you're doing in the test chambers, you said
there was going to be the same with only some small changes
because of the donning. What are we doing in the chamber?
They do, I suppose to know that. Are we lifting boxes and all
the other stuff that was done or is it (inaudible) an escape.
Can you fill me in on that?

FRANK PALYA: Well right now when we go ahead through the
procedures, we're reviewing the procedures, this 0352 is on
the website, but as we're going to go through and develop the
test procedures, we're going to have to go ahead and find out
exactly where the probe the respirators, may be from the oral
nasal region, may be for the under the hood area, the ocular
region. So with the test procedures, you're just going to
have to be some slight tweeks* to it. I mean to go ahead
there and follow one test procedure by step-by-step process
would be very difficult so then we're going to have to break
away from that again.

GÖRAN BERNDTSSON: What are the subjects performing in
the chamber?

LES BOORD: Yeah, Göran, I, questions relative to the
exercises they perform in the LRPL test. Those will not be
the full set of exercises that are performed under the gas
mask, but they will be a subset of those. Okay, so we don't
see all of those as being the applicable exercises that'll be
performed on this test. We haven’t actually identified
exactly which ones are included and which ones omitted, but
it’ll be from that list of exercises.

GÖRAN BERNDTSSON: Because I would assume that very large
proportion would be to run down stairways and that type of
thing when you’re escaping and that’s very very much different
than what we’re normally doing for the other testing.

PAUL DUNCAN: Paul Duncan, Scott Health & Safety, ques-
tion, two questions, for the breathing gas test, do you
actually have an STP established for that yet or is that one
of the existing STPs or is a new one going to be coming out
for that yet?

JOHN SZALAJDA: Yeah, the breathing gas is not an exist-
ing STP at this point because this is the first time that test
will be used.

PAUL DUNCAN: Okay, when do you expect that to be
available?

JOHN SZALAJDA: Actually we’re in the timeframe. We’ll
talk about the timeframes and the schedules actually this
afternoon. We’re looking in the August timeframe to have that
completed.

PAUL DUNCAN: Okay. Just getting to a general comment, a
sort of respectful request, it seemed like in the latter
stages of developing the APR gas mask standard in the last
draft a lot of design requirements showed up that hadn’t really been previously discussed. For instance the gasket material requirement got much more specific than it was in the previous drafts and there’s a last minute change in the lens abrasion testing. Lens abrasion testing in particular actually required manufacturers provide flat samples. So here in the last minute the last draft that came out all of a sudden the manufacturers had to go about the trouble creating molds to mold representative thickness samples of their lens and hard copy them and etc. There was a frustration in the fact that appeared that that standard that portion of the standard actually been developed in conjunction with one or more manufacturers and that information wasn’t generally available to all the manufacturers. So it appeared actually like an unfair advantage to one or more manufacturers that were involved in that. I was asking if you could in reviewing just the general portion of the standard, where do you anticipate major changes in this? This is a good job of reviewing what has changed since the last standard since the last draft was issued but where do you anticipate the major changes occurring between now and the next review period?

**JOHN SZALAJDA:** Okay, that’s a good question. First of all, I’d like to just backtrack a little bit on the two areas that you mentioned. In both of those, the abrasion, the
development of the abrasion concept as well as the development
of the specifications for the gasket were both the result of
comments that were generated at the last public meeting that
we had for the air-purifying gas mask as well as comments that
were submitted to the docket. So both of those were revisions
to those requirements that were actually implemented to
address comments that were submitted, raised at the meetings,
and submitted to the docket. So the answer to the second part
of your question, what we envision perhaps the impact of the
changes as we go forward that is somewhat dependent on the
kind of comments and the interactions that we get through
these types of discussions and submittals that are made to the
docket.

PAUL DUNCAN: My observation wasn’t . . . I could be
entirely wrong, but that last version of the material stan-
dards almost looked like a manufacturer’s, a particular
manufacturer’s material spec. I pulled out our engineering
drawing and plunked down the standard and all of a sudden so
one manufacturer had it and everybody’s going to have to meet
it.

JOHN SZALAJDA: Actually the requirement came from the
military specifications for the gasket material that’s used in
the military masks and that was done. I don’t want to go down
this far, this path too far because it’s related to the gas
mask, but that was done because in the earlier editions of the
case concept paper and actually into the last public meeting, the
design requirements for the gasket were very specific. They
were specific in that it said it needed to be EPDM. The
comments that were generated at that public meeting and in the
docket was that there are other materials that can pass the
agent requirements that by specifying EPDM we are being too
design restrictive and what we should do in lieu of that is
identify what the performance requirements that we needed to
achieve as well as the physical properties of the material and
that's basically what we did and to get to those requirements
we looked to the military specifications for the M40 gas mask.
So and then to try to anticipate the changes as we go forward,
I think . . . The only thing I could say in a definite
response okay at this time is that as we are going through
these discussions you see that there are things that we've
identified that we need to concentrate on. One is the comment
that Göran just mentioned relative to the exercises that will
be performed during LRPL. We pretty much know what the
parameters and we looked at the parameters and how to do that
and so forth, but we haven't focused on what the specific
requirements will be. So that would be an area I would look
to. Also in the area of the . . . as we get into this after-
noon's discussion, you'll see some of the discussions and
perhaps some open areas relative to the way that live agent
testing is performed. Okay, so those may be types of areas to
look at. So I think from listening to the meeting, you can
sort of glean where we think we need to do addition work and
we will do that work, but then we're always and we remain
responsive to input that we get.

**GÖRAN BERNDTSSON:** Göran Berndtsson from SEA again, one
thing you could have done better on the last one was that
actually you had a draft and then it went nearly 6 months and
then it was finished and there was no communication via your
website for 6 months and that I think how all of us who tries
to be ready to go and you can do that better in the future.
Make sure that you continue with what you started so well.
Update every once a month and we will all be ready when you
guys are ready.

**JOHN SZALAJDÁ:** Yes, thank you and that is a good com-
ment. We are sensitive to that, but unfortunately some of the
situations relative to timing and issuing or let's say posting
the requirements and the concepts are not ... there are
hurdles that we need to go through and it's really tough to
predict what those hurdles, what their timelines will be.

**PAUL DUNCAN:** Echoing Göran's comments, along the lines
of ... if something as simple like a monthly update, you
know those have to ... totally revised copy of the draft
which is like a monthly update saying hey we here at NIOSH in
developing these standards we’re looking at these areas. So
at least it gives a flag to the manufacturers like okay hey
something that I might be doing in my development work. I may
need to rethink this or may change my priorities a little bit
and be prepared for a change that may be coming out.

**JOHN SZALAJDA:** Good point.

**PAUL DUNCAN:** Because it was quite a long time.

**JOHN SZALAJDA:** That is a good point, thank you.

**UNKNOWN SPEAKER:** And to wrap up this morning’s for the
air-purifying part of the standard, we wanted to at least ini-
tially identify some of the costs that we envision that are
going to be associated with the application of material for
our evaluation. Basically and if you’re familiar with the
CBRN program, you know that we work with our partner and our
NIOSH test agent at SBCCOM to do the chemical warfare testing
and the LRPL associated testing. That will be no different
for this system. We are currently in process at the NPPTL
facility in Bruceton of establishing our own internal capa-
ibilities for conducting the environmental conditioning for the
respirator systems. We hope to have that in place by this
fall. What we’re doing is again we’re working closely with
SBCCOM to replicate the systems that they have established at
the Edgewood facility for conducting these tests. And again,
as Frank had mentioned in discussion at the tester base, primarily on the Mil standard, the Mil-STD-810 and you know we’re working closely with them to ensure that we get replicable results for the challenging of the respirators. Again, it’s a long test cycle, you know, and unfortunately with given the types of tests that are available for us to do the testers, we don’t see anyway to circumvent that portion of the process that we are looking at around 70-75 days to conduct the testing. And I think everybody can read the number at the bottom.

How that breaks down, you know again we’re looking at the testing but excuse me, button sensitive there, we’re looking at doing the testing at the two sites. We have the penetration permeation testing which is done by SBCCOM. Again we are considering as part of the application process to do the qualification testing first with two systems to ensure that they pass the chemical warfare agent testing, the penetration-permeation test prior to going to the expense of conducting the environmental challenging the systems. Again, we would end up ultimately testing six systems: the two qualification units and then the four units following environmental conditioning.

With the LRPL, the numbers are off the actually we’re looking at 30 to 65 escape respirators which will be dependent
on the design, the individual design from the applicant as well as the (inaudible) if the manufacturer comes in with one size or multitude of size that will determine the actual number of items that are required for the LRPL. Again, we’re looking at these tests will be done by SBCCOM using their facilities and their test subjects.

