NIOSH/NPPTL Public Meeting to Discuss Quality Assurance Standards Module for Respiratory Protective Equipment

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BOB STEIN: For those of you who may not know, my name is Bob Stein. I'm in an undefined position in the Respirator Branch in NPPTL. But today my position is defined as introducing Mr. David Book who will be presenting information on the quality assurance module concepts. We posted, after our public meeting in June, in which we presented concepts for a new quality assurance module, we posted a concept paper in July, and that paper has been up. It has drawn some comments. Today's presentation will go through that.

We've got two types of slides in two background colors. If you pay attention you'll notice that the background information is presented on the blue slides, and the information in response, anything that we've gotten since then is on the red slides so that you can tell the difference in what we did have and what has come in since then. With that, Mr. Book, it's all yours.

DAVID BOOK: Good afternoon. Just for my information, how many of you have seen the concept paper prior to this meeting? Those of you who have not seen the concept paper? Okay, that's a small group, so that will help. Those of you who haven't, there are copies in the back of the room. So if you haven't gotten on the Web site you can get a hard copy here.

BOB STEIN: There's apparently a third group, because that didn't account for everybody.

DAVID BOOK: I don't deal with abstentions. The presentation today really is broken into two parts, the background, basically a review and repeat of what was said at the last meeting, what's on the concept paper, so that we're all up to speed and on the same page here in the room. And then the questions that we received and the replies to those.

The presentation will be broken into thirds, because the concept paper was in three sections. At the end of each section we'll get to the questions for that section. The good news is the sections get smaller as we go on. So don't take the first third as being a third of the time.

Okay. The first section were General Requirements for the QA/QC portion of the quality module. The first requirement was to establish a quality system. And that was broken down into both quality assurance and quality control functions. We're trying to keep the specific requirements and the general requirements kind of in different boats, because we have to handle them slightly differently.

Quality assurance requirements. We're pretty straight forward that the basic requirement was that we establish an ISO 9001:2000 quality system. We adopted that by reference as opposed to trying to write all those provisions in. That's the major change from the past concepts that you've seen. The other requirements were that you do what you need to have a

quality system, you keep a good organizational structure.

We've asked that you submit a quality manual. That's standard practice at this point. A new requirement is that it be submitted at least every four years. And we'll get to the reasons for that. We wanted you to keep quality records for the lifetime of the respirator. That's a common sense sort of thing. And servicing records we wanted you to maintain for seven years.

The next section was on quality control records. And we requested a quality control plan flowchart, which is fairly expanded from the flowcharts we're asking for today. As part of that we've got design, production, and engineering drawings, the usual drawings you're submitting now. Assembly, inspection, and test procedures, again, there's not much new there. Classification of defects and sampling plan requirements, we do have some changes for the sampling plan requirements.

We are looking towards getting the quality systems to be based on capabilities. And as such, there's going to be a transition from the current sampling plan approach. We kind of have a three tiered version of that. We will allow a three year extension for 105 sampling plans for existing manufacturers. Where we still have a zero defect Mil-Std-1916 plan where the sampling plan and also we're using Mil-Std-1916

as a good guide and example for the process capabilities and SPC and as physical control.

We've expanded the audit program slightly, but we've spelled it out in significantly more detail than the existing standard. We're looking to have pre-approval audits. We'd like to see your site before you begin a new sort of production. The manufacturing site audits are conceptually broken down in a quality management system audit and a quality control NIOSH specific audit. Those do not need to be separate physical events. From some of the questions it looks like you have separated them in time and space as well as in thought. That's not necessarily how that will be implemented.

The product audits remain the same, except that we may ask you to supply us with products free of charge occasionally. That's current practice, but not current legislation. The CPIP audit program will continue. We'll continue to have investigations.

A new requirement was a revocation of approval for lack of maintaining the quality system. We've always had the ability to revoke approval for product that is found to be defective. We want to be able to say we're concerned that you may or may not be able to produce a good product. We don't want to have to wait until you've got a defective product there. So we've added that.

External resources. We're currently running a program where we have - are using external auditors. That seems to be going well. We're looking to add external laboratories. That's a little further in the future before that's fully implemented.

Reporting requirements. Information flows from the manufacturers to NIOSH. We obviously want you to maintain good production practices. There's no news there. If you make changes to an approved respirator, we'd like to know about that before the changes are made. First piece inspection has drawn a number of comments. We'll talk about that. We've asked that you do an audit of one of your products per year. This is one way to get your staff and your resources to help us to assure that the respirators in the field are good and working and practical devices. Complaint reporting, that's a requirement of ISO. It's also - we've put some specific requirements in there about what we want to be notified of and when.

Before we go on to the specific questions for the quality and assurance portion of the module, I thought it was important to point out that there are really two sorts of questions. There's strategic questions and issues which relate to general principles and guidelines, the framework for doing business, for setting up what we're doing. We're trying

to establish that framework at this point, and then once you have a framework established you move on to tactical, the specific requirements for the implementation.

Many manufacturers, most folks are really keyed into the tactical issues and are asking very specific questions. And we've tried to answer those as best we can. But until we're sure that the framework goes through and everything else goes through, we have to hedge a bit on those answers, okay. So when you see kind of short answers, it's because you're two or three steps ahead of where we are in taking this quality module and turning it into the rules that we have to live with.

General requirements. You should have a quality system and it should be good. Nobody had a comment on that.

Okay. Quality assurance requirements. How will NIOSH assess approval holders that claim ISO 9001:2000 status who are not formally registered? The way we do now. At this point we have a quality review, a quality manual review, and site audits. We're going to continue that practice to evaluate quality systems. The advantage that comes out of this is we now have a single standard as opposed to every single manufacturer having their own standard. So it should be easier on us. It should be more standard for you. And those of you who don't want to go through the expense, the

perceived bother of formally registering, we'll continue to do business together the way we have.

Can an ISO certificate be sent in lieu of submitting a quality manual every four years? We'll think about it. We really had that in there as a communication issue to assure that we're seeing your current version. I'd find it surprising that you could have a quality system in place for four years and not make a significant change. That happens, but I'd be surprised.

