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 23, 2009

Commencing at 8:36 a.m. at the University of Maryland University College Marriott, 3501 University Boulevard E, Adelphi, Maryland.

P R O C E E D I N G S

MR. HEARL: Good morning, and welcome.

My name is Frank Hearl, and I'm the Chief of Staff for the National Institute for Occupational Safety and Health, NIOSH.

And 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 for this action was originally published in the Federal Register on December 10, 2008.

And the -- I want you to know that the period to submit written comments on these proposed rules has been extended to April 10, 2009 to permit additional time for the parties to submit their comments to the docket.

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

First, should we have to evacuate the

building, this is pretty easy to get out of here. Just go back out through either sets of the doors in the back of room and keep going. And there's exits to the left and straight ahead, in fact.

Also, I want to let you know that the bathrooms, the nearest bathrooms are located out the door and to the left, and just past the restaurant is where you will find the restrooms.

And third, in deference to today's speakers and in consideration for everyone else attending the meeting, I would ask, if you could, please take a moment and put your cell phones and Blackberries in vibrate mode. And we will have a more pleasant meeting.

The purpose of today's meeting is to seek public input and comment on the proposed rules published on December 10, 2008.

This is the first of two public meetings that we are holding on these rules. The second meeting will be held on Monday, March 30, 2009 at the Marriott Los Angeles Airport in California beginning at 9 o'clock Pacific Daylight Time.

We will attempt to complete our meeting this morning by 12:30 p.m. Eastern Daylight Time, and we will organize our session as follows.

First, we will hear a brief presentation by NIOSH staff, who will briefly describe the changes that were in these proposed rules. Then we are going to invite to the lectern persons who have preregistered to speak in response to the Federal Register notice.

I have got the list of sign-up, which includes three individuals. I understand actually only two presentations.

If you do happen to have a presentation and you would like to make one, please let me know, or you can sign up on the sign-up sheet, and I'll take you in order.

So after everyone who has registered to speak, we will open the floor to anyone who has comments they would like to make. And we will go on from there as time permits with further comments.

I want to point out a few things to you.

First, if you haven't already done so,

please register your attendance by signing on the sign-in sheets in the back outside the room at the registration table.

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

There will be a question-and-answer period where you can question the NIOSH panel after the presentations are done.

And when you get up to speak, if you would please state your name, your organization, and use the microphone to make comments so we can accurately attribute all of remarks that you may make for the record.

On this particular rulemaking, 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 now introduce my colleagues from NIOSH who will be part of the panel participating in this meeting today.

First, I would like to introduce Mr. Jon

Szalajda. And Jon's current position is the branch chief for the Policy and 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 experience in the field of personal protective technology.

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

David Book is the team leader for engineering evaluation for the Technology Evaluation Branch at NPPTL. He is one of a series of technical authors and advisors who worked on these proposed rules, and he was the senior technical advisor to the team which generated the quality assurance proposed rule.

And to my left is Ted Katz. Ted is a public health analyst at NIOSH. He is the principal regulatory writer and coordinator of regulatory actions.

And sitting in the audience, also, I would point out we have Director of the National Personal Protective Technology Laboratory, Les Boord, who is in attendance.

I would like now to introduce Mr. Bill Newcomb, who will briefly describe the NIOSH proposed rules and will identify some of the specific things that we would like to have addressed out of this Federal Register announcement.

Bill.

MR. NEWCOMB: Thank you, Frank.

As many of you know, this rule has been in the process for several years. We have had a lot of dialogue with manufacturers and some public meetings in the past, and then we came out with this proposed rule on the 10th of December of last year.

A couple of highlights, just to refresh your memory about the rule. It adds quality

management to the quality control process in the forms of compliance with ISO 9001. It also clarifies some auditing procedures and the use of contract auditors.

It allows the use of various sampling plans. Right now the Code of Federal Regulations requires specific sampling plans that are based on some antiquated standards, and we hope to allow manufacturers to use more updated sampling plans in conjunction with things like statistical process control and the like to cut down on some of the sampling that they have to do and take credit for the procedures that they put in place.

It codifies the use of the standards application procedure. The standards application procedure now has been in use for several years as a policy at NPPTL, and it's codified in this regulation, or its use is.

It links quality control requirements in the drawings in the quality plan with specific sections of 42 CFR, Part 84.

In other words, if there is a requirement

that pertains to the respirator, there must be a link as to where that particular characteristic is checked or controlled during the manufacturing process.