As far as the particulate testing, we intend on doing that at the facility in Pittsburgh. Frank had mentioned the breakdown and the test that will be conducted as part of that application. A couple of things that I wanted to bring to your attention, things that may go away between now and by the time the standards are released. We had considered doing a particulate test following cyclohexane challenge. This was something that we had looked at as part of the development of the gas mask standard to ensure that we weren’t getting particulate penetration following exposure to organic vapors and this was a consideration for the gas mask because of concerns that had been raised over intermittent exposures of the filter to contaminants. In looking at the escape respirator as a one-time only use, there may not be a need to conduct that test and we’re in the process of evaluating the necessity for that. Everything else I think is fairly straightforward in terms of the sequence of doing the environmental condition-
of the service life testing or the bench testing for the human
factors types of evaluation. We don’t have a similar chart
for the afternoon session. We go and discuss the self-
contained units but I think you can pretty well identify the
things that would be included in this part of the self-
contained that we would be looking at . . . there wouldn’t be
a need for doing the gas testing as well as the particulate
testing and that’s about a $9,000 savings. So with that I
think we’re pretty much on scheduled. I wanted to at least
open up the floor for any comments from the attendees related
to the air-purifying respirator.

WILLIAM NEWCOME: Bill Newcomb, North Safety Products, is
it the intention of NIOSH that this is a single-use escape
device?

UNKNOWN SPEAKER: Yes.

WILLIAM NEWCOME: Then okay, I don’t think it’s specific
in there any place and there is a requirement for maintenance
in the proposed draft so I’m kind of confused as to whether
this was the intention or is the intention?

UNKNOWN SPEAKER: What I think part of what we’re working
and I guess this goes back to the gentlemen from Scott’s
comment as far as refinements to the standards. Part of what
we’ve seen and getting comments back is a need for training
and maintenance care and use of these systems and by main-
tenance, I guess as part of what we're doing in a concept
paper is we're going, and when we identify in terms of main-
tenance requirements we're going to define that characteristic
in the concept paper, but primarily we're looking at in terms
of maintenance is the long-term care of these systems.
Whether or not when a user which were to be, purchase one of
these systems, put it in a drawer, put it in a filing cabinet,
put it in a central location. Which should they do long term
with these systems? Should they inspect these at some sort of
relative frequency? After 6 months, should they perhaps con-
sult the manufacturer and go back and have the items evaluated
to make sure that they are maintaining the . . . meeting the
requirements? These are parameters that we’re still trying to
come to terms with, but I think in terms of what you’ll see in
the concept papers that will define what we mean by
maintenance.

UNKNOWN SPEAKER: Excuse me, relating to the actual test
method that we’re working toward, if you had . . . How flexi-
ble is this and how . . . For example, if you have 10 escape
respirators that qualify to be tested and 8 of them are
canisters, okay and one of them or two of them are fabric,
completely different structure and makeup and everything else,
is it up to the manufacturer to submit what a protocol for
what they would think fair and accurate, a fair and accurate
test of this filter material would be since it's so different
than the other ones. How does that work?

**UNKNOWN SPEAKER:** If I understand the question correctly,
I think you're talking about different respirators that may
utilize common components and how those would actually be
evaluated through a testing program?

**UNKNOWN SPEAKER:** Through different, yes, if there's one
set that has a canister and the other set that has fabric or
something different and the whole construction is quite dif-
ferent that you want, but the filter material, I mean, you get
past the leak test and everything else.

**UNKNOWN SPEAKER:** I think the answer to the question in a
general sense is probably the best we can do at this time is
that we do have guidelines that we use in both the CBRN pro-
grams that are already in place for the SCBA as well as the
gas mask to determine how and what materials need to be tested
and those guidelines come down to identifying materials that
form a pressure boundary or materials of contact can likely
contact the agent as well as materials that actually are used
to provide the protection if it's a filter. So there are
guidelines that we follow for the current programs and I would
anticipate that there would be similar guidelines applicable
for the escape.
GÖRAN BERNDTSSON: Göran Berndtsson from SEA, in regards to I think it was Nort’s (phonetically) question here. When a respirator runs out of shelf life, could it be sent back to the manufacturer for re-fitted, restored and sent out again. It’s never been used. The agent just ran out of shelf life.

UNKNOWN SPEAKER: I think that those types of issues, the issues and what I think John was alluding to is a lot of those maintenance issues are, when we talk about maintenance, we’re looking at what the manufacturer would recommend needs to be done to that unit as it’s sitting in the desk drawer or hanging on the wall or being carried around in the car. If there are procedures unit specific that a manufacturer develops for doing measures such as you mentioned, then I think those need to be technically rationalized and justified through the certification program through the certification process. So I don’t see that it’s necessarily prohibited but I think there needs to be a technical rationale behind it.

GÖRAN BERNDTSSON: Another question, is it going to be a maximum shelf life allowed from other approval process? In other words, if the manufacturer claims 10 years, is that going to be some kind of testing to validate that or is it...

UNKNOWN SPEAKER: The testing that we envisioned is basically the environmental conditioning that we expose the
unit to. The actual recommended shelf life is I think a manufacturer specific or driven type of a specification. Otherwise we would need to specify the packaging.

GÖRAN BERNTSSON: Isn't that a little bit loose? I mean that a manufacturer come in and say that I recommend 20 years. How do we know that the field tests are going to last after 20 years?

UNKNOWN SPEAKER: That's a good point. We are open for any original thinking there.

KAREN NELSON: Would not the test the filter materials, are they not themselves be of fabric or (inaudible) or whatever's inside the filter? Is that not subject to tests that can determine if it loses integrity after a period of time? I mean, just the materials themselves, would that, isn't that . . .

UNKNOWN SPEAKER: First of all address your name into the microphone.

KAREN NELSON: I'm forgetting, Karen Nelson, Safety Matters.

UNKNOWN SPEAKER: Okay, then to answer your question. I think that that, again, that perhaps becomes design specific. Okay, and the way the various materials that are used, the materials of construction are used and how those are packaged,
contained, or sealed from the environment, I think is a design specific type of a situation.

KAREN MELSON: Right, but my, as far as the question, would it not, if you're looking at this, at these materials as you test or as far as the construction of the item, is it not, I mean aren't there engineers who can tell you that like certain grades of rubber will loose integrity after and become brittle after so many years, so you couldn't claim a 20-year shelf life on that and just extrapolate that to the other materials.

UNKNOWN SPEAKER: To answer your question, I think there are engineering guidelines and so forth for the design process to do that type of work.

RICHARD METZLER: Rich Metzler from NIOSH, we have an experience with self-contained self-rescuers in the mining industry where there are substantial reliability problems with regard to the age of the unit and the use underground and the ability to inspect and know when to remove the products from service. While we invite your comments on the shelf-life issue, I can tell you if it comes down to a policy matter, there will be a limited shelf life of a short duration that's reasonable from an engineering perspective, but that age would be at the lower end not the 20-year end that I hear everyone talking about.
GORAN BERNDTSSON: Göran Berndtsson from SEA again, this is really important. We really need to settle some kind of guidelines or some policies here because the difference between (inaudible) to the end user is going to be very much dependent on the shelf life and the price charged for this. So we can't leave this. We have to make sure that this doesn't get left open and no open ended (inaudible). We need to have a discussion or a dialogue to solve this unsolved question.

UNKNOWN SPEAKER: Thank you. Just one other thing, I just want to remind everybody as far as we'll have individuals available to discuss the charts if you like to review the information that we've accumulated related to the breathing gas and the bench mark testing that we will have personnel available during lunch and the breaks to talk about that. I think at this point we'll go ahead and take our hour for lunch and I don't know exactly what time it is, but I'm guessing that it's 12 o'clock so if you can be back at 1, we'll resume with the self-contained portion.

UNKNOWN SPEAKER: Okay as far as what we're going to cover this afternoon, we're going to spend about an hour addressing the self-contained escape requirements. We'll have an open period for comments to close out the discussion on the escape respirators immediately following the self-contained
discussion of the escape respirator requirements and then
we'll conclude with the QA module and wrap up at the end of
the day.
I think to reset the stage you know this morning we
talked about part one of the standard. We addressed what
we're conceptualizing for the air-purifying escape respirator
and part way through the project of doing the air-purifying
respirator, we had thought originally, the original plan that
we had in terms of the sequence for developing the respirator
standards we had considered doing the escape, the self-
contained escape standard later in the cycle but you know we
felt there was enough commonality between the requirements
that it made sense from a programmatic stand point to go ahead
and address the self-contained aspect at this time and so part
two of the concept paper was born. And I think in looking at
any time with the self-contained unit. You know we like to
take advantage of the lessons learned and the modeling and the
other work that we've done in developing the concept. Then in
looking at, there's a lot of similarity between the self-
contained families of respirators and to that end, we went
back and looked at the SCBA, the self-contained breathing
apparatus, standard. The first CBRN requirement that we
developed and in that we had three tiers of requirements and
it make sense for the self-contained escape respirator to use
the same type of model and in that we're looking at compliance
with the requirements of 42 CFR enhanced performance require-
ments that we feel are necessary to harden the unit for this
type of application as well as unique CBRN APR requirements.