Can "significant" and "significant revision" be defined more clearly? We'll clarify this through policy when we get there. Two examples of what a significant revision of quality revision would be, would be a change in management structure, a change in ownership. We're not worried about dots and commas and documentation questions, but if you're changing processes or you're changing the way you're doing the math, that's significant.

What exactly are servicing records? Servicing records are records that apply to any respirator brought back to the manufacturing point or factory authorized service representative. Those of you who are making complicated respirators do the service and you understand that. There are some folks that are making simple masks, onetime use devices that probably aren't doing service. These are your questions.

If they're complicated or simple, it's just what we received.

Can the importance of product and process design controls be stressed? We're trying to do that. This module is a step in that direction. The adoption of ISO 9000 moves somewhat in that direction. We're working on balancing between design and inspection, and trying to find a reasonable place where we can do both of those. We have manufacturers that are across that whole continuum.

NIOSH is encouraged to embrace state of the art practices for the quality engineering field. My first response to that was thank you for the encouragement. It's the intent of the Institute to accommodate state-of-the-art practices without overly constraining the range of acceptable approaches. We're going to be flexible on that. I think you will see - I think you have seen that we're trying to update this module and everything we're doing is trying to move it in those directions.

NIOSH could outline the requirements of ISO 9000:2000 in the CFR. Our response to that is, that was our initial approach. And there are a lot - by adding - incorporating ISO 9000 by reference it's just simpler on everyone. This way we don't have to have a whole core of folks who are doing the NIOSH version of ISO. It just makes more sense to do it this way.

Here we have a specific command. Add the definition of the design verification, validation, design validation, process validation. These are important concepts. I don't think we use those phrases specifically. The concept should be covered in the ISO document which is incorporated by reference. Unless we specifically call those out, there's no requirement for us to define them.

Can language be added to stress independence and authority of the organizational structure? I think somebody out there has got a quality program that's getting flack from management and would like a little support. Hopefully the ISO 9000 requirements specify a structure that will allow this to happen. I don't think if you can follow the ISO guidelines you should have interference problems in your quality program.

Why does NIOSH have to have a quality manual resubmitted on an every four year or less cycle? The answer to that is experience. Quality manuals of many manufacturers are not submitted on a timely basis. This is an attempt to improve that performance. We've discovered from experience that when we announce a visit every three years or every fourth year, all of a sudden there's a new quality manual that's submitted that week. It seems to be the flag to say, "oops, we've been using this quality manual for two years, and..." So we're just trying to make sure that they will come in. We have current

records. We can see what you're doing.

Acceptable quality manuals should be defined. We'll handle this. We think that's a pretty straight forward phrase. Acceptable would be acceptable to NIOSH; acceptable within the application procedures.

Standard application procedures. Significant revision should be clarified. Again, we have very specific comments. A decision tree would be helpful for the industry. If you all did things the same way, that decision tree might be helpful. I don't know that I'd want to try to write it. Significant revision needs to be defined. We'll handle this. I think it's fairly clear language.

Servicing records. We had a similar comment in one of the other sections. Servicing records are records that apply to any respirator brought back to the manufacturing point or factory for servicing.

Can "or equivalent national body for non-US approval holders" be added to the ISO 9001:2000 statement? When we incorporated ISO 9000 by reference we said you will use the ANSI ASQ ISO 9000 standard. We have no objections to using the equivalent national standard if you happen to be standing in France or Germany or somewhere else where there's another body. We may have some difficulty getting that past the lawyers. We may have to word that a little bit. But we'll

try to incorporate that.

Can a letter be used in place of a quality manual submission at four years if no changes have been made? Again, we'll consider this. I'd find it an unusual quality system that hadn't changed at all in four years. We want this requirement as a notification so we know that we're communicating, that you're looking at your quality system. We wouldn't object if we were on good terms and we believe that you were a small manufacturer, you hadn't changed anything, and that really was just a notification issue.

Transition for Mil-Std-105D to 1916 will be costly and unnecessary. Neither comment should be true if implemented well and thoughtfully. And we'll probably talk about that later.

How will alternative sample plans be evaluated to determine equivalence? The short answer to that is statistically. We had looked probably at the equivalent consumer risk and producer risk, take a look at how your operating occurs compared to what we had specified. There are ways to do it, that are known out there. This isn't the forum to go through the details, but talk to us. We'll evaluate.

When is a destructive sampling plan or reduced sampling plan appropriate? The requirements for reduced sampling plans are outlined within both 105D and 1916, so they're in there.

Read the plans.

You'll notice that there's an arrow under the destructive comment. And little arrows are places where your comments have caused NIOSH to either learn something or change their approach to how these things are done. Because of this comment we went back and reviewed 1916 in detail and recognized that it does not apply to destructive sampling. We have some language that works around that a little bit, but we're going to have to rethink just how we want to handle that for those of you that do destructive testing. We don't have an answer to that question at this moment.

Will NIOSH expand the time frame from three to five years for sample plan transitions? We believe those three years are an adequate and ample time to accomplish the transition. You know it's coming, it's going to take us some while to get the standard published in the docket, into law, it should be sufficient.

For what reasons is the same information contained in the quality system requested for each individual application package? How can redundancy be reduced? Again, we've kind of got the horse before the cart here. Once the quality module is adopted, the requirements of the standard application package will be addressed. We'll try to reduce the redundancy. There's a set of rules out there, you've all

learned them, you believe that they're the only way the world can ever happen, and now we're changing this, and now you're seeing the same requirement in two places. Well, once the new requirement gets in place we'll look and try to eliminate the overlap created in that transition period.

The proposed quality plan flowchart requests much more information than currently. The answer to that is, yes it does. The requirements have been expanded based on audit results and field experience. We had very, very minimal requirements when the original standard was written for quality, and we're trying to - we're playing catch up here. We're trying to get to where what you've submitted is sufficient for us to truly evaluate your quality system and for us to be able to go out and audit against. We want to see if you're still using the quality system you've submitted.

