NATIONAL INSTITUTE

FOR OCCUPATIONAL SAFETY AND HEALTH

NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY

PUBLIC MEETING

COMMENTS ON PROPOSED RULES FOR:

QUALITY ASSURANCE REQUIREMENTS FOR RESPIRATORS

Monday, March 30, 2009

Commencing at 9:00 a.m. at the Los Angeles Airport Marriott, 5855 West Century Boulevard, Los Angeles, California.

P R O C E E D I N G S

MR. KIEFER: Good morning and welcome. My name is Max Kiefer. I'm the Denver Regional Office Director for the National Institute for Occupational Safety and Health.

We are here today to accept public comment on proposed rules revising Title 42, Code of Federal Regulations Part 84, quality assurance requirements for respirators.

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

The period to submit written comments on these proposed rules has been extended to April 10, 2009 to permit additional time for parties to submit their comments to the docket.

Let me start the meeting with a couple of significant housekeeping announcements.

First, if the need comes to evacuate, we go out the doors here. And then there's exits both to the left and to the right. I think the ones to the right are a little bit closer.

Second, the nearest bathrooms are located the right and then to the left and just to the right.

Third, in deference to today's speakers and in consideration of others who are attending, please put your cell phones and pagers in vibrate mode, although I understand that many of them aren't working in here anyway.

The purpose of today's meeting is to seek public input and comment on the proposed rules that were published on December 10, 2008. This is the second of two public meetings we are holding on these rules.

The first meeting was in Adelphi, Maryland on Monday March 23, 2009. We will attempt to complete our meeting by 12:30 p.m., and we will organize the session as follows:

First, we will hear a presentation by NIOSH staff who will briefly describe the changes that are proposed by these rules. We will invite to the lectern persons who have preregistered to speak at this meeting in response to our federal

registration notice. We have one person or organization registered.

This will be followed in order by those who have registered to speak, if there's additional ones, by signing up on the sheet at the registration desk outside of this meeting room.

Finally, as time permits, we will invite anyone to make further comments from the floor.

Let me point out a couple of things. If you haven't already done so, please register your attendance by signing the sign-in sheet outside of the room at the registration table.

If you want to speak and have not yet signed up, please sign the speakers sheet at the registration table.

This meeting is being recorded, and transcripts will be placed on the regulatory docket.

There will be a question-and-answer period after the presentations.

And importantly, when you get up to speak, please indicate your name, organization, and use the microphone to make your comments so we may capture

all of your remarks for the record.

NIOSH has not identified any specific questions in the Federal Register that we would like the public to address, however, any comment relevant to the proposed rule is welcome.

Let me call your attention to the slide now, which provides administrative details for those who want to submit additional information or obtain more information about the proposed rulemaking.

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

Again, my name is Max Kiefer, and I'm the moderator. The NIOSH panel consists of Bill Newcomb.

Bill is presently a physical scientist with NIOSH in the Policy and Standards Development Branch of National Personal Protective Technology Laboratory and is the project manager for the quality assurance for respirators proposed rule.

Tim Rehak is a professional engineer with the Policies and Standards Development Branch and

has been conducting research on SCSR, research and testing since 1995.

Tim is the project officer in the development of CCER testing and certification.

Ted Katz is a public health analyst at NIOSH. He is the principal regulatory writer and coordinator for regulatory actions.

I would now like to introduce Mr. Bill Newcomb who will briefly describe the proposed rules and identify some of the specific questions NIOSH posed in the December 10, 2008 Federal Register announcement.

Bill.

MR. NEWCOMB: Sorry about that. That it is obviously a lot taller than I.

The quality insurance for respirators was published in the -- December 10 in the Federal Register. But those of you who have been following this know that it really goes back to about the year 2000 or possibly before when we started talking about the quality assurance for respirators in general.

So what we have come up with is a culmination of input in I think the four public meetings that we have had so far on this. And finally came into rulemaking by proposing a notice of proposed rulemaking so that we could get it on as a final rule to make the quality assurance requirements a little different than they are today.