It adds, as I said earlier, quality assurance requirements as well as the existing quality control requirements.

One of the things that has happened in the last several years that has become very confusing to NIOSH is the ownership of companies. And in this proposed -- notice of proposed rulemaking, it mandates NIOSH notification of changes of approval holder ownership.

It also mandates NIOSH notification with certain customer complaints.

Again, there has been some policies in place for quite a while, and this makes it clearer as to when NIOSH has to be notified that there is a customer complaint of a serious nature.

And it clarifies the causes for quality related revocation of approvals.

So just to go over a few of the highlights

that are in the proposed rule and give you something to think about and talk about in your presentations.

Thank you.

MR. HEARL: Thank you, Bill.

Okay. We are now at the stage of the program -- let's go back here -- where we will take presentations from attendees, and we will take those in order.

I have got three people signed up, Diane Handeland from 3M; Fred Chu from 3M; and Janice Bradley from ISEA, and no others. So if someone else would like to speak, please let me know somewhere along the line here, and we will get you on.

We will begin with Diane Handeland from 3M. If you would like to come on up and present from here.

I think you have a presentation already loaded in the machine.

MS. HENDELAND: Yes.

Good morning. My name is Diane Handeland. I'm the division quality manager for 3M Occupational

Health and Environmental Safety Division.

And Fred Chu is going to be speaking with me. He will handle the second half of our presentation. He is our quality systems manager for our division. And Robert Weber is with us. He is regulatory affairs manager for our division.

These are the topics that we are going to cover today. First, some general comments, and then I listed the specific provisions of the proposed rule that we will cover. So we will go through these in this order.

So first, just some general comments. Regarding the standard application procedure, there are several proposed requirements that are tied to an anticipated update to the SAP. And we would like to recommend that updates to the SAP be communicated and reviewed in conjunction with the proposed rule in order to better understand the scope of the changes.

And additionally, we recommend that the proposed rule be written to reduce the amount of additional explanation potentially required in the

SAP.

An example of this is in the Contents of Application, there is a new requirement for a table listing each section of the 42 CFR that cross-references the stages of manufacturing, et cetera.

And it is described that an example of this will be included in the SAP, but that's not yet available. So it would be helpful to be able to see these proposed requirements in addition to the -- at the same time as the proposed rule.

Timing for implementation of all aspects of the proposed rule should be identified and also allow adequate time for manufacturers to implement any additional added requirements. I believe in the proposed rule, the changes to the quality control plan content are outlined as over a three-year period.

And we recommend that a grace period also be identified for the other -- or a transition period be allowed for the other requirements of the proposed rule.

And then just one last general comment. I think since the time of the writing of the proposed rule, a new standard of ISO 9001 has been published, ISO 9001:2008. And I would recommend that this should be incorporated into the final rule.

Specific section definitions under Section 84.2 -- and this is the page number in the Federal Register publication.

Manufacturing facility. The definition of a manufacturing facility is stated as including suppliers and implies the need for control over the supplier's quality system as well as potential auditing of the suppliers by NIOSH.

It is our interpretation that this requirement is actually referring to what NIOSH has previously termed as "subcontractor."

And we recommend that the definitions and requirements for suppliers versus subcontractors from the NIOSH letter to manufacturers that was dated April 7, 2005 be incorporated into the proposed rule.

And I won't read all of this, but this is

the -- directly out of that letter from 2005 where the differences between a supplier and a subcontractor are outlined, where a supplier is a -- produces components or subassemblies under their own quality system, and then the approval holder confirms acceptability of those by a certificate of compliance and incoming inspection.

And that is contrasted with a subcontractor where the approval holder may authorize the subcontractor to a actually release the NIOSH-approved respirators directly from their facility.

And that in this letter, there are very specific requirements for setting up a requirement -- or setting up a subcontractor relationship. And we recommend that distinction between supplier and subcontractor and also these requirements for setting up a subcontractor with the ability to release NIOSH-approved respirators directly should be included in the proposed rule.

Contents of application.

The proposed rule requires that respirator

and component parts submitted for approval are not prototypes and are made using regular production tooling.

This requirement could potentially add artificial constraints and delays to new product development cycle timeline. Prototype tools and our processes may ultimately be used in production. It may be a matter of definition.

And we recommend that the requirement should be only that the products supplied for approval be identical in all critical aspects, for example, materials, geometry, functional performance, et cetera, is the final product to be manufactured as opposed to a specific constraint on the type of tools used to produce it.