Under quality control requirements there's a quote that says, "The procedures in this paragraph are required... but do not have to be submitted to the Institute." How likely is this work to be performed? Apparently there are folks out there who believe unless we come out with a hammer and check up on you, you don't have to do it. I know there is nobody in this room who believes that. Okay. And the answer to that is, very. It's very likely that "that" will get done, because those are procedures that will be verified during the site

audits. Those were things like test procedures and protocols that we didn't want you to have the expense of sending to us, that we didn't want to clutter up the space storing them, but that we needed to know were in place if they look at it from an audit - when we do audits.

Can "classification of defects" be changed to "critical to quality characteristics"? So somebody wants a specific verbiage change. The Institute will consider this suggestion as it more correctly reflects current usage and practice. Frankly, when we've been thinking of classification of defects we have to translate it in our minds at this point, because that is such an old quality concept that we're kind of going, "what does that mean?" So this is more common usage and we may try to adopt this to reflect some of the shifts from inspection to process.

I just said, you know, we don't like the concept. Why is classification of defects required in a balanced quality system? It's part of the balance. We're not throwing it out. It's required as part of the initial review process as well as ongoing testing and inspection programs. So we may tweak how we think of it, but it's one of the drivers of what you test, how you test it, why you test it, how you evaluate the results of those tests, so the concept has to stay there even in a modern system.

Here's the trick question of the day. CPK indices require variable data. They cannot be calculated from attribute data. That's a true statement. But if you're evaluating the capabilities of a process, somewhere in that process you have key characteristics, and somewhere in those key characteristics, you have variable data. Measure the right data, create the right index, control the right things, and you won't have to do it on attribute data.

Can control chart information be used in place of zero defect sampling for attribute data? Yes. If you can do it. But it's going to take a little bit of work and a little bit of thought. You're going to have to understand a lot of concepts. But we don't have a fundamental problem with that if you can do it and do it properly.

Why does NIOSH specify requirements for minor characteristics that do not affect form, fit, or function? Great question. We don't know. We'll consider dropping this for minor characteristics. The history on that I suspect is that when the first set of legislation was introduced we adopted military standard where they're the purchaser. We're the regulator, we're not the purchaser. The Army might care if 10 percent of their helmets come in with a blemish. As a regulator I don't care. Your customer cares. He'll make you do it. But I don't need to make you do it. We never looked

at that. We never even conceived that there was an issue there. But this might be a place where we can save a bunch of data creation and data reporting if we truly don't have a reason to look at minor characteristics.

Mil-Std-1916 requires approximately four times as many samples for Major A characteristics as 105D. This will be costly. And the second half of that was, "...for no good reason." We understand that. And the additional sampling is part of our work toward using process controls. As sampling becomes more expensive, process controls become more viable. We shifted from looking at manufacturers' risk to consumers' risk. The result of that is that in order to achieve a higher level of quality assurance you end up with a higher level of inspection. Another good reason to move away from inspection based systems. As long as we're there, we have to improve the assurance that we have from those systems.

Audit programs. Certified ISO 9001:2000 manufacturers should be subject only to quality system and product audits. Others are redundant. Someone looked at all of the audit programs, thought of them independently, thought of them as things they were going to see every year, and said, "Oh, oh, help me, the government's going to be here every other day." That's not what we're planning on doing. The amount of redundancy should be minimal. There are ways that some of

those can be combined. There are a number of those that don't apply. The product audits are simply sending a sample to us. And we'll do the product audit off-site. If there are no problems, there are no CPIP investigations. So there's not a major expansion of the number of audits in this proposal if you read it carefully. If you've got a good ISO auditor and they look at the things they ought to, the NIOSH requirements can be incorporated.

Can NIOSH provide additional information on submitting a monitoring report in lieu of an onsite audit? Again, we've got specific requirements out there before the general requirements. We'll develop that. But we don't think it's going to be a hardship on anyone.

Certified ISO 9001 manufacturers should be subject only to the quality system - I think we just were there.

What are the details of the qualifications of NIOSH authorized representatives? At this point we're creating NIOSH authorized representatives through the federal contract procedure. So we're putting this out to bid, evaluating the proposals that come in, and the minimum requirements include RAB certification and familiarity with the respirator industry. We think those two are important. There are some folks who think that the auditors should have no contact at all with the respirator industry. That's kind of a chicken-

and-egg thing. They have to have some familiarity, but the question is, "How do we keep them separate - from using that information inappropriately?"

What mechanism is proposed for submitting ISO audits to satisfy the NIOSH requirements? The most straightforward approach to that - currently we send written notice of any audit, it's given to - prior to the site audit. It's anticipated that when you receive that we'll get a note back that says, "Oh, hey, we had an ISO audit that happened at such and such a time that meets your requirements. Can we submit that?" And our response would be to evaluate that and say, "Yeah, that looks acceptable."

Revocation of approval for lack of a quality system. There were no comments there. New pieces. There were no comments.

External resources. An appeals process to resolve any discrepancies between NIOSH and manufacturers should be in place before any private laboratory testing is used. Yes, we need it to control the folks who are doing the testing for us. We have an appeals process. We will have those in place before we begin to implement that sort of thing.

The use of an auditor associated in any way with the respirator industry presents a conflict of interest. This conflict always exists. We've been using external auditors

for about two years now. We've had no bad experiences in that light. We've inquired heavily. We don't think this is going to become a real issue, but we continue to monitor it.

Can NIOSH clearly define when a NIOSH versus a third-party auditor would be used? We're developing those details. In general, typically third-party auditors will be used for routine situations. Special requests by a manufacturer for a NIOSH auditor would typically be honored. In our letter that goes out to introduce any of the site audits, we identify if we're planning on sending a representative rather than a NIOSH person. There's a question about confidentiality in that letter. If there are any concerns, either we'll send a NIOSH representative with them, or a NIOSH representative will come out. But, there's always an invitation to talk to us if you have a concern. And that's not going to reflect badly on any manufacturer that makes that request.

External laboratories should be certified to ISO 9000:2000. Actually the testing standard is ISO 17025, and that's the standard that we've used with the military testing laboratories and that we anticipate being used as we develop laboratories for certification testing.

What accreditation do NIOSH laboratories currently maintain? Somebody wants to know our credentials. It's about time. The answer is none. To quote Sam Terry here, "We are

the gold standard." We're learning to move away from that comment. We're in the very early stages of adopting ISO 17025 ourselves. And we've begun to work towards that. We think it's appropriate that we would hold ourselves to the same standards that we will hold the folks who work for us.

