NATIONAL INSTITUTE

FOR OCCUPATIONAL SAFETY AND HEALTH

NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY

PUBLIC MEETING

COMMENTS ON PROPOSED RULES FOR:

APPROVAL TESTS AND STANDARDS FOR

CLOSED-CIRCUIT ESCAPE RESPIRATORS (CCERS)

Monday, March 23, 2009

Commencing at 1:00 p.m. at the University of Maryland University College Marriott, 3501 University Boulevard E, Adelphi, Maryland.

PROCEEDINGS

MR. HEARL: Good afternoon and welcome.

It's 1 o'clock, which is the appointed starting hour for this public meeting.

My name is Frank Hearl, and I'm the Chief of Staff for the National institute for Occupational Safety and Health. That's NIOSH. And we are here today to accept public comment on the proposed rules revising Title 42 Code of Federal Regulations Part 84, approval tests and standards for closed-circuit escape respirators, also known as CCERs.

This notice of proposed rulemaking for this action was originally published in the Federal Register on December 10, 2008.

Note that the period to submit written comments on the proposed rule has been extended to April 10, 2009 to permit additional time for parties to submit their comments to the docket.

I would like to start this meeting with a couple of significant housekeeping announcements.

First, should we have to evacuate the building, the emergency exits are real easy to find.

Just go out through either of the two back doors, and there's doors to the left and also just pretty much just straight across. You will be able to evacuate the building.

Second, the nearest bathrooms are located out the back doors and to the left and past the restaurant. You will see signs that will direct you there.

And third, in deference to today 's speakers and in consideration of others, I would ask that everyone please take a moment and put your cell phones and pagers and such in vibrate mode.

So the purpose of today's meeting is to seek public comment on proposed rules published on December 10, 2008. This is the second and final public meeting that we are holding on these rules. The first was held last Monday, March 16, 2009 in Denver, Colorado.

We will attempt to complete our meeting here today by 5 Eastern Daylight Time, and organize our session as follows:

First, we will hear a brief presentation

by the NIOSH staff, who will describe the changes that are proposed by these rules.

We will then invite to the lectern persons who have preregistered to speak at this meeting, or are in response to the Federal Register notice.

And as of this moment, I have got one individual, Mike Kay, from Ocenco, who has asked to speak.

We will then invite to the lectern persons who would like to speak who haven't signed up. But if you do want to get on a list, we have a list out back. I think this seems like this probably isn't necessary, so you can just identify yourself to me, and you can make comments.

And finally, as time permits, we will invite anyone else who wants to make comments from the floor.

I will point out a few things to you. If you haven't already done, so please register your attendance on the attendance pads in the back by signing those sheets at the registration table.

Secondly, this meeting is being recorded,

and transcripts will be placed in the regulatory docket after the meeting.

There will be a question-and-answer period after we are done with presentations, and so you could ask the NIOSH panel questions for clarification regarding these rules.

I would also that ask that when you get up to speak please, state your name and who you represent so that we can accurately attribute your remarks for the record.

NIOSH also identified some specific questions that we would like public comment on, and we did that in the Federal Register. And you will hear what those were during the NIOSH presentation.

But be aware that, you know, any comments that you have that are relevant to the proposed rule are also welcome.

Let me now introduce my colleagues from NIOSH who will be part of the panel participating at this meeting.

To the far left is Jon Szalajda. Jon's current position is Branch Chief for the Policy

Standards Development Branch at NIOSH's National Personal Protective Technology Laboratory, NPPTL.

He is in charge of the development of new standards and standard operating test procedures. Jon's background includes more than 20 years of experience in the field of personal protective technology.

Tim Rehak, to the left side of the table there, is a professional engineer with the Policy and Standards Development Branch. He has been involved with SCSR research and testing since 1995, and is the project officer and team leader in the develop of the CCER testing certification standard.

Bob Stein, in the center to my right, is a professional engineer with the testing and evaluation branch, and he has been involved in respirator certification with NIOSH since 1995 and is currently involved with the SCSR long-term field evaluation and is a member of the develop of the CCER testing and certification standard.

Ted Katz, to my left, is a public health analyst. And at NIOSH, he is the principal

regulatory writer and a coordinator for regulatory actions.

So I would like at this point to introduce Tim Rehak, who will briefly describe the proposed rules and identify some specific questions that we posed in the December 10 Federal Register notice.