One of the things we did was to add quality management.

The ISO 9000 didn't exist when the present standard was written back in 1972 when it was 30 CFR 11 and was not added when the regulation was revised in 1995. But it felt that there should be quality management from the top down for respirator manufacturers.

Also, it clarifies the auditing procedures and the use of contract auditors.

We do site audits as well as product audits, and the site audits sometimes -- in many cases have shown some concerns, and what we would like to do is audit new manufacturers before they actually start producing respirators with a NIOSH

certification, which is slightly different than what we do now.

Another thing we have done is to allow the use of various sampling plans.

The present regulation calls out an obsolete military standard and uses AQLs only for the ability to make manufacturers sampling plans.

What we have tried to do is to make it -- various sampling plans available to users as long as they came up with the same results, and that is making quality product for the end user.

It codifies the use of the standard application procedure. Those of you who may be manufacturers that have been making applications to NIOSH know that NIOSH has had the standard application procedure and look for electronic applications for probably more than a decade now.

And that procedure is not codified at all in the regulations. We would like to add that.

It also calls for linking quality controls to specific sections of 42 CFR Part 84.

For example, if there is a requirement in

84 for a specific performance requirement, we would like to see paperwork that links where that requirement is actually looked at in the manufacturing process or the inspection process to see that all requirements of Part 84 are somehow linked to a specific action by the manufacturer.

It adds some quality assurance requirements to the existing quality control requirements.

It mandates NIOSH notification of change of approval holder ownership. And over the last decade or so, there have been many consolidations in the industry. And sometimes it's kind of hard for NIOSH to know who actually is the manufacturer and the approval holder.

And what we are trying to do is to make sure that when there is a change of ownership, that the quality plan is carried from the present owner through to the new owner and the new owner has the same philosophy and uses the same quality control plans and so forth that have been submitted to NIOSH.

If not, we are going to require that they actually submit new quality control plans to go along with the new manufacturing site ownership.

It also clarified some requirements for NIOSH notification of some customer complaints and gives timelines. What it does not do is require that the -- all complaints are investigated in a certain period of time. What it does say, however, is if you get a complaint and you have investigated it and it is serious, we want NIOSH notified right away.

And the present proposed rule says, after you have made that determination that it is a problem, that you notify us within three days, which is something a little different than in the current regulation.

And it also clarifies some requirements for the revocation of approvals due to quality control failures or a lack of quality procedures and so forth saying that NIOSH does have the right to revoke approvals if it feels that the quality control plan that we have isn't being used or that

there are other problems within the plan.

And that's some overviews. If you have read the regulation, proposed regulation, they should be of no news to you.

But we are open to comments concerning the regulation. Thank you.

MR. KIEFER: Thank you, Bill.

Again, here is the slide describing the process for submitting comments. For those of you who want to note that information, I will leave it up here a moment.

Again, comments are due by Friday, April 10, 2009.

I have one organization scheduled for presentation. Is there anyone here who is going to be a speaker or who has signed up for speaking?

Okay, great. I will call on you after the presentation.

Now, I would like to ask Mr. Patrick Leseicki -- I hope I'm pronouncing that correct -- with SCI.

MR. LESEICKI: Good morning. My name is

Patrick Leseicki. I'm a quality engineer with Structural Composites Industries. We are a manufacturer of cylinders that are used in the SCBA units.

I will say up front that I may touch on an area, a couple of areas here that are not directly related to the general discussion here today, but are tied into it in a way.

While the proposal to require respirator manufacturers to be compliant with ISO standard for a quality management system is a step in the right direction, it's a vast improvement over the outdated quality control requirements of the 42 CFR 84 subpart E, which was established in 1972, it still falls short of guaranteeing top quality SCBA units to the end user for a couple of reasons.

Compliance stating a thing does not mean a thing and is generally not enforceable. Compliance means that you are trying to follow or you agree to follow what is written in the standard and everything.