So in effect, this would mean that the requirements on tooling should be deleted, or recommend that they be deleted from the rule.

Changes in device or applicant ownership.

The proposed rule requires that a new owner submit and receive modified certificates of approval from NIOSH prior to any continued

manufacture of devices after ownership changes.

This would actually -- it may be a matter of definition, but this would be impossible to accomplish immediately upon change of ownership since legal requirements prevent even, you know, detailed discussion and gathering of data needed for preparation of a submission until the actual date of ownership change.

So we recommend that the new owner be allowed to continue to manufacture and sell devices of the acquired entity under the existing approval, which includes the approved quality plan, manufacturing plan, et cetera, during a grace period that would allow sufficient time for the new owner to assess the product and potential changes to the quality plans, determine any changes needed, prepare the submission, and obtain approval.

We would recommend a minimum of two years for this transition, this complete change of quality plan.

And then also where there are -- where an acquired business will be run as a subsidiary, a new

submission may not necessarily be required if the existing quality plan and manufacturing system will continue to be followed.

Section on changes in manufacturing facility or quality system. The proposed rule requires a written notification to NIOSH within 20 days of a decision to change the location of a manufacturing facility or make substantial change to the quality system.

We feel that the submission that is seeking approval to change location of the facility or to make a substantial change in the quality system associated with an approved device should be adequate to inform NIOSH, and it's not clear why an additional notification prior to the submission seeking the approval of the change is necessary. So clarification on that would be helpful.

Quality system general requirements. The proposed rule requires compliance with ISO 9001:2000, that it's documented either through registration by qualified registrar or by a self-attesting statement from the applicant.

We recommend that third-party verification by a qualified registrar should be required and that allowing the applicant to self-attest to compliance is not adequate. This would remove any chance for bias.

We recommend that NIOSH define "qualified registrar" as was previously defined by NIOSH in the 2003 QA module concepts as a registrar accredited by the ASNI-RAB National Accreditation Program or equivalent body for non-U.S. approval holders.

Respiratory device complaints. The proposed rule requires applicants to report to NIOSH within three days any user complaint that arises from an incident involving safety or health of the user or that indicates a Critical, Major A, or major B nonconformance.

We agree that it is incumbent upon the manufacturer to investigate and evaluate complaints related to safety, quality, or performance of a device. We recommend that only complaints that impact user safety or health should be required to reported to NIOSH.

And depending on what's required to be reported, three days is insufficient time to adequately investigate, analyze, confirm, plan remedial action, and prepare a report and send it to NIOSH.

And audit programs. The proposed rule requires applicants to conduct annual audits on respirators or respirator families that are not tested as a complete system during manufacture.

We agree that it is incumbent upon the manufacturer to ensure the performance of the respirator system. This can be accomplished through many ways that could be more effective than an annual audit. We recommend that NIOSH consider these in lieu of the annual audit requirement.

Examples could be design and development planning and validation, robust quality plans for production, and a required validation of process and material changes.

And then if audits were to become part of the requirements, we recommend that only nonconformances that impact user safety or health

should be required to reported to NIOSH. And, again, three days would be insufficient time to adequately investigate, analyze, prepare action, prepare a report and send to NIOSH.

Now, I'm going to turn this over to Fred Chu, who is going to talk about the quality control plan content.

MR. CHU: Good morning, everybody. My name is Fred Chu. I'm the quality systems manager at 3M Occupational Health and Environmental Safety.

I'm here to kind of limit my comments on the area of quality assessment sampling plans stated in Section 84.42. We believe that the proposed changes from the AQL based plans of the ANSI Z1.4 and Z1.9 to the mil standard 1916 or the Q3 plan is a significant shift in the quality level requirements that currently exist today.

Now, the technical reference -- analysis reference in the proposal -- in the proposed rulemaking field does not adequately address the statistical differences between the current quality assessment plans to the new proposed plans.

A tool to assess these changes is a plot of the operating characteristic curves or, in statistical terms, the OC curves of all of the plans involved.

An analysis of these OC curves we feel between these plans will show that the proposed plans will increase the amount of sampling and inspection costs for most manufacturers.

We developed here an example of the OC curve comparisons for one of the categories, a Major A nonconformance. And you can see this graph, it depicts the OC curves for the current ANSI Z1.4 with the current AQL level of 1 percent, which is in the black line under the reduced inspection, the black line.

And the dark blue line is the ANSI Z1.4 under normal inspection. And the light blue line is the ANSI Z14 with an AQL of .65, which is the grandfather period of the AQL in the proposed rulemaking.