Again as I said, the first tier is the compliance with
the requirements that have been delineated in the 42 CFR,
Part 84 that have been established for a few years at least
for the community that's familiar with these types of pieces
of equipment that these requirements are the same. The second
are things that we felt needed to be considered for the
potential user population for people who may not have the
familiarity of respirator usage. When you look at a self-
contained self-rescuer type devices, there's certain parts of
respiratory protection program that the mining industry takes
into account for how the equipment is used. The worker, your
conventional worker, may not have that same opportunity so we
identified these requirements as considerations for the second
tier of the escape respirator and we'll get into that a little
bit over the next few minutes. The third tier is the require-
ments for the CBRN in particular the chemical warfare agent
testing and the LRPL and we're going to discuss those in some
detail. And with that, we're going to cover first is the
chemical warfare agent requirements and Les Boord,
Mike Bergman, and Ray Lins from SBCCOM will be leading that
discussion. Actually Les is so good he doesn’t need the
charts.

LES BOORD: To start the discussion on the agent testing
for the self-contained escape respirators, I’d like to just
back track a little bit to refresh what we had presented and
what we discussed in the April meeting. And basically, at
that point in time, we, in the April meeting, talked about
bench-mark testing for escape respirators and the self-
contained units in the form of testing that we did on hoods.
And basically when we look at the agent test requirements,
we’re looking at a self-contained unit so we’re talking about
high protections which really throws us into the levels of
testing and challenge that we’ve identified for an SCBA which
means sarin. We’re looking at 2,000 milligrams per cubic
meter and mustard, 300 milligrams per cubic meter. In the
April meeting, we reported the results of bench-mark testing
using hoods at those exposure levels and basically the result
of that was that we were able to come to the conclusion that
hood technology even at those levels of agent exposure was I
think in line with the requirements so we didn’t envision that
would be a problem. So that bench-mark testing proved the
hood capacity or capability. Since that time, what we’ve been
doing is taking it a step further and we wanted to look at
the, two things primarily. The first one is the challenge
concentration: the 2,000 and the 300 and basically profiles
for actually administering that type of a test on an escape
respirator. So some of the discussion that Mike gets into is
going to discuss different profiles for doing that test, but
then the second thing is that we actually wanted to gain some
experience and we’ll share that with you relative to bench-
mark testing existing escape units, self-contained escape
units against the hazard levels that we’ve identified and the
profiles that Mike’s going to talk about in his discussion.
And so with that, what I’d like to do is have Mike Bergman
talk about the agent, the live-agent testing profiles again
associated with the smart man testing and then following Mike,
Ray Lins will share with us some experiences of the bench-mark
testing on self-contained units. And before I go on any
further, I would like to point out which I fell to do earlier
is that we do have a smart man test set up at the back of the
room which I think probably everybody has seen already but
that is back there for your observation and questions to the
technicians available to demonstrate that.

MIKE BERGMAN: The concentration challenges for sarin and
mustard have stayed the same. They are the same as the
SCBA/CBRN standard. For sarin gas, the paper challenge
concentration is 2,000 milligrams per cubic meter and that’s
going to be an important number. That concentration is going
to tell us something about the time that we need to expose the
unit in the chamber and I have a graph on that that I'll show
you. If it's a 15-minute or longer rated unit, 15 minutes
will be the time that the agent is generated for the exposure.
The total test time will be twice the rated service time of
the unit. For mustard gas, the challenge concentration is
300 milligrams per cubic meter. Again if it's a 15-minute or
longer rated unit, it'll be exposed with a generated agent for
15 minutes and then it will remain in the chamber for a total
time of twice the service time. The profiles come out of the
fact that for GB it's not possible in 15 minutes to have a
10,000 CT and that will show that we need to vary the
concentration for that. For HD it is possible within that
15 minutes to have a 4,500 CT and that will be a constant
exposure at 300 milligrams per cubic meter. For GB, this is
stage one of the agent. This is, the time is at the bottom of
15 minutes and what we are doing here, the goal is to achieve
10,000 CT as a total exposure. We are increasing the concen-
tration up to 2,000 which is the maximum and then a decrease
of the concentration. And then here, this is the total sur-
face of, excuse me, the total testing time for a 60-minute
rated unit. That is the first 15 minutes, the agent is gen-
erated and then stage two there's no agent that is generated.
For HD, we have a constant exposure at 300 milligrams per
cubic meter for the first 15 minutes and then it will remain in the chamber for a total time of twice the rated surface time of the unit stage two. And now I’d like to take any questions about that and then we’re going to have Ray Lins come up for further comment.

GÖRAN BERNDTSSON: Göran Berndtsson from SEA, what’s the logic of leaving it in the chamber twice the duration time than it is in SCBA? I mean it is when you’re out of air, you’re out of air so?

LES BOORD: Yeah, but I think we all know that the service time on a self-contained unit is a function of the use rate.

GÖRAN BERNDTSSON: That’s true.

LES BOORD: So even under 42 CFR, we have testing that establishes the rate of duration, 15, 30, whatever it is, but we also have testing, sedentary testing that’s performed on the unit that goes well beyond the rate of duration of the apparatus. So the idea is to see what those affects are beyond the rate of duration.

GÖRAN BERNDTSSON: Yes I can understand that, but when it comes to escape, it is very likely that the duration would be shorter than the rate because you’re probably use much more than your testing.
LES BOORD: I think that depends on the escape mode, the mechanism for escape because I think one escape strategy is certainly as you mentioned. Put on the escape respirator and go as quickly as you can to a identified area, a fresh air area, but it also may be to put it on and go to another area and perhaps wait. So there are different escape strategies and scenarios that I think need, that are realistic and need to be addressed as well.

RAYMOND LINS: I'm Ray Lins from Aberdeen Proving Ground, Protective Equipment Team. We are accredited by ISO 17025 by A2LA and we're a certified testing laboratory for NIOSH for CBRN. It's kind of a timeline and you saw it this morning. In May we started on the (inaudible) testing of escape respirators. Recently we started testing the self-contained escape respirators to develop the standard test procedure and the goal is to start certification in October. In addition to the smart man testing that we do, we have swatch testing which we do and you just saw the swatch cup sitting in the back. It's important to look at the materials before you ever build the hoods. Escape respirators and know if they're going to last or not so we do have the system to do that. Three sets of six swatch systems, we use mini-cams for the agent detection. (inaudible) cups we use. That's a larger swatch for a semi-permeable material. A cheaper test,
fruit fly test on swatches, we do those and then we can put a
hundred of those in at a time so it's pretty inexpensive that
way. And we're also a certified testing for NFPA swatch
testing and we were certified by A2LA for that.

I have a couple of charts to show you on some testing
that we did. The first one was a hooded unit which used
lithium hydroxide as an passive scrubber. That was mounted on
a smart man head form. We only take one sample. One time we
talked about different samples inside the hood and inside the
breathing area. Since this just had a no nose cup or any-
thing, we just took the samples inside the hood.

This is an off-the-shelf item. Very short duration unit
and worked out fairly well. Another test of the identical
unit, both of these tests were with GB. HD, this kind of
shows it. It probably needs some work on materials but it did
perform for the first few minutes. Just a duplicate of the
second test of the same thing. Another unit we did a self-
contained compressed oxygen breathing apparatus contained
lithium hydroxide. This one was a little bit different. It
didn't use passive. You actually breathed through the lithium
hydroxide and we had to modify the smart man tests setup for
this. This actually used a mouth bit so we didn't have a
smart man head form to put it on. This one did much better,
test duration 1 hour and that was the HD. This was also an
off-the-shelf item. After doing leak test on it, we had to
kind of modify the hoses and seal them a little bit to make
them leak proof. They did leak on a TDA 99 test before we
ever put it on. So there was no sense testing it without
fixing it first but after we fixed some of the leaks, it
performed fairly well. As you saw the concentration profile
earlier, that’s a typical. That is the concentration profile
running this unit up to 2,000. Held it for a couple of
minutes then dropped down. The concentration profile that you
saw in the HD would also have a ramp up on the front. It
doesn’t start off at 300. So it would have a ramp up very
similar to this compared to what the other one did. Presently
we have five smart man agent test systems. One smart man CK
system, one medium leak test system, two small leak test
systems, one of which you see in the back. In July we’ll have
a small head form set up for agent test. September we’ll have
two additional smart man agent test systems setup mediums and
then to accommodate the self-contained tests that we’re doing,
we’ll have two additional units set up with automated breath-
ing simulator like the smart man. Questions? Pretty
straightforward.

UNKNOWN SPEAKER: Okay the next two requirements we want
to talk about is the breathing gas control and the LRPL and
these are basically a repeat of what we’ve discussed this
morning. The requirements are the same and the evaluation methods will be the same as we discussed. So the CO2 is a maximum average inhaled concentration 2 1/2%. Again, it comes from 42 CFR, Part 84 and the paragraphs there are actually referenced here: 101 and 97. And then the oxygen minimum inhaled oxygen concentration is 19%, paragraph 84-79. The establishment of compliance with a requirement will be through human subject testing. Again, two test subjects greater than 80, less than 60 and the work rate's standing 2 1/2 and 3 1/2 miles per hour and conducted for the duration of the, the rate of duration of the respirator.