MR. REHAK: Good afternoon. My name is Tim Rehak, and I'm an engineer with the Policy and Standards Branch for NIOSH/NPPTL.

And briefly, I'm going to give an overview of, you know, the development of the CCER module.

Our goals and objective in developing the standards was first and foremost to provide safe apparatus for the user, and we wanted to focus on consistent behavior for the devices.

We also wanted to make sure that the standard avoided any kind of ambiguities, and we wanted to develop the standard predicated on certification and not in use and deployment of the respirator.

We also wanted to make sure that test subjects didn't control the outcome of the

certification. That's why we are going more to the breathing and metabolic simulator for performance and capacity tests.

We wanted shared responsibility between the government, the users, and the manufacturers.

We wanted to make sure the units easier to inspect and also wanted to make sure that there was pass/fail indicators for temperature and mechanical shock.

Our whole philosophy in developing it was we wanted to be able to approve the simplest of the signs that meet appropriate performance requirements. Simplicity in design leads to ease and confidence in use and greater reliability.

This slide up here, it basically reviews the major sections of the CCER module. Basically what I wanted to point out, where the big difference is between the existing standards and the new standards.

Again, we are going away from human subject testing and going to using the breathing and metabolic simulator, which is spelled out in our

capacity and performance requirements.

The capacity test, basically we are going to use the constant work rate to set the capacity. And the capacity, in lieu of duration, we are going to be using liters of oxygen that the unit would provide.

We also added wearability test requirements to ensure that the respirators, when worn by the user, will perform whatever configuration it has to be in.

We also added environmental tests to ensure the ruggedness and reliability of the CCER.

And we also added post certification testing requirements. And basically for this, we wanted to be able to evaluate the CCERs in the field through our long-term field evaluation so that we could tell, you know, from the abuse the units take in the field, that they will perform as certified.

And lastly, we have a voluntary registration of the CCER units where we will want the individual users to register with us. In case there is complaint or recall, whatever, we will be

able to get that information out to the users.

So that's a general overview of the CCER requirements.

Basically, the comments from the -- basically the comments that we were seeking input from the community, the user community, the manufacturers, there is a lot of questions and a lot of discussions that went in by us to determine the schedule for phasing in the proposed rule.

As of now, we are letting the manufacturer -- they have -- after the final rule is in place, they have three years on their existing certification to manufacture the units. And those units will be certificated by NIOSH six years after the final rule takes place.

We are also looking for any input on work rates used for testing. We are also -- I mean, for MSHA's purposes, we also, for units that are going to be used in the mining field, that we still are going to require Man Test 4, and that would just be for those units, though, that are going to be used in the mines.

Also, looking for any input on evaluating units for hypoxia. And also on the safety and durability of the eye protection.

I know we received some comments from DOD on we should ramp up the requirements for eye protection.

So any questions or comments related to this or any input that you could provide us, you know, it would be reviewed.

MR. HEARL: Thank you very much, Tim.

So at this point in the meeting, we are ready to turn to the speakers who have signed up to speak, which would be Mike Kay.

Mike, how would you like to do that? Can you come up here?

MR. KAY: If it's all right with you, if we can break with protocol, I could swing this around here.

And I would like to address the panel with --

MR. HEARL: Yeah, you can use that microphone there. That's fine.

MR. KAY: It's not formal presentation. It's comments and questions.

MR. HEARL: Sure. Just state your name and who you represent for the record and go ahead.

MR. KAY: Is this going to work if I just...

My name is Mike Kay. I'm engineering manager for Ocenco, Incorporated. Thank you for allowing us the opportunity to come and provide comment.

We have been in the business a long time. Ocenco has been providing respiratory protection since 1981.

Like everyone else in the room today, our primary focus has always been getting the miner or the sailor, the industrial worker out of harm's way and into a place of safety.

What I would like to do is start out with some general technical comments I have regarding the proposed rulemaking and then maybe follow up with some broader comments and questions that I hope the panel can provide some answers to, or response to.

The first topic I would like to discuss is the capacity testing. The premise stated in the rulemaking, that low capacity devices are likely to be used for short, very challenging escapes that would induce exceptionally high work rates, is not supported by any evidence, and it appears to be somewhat arbitrary.

The proposed capacity one test requirements require capacity 1 CCER, short duration device, to provide a ventilation rate of 55 liters per minute STPD, standard temperature pressure dry.