And then the last two lines on the far left there in the red and the pink line, those

represent the mil standard 1916 and also the ANSI Q3 with the limiting quality plans that is in the proposed rulemaking today.

From the graph, you can observe that there is a dramatic shift to the left from the current plans to the proposed plans.

And what does this imply? Some conclusions that could be drawn or inferred from the previous graph include some of the following:

Under the mil standard 1916 plan, an improvement of 30 times to the nonconformance rate to an actual AQL of .004 percent and an actual RQL of .234 percent would be required to maintain equivalent pass rates that are acceptable today.

For given manufacturing process capabilities, this proposal will actually increase sampling by at least a factor of four if no improvements are made to the nonconformance rate that are sufficient under today's current plans.

The last example, a manufacturer meeting today's current requirements will have a 95 percent probability of accepting lots with a nonconformance

level of 1 percent.

While that probability will decrease to 15 percent under the Q3 plan and less than 5 percent under the mil standard 1916 plan, it can also be said that most manufacturers usually operate at a nonconformance rate much lower than 1 percent, but may not achieve levels necessary to routinely pass these proposed sampling plans, as was the case under the current plans today.

We recommend to NIOSH that maybe only product requirements stated in 42 CFR Part 84 should fall around the imposed quality level specifications and really should allow manufacturers the flexibility to assess and control other critical to quality characteristics.

Further, improved enforcement of the quality plan requirements may go further to ensuring quality of the product to the user than tightening of the quality inspection requirements for all manufacturers.

And that's all of our comments we have today.

Thank you very much.

MR. HEARL: Thank you very much.

Our third speaker I would like to invite up, Ms. Janice Bradley from ISEA to take the lectern.

MS. BRADLEY: Good morning.

I'm Janice Bradley, the technical director for the International Safety Equipment Association. Some brief comments today, oral comments on the new proposed quality assurance requirements, and ISEA also intends to submit significant comments to the docket by April 10.

The International Safety Equipment Association is the leading trade association representing suppliers of safety equipment. Our member manufacturers of respiratory protection appreciate the opportunity to comment on the December 10, 2008 notice of proposed rulemaking on 42 CFR Part 84 quality assurance requirements.

Regarding Section 84.2, Definitions, NIOSH proposes to have authority over the manufacturers' suppliers and to include them as part of the

certification applicant/holders' facility from the standpoint of oversight and audits.

Yet this facility may be entirely out of the certification applicant/holders' management and control. This places an undue burden on the certification applicant/holder because it will require them to have quality control over component parts as well as a component supplier's facility.

We believe it is sufficient for parts supplied to the certification applicant holder to be inspected by such means as first article inspections, receiving inspections, and certificates of compliance.

If the certification applicant/holder finds the parts acceptable, this will be considered adequate control.

The certification applicant/holder takes full responsibility for parts incorporated into the complete respiratory protection device as submitted to NIOSH and ultimately sold.

NIOSH should deem it adequate that the certification applicant/holder ensures the quality

of the parts supplied to them and as a part of a product submitted to NIOSH for approval.

ISEA recommends that NIOSH retain the definitions of "supplier" and "subcontractor" as stated in the NIOSH April 7, 2005 letter to manufacturers.

Regarding Section 84.11, the contents of the application.

NIOSH should add a statement to this section stating that the documentation provided to NIOSH on previous applications which remains unchanged can be referenced in subsequent applications in lieu of resubmitting the same documentation.

This will relieve NIOSH from maintaining duplicate copies of the same documentation.

The proposal requires that respirator and component parts submitted for approval are not prototypes and made using regular production tooling. However, there may be times then prototype tools and/or processes actually become a production tool or process.

It should only be necessary that the certification applicant ensure the product supplied to NIOSH for approval will be identical in all critical aspects to the final product to be manufactured rather than a specific constraint with regard to tooling and processes.

Changes in device or applicant ownership.

The new owner needs to be allowed to continue to manufacture and sell devices under the existing approval during a grace period of at least two years. This provides sufficient time for the new owner to address the product and quality plans, determine any changes needed, prepare the submission and obtain approval from NIOSH.

We suggested in the case of where an acquired business runs as a subsidiary, it should still be allowed to operate under its own approved quality plan and manufacturing systems and continue to manufacture its NIOSH-approved devices.

Changes in the manufacturing facility.

A submission seeking approval to change the location of the manufacturing facility or to

make any substantive changes to the quality systems associated with one or more approved devices should be sufficient to inform NIOSH.