And again, the LRPL is the same, same performance requirement that we identified this morning. Okay, so we have the purpose to establish a bench-mark level of protection under laboratory conditions and the 20 to 40 milligrams cubic meter of corn oil .4 to .6 micrometer mass media aerodynamic diameter. Again, factoring in the same panel, neck circumference, head circumference, face length and width, two areas of LRPL values, breathing zone and then secondly under the hood and so it's the same repeat of the APR requirement that we discussed this morning using the same panel with the F metric dimensions and the same application of the panel for small, medium, and large. Any questions?
RICH STEIN: Rich Stein, QPS, on that breathing zone protection factor of 2,000 for the high again it doesn’t quite fit in with the other categories which are low or specific which would also have an appropriate breathing zone LRPL probably lower which would make sense or raise this and then you won’t have any units that pass?

UNKNOWN SPEAKER: Thank you.

UNKNOWN SPEAKER: Yeah, I want to discuss the test sequence and required quantity. This presentation’s pretty much goes the same way as I did for the air-purifying respirators. Again, I have the charts set up where you have the various test categories: the breathing gas, human factors, penetration/permeation, LRPL. Again, the quantity is on the top here, required quantity for each of the test categories. The testing is at the very first test. It starts at the top and then it works its way down through. First I’m going to discuss the breathing gas. This is just a pretty basic here where 12 units are required for the breathing gas and the human subject testing methods will be used to test for the breathing gas. Again, the respirator will only be used once for personal hygiene reasons. The human factors, a total quantity of 5, between 5 and 11, again, it’s size dependent. A 1 size, only 5 will be required. If it’s 3 sizes, then 11 will be required. The first test will be the field of view,
then fogging resistance, and then flammability. Again, we'll try to use the same respirators for duplicate tests, multiple tests. The test method, again, field of view is 0312 and for the fogging resistance is the same as the air-purifying escape respirator. The permeation penetration testing, again, total quantity of six is required and same, we're going to have two respirators require two respirators for the prerequisite test which will not go through the durability testing of high temperature, low temperature, humidity, transportation, and drop. They'll be tested in the as-received condition for GB and HD. So, again, they'll be pre-qualifiers. If they pre-qualify, then they'll go through the durability testing and the test methods are indicated as such. And last is the LRPL testing. From Mike Bergman's presentation and we require quantity of between 30 and 65 respirators. Again, it's going to be size dependent. The donning procedures are still being finalized and then the LRPL STP will be used. Again, it's going to be similar to this 0352. Questions?

JAY PARKER: Jay Parker with Bullard, how will duration be tested? I don't see any test for the duration of the unit.

UNKNOWN SPEAKER: Go ahead.

LES BOORD: The first tier of the requirements that it be 42 CFR approved so duration is established under 42 CFR.
RICH STEIN: Rich Stein, QPS, I think there was a suggestion at the last meeting related to the vibration testing wherein you considered separating units and have categories A and B. Have you considered that?

LES BOORD: Yes, actually we did and I think the presentation that follows is going to go through and enumerate some of those types of comments, but on that one specifically, we did look at it and we actually bracketed what we thought those, I think we called them levels, level A, level B and we sort of theorized what they would be and bracket them, but it appeared to us that it was really well two things, making it a complex and complicated type of a requirement, okay, and then secondly, the opportunity for not following whether it's a level A or level B in the field in actual use I think was . . . There was no way to really see that you would adhere to it. In other words, if you had a unit that was designed to just be stored in a drawer, what's the guarantee that it's not going to appear out on a rail vehicle somewhere or a car somewhere being carried. So basically we just came to the conclusion that we decided not to go down that road, but it was considered.

UNKNOWN SPEAKER: In response to your feedback, this is something new and I think as Rich Metzler had said this morning, you know, NIOSH in taking our role in trying to
protect worker and safety and health, we realize the fact that
as Rich has stated, that we need to do things in partnership
not only you know in partnership with other Federal agencies
but you know partnerships with manufacturers, partnerships
with the stakeholders, partnerships with people that have a
vested interest in the development of these standards for the
protection of the worker and I guess this trial at least we’re
showing this at least as fair as the work that we’ve done with
the escape respirator. You know, we’ve had an open docket to
collect comments that individuals have made that felt that
they had a contribution of some meaningful data, meaningful
opinions to provide for us to formally consider as part of the
development of the standard. And I want to make sure and
reinforce the fact that you know with the docket has been open
a lot longer than just since October. NIOSH has actually been
collecting comments on CBRN since you know 2000 prior to my
employment with NIOSH but at least I know for the last several
public meetings in discussing this forum that we have invited
the comments from the stakeholders to the docket and we
welcome those comments and what we wanted to do is spend a few
minutes to kind of describe for you what we do with the
information. We certainly value the opinions and the data
that comes forward through this mechanism. We also value the
opinions that you know are voiced here in these meetings or in
one-on-one meetings that manufacturers or other parties may
request of being involved with us in developing the standard
and I want to encourage you know all of you as a stakeholders
in this process that if you feel you have a contribution,
position, data, information that would be of value for us to
consider in the development of these guidelines prior to us
moving too much farther along the path, I would encourage you
to make that submittal. What we try to do and what we’ve done
with the information that has been received is to generally
categorize the comments either in what’s listed up here is how
we’ve done it with the escape respirator. And we’ve done this
all along with the SCBA with the gas mask. As the information
has come into the docket, we receive the information, we ana-
lyze it, and try to make the determinations where it’s appli-
cable, where it may not be applicable, or things that we may
require additional research to investigate. What we try to do
as part of our internal processes are to address requirements
or address information that comes in in a narrative fashion
that we might not specifically address a certain topic but if,
we will look at the topic of the metabolic simulator in total
and look at the types of, type of information that’s being
submitted for consideration and provide a narrative to address
those concerns. And going through a little detail as far as
some of things that we’ve collected on the escape respirator
and I think you’ve heard in the discussion this morning a lot of these topics have been addressed in terms of our current conceptual thinking right now in terms of the need for the ABMS as part of the requirement. I think based on some of the information that we’ve seen and analyzed with our different research that we’re not considering that part of the requirement for the escape respirator.

Fees obviously is a big topic and whether or not we can see any economies in reducing the number of test items that we subject through the certification process and that is one thing that we still have under consideration whether or not there is some flexibility of changing the number of items that we test. With this type of device, we’ve seen different concerns regarding beards and glasses and one particular comment was the need for having a good face seal or a good potential seal with the respirator whether it’d be with the nose cup or other concerns have been with use a full facepiece type system that you would need a seal around the face and how that would impact potentially wearing beards or the use of glasses and we see that concern really being addressed as part of the cautions and limitations aspect of the program. Then consideration for whether or not you would want a hooded device or some other type of system. This would really need to be addressed as part of the user’s needs analysis for why they would need
to have an escape respirator and how they best wanted to serve
the population whether that they wanted to provide you know a
hooded type system to accommodate certain things or if they
would prefer to go another track with the device that they
would select as part of their analysis.
Breathing gas control, again, I think we've heard a lot
of discussion about that over the last few hours but where
we've ultimately ended up at this point following our review
and analysis of the existing bench-mark data is falling
back . . . the breathing gas as part of the requirement.
Breathing resistance, I guess another topic as far as the,
what's currently been specified in the concept paper as being
too restrictive enforcing the use of ventilation and exhala-
tion valves, but the one thing that we have considered and
based on the population that could potentially be using this
device being diverse and various physical conditions that we
felt that the 20 millimeters of water was probably appropriate
to encompass a wide range of the population.
Communication, this was another issue that we bannered
about. We do have a communication requirement for the gas
mask. Originally we considered it as an option for the escape
respirator, but, you know, from reviewing the docket comments
as well as doing some additional conceptual thinking in the
application of this device as being an escape respirator that
there probably isn't a need for having a communications
requirement, especially in the light of, you know, the poten-
tial for using a mouth bit type system.

The chemical warfare agent testing, I think the community
as a whole is getting a little, a little more comfortable with
regard to how or how this testing is being done. There have
been some, I guess, inconsistencies with what we've specified
in the concept paper and I think to that and we've tried to
resolve those inconsistencies. I think one thing that we can
appreciate with the technology, the test technology that
SBCCOM has is that they truly have developed a capability of
to test a wide spectrum of respirators and I think it's, the
trend is that, you know, that capability will continue.

One of the topics that was discussed at the last public
meeting was the need for dermal protection and leaning towards
the design for having a hooded-type hood requirement for the
respirator and we feel that as a very important part of the
overall design for the system. I think the concept was
pretty, I think pretty well explained this morning with the
selection of the two different criteria for sampling in the
breathing zone and also sampling underneath the hood. And,
again, the overall use of the respirator in conjunction with
any other protective clothing would need to be addressed as
part of the cautions and limitations associated with the
respirator, you know, granted that, you know, considering
using the escape respirator that people will probably maybe
dress the way we are today, but in terms of being able to
identify for the user community what, what this hood or what
this system, the respirator system will and won’t protect
against.