Yet, the NIOSH-approved five- and ten-minute open circuit escape devices, the compressed air devices, are required only to provide a ventilation rate of approximately 35 liters per minute STPD. They are tested at 40, but that 40 is at ambient temperature.

It's a 55 percent higher work rate that the closed-circuit apparatus will be required to perform at over an open-circuit device of the same duration.

These devices are used successfully.

Open-circuit devices are used successfully in the same hazardous environments as the closed-circuit escape respirators. They are used in underground mines. They are used onboard ships, in numerous industrial applications.

They are used by the identical populations and identical escape ways that closed-circuit escape respirators are used in.

So my question is, where is this -- is this high work rate coming from when currently approved five- and ten-minute open-circuit escape devices are not required to perform at the same high work rate?

And I don't know if you want to -- if we can discuss that now or should we wait until I'm done with my presentation?

MR. HEARL: What would be your preference?

Maybe we should deal with the questions as they come up.

MR. KAY: Yeah. I think that's a better way to do it.

MR. REHAK: Continue.

If you want to just go through the whole thing, and we will take it one at a time.

MR. KAY: I'm sorry?

MR. REHAK: Do you want to just go through your whole -- what your questions are?

MR. KAY: All right. I can do that.

The second thing I wanted to talk about is the performance testing.

Again, no data has been provided to support the high respiratory performance test requirements, like the Capacity 1 requirements, the proposed 65 liter per minute ventilation rate, the 3.0 liter per minute VO2 appears to be somewhat arbitrary.

If you look at the 1983 Penn State study, I think that -- is John Kovac here?

MR. KOVAC: Yes.

MR. KAY: That John and Mr. Kmon (phonetic), Dr. Kmon were involved in, the oxygen cost of escape from an underground coal mine, that study found that the average peak VO2s of motivated coal miners -- these guys were motivated to get out

of the mine -- performing a series of underground escape trials, was only 1.92 liters per minute. Although their maximum VO2, when measured on a treadmill was much higher, at almost 2.47 liters per minute.

Where I'm going is that the study concluded that factors, such as roof and floor conditions, darkness, limited muscle movement, and fatigue, all of those contribute to the miners not being able to work at their peak VO2 rate.

A shipboard escape will also present factors that prevent crew members from working at their peak VO2. Reduced visibility, tight quarters, other crew members, all of these contribute to lower VO2s.

So instead of relying on laboratory testing, which gives you these high peak work rates on a treadmill, I think a series of escape trials should be conducted to determine what the actual escape respiratory requirements are for these different environments.

The third topic I would like to discuss is

the hypoxia scenario, the conditions that you had mentioned earlier.

The proposal claims that hypoxia could occur with a compressed oxygen escape respirator if an inexperienced user fills the bag with nitrogen.

But yet, again, no evidence is given in support of this. We have never seen it. We have been manufacturing closed-circuit compressed oxygen devices since 1981. We haven't seen it in any field evaluation.

In contrast to that, NIOSH performed 30 No. 4 man tests recently, a few years ago, on one of our compressed oxygen devices.

These test subjects had little to no experience wearing closed-circuit escape respirators. None of the test subjects had ever worn a device before. But despite this, none of test subjects began the test by exhaling into the device.

Exhaling potentially toxic air into a closed-circuit escape devise is an unnatural act. We just don't see it happening.

The only time users are taught to do that, the only time they are taught to exhale into a device is when the oxygen starter fails on a chemical device.

Then according to Phase 10 field evaluation, this occurs on 16 percent of one brand of chemical CCER that NIOSH has tested.

When this occurs, the approved procedure is to exhale six to ten times into the device to activate oxygen generation. According to the NIOSH report, expectations training for miners using self-contained self-rescuers in escape from underground mines -- long title -- it was reported that it may take as long as seven minutes for the device to build up to 19 and a half percent oxygen, ambient levels of oxygen.

The LTFE reports phases 7 through 10 show that that same chemical CCER frequently produces inhaled oxygen levels down to 12 percent.

To help the device pass the LTFE testing, NIOSH has modified the approved donning procedure by first cold-starting each device and then activating

the starter only after inhaled oxygen levels reach 15 percent.

Therefore, we recommend that the proposed rulemaking drop the requirement to exhale twice into the CCER as it will tend to hide the known hypoxic risk associated with chemical devices.

I mentioned cold starting. The cold starting maneuver becomes impossible when the user needs to transition from the device he has on to a second device. The surrounding atmosphere is toxic. He does not have sufficient volume in his breathing bag in the device he is wearing to start up the second unit.