Respiratory device complaints.

The requirement to notify NIOSH in writing within three work days of any such complaint, be it critical major A or major B, is unduly burdensome and unrealistic to administer.

Three work days is not sufficient time to validate and research the complaint, gather information, and prepare a report. Situations occur where a major B complaint is made, yet, there will be no little consequences to the user depending upon the time when the event occurs. For example, it might be a strap breaking when donning a respirator prior to entering a contaminated area. Although the strap breaking when in a contaminated area could be considered a significant event, breakage of that same strap outside the contaminated area is not a significant event.

NIOSH should consider requiring manufacturers to report only user complaints that

are deemed to impact user safety or health as stated in clause (3)(A)(i).

A time period should be established from the date of the audit to the time the report is sent to the management representative of the applicant.

Quality systems.

NIOSH needs to establish a means for updating references to standards when a revision is published.

For example, ISO 9001 quality management systems published a new standard in November 2008.

NIOSH should review standard revisions and, if acceptable, establish a means to recognize them in the revision.

NIOSH proposes to evaluate the applicant with ISO 9001:2000 compliance and should provide a procedure for resolution in cases where NIOSH has determined a major noncompliance to the standard with the applicant and their ISO system registrar.

Quality systems.

We support the requirement that NIOSH -- that applicants shall be certified to ISO 9001:2008

standard through a recognized, accredited registrar or equivalent national body for nonU.S. approval holders, such as ANAB, RvA, UKAS.

This establishes a consistent set of quality management practices for every manufacturer -- every manufacturer of respiratory devices must maintain. ISEA does not believe that NIOSH should allow any certificate applicant holder to self-certify to ISO 9001.

NIOSH should only require submission of new quality manual when it's substantially revised. Manufacturers should not have to provide NIOSH with a quality manual every four years if no changes have been made to the manual.

QC plan content. There's a broad range of valid statistical tools which may be used to assess and assure the performance and consistency of products. It is to the benefit of the end user that the manufacturer has the flexibility to apply the methods that are most appropriate and efficient for their products and processes.

While the more commonly used quality

assurance tools and relevant criteria should reference in the regulations, the specific tools to be used should not be limited by the regulations. Continual improvement towards one hundred percent quality is an inherent goal of ISO certification. Therefore, it is important that the manufacturer have the flexibility to determine the processes they believe are most appropriate to measure and determine the level of confidence that is required for their product and process capabilities to meed NIOSH regulations.

Manufacturers must retain the ability to use the statistical methods and analysis to consistently deliver quality products.

NIOSH should not mandate the statistical analysis tools for every manufacturer. In addition, sampling plans and the degree of control required for product inspection and acceptance should be based upon the severity of the hazard where the final product is intended to be used, for example, disposable respirators versus an SCBA.

Audit programs.

This proposal requires an annual audit of each manufacturer or respirator family for which the respirator or respirator family is not tested as a complete device during the manufacturing process.

NIOSH should consider requiring manufacturers to report only audit findings that are deemed to be of a health and safety or regulatory compliance issue.

NIOSH also needs to further explain respirator family for the respirator or respirator family is not tested as a completed device during the manufacturing process.

In addition, again, three days is insufficient time to research, gather information, prepare a report and notify NIOSH of any nonconformance of a critical or major characteristic as classified by the applicant under 84 Part 42(a)(iii).

We think it is important that NIOSH audit all manufacturers equally, no matter what their country of incorporation is. We realize that this may be an added cost or hardship on the agency in

terms of onsite audits, field audits, and meeting with manufacturing entities outside the U.S. However, NIOSH must be particularly vigilant with respiratory protection devices that are necessary to protect workers and the public health.

Again, we appreciate the opportunity to be here this morning and look forward to submitting comments to the written docket.

MR. HEARL: Thank you, Janice.

We have now exhausted the list of people who have signed up in advance of the meeting here to speak, and so I would ask for the NIOSH panel to come back to the front table, please first.

And as I noted at the beginning, we can now take comments from the floor or questions for the NIOSH panel, if anyone has any.

Anyone else like to make remarks at the public meeting?

There you go. Please state your name, affiliation, and then your remark.

MR. OSCHE: Good morning. My name is Jay Osche. I'm with MSA, Mine Safety Appliances, out of

Pittsburgh, Pennsylvania, quality assurance manager.