Registrars don't audit for compliance.

Registrars come out and audit people who want to uncertified and register to a standard. So it may be a matter of semantics, but compliance I think is the wrong term to use in this.

Secondly, most of all respirator manufacturers are OEMs, are not manufacturers in the true sense of manufacturing. What they do is they take components, which are made by other manufacturing outfits, such as the cylinders, regulators, masks, et cetera, and they assemble it into a unit or product, which is the respirator, SCBA unit.

The OEMs have absolutely no effect on the quality or control of the quality of the individual component items, the cylinder, the respirator, mask, or the valve or anything.

So to require their compliance or certification be kind of -- to me appears kind of not fully the right way to go.

NIOSH and the end SCBA users as well as the general public would probably be far better served by mandating registration certification to

the ISO standard rather than a compliance from individual component manufacturers all the way up through the OEM, not just imposing it on the OEM, who is not manufacturer to begin with, but requiring that anybody who makes a component that goes into the unit to be an ISO registered certified to standard.

A good way to do this would probably be -- there's a model which has been in place for decades, which is the FAA PMA approval for aircraft and everything. That would be a good way for NIOSH to consider going, with a program like this. It's been around for decades and works very well. And there's been very little problems with aircraft because of their good control practices and everything.

And I'm going to present a brief presentation on how such a program might work.

The FAA grants what is called a type certificate to aircraft manufacturers. I propose calling it a -- for NIOSH, a class certificate for each different type of respirator and everything.

The OEM would have to prove to NIOSH that

the units meet the NIOSH current prevailing requirements for safe use, protection under the -- all conceivable conditions.

If NIOSH is satisfied through testing of their documentation from the OEMs, then NIOSH would issue the OEM a class certificate for a particular unit that they submitted. All different models or types would have to have their own class certificate.

The class certificates are the foundation for other approvals, including a manufacturing of component parts. Now the class certificate would be issued for the entire SCBA unit, the respirator, not the individual component parts.

So us, as a manufacturer of cylinders are mass manufacturer -- a regulator manufacturer could not have a class certificate. That's only the property of the OEM.

We could obtain what I call a component manufacturer's approval, which is the -- would be the equivalent of the FAA's parts manufacturing approval in two ways.

The OEM being holder of the class certificate could license the manufacturer. So MSA or Scott (phonetic) or whoever could license us to produce NIOSH-approved cylinders for use in their respirators via identicality (phonetic), where we prove to them that our cylinder, through testing and comparing with the drawings or whatever they use are exactly identical to the cylinder that they are using in their completed unit right now.

The other option would be for the manufacturer to apply to NIOSH for CMA via a full qualification.

Now, in the FAA process, the FAA licenses manufacturers to make parts, replacement parts for the aircraft.

A manufacturer can go to the FAA and require -- request a PMA approval on their own. And they would have to go through a full qualification where they would have to prove to the FAA that the part is identical to the original part and then have to go through testing and everything to verify that it functions properly and safe.

And once the FAA has reviewed all of the data and witnessed everything, they would grant PMA. I propose the same kind of process for NIOSH, for the CMA for the individual component parts.

In either case, the manufacturer must maintain a quality system certified to ISO 9001:2000 as a minimum. There is AS 9100 also, which is for aerospace, which is a little bit above and beyond probably what NIOSH would need, but we are an AS 9100 certified manufacturer. And because AS 9100 is ISO 9000 plus additional requirements for aerospace industry, we have both AS 9100 and ISO certification.

So I would propose they use that AS 9001:2001 (sic) as a minimum requirement.

The CMA would not be transferable.

The gentleman earlier talked about if the company was sold, the new owner would inherit it. That's not the way it works in the FAA, and I should think or feel it should be the same way for NIOSH. The new owner would have to reapply and prove his system and everything to NIOSH rather than inherit

it.

It also would be valid until surrendered or withdrawn or voluntarily withdrawn by the manufacturer, or, if NIOSH found some violation, terminated.