And, I guess one of the concerns from the last meeting
was what specific and low and general and high all meant and I
think you know we’re trying to define that a little clearer as
we move along. I think with the re-definition and I think by
the time we get around to identifying the final concept paper
that we should have this fairly well defined. Carbon monoxide
we’ve also been discussing and you know that we feel that’s
important to leave as an added option for the manufacturer to
pursue as part of his respirator if he so chooses.

The field of view we initially started out in the concept
paper using the requirements that were established with the
full facepiece gas mask. Recognizing that, you know, there
are intrinsic differences in the design of the system that
we’ve established less restrictive criteria for the use of
these hoods versus what had been originally identified.

The fogging requirements, I think Frank had articulated
this earlier that there are some deviations with how this test
has done as compared to the way the requirement was originally
established for the gas mask and at least at this point we feel those are adequate for providing the required protection. Flammability testing and wanted to make sure that we didn’t ignore Jay with the comment about alternative tests. You know I think this is I guess of interest to the community in particular of using this in conjunction with you know evacuating from a or escaping from a scenario where fire and products of combustion may be involved. You know we have been looking at, you know, the different tests that have been required and we’ll make a determination based on what we feel is appropriate for this type of system. Again, as I think Les had mentioned this morning, we are looking at a single burner not a multiple burner test for the requirement.

There’s been some general debate regarding the gas life and gas capacity and we did receive several comments regarding what should be established as the test challenges as well as the test breakthroughs. I think, in general, and I can’t reiterate, I think reiterate this enough that you know in looking at the filter life is that we’re really trying to achieve an overall balance of protection. You know in looking at this system as being an escape device to you know ensure that we’re providing enough capacity in the filtration system to allow an individual to escape from an area. I think one of the things that we’ll be continue to evaluate with regard to
the gas life and looking at the breakthrough as the potential use of the emergency response planning guidelines and their appropriateness for this type of device. Also as Les had mentioned about the debate on the ratings, looking at level A, level B, you know, we could see this getting into a not just a certification, but also potential use nightmare for trying to sort out, you know, which devices go where and the lack of control in where these items may be used when the user purchase them and where they would potentially place them for use at a later time.

I guess no one has commented on LRPL, but I think, in looking at the 2,000 value, you know, from our perspective, you know we’re trying to identify values that are consistent with the protection we feel is necessary. I think, you know, in terms of doing the dual sampling I think is a step forward to helping protect the individual with the respiratory hazard as well as anything that they may encounter in the sensitive areas underneath the hood. You know, 2,000 I guess the, you know, we have some precedence in where that number came from. Obviously it’s from a gas mask standard, but I think even with the experience with the military systems even though that the military and the joint service requirements may have a lower value that historically much higher protection values have been seen in testing. And, again, this is something that we
will continue to consider over you know the next several
weeks.

Panic demand, you know, again, in trying to be responsive
to some of the concerns that had been raised from stakeholders
about providing excess capacity in the system for situations
where people may be breathing at a higher flow rates that
we’ve incorporated that requirement for both the general and
specific category.

One other, we didn’t address this specifically as part of
this presentation today and I think the manufacturers and
other stakeholders that have been tracking the program know
that we have a research and development program set up with
our partners at SBCCOM for helping the manufacturers conduct
pre-certification testing to see how well their materials or
high well their systems may perform as part of the overall
protection against penetration/permeation, effects of chemical
warfare agents. Again, one of the things to note here is that
for the R&D program that if there’s certification testing to
be conducted, certification testing will always have priority
over the evaluations of the R&D program. You know, I think
that’s, I think with the system as SBCCOM continues to expand
their capabilities as well as some other activities we may be
considering that, you know, trying to ensure that we’ll always
have that capacity to be responsive not only to the certification program but also to be responsive to the R&D program.

The R&D, and again, this is a good tool as far the pre-submission data. If you choose to participate in the R&D program, that information can be included as part of the, as part of the application package, but it won’t be counted as certification data. I think we addressed this a little bit on the earlier slides as far as the different levels of classification, but again, you know, we felt that, you know, by trying to do too much with levels and with different description that we may be opening ourselves up to a cumbersome process not only for certification but also for user selection and use. I believe this came out of the October meeting that there was an issue raised regarding the population for who the escape respirator should be designed for and the suggestion was or the question was raised whether this system would be designed for the for non-ambulatory escapes or for children and the response at that time was that you know this is designed for the general working population and that still holds for what we’re trying to do with the standard.

And, in conclusion, this is where we see the program going over the next couple of months. Based on the oral feedback, we’ve received from you today as well as the information from the docket and other information that we may receive from
stakeholders, we'll be updating our concept paper within the
next week and putting out a June 30th version and I think along
with that it's important for you to keep in mind at this time
is that we'll be looking for comments on this version of the
standard and the information that we've discussed here today
by the end of July and what we'll be doing at that time is
reviewing, reviewing your comments, reviewing comments from
other stakeholders as well as any new information that may be
provided to NIOSH through the docket and make any final modi-
fications to the concept paper. From that end, once we've
completed that review, we will, we're planning on releasing
the statement of standard for the escape respirators in August
with the potential for beginning the actual certification pro-
gram in the October timeframe. The next step in our process
is we're going to begin work on the powered air-purifying
respirator standards and we are planning on or developing and
putting out our initial concept paper for defining the stan-
dard in the August timeframe. And I guess just to keep in
mind that you know with the concept paper process, it's an
iterative process that types of things that you're going to
see in August are more of the program goal and the criteria,
the overall, the overarching structure as far as the types of
requirements we envision for the PAPR. We aren't at this
time, the actual definition of specific tests and specific
requirements may not be as well defined as you're seeing now
on these current versions of the escape respirator, but, you
know, we are going to be moving forward in the development of
that standard and to that end, that we envision that somewhere
in the October timeframe we'll be conducting our next public
meeting to introduce the powered air-purifying respirator
standard and begin dialogue on the concepts associated with
that. I am aware there are several other conferences going on
during October. The fire fighters have the red-man conference
in October. NIOSH has a big research agenda conference in
October and we will be you know try to be sensitive to the
scheduling of that meeting to allow you to make a choice or
allow you to be able to participate and not have to make a
choice between attending one or attending another. And with
that, what I'd like to do is open up the floor for any general
comments on the escape respirator and then we had a request is
Mr. Bennett still in the audience? Mr. Bennett, okay, but at
this point, I'd like to open up for any you know comments
regarding the escape respirator, either the air-purifying or
the self-contained.

GÖRAN BERNDTSSON: Why should I break the tradition?

Göran Berndtsson from SEA, have you considered to classify
this in some other means than 15, 30, 45, and 60 minutes
because the reason why I raised this is because the end users
are going to expect that number to be the performance and
that’s not necessary true. Maybe classes should be 1, 2, 3, 4
or it’s only a test method as against a certain criteria or go
to step numbers.

UNKNOWN SPEAKER: I think, part of answering that ques-
tion, I think gets into developing the guidelines for use
associated with the respirator. I think along with the gas
mask standard, we took the approach of identifying the rating
as the tested period that you know you tested for 15, 30,
45 minutes and part of what we followed on with that program
is the development of guidelines to assist the user in how to
use the system and what that means in terms of, you know, some
of the things that we’ve conceptualized is that to help an
industrial hygienist or someone know, you know, CBRN 15 means.
Means what? It means that, you know, that you’ll provide
15 minutes worth of protection at this concentration and
you’ll get this breakthrough and you’ll determine capacity for
the system and basically what we’re doing is we’re determining
system capacity for the filtration and I think the next chal-
lenge for us is to take a look at in developing supporting
guidelines and information associated with this product to
carry that type of a discussion forward.

GÖRAN BERNDTSSON: There is possibly a different audience
here. I mean there is no fire fighter who doesn’t know that a
30-minute (inaudible) doesn’t last 30 minutes. There’s a lot of people in this industry who understands that and here we’re going to go out to public who might not understand that what you are testing it against. I mean it could last 50 minutes, escape respirator could last 30 minutes or 20 or 25 depending on what (inaudible) could last 12 or 14 or 7. So that’s why I think it is, it could be misleading to a novice audience.

UNKNOWN SPEAKER: I appreciate, I appreciate your point on that, Göran, and I think part of the education process that’s associated with the escape respirator, you know, falls into the analysis, the analysis and need for individuals or businesses when they make a determination that I need a respirator and part of that goes into if I need a respirator what kind of a respirator do I need and select a respirator based upon that need. You know one of the sidewalk conversations that we had earlier was somebody from one agency said they did their own, they did their own risk analysis and they made a determination that they weren’t going to provide or they weren’t going to purchase an escape respirator. It didn’t make sense for their application and I think in dealing with this population that one of the criteria in looking, in looking forward and how it’s going to be used is to raise the general understanding of the users as far as why do I need the respirator and then in turn how do I need to make that
selection of a respirator that will provide the protection that I’m looking for.