Here's my favorite comment. "Several of the requirements outlined are costly without adding benefit." We believe that all of the requirements add a benefit. We didn't intentionally put any thing in there that we don't think adds benefit. But this question is so general that it really can't be answered in a straightforward kind of way. If you have specific concerns about specific provisions, let us know, we'll think about it. We'll decide if, and why we think it has, value. And if it doesn't, we'll consider (changing or removing) it.

Can NIOSH provide additional guidance in defining form, fit, and function? We've been using form, fit, and function for 30 years. You would have thought we knew what it was by now. This is standard existing language. We've got a number of letters and notices and clarifications on what that is. If you've got a specific question about a specific item, we'd be happy to give you specific guidance.

"First piece inspection is redundant and a non-value added activity." There's a number of thoughts on that

question, and we're currently considering the cost benefit value of requiring first piece inspection. We've had a lot of comments on how to do first piece inspection, and we're looking at whether or not it's worth the time and energy to define it in a way that produces value for everyone.

Under reporting requirements - which was a new section. The exact quote says, "Manufacturers should only report complaints of death, injury, and hazard." The commenter added "serious injury or serious hazard." NIOSH feels it's part of the agency's responsibility to collect information on any injury or hazard. If you look at the specific language that was used there in the section 1.7, it doesn't - it says only substantiated and goes on. So we're not asking for frivolous complaints, but we are asking for anything that's real to be reported. Or proposing to ask for anything that's real to be reported.

NIOSH should define "major" classification of defects as used in this section. We're using it the same way we've always used it. See CFR 42 84.41 if you want a specific definition of major. I bet I could ask and I could get it from half of the people in this room verbatim.

Reporting requirements. "A decision tree to aid in determining significant changes would be useful." I don't know that we can give that level of guidance. Any aids

developed to determine significance will be generated after the quality module is adopted. Again, we think this is clear language, clear common use language. We're not interpreting it in any unique, special kind of way.

We had a three day audit failure time reporting. We wanted the manufacturers to do audits of their products once a year - of a product line once a year, and we wanted the reports of failures within three days. We're considering a slightly longer time frame. Three days probably was excessively zealous on our part. Uh-oh, I think I used a legal term. I may be in trouble now.

Is the audit of each product line strictly a performance audit? The answer to that is, as we've discussed it internally, yes. We're asking you to go out, see if your product performs as you said it would, once a year, and letting us know that that's the case. If it fails, this is something both of us need to know.

We also ask that complaints be sent to us within three days. Can this be lengthened to 10 days? You've got the same answers as the last slide. We'll consider bumping that up somewhat.

This is one of the fun pieces. "First piece inspection is redundant and a non-value added activity." "First piece inspections are common practice and the requirement should be

529 removed." So it's so common and so irreversible that it's
530 needed by everyone or it's a complete waste of time. Both of
531 those comments came in. We're somewhere in the middle, I
532 guess. Again, we're looking to see whether we need to specify
533 this in the law, or whether the manufacturers are doing it as
534 a matter of practice and you don't have to do that.

535 Okay, that gets us through the long section. A little
536 bit of review now on administration and fees. Application
537 procedures. Applications will go to NIOSH. That seems like
538 an appropriate place. Examinations will be conducted by NIOSH
539 who may use external labs, but that will be developed.
540 Applicants may consult with NIOSH. Again, if you want to talk
541 to us, we're always here. Mergers and changes will be
542 reported to NIOSH. When you buy somebody, tell us. If you're
543 bought by somebody, tell us, please.

544 What needs to go in the application package? They'll be
545 in a standard format. We need a complete description of the
546 respirator. We need plans for quality control and quality
547 assurance in the broad senses of those terms. We're asking
548 for pretest data exams, inspections, and tests, stuff you're
549 used to seeing. A note that standard production tooling was
550 used, and a complete respirator for testing. There are no
551 changes, significant changes there, from what we're doing
552 today.

We also removed some language in various sub parts. If you withdraw an application, an approval, we'll want to be notified, and we think you should notify your agents and distributors.

Fees. We have lots of fees. Fees for examinations. Fees will be refunded if no work is done. We're trying to be good about this. Novel products will be charged per hour. Fees for site audits will be charged. Problem investigations may be charged. Fees for product audits may be charged. Travel costs will be billed at actual cost. There's a transition there that we're trying to use the fee structure to cover a significant portion of the NIOSH cost. This is not news anywhere. This is how the Federal Government is evolving.

Typical fees - there's a whole series of charts and tables. For new approvals most are between $2,800 and $5,000. Gas masks have a base fee within that range and then a per-additional-gas fee on top of that. Extensions. Most extensions are $2,200 to $3,500. Fit test was $5,000. This is just a short summary so we're on track with what the overall numbers are.

Maintenance fees would be based on the number of active approvals. So if you want to drive some costs down and you have obsolete products ...

Administration of fees. You make an application, you send us a check. If we travel to visit you, we'll bill you. That's the way we envision it. Maintenance fees, we'll ask for the fees once a year.

Questions and replies. Electronic transfer of funds was included in the July 14 draft. Can this be retained? Somebody managed to read the July 14 draft before the July 17 draft was out and caught this. Good job. We've discovered that we don't have a mechanism to accept electronic transfer of funds. We are as amazed by that statement as you are. And we will try to find a way out of that. But until we do, we can't propose it. We'll see that it happens.

A separate statement requiring pre-testing is redundant. It's redundant, but I don't know from where. That's the only place it's mentioned in the draft proposal. So if we take it out of there, it doesn't appear anywhere. It's redundant from what we think we remember.

Specifying prototype or regular production tooling is restrictive and unnecessary. This is existing language. We'll consider if it's too vague, if you don't understand what it means. We don't want you doing special, special things just to submit something and then producing product in a completely different sort of way.

Would products have to be delivered in cases where NIOSH

uses external testing laboratory? Well, yes, they have to be delivered. "Where they need to be delivered," will be generated, whether they go directly to us or directly to the laboratory. When we get to having laboratories external of NIOSH we'll tell you that. In the case of CBRN, we've addressed that issue and it's being delivered directly to the military testing laboratories. So if it makes sense we'll do that.