Just wanted to echo a lot of the sentiments voiced thusfar from 3M and the ISEA, specifically with regards to documentation. The new proposals would significantly affect additional resources to -- just to be in compliance with the new proposals without adding a lot of value specifically.

As far as changing all of the inspection plans, the approvals documentation that MSA has on file, again, would add significant man years of activity without specific value.

And also, with regards to suppliers, there's been a lot of gains as far as supplier quality management and supply chain management. And to restrict verification levels and to specifically require incoming inspection across the board would add significant inspection resources, again, without any significant value.

A lot of the suppliers are already doing the required sampling in accordance with the approvals. And then to duplicate that on incoming

inspection at that point doesn't add any value because the product is already made.

The key is to work proactively with suppliers, not to be reactive and with the old adage of inspecting and quality.

So that would be a huge step backwards.

Thank you.

MR. HEARL: Thank you very much.

Any other comments or questions for the panel?

If there is no one that would like to speak at the moment, what I will do -- we are supposed to meet until 12:30, so I could put the meeting into recess, and if someone would like to make a statement, will they please see me and they will call us back.

Oh, Bill.

MR. NEWCOMB: Yes, I have a --

MR. HEARL: Go ahead and state your name again for the record.

MR. NEWCOMB: Bill Newcomb from NIOSH.

A couple of things we have heard this

morning that we would really appreciate more input on from the manufacturers in their comments to the docket. One of them concerns the number of entities that are ISO 9001 registered versus those that aren't.

This would be very helpful to know from NIOSH's standpoint in looking at the cost involved in the eventual final rule.

And also some more specific details on the cost of the changes that would be required to comply with this proposed rule.

We have heard a couple of times that there will be changes necessary here and there. It would be very helpful to have some quantitative measurements as to what these actually -- the value of them would be.

Thank you.

MR. HEARL: Thank you.

Are there any comments or responses from the floor? Don't everyone jump at once.

Okay, I think what I will do, as I said, I'll put the meeting into recess briefly, unless

someone would like to speak. I will call us back into order.

Go ahead. Did I see any motion there?

And point out that the means of submitting comments to the docket, which remains open until April 10, appear on the screen, which includes you may send in your comments by postal mail to the address shown here, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio, 45226.

Or email to NIOSH niocindocket@cdc.gov.

And alternatively, you could also submit comments through the federal e-rule making portal, which is located at www.regulations.gov, and then follow the instructions for submitting those comments.

So those are the means that you have available to continue to submit information to this open docket until April 10, 2009.

Seeing no other commenters at the moment, I'll declare that this meeting is going off the record, and we will be in recess until such time as we have speakers, or just before noon. I think I

will bring us back into session and then close the meeting out at that time if there is no is else that would like to speak.

So thank you, and we will go off the record.

(A recess was taken.)

MR. HEARL: Okay. I would like to ask the NIOSH panel to come to the front of the room. It is now 11:15, and I would like to take the meeting back on the record. We are now back in session.

We had a request for additional speakers, and if anyone else also has any other questions or comments that they would like to make, we would like to entertain those now.

So the floor is now open for public comment.

And please remember to state your name and affiliation for the record.

MS. BRADLEY: Okay. Janice Bradley, ISEA. We have some additional -- a couple of questions of clarification for NIOSH and a few comments.

First, the questions of clarification,

what will happen to submissions that are in process at the time the rule takes effect? Will they continue to be processed under the existing rule?

MR. HEARL: Okay. Gentlemen.

MR. BOOK: This is David Book.

Historically, we have processed things on an as-received basis. So things that have come under old rules, they have been processed under old rules. And new items, when they arrive, get processed under the new rules after the rule change.

MS. BRADLEY: So it's totally based on the effective date?

MR. BOOK: Yeah. I don't see a reason that that should be changing.

We can give you further guidance once we get a little closer, but that's the historical precedent.

MS. BRADLEY: A follow-up to that: What if the submission pending is rejected after the rule takes effect? Will the manufacturer be able to fix the nonconformance under the existing rule?

Will they be required to provide fixes

under the new rule?

MR. BOOK: Well, we are going to probably have to deal that on a case-by-case basis, but I don't know that I can say more than that right now.

MR. HEARL: Did you have a comment. State your name.

MR. KATZ: This is ted Katz with NIOSH.

I'm not clear what you mean by rejected, whether it's the case is closed with that application completely, or whether it is something where you have been asked to make changes?

MS. BRADLEY: You can assume that the rejection is that you have been asked to make changes.