And it's only good for the location where the manufacturing and inspection system is. So if a company were to start another facility in another state, they would have to apply for a separate approval. They couldn't piggyback onto the approval of the other facility.

The way this would be done rather, than setting up a whole bureaucracy and everything due to this is that the FAA uses what are called DARs, Designated Airworthiness Representatives, that are not employees of the FAA, but they have been tested and approved. And through their experience and education and testing, proven to the FAA that they have the knowledge to perform the inspections and inspections testing as are necessary to issue the approvals.

I would propose a designated manufacturing

representative for NIOSH, which would be equivalent to the FAA DMR. They would be appointed by NIOSH, but they are not employees of NIOSH. They are independent contractors whom the individual companies would have to pay to come out and inspect their facilities and examine their data and everything.

And then the DMRs would submit their recommendations to NIOSH, and NIOSH would have the final say so-on whether to approve or deny their requests.

That's it.

MR. KIEFER: Are there any questions?

I would like to now ask the NIOSH panel if they have any questions for Mr. Leseicki.

Thank you very much for the presentation.

You can use the microphone when you respond.

MR. NEWCOMB: Thank you. That was a slightly different, as you say, concept that is used in the aircraft industry.

One of the things I was concerned with is

who specifies the component requirements?

MR. LESEICKI: The manufacturer submits to NIOSH their -- what their component -- the specifications for their individual components.

NIOSH may have their own regulations. They would decide whether the individual component meets their requirements or specifications.

So you don't tell a manufacturer how to make a cylinder or a mask or anything, but you have some operational requirements and parameters and everything.

So they would submit a data sheet with their operational requirements or parameters of their particular item. You would review it against your standards and requirements and decide whether it is acceptable or not.

MR. NEWCOMB: But all components -- the aircraft components are interchangeable.

Is that not correct?

MR. LESEICKI: Correct.

MR. NEWCOMB: That's all the questions I have.

MR. KIEFER: Any other questions from the NIOSH panel?

Thank you very much, Mr. Leseicki. We will -- for the comments. We will consider your input.

We have a speaker registered, Mr. Jeff Birkner from Moldex.

If you would stand up, come to the microphone, and introduce yourself. Thank you.

MR. BIRKNER: My comments will only take a minute, so...

I'm Jeff Birkner. I'm with Moldex-Metric. I'm the EPA technical services. And Moldex-Metric respectfully requests an extension to October 9 so that we have adequate time to review the impact of the proposed regulation on our company as well as the end users.

MR. KIEFER: Thank you, Mr. Birkner. We will take your comments into consideration and your input.

Does anyone have any questions from the NIOSH panel for Mr. Birkner?

Thanks again.

Is there anyone else who would like to speak?

Thank you. Given that we have no more speakers, we are going to put the session into recess until 12 o'clock. Thank you.

I apologize. I didn't ask the open session.

Please identify yourself, again.

MR. LESEICKI: Patrick Leseicki, Structural Composites Industries.

Why have you chosen in your wording the Federal Register there "compliance" versus "certification and registration," as I indicated in my presentation?

MR. KATZ: I can answer that.

Yeah. It wasn't quite the sort of nuance I think you were thinking in terms of compliance. We used that term because the proposal does not require registration, okay, which would be a cost to some manufacturers who are not registered right now.

It requires a compliance with that

standard. And, hence, if someone was not registered, if a manufacturer was not registered, they could be evaluated, for example, by NIOSH to see that they are complying with the requirements without having to go through the formal process and expense of registration.

MR. LESEICKI: And does NIOSH have auditors that are formally trained and certificated by RABQSA or any of other international bodies to perform audits to standard?

MR. KATZ: Bill, you can address that.

MR. NEWCOMB: I don't think we are there yet.

We do use contract auditors, and I'm not sure of the qualifications. But, obviously, if we were going to audit for compliance with ISO, we would have to have those qualifications.

MR. LESEICKI: All right. That's all for the moment.