There were no comments on the language and section changes.

Voluntary withdrawal of approval. "Notification of agents and distributors serves no purpose or is redundant of activities performed during voluntary withdrawal." I always love people who know there's only one way to do anything, and that's the way they've been doing it. The comment ignores the possibility of a manufacturer leaving the respirator business. There are a number of scenarios where people will not be notified as part of good ongoing business practices, especially if you're no longer going to be ongoing in that business. We've had problems where the appropriate folks haven't been notified. That's why it's needed.

"Why would NIOSH be interested in the voluntary withdrawal of approval other than to know that the product is no longer being offered?" Well, that in and of itself - I

think would be sufficient. But at this point we'll stop billing you - the manufacturer - annual maintenance fees. We'll quit asking you for money.

Fees for approvals. "Manufacturers should not have to support indirect costs with fees." This is a cost of doing business for NIOSH. That's a true statement. The government and private sector operate in kind of different modes. In the private sector the indirect costs would be rolled into some overhead or profit number. The government doesn't have that option. Current guidelines indicate that we should recover the full cost for any goods or services that are provided. That includes direct costs and indirect costs where those indirect costs can be related to the service. So it's the way the government does business.

How are direct costs calculated and controlled? We've got an accounting system. That's how they're calculated. They're controlled through all of the government control mechanisms, most of which work. Occasionally there are newspaper articles, but they're fairly rare. The initial fees are based on historical data. So we went and looked at what we had been doing and how we'd been doing that and used that as our first baseline.

"Can the new fee schedule be phased in over time?" And the answer to that is, "It's not possible to phase in a new

fee structure." We will however try to grandfather or delay implementation of it - once the quality module has been adopted - of the initial implementation of the fees to allow you time to retire respirators, to make some plans, to be aware of that. So we're not going to try to jump on that. We'll try to be a bit relaxed about that and let you know so that you can make appropriate plans.

"How will manufacturers be notified for request of payment for non-certification fees, such as audits?" We'll develop those details. My first answer to that was by mail. We'll develop a billing system.

"NIOSH should describe (services) performed for which fees are assessed." I think if you read through the concept paper those were fairly well delineated in pretty good detail. By the time we get through the CFR submission process they'll be developed in even more detail.

"Can ample notification of pending implementation of maintenance fees be given to allow manufacturers to voluntarily withdraw approvals?" Well, if we can define ample, yes, we can do that. Again, take this as notice it's going to be a while before it works through all the formal government requirements to go from a proposal to a rule.

Administrative fees. Nobody cares that we're going - how we're going to bill you there.

Section three. Approval labels. We asked for comments on approval labels. We received exactly one. NIOSH should look for ways to eliminate the matrix from the label. Well, "looking for" is easy. We think there are some ways to do that. The specific persons with the specific concerns should come forward and talk to us. In some cases that should be doable. Okay. We had some questions - well, we had some, we got one question that didn't fit into any of the categories, so it gets its own little box here. NIOSH as a test facility should seek certification by an ISO 9001:2000 registrar. And again we repeat, we're in the early stages of looking into the ISO 17025 certification as a testing facility, as NIOSH itself. So we're beginning to look in that direction.

We did actually make it to the end of the slides. If there are any questions, I'd be happy to take them at this point.

JOE DUNLAP: I'm Joe Dunlap of ILC Dover. I had a question on paragraph 1.3, down in sub-paragraph (2) (b) where we talk about part numbers being clearly and permanently marked on the component. Many of the products now that NIOSH is getting ready to release with the new CBRN spec are escape only, visualized as single use items. And I'm wondering whether this would really be pertinent to single application items where you would not necessarily be maintaining or

servicing these items.

BOB STEIN: For single use - if it's truly a single use - and it's sealed and so you're going to tear it open and you're going to get one shot at it, it's still good to have at least one part number for that so you can refer to that unit. Because as you go through various iterations, that might be one way to distinguish between some sub-variant or something, okay. And what we end up with... that only refers to part numbers that are identifiable to the user. Like on more complicated ones, it's only those subcomponents that they can distinguish. It's not down to the nut-screw-washer level. Okay? But the other thing we end up with on single use is on the matrix, besides having a part number for the unit itself, we need a part number for the user's instructions. And then that helps to control the revision levels and so forth. So it is a real simple system, and we don't view that having one part number as being overly burdensome. That's all we would be asking for.

JOE DUNLAP: So you consider clearly and permanently just to be a labeling system, it's not some sort of laser marking or indelible ink markings or color coding in some form?

BOB STEIN: The standard for permanent has been that it should either be there, or that if it's not that evidence of it having been removed should be obvious to anybody looking

for it. In other words, you identify in your drawing, "here's where the part number belongs," so if we find one without a part number it ought to be, "Oh, we can see why it wasn't there," or, "Somebody took a key and scratched it off.", or something like that. It's kind of the standard. It's difficult to define it precisely.

BODO HEINS: Bodo Heins from Draeger. I would suggest concerning the fees NIOSH should think about it again. And I would suggest to increase the fees for the actual approvals and not give the - or make actions creating costs and sends one to the manufacturer. It would be a unique act that somebody would make actions, which we didn't give an order and we have to be invoiced at the end of the year. I can agree that you need to be paid for all your activities, but I think it's the wrong way to do it with an invoice once a year. Add it to the fees so that you come to your costs, but don't make actions and send an invoice. That's the wrong way I would say.

BOB STEIN: Are you talking about the maintenance fee, Bodo?

BODO HEINS: Every fee you're invoicing to us. Yeah, maintenance fee.

ROLAND BERRY ANN: Are you including the audit fees as well in there?

BODO HEINS: Everything for which you are sending us an invoice. We have to pay without having - getting the order. Something has to be done. Like we are doing with extension of approval, then you require some work and we have to pay for that.