This is a known current risk that continues to go unresolved.

We recommended that the rulemaking require that CCERs that use oxygen starters are equipped with an indicator that allows the user to assess the condition of the oxygen starting device.

Which brings me to indicator correlation.

For an indicator to have meaning, it really much demonstrate a correlation to the

intended performance attribute by minimizing false positives and false negatives.

LTFE reports show poor correlation between the shake tests that are performed in some of these devices and CO2 performance. It has varied widely over the last several phases of the LTFE.

Some temperature indicators will show a false positive when exposed to sunlight. I have seen moisture indicators that have been exposed to ambient air for days, and they still remain blue.

My point is, is NIOSH planning on establishing and monitoring the sensitivity and the reliability of these indicators? Again, for them to be of value, I think -- I think that really needs to be established.

Much like the way a pressure gauge has a 5 percent accuracy on it, I think that same type of accuracy needs to be applied to these other indicators.

These are kind of focused comments I had on the proposed rulemaking. This is a bit more of a global comment, and it speaks to the exclusion of

open-circuit devices from the rulemaking.

The reasons cited in the need for rulemaking really apply equally to open-circuit escape respirators.

Any concerns NIOSH has regarding storage environments, nonuniform test regimes, or potential confusion over duration-specific certifications, all of those apply to all self-contained self-rescuers, open-circuit or closed-circuit.

The proposed rulemaking speaks to the market of CCERs. The market is really self-contained escape respirators. Excluding open-circuit escape respirators from the proposed rulemaking artificially narrows the scope of the market and creates an unlevel field of competition as only the CCER users and CCER manufacturers are forced to shoulder this burden.

It will force users to deploy larger, heavier compressed air devices that cannot be worn and therefore may not be used when needed. Therefore, in the interest of safety and fair competition, I believe open-circuit escape

respirators must be included in the rulemaking.

Which brings me to my last point, and I have been struggling with this because I don't want to come off being negative or combative, but I'm trying to find the need for the rulemaking.

The proposal cites that CCER damage and performance degradation reported in the 2002, the seventh phase, field evaluation as a reason for the proposed rulemaking.

Yet, in that same report, phase seven, showed no difference between a new EBA and a deployed EBA. They both test the same performancewise.

The phase 9 report stated the same thing for an M-20, that an M-20, new, tested no different than an M20 deployed. No degradation seen in the performance.

Again, I don't -- my intent isn't to get negative, but it is really to highlight the problem that everyone -- that no one seems to want to talk about, is that there's one device out there through phase seven, eight, nine, and ten that shows a

continued increasing performance degradation, and I don't see the proposed rulemaking fixing that problem.

The problem -- instead of applying a rule to all CCER manufacturers, the problem exists with one device. And I think agencies need to take corrective and preventative actions on that matter.

That's all I have. Thank you.

MR. HEARL: Okay. Thank you for your comments.

You cited a few things in your presentation, and if you have supplemental supporting data that you would like to offer, we would be happy to receive those things into the record.

MR. KAY: Okay.

MR. HEARL: I think the nature of our question and answer here for the most part isn't to debate judgments about the data as much as it is to clear up questions or, you know, clarifications and that and sort of thing, so we will go with that. And with that as a preface, I want to see if any

panel want to remark?

MR. KATZ: Just before we start, you how would you like that -- should I submit that to --

MR. HEARL: Well, you actually submit that in any of three different ways. You can either submit it by email --

MR. KAY: Oh, there it is.

MR. HEARL: -- to the address shown there.

You can mail it to the address there, or you can submit it through the federal e-rulemaking portal, which is www.regulations.gov, and follow the directions there and refer to our appropriate docket number from the announcements.

So those are the three different ways that we can receive the information.

MR. KAY: Thank you.

MR. REHAK: Mike, any research or studies or test results, you know, that support any of your comments, you know, that would help out too.

MR. KATZ: I can provide that.

I would really if like if we can have a little back and forth, though, on some of the issues

that I have raised.

MR. HEARL: I think within the scope of what I mentioned in terms of clarifications, that would be fine.

MR. SZALAJDA: Thank you.

This is Jon Szalajda. Thank you for your comments, Mike.

We were just side barring at least as far as the areas where we thought we could provide clarification. I think they were on your points 1, 2, and 5 relative to the basis for the high work rate, performance testing data for the high work rate, and then also for the sensitivity and reliability of the indicators.