MR. PODLOGAR: My name is Bob Podlogar, ICS Laboratories. We are a contract auditor.

Part of the requirement solicitation for

an auditor was that the auditors be RAB certified or equivalent. So all of the auditors, as far as I know, are RAB certified. I know I am, so I presume that everyone else is, also.

While onsite, as far as being certified or just following the rules, most manufacturers, not all, do comply. And whether they are officially ISO certified or not, most management systems have all of the key structures in place currently, at least from what I have seen. There are a few that do not, and I believe this will just bring them into the fold.

Thank you.

MR. KIEFER: Thank you for your comment.

MR. ATUNES: Hi. My name is William Atunes with Structural Composites Industries.

Just a couple of clarifications.

When you talk about codifying the standard application procedure, can you elaborate on that a little bit more? I assume that means simply putting it in writing in some form, but perhaps you can elaborate on that.

MR. NEWCOMB: By codification, we mean actually making it part of the law, which means that it appears in the Federal Register as -- and eventually in the CFR, which is the Code of Federal Regulations, which is where things are codified.

So by making it part of the language in 42C CFR Part 84, we are in fact codifying it.

MR. ATUNES: Thank you. And then also you had in the earlier presentation by Max -- or, excuse me, by Bill, you talked about linking quality control plans specifically to sections of 42 CFR Part 84.

Could you elaborate on that a little bit more?

MR. NEWCOMB: I can try.

Right now, the drawing that NIOSH gets of the respirator and the components has specific information on them for requirements, but not necessarily linked to requirements that the respirator has to meet in Part 84.

So what we have envisioned is sort of a matrix where you have the requirement that pertains

to that respirator, and you also have a link or a description of where that characteristic is in fact checked, be it in process or at an inspection point or some other place where that specific element is checked.

So that if an auditor wants to see if you meet a specific requirement in 42 CFR 84, he has essentially a road map to where that is looked at, inspected, or otherwise verified.

MR. ATUNES: Okay. All right. And then when Pat spoke of the component part, the quality, I'm confused a little bit how NIOSH intends to insure component part quality assurance other than through the approval holder's application.

Is there more to that? Does the new -- does the proposal cover that in greater detail?

MR. NEWCOMB: The only entity that NIOSH has control over is the applicant, and we go by the applicant's quality control plan, the applicant's quality control module, and their inspection plans.

It's up to the applicant to control their incoming, whether it's from a subsidiary of their

own or it's an OEM manufacturer or anything else.

We cannot control the subcontractors. The only thing that NIOSH deals with is the applicant, in essence is the approval holder as well.

So he's the only person we really can write the requirements for.

MR. ATUNES: And then just to echo the comments of the other fellow, I would like to also propose or ask that this docket period be extended as well.

Thank you very much.

MR. KIEFER: Thank you.

MR. LESEICKI: Patrick Leseicki, Structural Composites.

You stated that you have no control over anybody except the applicant or the approval holder.

Why is that?

MR. NEWCOMB: That's the way the regulations are written right now.

MR. LESEICKI: Who writes the regulations?

MR. KATZ: Perhaps I'm misunderstanding what Bill is saying, but the applicant is

responsible for the quality of the components that come in.

Via that, NIOSH has control -- via -- so NIOSH doesn't have direct control over the components in the sense that it's going out and inspecting them independently. But if an applicant -- if a component is produced somewhere in another factory, for example -- Bill, just correct me if I'm wrong, but under this proposal, and that's part of the quality control plan of the applicant by necessity because that component is an essential element of the product, then NIOSH could do an inspection of that component manufacturer.

It's just that it is done under the aegis of the applicant since the applicant is the one who is applying to NIOSH for approval.

So it's not that component manufacturing is not overseen by NIOSH, but it's just not a direct relationship. It comes by virtue of that component manufacturer supplying the manufacturer -- the applicant.

MR. LESEICKI: So is --

MR. KIEFER: Maybe I need to be certain I'm correct.