ROLAND BERRY ANN: Right. And the idea behind segmenting on the way we set them up is so that you pay for the services that you receive and don't pay for the services that you don't receive. For instance, if we send you notification that we would intend to come for a site audit, and you say, "Wait, we just had an ISO audit last week.", and send us the report and we accept that in lieu of our doing the audit, we wouldn't charge you for the audit. But if it's included in the price of the approval, then we've already charged you for that. The other aspect of that is we don't have time-limited approvals. So we would have to prorate the cost of doing audits and the other things over the projected life of the approval, and we were trying to avoid that.

BODO HEINS: But you should understand the manufacturers, we have to calculate our costs one year or more in front of us. And if you do not know who's doing something for us and sending us an invoice of which amount of which we do not know, which we cannot calculate, that's not a way which a company can practice.

ROLAND BERRY ANN: I understand that. We'll take that into consideration. One of the things that we intended to do was, in calculating the cost based upon our previous year's experience - is to post the new fees on a yearly basis and give a phase-in time before it would take effect. But I understand you're also concerned, the difficulty that you may have in projecting whether or not you're going to have that particular fee imposed upon you because we may or may not have an inspection.

BILL NEWCOMB: Bill Newcomb, North Safety Products. A comment and a question. From a manufacturer's standpoint, the maintenance fees, one of the issues that manufacturers have is the sort of open-endedness of the fee structure as it's delineated. For example, at this meeting for travel you only see one person from North. How many people do you see from NIOSH?

DAVID BOOK: We traveled a lot less further than you did, but your point is taken.

BILL NEWCOMB: I assume that this is going through the standard rule-making process rather than the expedited.

DAVID BOOK: That's correct.

BILL NEWCOMB: And in that case I'd like to know what you're looking, the timetable.

DAVID BOOK: Can we identify a timetable here? This should be the last preliminary event before it goes into the formal rule-making procedure. There's probably about two months of internal review. There will be a one month public comment period once it's been published in the Federal Register. So, we're three or four months out, at least, at this point. But those are our first pass at that. This will have been our second preliminary public meeting on that. So we feel we've gotten through the first stage of that. And then as part of the formal rule making there will be an additional public comment period. Rich?

RICH METZLER: As a rule of thumb, can you use 18 months after the time you go out with your first notice of proposed rule making. That's what was done with the 1994 particulate-filter standards. And it seems it took about 18 months to go through the entire process once you have the standards identified. And within 90 days, that standard hopefully will be identified and published as a proposed rule. So that would start the clock ticking and approximately will take anywhere to about 18 months.

JAY OSCHE: Jay Osche, MSA. Questions on sampling. As far as incoming inspection for purchased product. Will there be any provisions to use the switching rules for normal, tight, and reduced, and/or "S" levels that are currently

available, or even Z1.9 for variable data, destructive testing, use of skip lotting are alternate plans, and how would they be improved?

DAVID BOOK: Well, once - at this point the proposal for sampling plans consist of the rules that are in 1916, which include tightened and reduced inspection. Now some of the skip-lot sampling and some of the advanced concepts that you've advanced there are not included in that plan.

JAY OSCHE: Right. 1916 addresses in-process inspections. But, for purchased items that you're inspecting on a dock basis, you're no longer in-process, you're doing end-item inspections. So will those techniques to complement a good performance by suppliers be - still be able to be utilized, for again, going to reduced, skip-lot, approved suppliers, things of that sort?

DAVID BOOK: I suspect the answer to that is - when we have final rule - the answer will be yes. If you can present a reasonable recognized plan that meets the over all requirements, we'll recognize it. Those over all requirements at this point are a bit vague, I'm willing to admit.

JAY OSCHE: Looking at the current ANSI Z1.4, using the "S" levels, those are essentially accepting with zero rejects, so why would those not be allowed to still be used?

DAVID BOOK: I'm going to have to look at that

specifically, because my statistical experience doesn't extend to the "S" levels. I'm going to have to go check.

JAY OSCHE: Otherwise, that would increase sample sizes significantly and, of course, cost.

KATIE DAVIS: Katie Davis from MSA. I also have a question on the maintenance fees. We have a number of respirators that are what we consider inactive. We're no longer asking for any approvals of any components or adding anything to them. However, we're still supporting those products in the field. We'd like a way perhaps for NIOSH to separate those particular respirators out as inactive but still valid approvals, and either have a smaller maintenance fee or no maintenance fee because NIOSH is not going to be doing any work on those and not going to be asked to evaluate those respirators for any updates. And we don't - we'd like to list those as inactive, but we don't want to list them as obsolete. And we don't have any way to do that right now.

BOB STEIN: We always have an issue with this, because the way you've described inactive, we would describe obsolete, in a sense. Because any respirator - you know, you put it out in the right form, the user buys it, we don't know what they do. They put it on a shelf or something and it might set there for a number of years, assuming it's not a type that has a definite shelf life to it. If nothing has happened to that

and it's still in the right condition, they could still use it as an approved respirator for whatever, whatever purpose they originally purchased it for. The expectation with anything that would be active, I guess by the way you're saying, is that they could still buy new parts, new filter cartridges, new gas cartridges, just whatever it was they needed to continue use of it beyond whatever original supplies they purchased. That would be active. So like - it only becomes - only if there's a problem with it - then it has to become non-approved. You know, we've identified that a certain type of respirator, you know, something, something went wrong and we can't define within, you know, we can't confine it to a particular lot or anything like that. Then at that point it has to become withdrawn, in other words rescinded, altogether off the shelf. But suppose there's a twilight world there where there are approvals that are kind of maybe still on your books and kind of maybe still on our books where you're not supplying parts for them. We don't know whether people in the field still have them or not, but they're so doggone old, and it's like the older - they're not like wine, the older they get, they turn into something good. And it's like when we get questions on them - it's difficult to answer, because those records are old and it's difficult to find that information. And those are the ones that we're really kind of aiming at to

try to say, you know, if you don't ever have any intent of ever producing it again, you don't want to support it, we don't make it, we don't make parts for it, some of those - we'd like to see those kind of go away if it's possible. So I don't know whether it's just a matter of definition of terms or what, because we would still assume that if you're still making parts for it, even if you're not selling new ones, it's still supported, so people can still maintain that respirator in a condition ready for use, so …

KATIE DAVIS: Correct. But we wouldn't be asking for any new components to be added to that inactive respirator. So if we made a new change to a hose or to some component of that respirator, we wouldn't be submitting that new hose or that new canister or anything on that product. It just would not happen. They would either have to buy something that existed the way that approval originally was last approved, or it wouldn't be supported. So in a sense these products are kind of in a state of, you know, they're frozen there in time. And for a period of time, I don't know how many years, but you can send a customer replacement parts for something that would break or they would lose or whatever. But if there's no way to say these are inactive, you know, we're still --

BOB STEIN: No, they couldn't. They absolutely couldn't be by the way you're defining them.