MR. HEARL: Could you guys state your names as you speak? This way we make sure we get it correct for the record.

MR. STEIN: That was Jon Szalajda speaking. This is Bob Stein.

The first point, I think, Mike, was the low capacity device versus the long capacity device.

The different work rates that are applied

is kind of like an average work rate for that capacity.

And it's not so much that a low capacity device would be used in a higher performance escape, just that for that duration, for that capacity, a person can work at a higher percentage of their ultimate for that period of time. Therefore it's necessary to test the device to be able to provide that higher average output over that short period of time.

Over a longer period of time for a higher capacity device, a person is not likely to be able to sustain a high output work rate over that longer period of time. Therefore, it doesn't behoove you to see that it could provide at that high rate over that entire duration like it does with a low capacity device.

That's the basis for the difference in those two regimes. Okay.

MR. KAY: Thank you, Bob. But I feel it's somewhat of a non sequitur to say that because someone can work at a high work rate for a short

period of time, therefore they will work at a high work rate in a short duration escape, there's a bit of a disconnect.

And my point in my presentation is to refute that, is that open-circuit devices are a fixed flow. They are fixed at a 35 liter per minute STPD flow rate. There is, I think, 35 of these devices out on the market right now, NIOSH-approved devices, that are used in the same escapes that a Capacity 1 CCER will be used in.

Yet, there have been no instances that we are aware of where these devices, these open-circuit devices, have failed to meet the ventilation requirements of users during escapes. They have been used for years.

So the lack of that evidence, the lack of that reporting would strongly indicate that users do not work at exceptionally high work rates for a short duration escape.

They work at a work rate that is below the 40 liter per minute ventilation rate that these fixed-flow open-circuit devices provide.

MR. HEARL: Okay.

MR. STEIN: The next point of clarification was I think going against the maximum work rates that are called out.

And I think your -- I'm not quite sure how to respond to that one just in the way of clarification.

I don't think -- maybe there isn't any clarification to provide on that one because it was just kind of a philosophical stance I think on that one, too.

MR. KAY: Well, it was more of a I think a technical stance in that the work rates that are being recommended really don't seem to have any basis in actual escapes.

And, again, I cite the 1983 Penn State study with actual coal miners in an actual underground coal mine escape did not generate anything near 3 liter per minute VO2 oxygen consumption although they were able to on a treadmill produce 2.74 liter per minute.

In an actual escape, I cite the limiting

factors, darkness and terrain and all of that, all of those prevent that person from reaching their maximum VO2, their maximum ventilation rate.

And, therefore, instead of looking at lab data where we can say, well, we know that a test subject on a treadmill can -- his maximum VO2 is 3.0 liter per minute, it's not going to be 3.0 liter per minute if he's making a shipboard escape or if he is making an escape from a mine.

So that's what my recommendation is that instead of relying on that laboratory data, go out and measure.

We have the technology to measure ventilation rate, to measure VO2 and CO2 production, and see what these escapes actually cost -- or what the metabolic costs are to the user.

MR. HEARL: The next question was?

MR. STEIN: The next point of clarification, as I recall, was about the efficacy of indicators.

And for clarification, Mike asked if we planned on evaluating of the efficacy of those

indicators.

And I would say, yes, we do.

MR. KAY: Any comment on the hypoxia?

MR. STEIN: I didn't -- I listened to you very closely, and I didn't recall a question for clarification in there.

MR. KAY: Well, it was basically two recommendations, and I just like to get your comments on it.

One is we recommend that it be dropped because by exhaling basically five and a half liters of humid air into a chemical device, you are aiding that chemical device artificially in starting. The user will not do that.

And the risk in that is that the LTF data, LTFE data shows that, at least on one particular device, if you don't do that, it goes hypoxic.

So in the interests of safety, I think it be dropped. Otherwise, that two exhaled breaths is going to help mask any hypoxia scenario.

I understand it's geared towards compressed oxygen, but we are not seeing hypoxia

with compressed oxygen. We are seeing the hypoxia with the chemical sets.

And I think the way the test is written, it is counterproductive to that. It is helping prevent hypoxia as opposed to trying to encourage it or to see what the actual hypoxic risk is of that device.

Does that help?

MR. STEIN: I understand what you are saying, but I mean, I don't -- I can't extract a question, you know, to clarify what's in the proposed standard to that.

MR. KAY: Okay. Well, then do you agree that exhaling into a chemical device twice is a benefit for that device and may mask a potential hypoxia scenario based on NIOSH's published data?