MR. NEWCOMB: The way 42 CFR is written right now, it's written for the manufacturer. And the products that are approved are complete respirators. There are no components approved.

And that's the way it has been since 1972, and it would probably take an act of Congress to change that.

But what Ted was alluding to is, if a manufacturer has a quality control plan that has been extended to a subcontractor or a subsidiary, then NIOSH right now has taken the impetus to be able to inspect and do audits on that manufacturer's site as well, as long as that manufacturing site is under the auspices of the applicant's control.

If it is just something that is just being purchased and, for instance, in the case of, I believe, many cylinders for SCBAs, the manufacturer -- the SCBA manufacturer is purchasing the cylinders, but those cylinders are not made under the quality control plan of the applicant.

So, therefore, NIOSH would not audit the cylinder manufacturer.

It is then up to the manufacturer of the respirator to make sure that the cylinders that he is buying as a component of his end item are in fact made properly or made by an ISO-compliant manufacturer, or whatever those inspections or contracts that he has to make with a supplier. Because there isn't a link between the quality control plans, so, therefore, there isn't a link, from NIOSH's standpoint, down to the manufacturer of that subcomponent.

MR. LESEICKI: All right. Back to the previous question before you gentlemen finish this, who wrote the regulations initially?

MR. KATZ: Well, in 1970, if you mean initially --

MR. LESEICKI: For 42 CFR.

MR. KATZ: The Department of Health and Human Services.

But the proposal before you, NIOSH wrote.

MR. LESEICKI: Okay. I was looking for

the original because you said that there is nothing in the regulation.

If I recall right, and I would have to verify this to be sure. The CFR that controls the FAA does not mandate component part approval either. It just charges the FAA with the overall responsibility for the safe transportation of passengers on aircraft and everything.

And they leave it up to the FAA to use whatever means are necessary. And if FAA has their own orders, 8100 and 8110, which the control the PMA process and the DARs and do the approval and everything.

So in effect, you could write your own stuff then similar to the FAA because it doesn't have to be specified in the CFR. You are charged with, you know, the safe operation or whatever, you know, of these things and everything.

You could decide how you want to do that.

MR. KATZ: We wouldn't (sic) have to specify it in the CFR. I mean, we would (sic) have to do that. I'm not saying that our statutory

authority doesn't allow us to do that.

I'm not going to opine on the limits of our legal authority, but, yes, we would have to -- we would have to propose that as a statutory -- as a regulatory change to be able to approve components.

It's not in the proposal as it is written now except to the extent that I explained where you are covered by the quality control plan.

MR. LESEICKI: But you could do it if you chose to?

MR. KATZ: I'm not disputing that or affirming it, actually, what our legal limits are.

You know, I guess we do have the statutory authority because our statutory authority is fairly broad and not specific at this level at all.

What Bill was saying is that as the respirator regulations were constructed originally in 1970, that wasn't even -- that wasn't foreseen and provided for. And we are sort of working under that regulatory structure at this point.

We appreciate your comments because it's another point of view, another way to go. It's just

not reflected in the history of the rules for this program up to date, but we appreciate that.

MR. LESEICKI: All right.

MR. TECON: My name is Pierre Tecon, and I'm with SCI.

I would like to make a comment about one particular component of the SCBA, that's the cylinder. And this relates to the quality control of this particular component.

Cylinders are regulated by federal specification, by the DOT. Therefore, any operation by OEM on the cylinders are prohibited. Therefore, there is no improved performance or enhanced value brought up to this particular component by the OEM. And this was related to the quality control of this particular component.

Thank you very much.

MR. KIEFER: Thank you for your comment.

MR. STEWART: James Stewart, support contractor from the Office of Law Enforcement Standards at the National Institute of Standards and Technology.

Pat made a point about restricting the transference of certification approvals from one company that has been purchased by another.

Can you elaborate on reasons why you would approve such a transference being that sometimes companies who absorb or purchase other companies haven't proved that they can comply with quality assurance programs.