MR. KATZ: Because it seems to me, if you have submitted an application, you have gotten comments back from NIOSH about things that need to be changed, it is still the date of submission of the application that would count.

MS. BRADLEY: So if it's still operating --

MR. KATZ: (Simultaneous) So if it's

within -- so if you submitted before the rule became effective, the day of effectiveness of the rule, then you would be operating under those rules.

MS. BRADLEY: Okay. Thank you.

All right. So additional comments based on some requests that came from in from NIOSH this morning.

ISEA believes that the costs associated with the proposed QA requirements related to inspections, audits, documentation, complaint management, and document control administration are significant. The value of the additional quality assurance burdens are uncertain at this time.

Based on NIOSH's requests today for additional cost data, ISEA intends to develop an analysis of the additional costs related to inspections, audits, complaint management, and document control administration for the following product categories: Filtering facepieces, half-mask and full-face filtering devices, PAPRs, and SCBAs.

To prepare this cost analysis, ISEA requests an extension to submit comments to the

written docket until October 9, 2009.

In addition, in the notice of proposed rulemaking, in the background section, NIOSH discusses some statistics, specifically 8 percent of NIOSH audits of manufacturing facilities since 1999, there were nonconformances found.

Since 1999, 40 percent of NIOSH product audits identified nonconformances with 5 percent of those resulting in a recall or a retrofit.

The industry would be grateful if NIOSH could share a summary, not specifics necessarily, but a summary of those findings with the industry. We believe they would be helpful.

MR. HEARL: Can I ask what you mean by the summary of the statistics? You mean --

MS. BRADLEY: I'm assuming -- I should say that the information associated with the statistics that were stated in the background section, that there's industry data perhaps dealing with specific manufacturers' names.

That's not what I'm asking for.

If there is kind of a sanitized summary of

the data --

MR. HEARL: The specific counts, for example?

MS. BRADLEY: Exactly. If that could be shared with the industry, that would be helpful.

Thank you.

Jon, identify yourself for the record.

MR. SZALAJDA: Yeah, Jon Szalajda.

Janice, I just had one question relative to the request for extension.

I guess is the rationale behind that is that you intend to go in through your member organizations and have them help develop the supporting data?

MS. BRADLEY: Yes, that's correct.

Our intention is to develop a template that we could give to ISEA members and have them fill in data associated with additional person hours needed to accomplish some of these tasks by product type, and then submit them and summarize them.

In addition to other comments, the oral comments I gave today were pretty generic, but there

are details that are associated with those comments in addition to this new analysis for cost data that we believe would be helpful to NIOSH to get a bigger picture of what the total cost in the industry would be.

MR. SZALAJDA: And I guess as a follow-up to that -- and you could answer this at a later time if you need to, but, you know, given trying to maintain a degree of consistency between all of the potential respirator manufacturers, some of which are ISEA members, would you be able to package this type of template into a format that we could make it available for other manufacturers to be able to submit similar type data for us to consider.

MS. BRADLEY: I don't know that at this time.

I mean, I'll have to answer that later. I don't think -- I don't intend for it to be anything -- obviously, we need to get this information sooner rather than later, but it does have to be useful and in an appropriate format.

So at the time when I can talk to my

membership and data gathering, I'm sure we would consider sharing anything that we get to develop this relevant data.

MR. SZALAJDA: Okay. Thank you.

MR. KATZ: Could I again, before we -- this is Ted Katz, again, for the record.

Let me just ask, too, when you are constructing this analysis, if you could just be careful to attend sort of the basis for the estimates that they are to produce, each manufacturer, so it's very clear how they derive their cost estimates for each, you know, cost factor.

MS. BRADLEY: I should tell you that -- I mean, what an industry association can gather from its members based on its members' comfort of disclosure of certain types of information and certain categories of information may not be exactly what you had on your wish list.

MR. KATZ: No.

MS. BRADLEY: But it's what we can do as a matter of consensus, sharing information on behalf

of the industry.

So it will -- my hope is that it will be in the best most efficient, useful format that is allowable.

MR. KATZ: And I appreciate that.

I guess just my point is to the extent that there's -- you know, if you, for example, just are producing a set of statistics that say, you know, respirators, say, the cost will go up by X percent because they will be doing more inspections, et cetera, in sort of vague terms like this, you know, the substance of that just doesn't allow us to do much with that kind of very general information where, you know, it's hard to substantiate the cost increases that are of concern or to address those in terms of a final rule.

So it's -- all I'm saying is the more substance that goes into the -- that is provided with the analysis, you know, the better a job NIOSH can do in responding to that in an effective way.