MR. STEIN: Base on the published data.

MR. KAY: The LTFE?

MR. HEARL: I think that's something we may need to take under consideration.

And is your recommendation then specifically that instead of five breaths, that the

test -- or the instruction should be two breaths?

Is that what I'm gathering? Would you state what you're recommending?

MR. KAY: I'm recommending no breaths.

I'm recommending that you start the device in accordance with the approved manufacturer's donning procedure.

MR. HEARL: Okay.

MR. STEIN: Okay.

MR. KAY: Okay.

MR. HEARL: Thank you.

MR. KAY: And then under hypoxia, as a little sidebar, I had recommending an indicator to allow the user to assess the condition of his oxygen starter.

So do you agree that maybe -- is that viable?

MR. HEARL: That may be beyond the scope of what we are doing here to be able to answer that question.

MR. KAY: Okay.

MR. ROSS: May I offer a comment?

MR. HEARL: Sure, if you state your name and affiliation.

MR. ROSS: My name is Bill Ross, and I'm an attorney with Latham and Watkins.

The comment is this. Obviously you can set the rules as you like, but these gentlemen have come a long distance in the hope -- I mean, their history is one of working with you, not talking at you. And they just came with in with the hope of being able to do that today, just to talk and work together.

So that's why they are -- that's why the presentation is made the way it is. It was just -- I mean, their objective is to save lives, and that's your objective. The hope was just to understand and talk and, through that, hopefully produce a good solution.

That's the whole thrust. And the hope was that the responses would be in the same -- with the same idea, and so that's why they attempted the dialogue.

MR. HEARL: Sure.

MR. KAY: And I would like to get some response on the -- on the scope of the exclusion of open-circuit respirators from the rulemaking.

And can you give reasons why that would be?

MR. HEARL: Ted, do you want to take that one?

MR. KATZ: I mean, I can't speak to much of what you have said about the open-circuit respirators. I'm not an expert on respirators myself.

But, I mean, this was a priority module scoped out as this when we set priorities for rulemaking.

This is not to say there won't be any rulemaking in the future about open-circuit respirators. I don't know if it's on the agenda right now.

But this was -- I mean, NIOSH has taken a modular approach in identifying high priority regulatory items for amendment, and this was one of these defined as such. So it never was considered

to be part of the scope of this rulemaking.

That's not to say there won't be rulemaking on it, but that was not -- we are doing rulemaking on a whole series of subjects, and they are very well defined.

MR. HEARL: It wasn't actually an exclusionary as it was just this is what we came to take up.

MR. KAY: But I think by excluding it, though, and then maybe potentially coming back or coming to it later on down the road is you really -- the rulemaking talks about potential confusion over duration specific certifications.

MR. KOVAC: Mike, can you raise your microphone?

MR. KAY: I'm not used to talking this long.

It raises -- it mentions confusion, potential confusion among the end users when they are looking at a duration specific CCER.

I think that confusion is now magnified when you have industrial hygienists or a safety

manager of a mine or an industrial plant that is making a decision between a ten-minute open-circuit device and a Capacity 1 closed-circuit device.

At least before, he can look at, well, it's a ten minute and a ten minute. But now he has nothing to compare that to.

And if there's a risk with duration specific devices being classified that way, well, then that risk applies to all self-contained respirators, not just closed-circuit.

And then by singling out closed-circuit, you increase the potential of confusion to the end user.

MR. KATZ: I appreciate that perspective.

MR. KAY: And, again, the point I made about open-circuit is that they are used in the same environments. Open-circuit devices are now used as the primary escape respirator in a U.S. coal mine.

They used on board ships. They are used in tunneling projects. They are used every place closed-circuit escape respirators are used. We compete routinely with them. The same user groups,

the same demographic.

To exclude open circuit from the rulemaking I think is -- it was an economic burden for us, but I think a greater issue is that it's -- it poses an increased safety hazard to the end user ultimately.

Can I get any comment on why it would be excluded?

MR. REHAK: This is Tim Rehak.

I mean, when we started, it was basically what we are looking at in this whole module was for the closed-circuit escape class of respirators where we were updating the certification standard.

And as Ted said, I mean, we are in the process, you know, of updating all of the respirator classes with certification standards.

It takes time, and it's just that was what we viewed as the one that needed, you know, updating first.