RANDALL TEMPLETON: It’s Randy Templeton, DuPont. Your comments lead into my question and that is are we receiving, I’m sure you’re in communication with OSHA on a regular basis, but is there a sense that there will be OSHA guidelines helping the general working population for which this standard is being written to assess their requirement to supply their employees with this product? We can develop a standard and we can design products and we can certify products against that standard, but who is it for? It seems to me that there’s a limit for voluntary decision to use that.

UNKNOWN SPEAKER: It might fall in NIOSH’s realm.

RANDALL TEMPLETON: Exactly.

UNKNOWN SPEAKER: Thank you for that question. Actually I hate to put her on the spot, but we have a representative here from OSHA today, Caroline Freeman, who we’ve been working with, you know, during the development of the standards process and may be she can address that a little better than I can. So if you don’t mind Caroline ...  

CAROLINE FREEMAN: Ah yeah, I’m Caroline Freeman from OSHA and you mentioned guidelines. Guidelines are certainly doable. We don’t have anything on our agenda right now for guidelines from the agency, but we certainly would consider
guidelines. I don’t know if your question is really directed
towards requirements or recommendations or guidance or what we
allow. Perhaps you can clarify that because certainly we can
do guidance materials and think that they’re important along
with the training aspects perhaps even prioritizing what
we . . . Who was the Federal agency who did a risk analysis
and said that they didn’t have any risk? Anyway, we would
like to work with a, we would absolutely be in concert with
NIOSH and working out guidance on these on these CBRN tests.
We are very glad to see them. The more CBRN tested equipment,
the more tested equipment that there is, the more we know and
we can separate what we don’t know and it reduces the need for
professional independent judgment so certainly we’ll be work-
ing on guidelines, no problem. We just don’t have it on the
schedule now. None scheduled now. We are working on a
guidance document right now that will tell you what OSHA’s
standards currently require and CBRN tested equipment comes up
with that guidance document. It’s not a particular guidance
document on CBRN equipment. This is in a simple, single-to-
use document. What do OSHA’s standards, safety, health,
construction require in the event of an intentional disaster
or other types of situations where PPE are required? What is
the bottom line on the current patchwork of Federal standards
that are out there for the workers and certainly we are
considering talking about CBRN equipment in that, but it's not specifically . . .

UNKNOWN SPEAKER: That's after the fact? Right?

CAROLINE FREEMAN: After the event.

UNKNOWN SPEAKER: The escape respirator designed anticipating the standard, what you just said (inaudible).

CAROLINE FREEMAN: So does all of this, the purpose of this document is to anticipate the event.

UNKNOWN SPEAKER: (inaudible)

CAROLINE FREEMAN: To participate, yes, absolutely and OSHA's reactions as far as, may be I don't understand the question because OSHA's reaction in terms of enforcement capability would depend upon the, certainly we would want to go for prevention and planning and training. We hope that the document we put out is a planning tool. We certainly hope any guidance we write on CBRN equipment is a planning tool whether it's planning to escape or . . . We hope these are planning tools and we would take a lot of consideration at the amount of effort employers or other groups have taken in setting up strategic plans. Does that answer your question?

RICH STEIN: Rich Stein, QPS, it appears that this document that we've looked at today is, I don't know, pick a number 70% complete and there are a lot of holes and if I understood your schedule, the next step is to have a full-
blown completed document which then we have no ability to comment on and change? Is that the system? Is that how it's going to work?

**UNKNOWN SPEAKER:** It sounds like a policy question.

**LES BOORD:** I think in line with some of the comments we've heard earlier relative to how we continue to follow through or perhaps drop the ball with the full facepiece, we would intend to keep posting this document and our guidelines there were middle and end of the month. I see no reason to not continue to do that. We do know that on June 30th we will have a revision because we've talked about some of those revisions today that are going to appear in that document.

**RICH STEIN:** But by revision, do you mean you're going to have a complete set of standards so that we can look at and say okay this is what they think is a complete standard then we can make our comments or is it going to be pieces again?

**LES BOORD:** I guess I don't understand the pieces. I think the concept is a, it is an evolving, whoops, excuse me, it's an evolving document so it does become more mature with each, with each revision level.

**RICH STEIN:** Okay, but then there'll not, at some point in August, there will be a completed document and that'll be it, it'll be done.
LES BOORD: The goal is that towards the end of August, we should be looking at, I always use the word near, near final, yes, final.

UNKNOWN SPEAKER: I’ll take both of those last two questions. I tend to go out on a limb. With regard to cautions, limitations, restrictions of use, guidance, NIOSH is working on the guidance on these escape hoods as well as on other respirators. We’ll be collaborating with OSHA on those. We do have some drafts already available, but with regard to the escape hoods specifically, we’ve looked at the manuals on the three escape hoods that we’ve tested and they’re excellent and if anyone would refer to those manuals and read them, they would see what cautions, limitations, and restrictions of use are in fact important. So they’re on target. With regards to the second question, it is a fact that within 2 months, we will have a final standard. I don’t think it’s only 70% complete. I think it’s almost complete and I would say 90% complete. The issues you raised today on the 2,000 protection factor we’ll look at, but within the next 30 days, we’ll be finalizing the standard and our implementation date is some-where around the end of August and you probably will not have another opportunity other than what you send into the docket office to comment. We’re seeing this as a near-complete stan-dard. So unless we see a major issue that would delay our
implementation, we’re on line for implementing in the sched-
ules that you saw. Call me or write me a letter if you see it
differently, but that’s where we’re going right now.

**SAM SHEARER:** May be I can give them something to delay
it with. Sam Shearer, CSE Corporation, this afternoon I heard
a couple of words that sort of caught my attention and one was
a nose clip, mouth piece. We’re thinking may be we can use
those.

**LES BOORD:** There are escape respirators that do utilize
nose clips and mouth pieces.

**SAM SHEARER:** Okay, we use that in CSE’s unit. Could I
ask for one more piece: goggles which we use in . . .

**LES BOORD:** The requirement for the CBRN escape respira-
tors, both air-purifying and self-contained, are for a unit
that does provide eye protection in the form of a head cover-
ing. So it really is an integrated system that could include
a nose cup or a mouth bit and nose clips with a hood.

**SAM SHEARER:** I’m just wondering if I have goggles on,
why do I need a hood?

**LES BOORD:** Yeah. We’re looking at the actual head
protection, the percutaneous exposures for the agents on the
head.

**SAM SHEARER:** Yeah, but I have hands, arms, all of that
that could be exposed.
LES BOORD: True, but I think the experts will tell you
that the eye is probably a little more sensitive than
skin . . .

SAM SHEARER: Yeah I know, but if I have goggles on, I'm
sealed around. So that's protected.

UNKNOWN SPEAKER: (inaudible)

LES BOORD: That's a good comment. As it is now, it is
stated as a hood, head covering.

SAM SHEARER: Okay, I lost!

JAY PARKER: Jay Parker with Bullard, you know I was
struck a little bit by the fact that you're allowing a nose
cup which you then say means that you have to be clean shaven
and there's going to be a warning to that effect. Yet you're
also saying that you know the unit has to be a hood so that
people with beards can wear it. So I think there's a little
ambiguity there that you might want to think about a little
bit.

LES BOORD: Yeah, I think that's a good point and I think
that the facial hair issue is still an issue that still needs
to be addressed through the proper cautions, limitations, and
restrictions of use and the presence of facial hair can be
damaging to any seal, okay, whether it's a nose cup or
whatever.
BODO HEINS: Bodo Heins from Draeger, what turnaround
time do you expect for the R&D testing? You only said that
it's probably two, but if I look to the actual, then I would
expect it mostly a year until we would get results from it and
that is much too long for a development.

LES BOORD: The research and development program that we
were addressing is the R&D program that we've implemented and
instituted for the CBRN evaluation. That program is a 3-day
test period. So and I think that is pretty well defined with
the information that's on the internet and I think also
provided in your information packets today. The, so the idea
is the research testing is 3 days. You're in; you're out.
The test data is yours. You have the data to utilize. The
only conflict in scheduling that we run into is priorities
relative to certification testing. So on a given day, if
there's certification testing scheduled, that would have a
priority and I think until this point that hasn't been a major
a major issue.

GÖRAN BERNDTSSON: Göran Berndtsson, SEA, I'm not really
clear on that question to OSHA and may be I can refresh that
again. Will OSHA have the requirement for buying hoods for
escape purposes? If it is yes, that's fine. If it is no,
would it have a guideline saying that if you buy escape hoods,
they should be NIOSH approved, yes or no?
UNKNOWN SPEAKER: Is that what you wanted to know?