So why wouldn't you make them prove that once the company was purchased instead of basically absorbing that compliance level of the company they purchased?

MR. NEWCOMB: That's actually what the approval does.

And right now we don't have the -- a lot of times we don't even know when a company is purchased. So what we have tried to put in this proposed rule is that we be notified and in fact, that the -- there be proof that the new entity is going to make the product with the same quality that the old entity did.

We are not going to just allow change of

ownership between companies without knowing some of the background of the quality control and management structure and so forth of the new entity.

MR. STEWART: Okay, thanks.

MR. NEGUS: Good morning. Teg Negus, Allegro Industries. Just a quick comment.

Has there been any discussion about the ISO requirement as a barrier to entry into the new markets?

And the point of view I'm trying to take here is that you may have a new industry -- or excuse me, a new manufacturer trying to enter the industry.

And specifically I was looking at your Section 84 40 Subpart C listed on page 75049, where it states the statement of compliance, if the applicant has not undergone an audit, basically you are requiring a statement versus actual compliance with ISO.

Part of the history, as I understand it, we all want to become ISO certified. And we may need to use that down the road, thinking ten, 15

years, we may have smaller industries or manufacturers wanting to enter the market.

Do you have any response?

MR. NEWCOMB: One of the reasons for looking at requiring compliance and not registration was just what you have suggested, the fact that it may be a barrier to entry into the market.

And so the way it was written, it did not require the registration, but it required the compliance, whether you state it or NIOSH or somebody else goes in and audits for it, rather than requiring the registration.

MR. NEGUS: Understood. Thank you.

Is there any discussion in regards to compliance by volume?

And specifically I'm thinking of that small industry whereby they may not have the sample parts to be able to use the quality sampling, and, therefore, they may not actually need an ISO certification.

So that down the road, say a small industry, small manufacturer is continuing business

with, say, under 10,000 parts, is there any feeling for the need for them to have an ISO requirement because it may be cost prohibitive?

MR. NEWCOMB: There has not been anything in the regulation concerning -- in the proposed regulation concerning volume at this point.

MR. NEGUS: Thank you.

MR. PODLOGAR: Bob Podlogar, ICS.

I would just like to make note that all ISO certifications are definitely not equal around the globe. Some people who are not ISO certified have systems and perform much better than organizations who do.

And as a second note, the current standard application procedure in the body of that procedure lists 90 percent of the ISO requirements already as NIOSH requirements.

Maybe a few things aren't present, like management review. But typically most of those things already are a requirement, though not specifically in the CFR.

MR. KATZ: Just to respond a little bit to

that comment. I appreciate the comment. We appreciate that comment.

And that was I think addressed -- we discussed that in the preamble of this rule, and that's one of the reasons, even if a manufacturer were registered as compliant, that doesn't mean that NIOSH wouldn't go beyond that to determine actually, you know, whether they are compliant separately if we had any concerns that, though they are registered, they may not performing at that level just the same. Thank you.

MR. PODLOGAR: I said that in support.

MR. AVILES: William Aviles, Sperian Respiratory Protection.

Could you elaborate a little bit more on the sampling plan that you have proposed in the new regulations?

MR. NEWCOMB: Well, I must admit, I'm not an expert in sampling plans, but we have tried to do a couple of things.

And one is to make it less restrictive as far as which plans are used to allow manufacturers

to use different plans that might suit their manufacturing process better than the prescriptive antiquated requirements that are in the current regulation.

And the other thing that we have done is looked at it more from the consumer's point of view than the manufacturer's. The old regulation was written pretty much around the manufacturers' needs for quality and not around the consumers' needs for quality.

So we think that the sampling plan that -- or the sampling plans that we came up with will give the consumer more confidence in the products that we certify.

MR. KATZ: And just to elaborate. Another point that I think was talked about in the sidebar in the meeting in Maryland, but I don't think it was addressed during the discussion on the record.