So that's all.

MS. BRADLEY: Thank you.

MR. HEARL: Anything else from the panel?

Thank you very much.

Are there any other comments or questions that anyone has that they would like to raise at this time?

MS. HENDELAND: This is Diane Handeland of 3M Company. A question of clarification around the definition of manufacturing facility, which includes the -- the definition includes the supplier's facilities as well.

Is that, as I stated in our presentation earlier, it was our interpretation that that was actually referring to what was previously referred to as a subcontractor in the April 7, 2005 letter.

Can you clarify if that was indeed the intended definition, or is that something else?

MR. HEARL: Who would like to -- over on this side?

MR. BOOK: This is Dave Book again.

As I read that definition, it closes with "by any supplier whose quality system is a component of the applicant's quality system."

And I think that phrase is at the heart of the communication error that we are having.

I believe that we were trying to use that phrase to limit the scope of what we considered a supplier to organizations that were divisions of a company or somehow specifically controlled by the approval holder.

I think the interpretation I'm hearing from the room is that when you get into supply chain management, you have now extended your reach out into areas that we would traditionally have called suppliers where their quality system is not your quality system, but now because of supply chain management, you have some sort of strong interaction with them.

I don't believe that was our intent to reach quite that far, and we will try to clarify that language so that exactly what it is we mean by that is more clear.

But I think the heart of the distinction is what is part of your quality system and what is not.

And because there is such a diversity of manufacturers out there, it's hard to get language that is understandable to everyone and yet has any degree of specificity.

We will try to work on that.

MS. HENDELAND: So the previous letter in 2005 about subcontractors and setting up a subcontractor to be an approved manufacturer for the applicant, is that addressed -- is that -- the requirements of that, is that intended to be addressed in the new proposed rule?

MR. BOOK: We will try to work that all in.

MS. HENDELAND: Okay.

MR. BOOK: In that letter, we specifically allowed the subcontractor to have an alternate quality system.

So we didn't try to -- this language was not intended to try to address both of those issues. And we will try to separate and clarify that.

MS. HENDELAND: Okay. Thank you.

And then one other question that I had

regarding the audit program.

The proposed rule requires applicants to conduct an annual audit on respirator or respirator families.

Is there any intent or further clarification about what NIOSH intends that audit to comprise?

Is it in terms of like, you know, is it just a full -- it almost seems from the preamble that it was meant to be the full NIOSH certification testing conducted again on the respirator system. Was that the intent, or was there any definition implied by what should be comprised in that annual audit?

MR. NEWCOMB: Bill Newcomb, NIOSH.

One of the type of things that we were thinking of were, for instance stance where respirators are sold in components, such as facepieces and filters are sold separately or where, in airline equipment, the hood and airline hose or the respiratory interface in the airline hose are sold separately than the air supply hoses.

It's a more or less a check to make sure that when you put the whole thing together, it still works as a system.

Now, whatever requirements would be controlled by the system rather than the components, those are the ones we are looking at. So to make sure that the system still works as the system is supposed to.

It wouldn't be -- it wouldn't necessarily be requirements that are specific to a facepiece or specific to a filter, but with a facepiece and filter, the main thing that you are concerned with is probably resistance, once you add the resistances together.

Or facepiece fit. If you have filters that are extremely heavy that are put on a facepiece, does it still fit the same way as it does with other things.

What we are looking for is to make sure that there is a way of quantifying the completeness of the system rather than every requirement that's in Part 84.

MS. HENDELAND: Okay. Thank you.

MR. HEARL: Thank you.

Are there any more comments or questions from the floor? Any more questions from the panel?

Hearing none, and seeing as we have been in session, or here, since 9 o'clock, I think I would like to take this time to close the meeting out and say thank you all for attending, remind you that we will have a second public meeting this afternoon on approval and tests and standards of closed-circuit escape respirators. And that that will begin at 1 o'clock Eastern Daylight Time in this room.

And I turn your attention to the screen once more.

Written comments will be accepted on this rulemaking until April 10, 2009, and they will be taken either by mail, by email, fax, or through the website.

And the website that you can use is the one for -- again, used for fed regs dot gov.

And let's see. Let me get it for you.

Www.regulations.gov. And the instructions are found on that website for submitting them over the internet should you choose to use that mechanism.

So with that, I declare the meeting closed, and thank you all very much for attending.

(Whereupon, the proceedings in the above-captioned matter were concluded at 11:33 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