CAROLINE FREEMAN: Thanks Göran, these decisions will be made at a high level after careful consideration and discussion with NIOSH. This is a major question before OSHA now. As I said, as CBRN-tested equipment comes out, there's a sigh of relief by this Federal agency in terms of the need for personal judgment. So we'll be making that decision at a high level. We've been asked by several first-responder communities. Well are you talking about escape hoods only or CBRN in general?

GÖRAN BERNDTSSON: (inaudible)

CAROLINE FREEMAN: CBRN in general and escape in particular, what NIOSH is doing has tremendous impact and with the findings from NIOSH in their hands OSHA will certainly take appropriate steps and this will be made, this decision is being made and will be made at a high level with a lot of careful consideration. There's money issues out there and there's possibility and likelihood of the events and who is the target and how much time do we have in a situation where we probably have some certainties. We'll be moving fast on that high-level decision.

LES BOORD: Thank you Caroline. As mentioned a little earlier, we do work closely with OSHA and they are aware of what we're doing and they are pretty much informed on the
progress that we make and as Rich mentioned, the project to
identify specific guidance documents, cautions, limitations,
and restrictions of use is something that we are looking at
and we've identified resources to do that and actually carry
out that function.

Okay if there are no further questions, what we'd like to
do . . .

UNKNOWN SPEAKER: I'm actually going to do something dif-
ferent. I'm going to say I think you do a really, really good
job. I'm pleased to see how this is developing as a part-
nership with the industry and this meeting, I think, is very,
very helpful. So I thought I . . . I want to say that.

LES BOORD: Thank you. We can take a few more of those
comments. What we'd like to do is according to the agenda, we
had a comment period and we didn't have any official partici-
pants and what we have is we've scheduled the discussions on
the QA Module to begin at 2:45 pm, so we're running about
5 minutes ahead from our break, but what we should do is I
think let's take that break and let's resume at 2:45 pm at
which time we'll take up the QA Module discussions. Thank
you.

ROLAND BERRYANN: We're ready to begin now about dis-
cussions about the quality assurance module that will be
coming out as a proposal this fall and I'd just like to make a
few comments. The first one should make everyone happy is due
to popular demand by participants, we’re going to start tomor-
row morning’s meeting with the manufacturers to talk about the
certification process and possible improvements to it till
8 o’clock rather than 9. Please hold the cheers down. I
know. Okay, uhm, what we’re going to do here in the next
about an hour is we’re going to update everybody on what we’ve
been doing on the quality assurance module and basically we
have been revitalizing our efforts in the development of the
concepts for the quality assurance and administrative pro-
visions for a proposed rule that we intend to come out this
fall around October. And, the first change has been personnel
changes. Matt Boyer* was heading the project previously and
when the transition to NPPTL, Matt did not transfer with the
program and we’ve been lucky that Bob Stein and David Book
who’s joined our program and QA program have assumed the task
of taking on the project and moving it forward and we’re very
pleased. They’ve been doing an excellent job. They’ve been
building on the work that Matt did previously and what we’re
going to discuss today is, as I think a lot of you probably
remember a few years ago, we had some public meetings and
talked about the concepts. They were I think in 2000 as Rich
said before the 9/11 events, relocation of the lab, and
several other things that kind of slowed down the progress,
but the good news is there's a new ISO standard that came out
in 2000 that we're revisiting and looking at as to how we can
implement that into our program. David's going to tell you
about that. So we've done reassessments of the ISO standards
and how we think we can implement those into our process,
upgrade the standards. We've had some limited experience in
the use of private sector auditors in doing quality assurance
auditors and we've been reorganized into the NPPTL from our
previous structure in the division of respiratory disease
studies. So today's presentation, like I said, is going to
focus on the changes and the concepts from which you saw and
heard a few years ago and the concepts, the complete concepts,
will be mounted on the web page within the next few weeks. So
with no further ado, here's Dave Book. By the way, we value
him so much. Ask any questions you want while he's here
because next week, we're sending him to Toronto.

DAVE BOOK: It's so nice to be loved. As Roland pointed
out, we're trying to create a summary of what we've done.

Most of this has been done through presentations and small
group discussions rather than the formal paper and posting
process that has been being used with the other standards that
have been introduced. We're trying to catch up to that and
get that information out to you on the website. These slides
should be available with the packet that's coming later so
we're playing a little catch-up here, but I think if you bear
with me, you'll get some new information.

Looking back, where were we? Let's get these up. Okay,
from 1972 to 1995, we really had no new respiratory standards
introduced. In 1995, we introduced the 42 CFR and a number of
things happened with that. First off, it itself was a stan-
dard for particulate filters and it was nice to have a newer
standard, but it also introduced a modular process where we
were looking to update the standard on a regular basis and it
really began our standard development activities. Since 1996,
you've seen the results of a number of those. The CBRN self-
contained breathing apparatus standard is out. The CBRN air-
purifying respirator standard is out. We've talked here
extensively about the CBRN escape respirator and the self-
contained self-rescuers so you know there's a bunch of
activity on those fronts. And this is the new one the Quality
Assurance Module and it's technically the Quality Assurance
and Administrative Module, so you'll find a number of things
outside of strictly quality assurance that are kind of
attached here because it's an opportunity to move to role
making and we like to take advantage of all opportunities.

I'm not responsible for the little swooshing sounds.
The, we, as Roland pointed out, we began this process in 2000.
We had stakeholder meetings with individuals and groups. We
actually had an announced conference with private sector laboratory folks and auditors to get their input to what they thought might be an approach to using their skills efficiently and effectively. And we had a . . . We had a public meeting in August on this subject. What we're trying to do is update you with information that's happened since that time. Since then, ISO 9000 has moved on from the 1994 standard to the 2000 standard. The 2000 standard requires both a process focus and an effectiveness focus and we think those are really critical to some of our decisions subsequent to that. And, of course, the laboratory, the NPPTL laboratory itself was established a year and a half ago, and, of course, we have new personnel which is why I'm here and Matt isn't. And we're actually pretty excited about the new personnel. They came with a lot of experience from the industry and a lot of academic background also, so we had the best of both worlds in that we got to see the experience of the long-time Federal employees that had worked on the respirator community and some new fresh faces and ideas and they worked really well together.

Okay, the impact of the new QA Module, there are a couple that really rely on the manufacturers or the approval holders, would like to be able to encourage the youth of contemporary manufacturing processes and we'd like to be able to replace some outdated quality requirements. We don't want to be in
the position of having manufacturers out there saying we could
do this better except as NIOSH requires. So we’re trying to
get past some of those hurdles. We’ve also, we run a number
of audit programs through NIOSH. One of which is a . . . and
as we go out into the field, we really have found significant
nonconformance rates. The statistic that’s quoted most often
has to do with the product evaluation program where we find
40% of the products we look at out of compliance. Well at
first (inaudible), that’s really bad. Most of those are label
or documentation problems which don’t affect product, but 5%
what of our product audits do reveal a significant
health/safety performance problem that requires a retrofitter
recall and we’re going to . . . we’d like to be able to get
that figure done. We hope this will help to do that. Also
internally for NIOSH, we’ve hope the new standard development
will allow us to use our internal resources better to utilize
outside resources better, and of course, there’s that fee
issue we’d like to be able to retain those so that we can keep
the program viable and that’s part of the proposal.

These are the slides . . . these are what was actually
presented in 2000: these two-section slides and I’m just
going to go through the objectives here and then as we get a
little later, we’ll see what our proposed mechanism was and
what our current mechanism for meeting that objective are at
this point. Sometimes they've changed; sometimes they've stayed the same so that'll give you some idea of where we're being consistent and where we're having new thoughts. We'd like the quality assurance program to be consistent with international standards. I don't think there's any disagreement with that from this room as far as I've seen. We got a number of products specific quality assurance requirements, quality plans, sampling procedures, quality production records. We had specific recommendations in those areas and you'll see how they've evolved. We'd like to validate a quality system prior to approval. At this point, the only validation step we have is a paper validation step and we're seeing that's not always effective.

We'd like to be able to audit our manufacturers on a more frequent basis. That again goes back to what we're seeing as end-product questions. Semi-annual site audits was the most frequent requirements. We're not actually planning on showing up every 6 months, but we'd like the authority to show up that often if we like you a lot. And annual product audits and we see those two as tied together. Trying to be able to see what you're system is doing and what you're actually producing.

The fees question we'd like to recover and retain fees. We'd like those fees to be for the approval processing that we're currently doing. There's a new records maintenance fcc.
We’ll talk about that in a bit. Quality activity fees, we’d like those simply to cover our costs and we’d like to retain the fees within the program. This is consistent with what we’ve done with the CBRN program so again we see old programs and new programs walking hand in hand down pretty much to the same path.

Label adequacy for air-purifying respirators, there was in 2000, there was a significant requirement to make them simpler to really put on there what the users need. Okay, so where are we at today? The QA Module, itself, is relatively mature. We’ve worked on it in house a lot. We’re fairly happy with where it is and we’re comfortable bringing it forward to say, let’s see what you have to say; let’s see how we interact; and hopefully we can go from here to CFR language fairly quickly. It’s a hybrid process. It’s like the CBRN process, but it’s a little different. It says periodic posting of concepts. Well, the first period will be pretty soon. We’re getting to that and again we’re taking the opportunities to interact both electronically and in person.