KATIE DAVIS: Then how would we ever audit a product like that? We wouldn't be making it or producing it anymore.

BOB STEIN: So you're saying that you count on, even though you're supplying replacement parts, you're counting on them having certain components that you don't even have anymore?

KATIE DAVIS: No.

UNIDENTIFIED: If you're not producing it, you wouldn't have to audit it in your annual audit.

DAVID BOOK: And the annual audit is not of every single respirator that you make, but a product line or a respirator.

BOB STEIN: And the other thing, on the maintenance fees, is the maintenance fees were not designed to - they're not anticipatory, so they don't cover any kind of cost of you continuing to submit applications on them. So that's not the way we thought of them. So removing them for that reason wouldn't be a good reason to remove them.

BODO HEINS: Bodo Heins from Draeger again. My question is, would it not be enough if a manufacturer has a certified quality system and not to do all this annual audits and the first sample of production, all these parts are covered by sufficient quality system, so it should be enough if the quality system is certified and agreed by NIOSH to believe in this system. You don't understand?

BOB STEIN: There's some kind of a disconnect, because if you were ISO, there's an ISO requirement to audit. And we're not anticipating that - it's not going to be ISO and then NIOSH and then, you know, so on and so forth.

BODO HEINS: We just have been audited and I said I would have the door open for all the people which are auditing us, the door would be really open the whole day. But my opinion is that if the quality system of a manufacturer is certified and agreed by NIOSH that it's good enough to make sure that the products are following the quality requirements, why is it then necessary to make an audit if the product is reading the same as the quality system said?

RICH METZLER: A quality system is only one component of a quality program. About two years ago when we were actively working on this module, I recall data that we had that suggested that 50 percent of the products that had been recalled over the past few years were from companies who held an ISO 9000 registration. So the registration to ISO in itself does not guarantee quality products. That's why you need these other elements, to add additional assurances.

BODO HEINS: The quality system normally makes sure that any product is - which it's not sufficient, because the quality system is going to the customer. If you do have problems in the company and we are manufacturing something,

it's of anybody's interest, it's our own interest to reduce this. But not to be published. Because those parts are never to show up to the customer.

BOB STEIN: Okay. I mean the only way I know how to respond to that, and I don't know whether it's getting at the point you're driving at or not, is the way it stands right now - we don't get out to see everybody every year. Okay? Some people we see every year. We don't get out to see everybody every year. And what we would like to increase - we'd like to increase that frequency by adding other resources. By going to an ISO standard it facilitates that, because now we can find other auditors besides ourselves that understand your quality system and that we all kind of speak the same language. So we understand when they tell us, yes, it's up to ISO standards. So that's good. Now we have to figure out, well, how do we regard - how do we work that into, our system. We don't want to be redundant, but we want to make - we want to increase the oversight without being redundant and without interfering with what goes on with ISO and making the most use of those things that you're already, you know, you have some expense involved with being ISO certified. We understand that. We want to be able to make use of that as well. So it works better for anybody who is ISO certified, it works better for us too. Because that is part of the framework. But we

feel, and I think that's the point Rich was making, that there are some requirements beyond ISO that we need to have oversight of. That at least occasionally, we will still need to check on those parts. So, yeah, an ISO audit's going to have some validity and it's going to carry some weight, but we still, you know, that's part of the details, is reckoning how we make the best use of that so we're not out there all tramping all over each other. You know, we don't want that situation either, so, you know, one guy just leaves and then the next one shows up. It's like you say, the door's always open because you can't get it shut between one guy leaving and the next guy coming in. And it's not a good use of our resources either - to do something like that. So if we get the details laid out right, hopefully - we'll still be coming to see you. And there will be, you know, a fair amount of face time involved, but it shouldn't increase to the point where you're never getting done with audits, at least not by our perspective.

JAY PARKER: Jay Parker with the Bullard Company. I was interested in the question about the classification of defects. I'd like to just tell a little story. Back in the 1970's when I was working for that legendary respiratory company, Puldisand (phonetic) Safety Equipment Corporation, we had a very well known consultant for quality assurance and

control. And he said way back then that classification of defects is not a proper term, and the proper term is classification of attributes. So I just thought I'd favor you with that little story.

Also I'd like to say that I was interested by the requirement on the QA manual every four years having to be submitted. Because it is a requirement now to submit significant changes. So maybe all you really need to do is to enforce the existing requirement. And finally I'd just like to say that I'm going to put on my ISEA hat for a minute and say that ISEA would like to work with NIOSH on the approval label format, which is something we have been working on for quite some time. So ISEA is still interested in pursuing that further. Thank you.

BOB STEIN: I would like to respond before I sit down, because I might let Dave respond to part of that, but we kind of realize or are sensitive to the fact that defect is an anathema to anybody, because it's just something - it's like I'm checking a diameter, and just because that diameter might be a thousandth off, you know, I hate to call that a defect. And we're sensitive to that. So when we reviewed even the responses that we've got so far, in particular the terminology that was up there one, critical to quality characteristic, attribute, you know, whatever you want to call it, perhaps the

terminology could be changed. And it might give a better - it might give everybody a better sense of what it is exactly that we're trying to do, you know, is to evaluate these things for how correct they are. Not evaluate them and if we find one that's horrible, get it out of there, you know, it's a defect. And we understand that. So if we - if the terminology helps improve the work, we're all for changing the terminology. Do you remember the other parts? The thing about the quality manual? We went around about that a few times.