And that is, as the proposed rule explains, there's a number of plans that are called out as possible options in the proposed rule, but then there's also on open door at the end of that,

if you read it carefully, for the manufacturer to use other plans that aren't reflected in the rule providing that they provide the same level of consumer protection that the ones called out for in the rule do.

I just wanted to make that clear, if that wasn't understood.

MR. LESEICKI: Patrick Leseicki, SCI.

You stated a couple of times that you would accept a statement of compliance or certification, a certificate or something.

So you will accept a manufacturer, OEM's, letter of compliance to you without any verification that they really are?

MR. NEWCOMB: No. We intend in our audits to look at the plan and make the determination whether or not we believe that the certificate that's being supplied by the manufacturer is in fact valid.

It's the same way as was just brought up a while ago that different ISO certifiers -- different bodies around the world are not equal.

So that we will always reserve the right to look at in our audit those things that we feel that are necessary in the ISO certification -- or ISO compliance, I should say, to make sure that they are in fact in place.

MR. LESEICKI: Okay. Now you said the manufacturer, OEM, or whatever is responsible for the quality of the components that go into the respirator or anything.

Do you have a statement anywhere in the proposed rule then that the OEM must flow down the requirements to their manufacturers or subcontractors to ensure that their systems or their products meet those requirements?

MR. NEWCOMB: I don't recall any.

Again, the impetus that we had is on the applicant and making sure that the applicant quality control plan is sufficient.

And if the applicant is looking at its suppliers, then its program probably will not be compliant.

MR. LESEICKI: One final question. I'm

not exactly sure.

You talk about NIOSH certification of the respirators. What exactly does a NIOSH certified respirator give the OEM or the end user?

What does that mean exactly?

MR. NEWCOMB: The certification means that the product has been type tested and is in a certification mode. It is listed. It's audited, and so forth.

So it goes through a procedure that any third-party certifier would use of initially doing a type testing.

As part of that, we look at the quality control plan. We look at the user instructions and all of the components, if you will, that make up the certified respirator.

And we list it then on the certified equipment list, and we do product audits, and we do site audits on those products once they are -- have received a NIOSH approval.

MR. LESEICKI: So then it doesn't give or provide the OEM any, I don't know, protection or

whatever from the standpoint -- let's say that out in the field, a fire captain was out in the field and the tank blew up on the cylinder, something out in the field.

You wouldn't give the OEM any legal protection resulting from lawsuits or anything that would occur because of that failure of the tank?

MR. KATZ: No. I mean, there's no liability protections conferred as result of being NIOSH certified, if that's your question.

MR. LESEICKI: No, I'm not -- but you certify things, so you wouldn't assist the OEM in their legal defense?

MR. KATZ: No, absolutely not. The Federal Government wouldn't do that in any circumstance that I know of.

MR. LESEICKI: All right. Thank you.

MR. STEWART: James Stewart, support contractor, Office of Law Enforcement Standards at NIST.

There is a program called the Safety Act where in an incident of a natural disaster or such

or a terrorist event, if the equipment was purchased through the grant procurement program at FEMA, there would be some support afforded to the manufacturer of a piece of equipment if there was a devastating event that caused an accident where there was a liability involved.

So the Safety Act was put in effect through DHS, Department of Homeland Security, that would afford you some liability protection.

So that's on the DHS website. If we can speak offline, we can discuss it a little bit more.

MR. KATZ: Just -- that's Department of Homeland Security for anyone who might not know that.

MR. STEWART: Right.

MR. KIEFER: Are there any more questions for the panel at this time?

None heard, then we will go to recess at this time. Thank you very much.

MR. NEWCOMB: We will reconvene at 12 o'clock.

(A recess was taken.)

MR. KIEFER: Good morning. I'm reopening the meeting, but I see that there are no more participants, so the meeting is adjourned.

(Whereupon, the proceedings in the above-captioned matter were concluded at 11:30 a.m.)

CERTIFICATE OF REPORTER

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

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Joseph A. Inabnet

Court Reporter