Alright, probably the first and biggest change, when we talked last, our approach to being consistent with internal standards was to incorporate the ISO 9000 elements into the body of the CFR. So you would have this whole extended NIOSH-specific ISO-like thing to comply with or to audit to. We’ve
decided to bite the bullet and simply incorporate ISO 9000/2000 by reference. What this means is that those of you out there who are ISO certified are registered at this point should have a compliance system and shouldn’t need to do a lot of NIOSH-specific things. There are some. We’ll retain some NIOSH-specific things, but not nearly as much as if we’d taken the other approach. Those of you who are not ISO registered, ISO is a standard. It can be applied whether you’re registered or certified or not. So you’ll have to create a quality manual as you do now and simply have it meet those elements. We’ll leave that there.

Product-specific QA requirements in 2000, we were looking to add specific end process controls. We decided that the manufacturers had a much better idea what their processes looked like than we did and we’re simply asking that you upgrade your systems through your ISO 9000 process through your corrective actions, your preventive actions, your internal audits that that should meet that requirement.

There was a large discussion on sampling, sampling plans, and approaches on those subjects in 2000. What we’d like to do is to allow for a transition from a sampling and inspection mentality towards a statistical process control approach. Right now, I got one thumbs up anyway. Right now, the current sampling plan is based on military standard 105D which has
evolved to ANSI Z1.04 and Z1.09, Z1.9, it's okay you know what it is. We're going to allow a transition period for those manufacturers out there use to that, working with that, dealing with that. We think we might upgrade the quality levels a little bit for consistency, but no major standard for a transition period. The, we, there are a number of manufacturers who prefer to use a sampling plan or in position where they're purchasing a lot of their components and really can't do process, statistical process control of their suppliers. So we've left that option available through a zero-defects sampling plan which will go forward and that's really part of military standard 1960 for those of you who are working in this area. We think that provides the end user a little better protection. It should be a little simpler to use. It's, we're always going to need some sampling plans. Our preferred approach is to do statistical process controls specifically to monitor processes and we're measuring around CPKs and again those we looked at military standard 1916 which also lists a very comparative set of CPKs for minor, major, and critical components. That's very similar to what we've been doing. So we've adopted basically those levels of CPKs. That's sampling plans in a nutshell. I'm sure I'll have questions and we can expand on that a bit.
We wanted to incorporate first-piece inspection and tests. We’re going to have limited implementation of that. There’s still some in-house debate about what’s a first-piece inspection, how long does a process have to be down before you start doing that. We’re going to need some dialogue on that. We wanted a complaint notification program so that NIOSH knew when you were having major field problems because we get kind of blind sided with this stuff occasionally. We’ve left that in. We haven’t changed that.

Retention of quality records for the life of the major components, that seemed like a reasonable requirement and we really haven’t modified that since we talked last.

Now a day* quality systems prior to approval, we were looking at having a manufacturing site audit before granting an approval. That seems like a prudent thing to do. We’ve retained that without significant modification.

Audit frequency consistent with current quality practices, the original plan was to authorize RAB accredited auditors. That’s a little bit redundant since they’re already been screened and approved and vetted and all that good stuff. So we’re going to use them. We’re not going to try and set up our own accreditation of an accreditation program. And we’ve had some experience with that over the last year and a half where we’ve had external auditors doing some of the field
audits for us sometimes accompanied sometimes alone. And that's going fairly well and we've learned a lot about how external auditors are going to approach the audits that we've been doing internally for years. And the mind sets are a little different. So we're hoping to be able to incorporate that information. We wanted to use authorized accredited labs. We've retained that. Again, we've had some experience with that, some limited experience with that with SBCCOM folks. We haven't expanded that at this point outside of Governmental laboratories but again the interaction has been valuable to us and we're looking to do that on a test-by-test basis not as a blanket laboratory approval program.

Recover and retain fees, obviously, from this slide we had a lot of good ideas in 2000 and we've kept them all. We'd like to recover the cost for approval process. Those fees will go up, but there not the kind of changes you've seen with some of the CBRN fees. We're just trying to cover our actual real costs not that we're doing anything else over there in CBRN mind you but I know there's been some sticker shock over there. We'd like to have a maintenance of approval records fee and that's really two-fold. First off, it recovers our cost for doing those services, but the other thing is it forces us to be in dialogue at least once a year to see whether the check came in or not. We've been having a lot of
difficulties with folks who've been maintaining obsolete
approvals even though they haven't manufactured a respirator
in 5 or 10 years and then you get to where they've gone out of
business and you have this whole kind of gee I didn't know,
gee you didn't tell me kind of scenario goes on. So that at
least creates at least an annual dialogue to say you haven't
sent me a check you're really still in this business and we'd
like to recover the cost of the products audit and compliance
investigations. One of the sneaky things we might ask for is
when we do product audits is to have the manufacturers supply
us with those devices, those respirators. Right now most of
you've been very good about that and it's been a kind of a
goodwill-okay-sort-of deal. We'd like to formalize that.

In 2000, we were looking seriously at air-purifying
respirator labels. It was considered that they were too
complicated and they provided the user with information that
they never used and there was a cost problem there. We're not
at this point sure if the needs and the demands for that are
still there, whether we want to clutter up the QA module with
a label requirement so we need your feedback on this. So if
this is an issue for you out there, let us know and we'll see
that we get in here and we get this passed forward. This is a
place where we actively are encouraging you to send us notes
and letters and comments.
Gee I wonder if there's a fourth one. Opportunities to improve, this is one of those is that we hope that by having these discussions that there'll be better acceptance of the rules as they come out and so . . .

. . . will substantially improve the quality, the reliability, our ability to verify that on an ongoing basis and we think that retaining the fees will help us as we move forward in our program.

Schedule, as in any schedule that involves Rich Metzler, it's ambitious. The QA concepts are currently being revised. This is, we've been working diligently on those. We're having our public discussion of the concept in June. We hope to have the formal document that outlines what we've been thinking, where we want to go, what our first pass of this might look like, post it on the website by the end of June. Those of you who have calendars know that that's soon, soon. The concept docket, hopefully we'll have that up by June and we can have some discussion over that, have those comments in by the end of July. We will piggyback on the next public meeting to have some additional discussion, do a whole bunch of internal pushing-this-through-Federal-Government stuff and hopefully have a notice of proposed rulemaking out by December/January. So that's an ambitious time schedule, but we think we can do that and we hope this is of sufficient interest that we will
get feedback quickly and voluminously so that anything we
might have missed or passed by we won’t let it linger very
long. That’s the end of that for now. Questions?

WILLIAM NEWCOMB: Bill Newcomb, North Safety, could you
go back to that first slide?

DAVE BOOK: Maybe, ooh, let’s see, you want to help drive
Bob? You can go out and come back. Yeah, because I’m not
going to slide; here you go. (inaudible) I assume you want
the next first?

WILLIAM NEWCOMB: No, that’s the one I wanted.

DAVE BOOK: Okay.

WILLIAM NEWCOMB: Is that really how you picture the
manufacturers as dollar science?

DAVE BOOK: No, no, we picture them as generating dollars
for themselves. I don’t really know why the dollar sign was
picked. I didn’t pick it, but you can interpret that however
you want.

WILLIAM NEWCOMB: On the NIOSH approval labels issue, we
as a manufacturer have started to post our labels on our
website; however, some of them are too big to get into a pdf
file actually pulled on a website. So it’s still an issue,
but I think it’s a good place to put them. Thank you.

DAVE BOOK: Thank you.
JAY PARKER: Jay Parker with Bullard, am I correct in that I think I heard you say that you’re going to allow either the zero-defect sampling plan or increased sampling or higher or more stringent AQL levels under P105E?

DAVE BOOK: Right. We’d like to grandfather folks in who are current manufacturers to 105T or E for about a 3-year period as a transition. We would then like to have two possibilities for your sampling assurance programs: (1) zero-defect plan or an equivalent and/or to go to a statistical process control based around CPKs. So those are what we’re viewing as a long-term answer to that question.

JAY PARKER: But you won’t accept 105E with more stringent levels as I believe ISCA had recommended to NIOSH back in 2000 instead of zero-defect plan?

DAVE BOOK: We’ll take it under advisement, but that’s not, we’ll go try to, that’s news to me, and we’ll go relook at that issue.

JAY PARKER: Thank you.

DAVE BOOK: I like this part where I say, “Seeing no other questions.” Alright, what’s next on our agenda?

LES BOORD: That wraps up the program for today. I think the only message or information is that if you fill out your surveys that are provided in the information packet, that
information is really helpful to us in building these meetings
and also at the reception desk there is an attendance list
available. So as you exit, drop off the survey form, pick up
the attendance list. And, again, the start time for tomorrow
is 8:00 a.m. Thank you.

(END)