DAVID BOOK: We've added the every-fourth-year requirement to the quality manual because based on this year's experience doing audits, about 80 percent of the manuals we have are not - in the field - are not the manuals that are on file. Now, we're working on that actively to say, look, folks, get those in, there will be consequences. But at this point we felt this was required stop gap simply to say, alright, if sending you three letters isn't sufficient, here is a section of the law that says it's out-of-date, I don't have to dance, I don't have to refer to internal documents, just do it. And that's where we're at.

GORAN BERNDTSSON: Goran Berdtsson from SEA. Are you intending to do (unintelligible) recognition agreement with organizations like (unintelligible) Australia? I mean we get audited by Inspec, we get audited by (unintelligible)

Australia, we get audited by you guys. I mean I suggest we have one organization --

DAVID BOOK: You're going to have to repeat that question at about half the speed you asked it. I got that you're working with Standards of Australia.

GORAN BERDTSSON: Standards Australia. Inspec in Europe. Is this new system going to allow you to have --

DAVID BOOK: This new system should allow you to do that, yes. And in the specific language that said "or recognized national body" is an attempt to address exactly your question. If you've got - you have ISO registrars in those countries, they are recognized through the ISO process, we will work with them and view their audit reports similarly to domestic audit reports, yes.

BILL WAWRZYNIAK: Bill Wawrzyniak with Moldex-Metric. You made a comment where you related the ISO 9001:2000 to the 17025. And I believe those two documents are very different. One actually pertains to laboratory testing type of facility, which of course NIOSH does. But it sounds like NIOSH is extending into areas above and beyond just laboratory testing. And there are elements within the ISO standard 9001:2000 such as management responsibility, continual improvement, et cetera. And I think it's important for any organization that goes out and audits another organization to have a basic

understanding of those requirements in order to do an effective job. Now, I don't know what qualifications the auditors will have that come out to do these audits, whether it be lead auditor certificate or the facility is actually ISO approved or what. I'm not sure how that's going to work.

DAVID BOOK: Yeah. There's no activity to get NIOSH as an organization into an ISO 9000 certified government agency. That's not out there. We have made efforts internally to have all of the auditors that go out have been trained in at least ISO 9000 in order to evaluate quality systems. We do a lot of internal training in addition. The past practices were that the same people who reviewed all the applications were the people who did the audits. So they were very, very familiar with both our systems and your quality systems. At this point we've segregated the audit function away from the application function, which gives us some independence, which is the other side of that. At this point the auditors that you see have been certified by someone like a certification. Some of our other auditors have been certified by other folks in the past. But they all have background. And we have the same requirements for the folks that we're contracting with. So you're not going to get an unqualified auditor, not through us. We could discuss those details if you want, but I'm quite comfortable with the level of knowledge and skill of the

auditors that we're sending out. If any of you have alternate experiences, see me and we'll see what we can do.

BILL WAWRZYNIAK: It also seems kind of redundant to if a company's ISO 9001:2000 approved they just go through let's say a three day continuum assessment audit to have NIOSH come and basically go through he same routine and charge that as well, since.

DAVID BOOK: Right. And that's not our intent. That's not our intent. The difficulty we have is that the ISO requirements cover maybe 85 percent of what we need to know. We want to always use that 85 percent. There are about 15 percent of what we need to know which are NIOSH considered requirements, specific test procedures, specific recording requirements. Now, if you've got a very bright quality program for registrar, one of the requirements of ISO 9000:2000 is that all government requirements must be met. If you're aware of that and you write your quality system such that they review every time they visit all of the NIOSH specific requirements in general, we should accept that and say they looked at everything we want to see. Now if they don't, then we don't have a choice but to say we have to occasionally come out here and look at what we're required to look at by law. As these things evolve, I suspect you folks will get very bright and learn to do it that way. We'll see

you less often. But we still have to come visit occasionally. Okay?

BILL WAWRZYNIAK: My final comment is, this is the second meeting I've attended. And I was thinking about it the other day. I'm the director of quality assurance for Moldex-Metric. And everything you're proposing here seems to be an extension of my department, if you will. I'm saying gee-whiz, we're doing these internal audits, we're doing first article. Why do I need someone coming in kind of big brother overlooking to make sure we're doing our job. The whole thing with ISO is to continue improvement, and I'm constantly doing that daily. And you mentioned about the services that you provide. Are there any alternatives to really not asking for the service if you really don't need it?

DAVID BOOK: I don't think we've evolved that far. Rich, did you have a comment?

RICH METZLER: The question came up several times about redundancy of manufacturing site audits. In the philosophy of creating this program, we expected to continue NIOSH audits or NIOSH authorized representative audits at around the same number we do today, which is about 25 percent of the manufacturing sites every year. Any additional audits that we would expect to use, those audits would come from the ISO registered authority who has audited you. Unless we have

reason to increase our surveillance because of nonconformance or other indicators that we may have about your quality record.

DAVID BOOK: Okay. As Rich readily points out, that procedure would allow your workload not to increase not at all or significantly, but would allow us to get information back on a much more frequent basis by using those ISO auditors. Okay? So I think maybe he outlined the goals of frequency a little better than we have at this point. But we're in consistent agreement with that.

BILL WAWRZYNIAK: Bill Wawrzyniak, Moldex-Metric. One of the parts of the ISO standard is internal audits of your facility. You have team members who they've gone through training and you do internal audits periodically to assess your system and make sure you're still in compliance. Does NIOSH have any programs like that internally?

DAVID BOOK: We're working on them. One of - I just mentioned we had separated out the quality audit group from the application group. One of the reasons for that was internal so that we kind of have an independent body to do that. Seeing no other comments - seeing no other comments, I take this meeting to be adjourned. Thank you.

(Meeting adjourned.)

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STATE OF WEST VIRGINIA,

COUNTY OF MONONGALIA, TO-WIT:

I, Carol A. Ashburn, Certified Court Reporter and Notary Public within and for the County and State aforesaid, duly commissioned and qualified, do hereby certify that the foregoing proceeding was taken by me and transcribed to the best of my ability and for the purpose specified in the caption hereof.

I further certify that I am neither attorney or counsel for, not related to or employed by, any of the parties to the action in which this deposition is taken, and further that I am not a relative or employee of any attorney or counsel employed by the parties hereto or financially interested in the action.

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My Commission expires October 15, 2011.

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