MR. KAY: Would you then anticipate that open-circuit would then eventually apply the same rules --

MR. REHAK: Eventually, yes.

MR. KAY: -- as the --

MR. REHAK: Well, I can't say what -- I mean, as of right now.

I mean, until we get in and develop the rules and look at the standards, you know, I can't give you a definite, you know, what will change and what won't change on that, Mike.

MR. KAY: Because doing it piecemeal like that seems to kind of minimize the economic impact. Well, it's just a few users here. But if it were done as self-contained escape respirators, then the true economic impact would come out. The economic impact to all of the end users would come to the forefront.

Does that make sense?

MR. REHAK: I think I know what you are saying.

I mean, I can't say yes or no at this time.

MR. KAY: And, again, I get back to the need for rulemaking. And the LTFE reports show that

by and large, most closed-circuit respirators are doing pretty well.

They are holding up. There are a few instances where manufacturing defects are found or a device may have been used outside of its conditions of use.

But by and large, they are holding up pretty well, except one. And I think that needs to be addressed.

MR. HEARL: Do you have a recommendation for how you think that needs to be addressed?

MR. KAY: Well, up until 2002, user notices were issued and -- about one per year.

And a user notice has not been issued -- it's a self-contained self-rescuer -- since 2002.

From an outsider -- a casual observer looking in would conclude it looks like there aren't any problems with closed-circuit escape respirators.

But if you look at the LTFE reports, phase 7 through 10, you see continual degradation on one product.

And you have got a vehicle to address it.

I recommend you use it; you issue a task number.

MR. HEARL: Okay.

Okay. Any further comments?

MR. KATZ: I would just like to say -- this is Ted Katz, again -- for your colleague -- I'm sorry. I forgot got your name.

But you asked about -- your wish that there would be more dialogue about technical issues and so on here.

And I just -- you have understand, in a regulatory public meeting like this, there cannot -- by the rules, there cannot be that kind of open dialogue.

I mean, your colleagues are welcome to have technical dialogues any time with the NIOSH technical staff about issues like this. We welcome it. It only improves the program.

But you can't do that when you are discussing rulemaking because you have to say within sort of the four corners of the rulemaking, by regulation, in effect.

MR. ROSS: Well, I don't want to get into

a debate, but I think it's a matter of policy rather than law that's dictating your willingness to engage in conversation today.

But we certainly appreciate the opportunity to come and present. And perhaps more than anything else, I was just trying to underscore the fact that we are all here for the same reason.

And the comments that are offered today are intended to save lives, and we understand you are trying to do the same thing. And when that's the mission, you would like it to be as much talking with each other rather than talking at each other.

That's all. Thank you.

MR. HEARL: Indeed. And we look forward to getting your comments, and we look forward to any background material that you would like to put into the record in support of the statements you made and so forth.

And in fact, as I said, the record is open until April 10, 2008 (sic) for submission of such background documents that you may wish to put on the record.

MR. ROSS: Thank you, and that actually brought up another point.

If we need additional time, is there a mechanism in this case for seeking an additional 30 days to put materials into the written record?

MR. HEARL: I think you could submit us a letter to ask for an extent of the comment period, and we could take that under consideration.

MR. ROSS: Very good. Thank you.

MR. HEARL: Any other comments from the panel?

No?

Any other comments from the floor? Anyone who would like to make a statement?

Please state your name and affiliation.

MR. WATZMAN: Bruce Watzman with the National Mining Association.

Just a question.

Since passage of the miner act in 2006, the industry has purchased and deployed tens of thousands of new SCSRs underground at a considerable cost, upwards of $50 million.

Can you tell me what the impact of this rulemaking, if it is completed in its current form, what the impact of that will be on the SCSRs that are now in the mines?

MR. HEARL: I think basically the period for grandfathering of existing units goes out to six years.

MR. WATZMAN: Yes.

MR. HEARL: So at the end of the six-year term, from the date of -- that this rule is put into effect, those units would no longer be usable.

MR. WATZMAN: So units that were brought in today that have a defined life span to them, be it ten years or greater, are going to be arbitrarily withdrawn from the mine in six years?

MR. KATZ: I'm sorry. I didn't understand what you were asking, but now I do.

So a unit sold today, right now we don't have a final rule and an effective date. So I can't tell you how much how much time to add to six years to cover the unit that is sold today.

At the point that we have a final rule and

an effective date, at the point of that effective date, any units sold after that effective date would have a time limitation of six years to be considered an approved NIOSH device.

MR. HEARL: And any units sold before the effective date, the six-year clock would begin running at that time --

MR. KATZ: Exactly --

MR. HEARL: -- or until the expiration of the unit, whichever came first.

MR. WATZMAN: So you have answered my question there, Frank.

So by virtue of this rulemaking, there exists the potential that a significant number of units that are in the mines today will have a shorter life span than they would in the absence of this rulemaking?

MR. HEARL: Correct.

MR. KATZ: That's correct.

MR. WATZMAN: And we have seen, just by virtue of the Miner Act, the backlog that it has taken the manufacturers to achieve the production

levels to meet that.

You know, I think you need to consider the production constraints that exist on the manufacturers who supply to this marketplace and their capacity to deliver units.

Because you may well be putting us -- besides the financial considerations, which are significant, you may well be putting us into a situation whereby virtue of setting this arbitrary six-year period, that we can't -- we don't have units underground, and, therefore, can't operate the mines.

And I think that's a consideration that you need to think about as you work on this.

Going forward, new units, you know, that -- people understand that when they make -- when they design their mine, when they talk about mine plans, when they make capital expense considerations.

But to apply this retroactively I think raises a whole series of considerations that you probably haven't thought about and are real-life

considerations in the operation of the mines.

MR. HEARL: Any comment from the panel?

I want to just point out one thing, actually.

Part of the provision that we were asking for question on in terms of the phase-in proposal is that the manufacturers are allowed to continue to sell the units that are currently certified for three years, and then it is three years beyond that.

Admittedly, if you are buying during that three-year period, you know you are having something that's going to run out six years after the enactment date, but it did provide for basically what I think you were getting at, which is that a mine that is required to have the units on could still be purchasing from a manufacturer before they are ready to produce new units for a three-year period.

And at that point, that's the way that the proposed rule is set up.

MR. WATZMAN: I understand that. I'm just not certain that the three and three is sufficient

and that it -- that a longer phase-in may be warranted and would ask you to think about that.

MR. HEARL: Thank you very much. Will do.

MR. HARKNESS: Yeah, Ira Harkness. I'm an engineer with the Navy, NSWC, Panama City Division.

And I just want to say that we do support the proposed capacity tests and performance tests.

And basis for that support is data from tests that we ran, the Navy ran, probably back in the '90s.

I know you are going to ask, well, can we have that data, and it's not my position to make the promise or even to authorize the public release.

Just sufficient it to say that we did do testing, and we know that a sailor can get from the deepest space in the ship to weather in about five minutes. And the people who did the test and made the recommendation concluded that a SCSR with a -- the minimum rated duration SCSR that would provide the oxygen necessary for that escape would be a ten-minute rated device.

So, like I said, I just wanted to make the

point that we do support the proposed rule on those two requirements.

Thank you.

MR. HEARL: Thank you.

Any other comments from the floor? Anyone who would like to -- if there are no further comments, at this point I think what we will do is go into recess and wait until around 4:30 or so. And then we will adjourn after that if there is no one that shows up that wants to make comments.

So going once, going twice. And I guess we have none, so we will now go into recess and go off the record for about two hours, two and a half hours.

If anyone wants to make further remarks, please see me, and we will come back into session. Thank you.

(A recess was taken.)

MR. HEARL: Okay, I think we can go back on the record again for the public meeting on -- this one is on the closed-circuit escape respirators.

And it is now roughly 4:25, and I would open the meeting and see if anybody has any closing remarks or comments or questions or anything that they would like to offer at this point in time.

From the panel? No?

In that case, I think what we will do is we will declare the meeting closed, and I want to thank everybody for coming.

And I thank those who offered comments very much, I want to remind you all that you can continue to submit comments through April 10. And the three routes of entry for doing that is, one is the www.regulations.gov, which is the federal government's submittal portal.

The other is by mail to the docket office at the Robert A. Taft Laboratories, Mail Stop C-34, 4676 Columbia Parkway, Cincinnati, Ohio, 45226.

And the third sway is by email to niocindocket@cdc.gov.

And we will be happy to take any comments or supporting data materials that you would like to submit to the record by any of those means.

So with that, we will call this meeting to an end and thank you all for coming, and travel safe.

Meeting adjourned.

(Whereupon, at 4:28 p.m., the proceedings in the above-captioned matter were concluded.)

CERTIFICATE OF REPORTER

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

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Joseph A. Inabnet

Court Reporter