

Section 5144, Respiratory Protection Assigned Protection Factor (APF) advisory meeting
Held in Oakland, Ca on 12-6-07

Chris Anaya, Sacramento firefighter
Darrel Bevis, Bevis Respirator Consultants
Goran Berndtsson, The SEA Group
Kim Berndtsson, The SEA Group
Maggie Berndtsson, The SEA Group
Jeff Birkner, Moldex
Heather Borman, SCIF (State Compensation Insurance Fund)
Janice Comer Bradley, ISEA (International Safety Equipment Association)
Lisa Brousseau, Consultant to ISEA & Associate Professor, University of Minnesota
Juli Broyles, Cal Advocates
Edward Garcia, CC Myers
Jim Hornstein, Moldex
Larry Janssen, 3M
James Johnson, JSJ& Associates and chair, ANSI Z88 Committee
Anne Katten, CRLAF (CA Rural Legal Assistance Fund)
Jim Kegebein, Kegebein Associates
Adrienne McCambridge, SCIF
Edna de Medeiros, North Safety Products
Jane Murphy, Phylmar Regulatory Roundtable
Fred Nagel, Cal/OSHA
Mark Nicas, Adjunct Professor, UC Berkeley School of Public Health
Janice Prudhomme, MD, Calif. Dept. of Public Health
Tim Roberts, Lawrence Berkeley Laboratory
Walter Robinson, LIUNA (Laborers International Union)
David L Smith, Constangy, Brooks and Smith LLC
Kevin Thompson, Cal/OSHA Reporter
Ray Trujillo, N.CA Regional Director, State Building Trades Council AFL-CIO
Supinda Wadsantad, Cal/OSHA
Robert Weber, 3M
Justine Weinberg, Calif. Dept. of Public Health

Cal/OSHA Representatives facilitating the meeting:

Mike Horowitz, Cal/OSHA Research and Standards Unit
Tom Mitchell, Cal/OSHA Standards Board
Steve Smith, Cal/OSHA Research and Standards Unit Principal Engineer
Bob Nakamura, Cal/OSHA Research and Standards Unit (chief note taker)

Mike Horowitz opened the meeting, gave basic orientation to building, etc... and for the benefit of out of state people, overview of rulemaking. Overriding goal is to protect the employees of California. DOSH makes recommendations to the Board. After public

notice, there is a 45 day comment period, formal comments to be made, revisions of the proposal.

Horowitz discussed the documents provided today, Federal documents, others that were provided for the Federal rulemaking. There are other research documents that emphasize the importance of fit testing, and other research on fit test errors. This includes the New Orleans experience, variability in user fit means, response to petition from 3M, submittals from Labor, and 3 from AFL-CIO (basically from the Federal docket in the rulemaking process).

Today's agenda will be flexible, but would take up each issue raised by the petition sequentially.

Background:

NIOSH defined fit protection factors in the respirator selection logic produced in 1987. Many professionals believe that APFs derived just from laboratory testing should be viewed with some caution; these are not based on sufficient amount of testing. This was expressed in the form of a petition to the Standards Board. The Division needs to determine if this concern still holds and what action to take with respect to the petition. Horowitz asked Mr. Roberts to discuss the first point of his petition.

Tim Roberts thanked all for coming, noted he filed the petition over concern about the Filtering Facepiece Respirators (FFR) in regard to how the fit testing is done and the protection factor that can be really expected. He summarized the first point of the petition. It is illogical to think that the FFR can be as protective as a half-mask elastomeric respirator. FFR in the asbestos standard, for example, is not given the same protection rating and 5144 should be consistent with that. One significant problem is that the user check cannot be done with an FFR.

Horowitz asked for comments.

Darrel Bevis said he has been in the field of respiratory protection for 45 years. He saw the first FFR in Los Alamos, in 1971. No provisions for approval were established or were set at that time. He supports Mr. Roberts, commends him for petition. There was a testing and research group in Los Alamos which found that the FFR did not seal and could not match the elastomeric, and they could not assign a real protection factor to that class of respirators. In 1987 or so, NIOSH again acknowledged that FFR did not match performance of a half face, and in the evaluation a factor of 5 was assigned as with quarter face masks. Los Alamos did not have problem with the quarter, but felt there was no good protection factor for the single use mask. The user field or seal check provided no meaningful result; essentially because of the importance of how the device is put on each time it is donned. Although consistency of donning the respirator is imperative, in actual usage donning is not really consistent. There was a testing cup for some models, but all that did was test the cup, not the mask. The data collected at Los Alamos established his conclusions.

Bob Weber, 3M, says he respected Mr. Robert's opinion, but this is about the research that has been done. Regarding the assertion about the cotton and asbestos standards

having different ratings for the FFR, the Feds said they didn't want to take the time to go through the rulemaking process to make the change consistent. Look at the research done on protection factors. When they compiled the data they selected the employers with good respirator programs, the FFR tested needed to be NIOSH approved, and every user had to have a fit test, passing with a fit factor 100 or more. Federal OSHA had 706 data points for FFR. For elastomeric respirators there were 579 data points...Federal OSHA gave them (elastomeric half face respirators) [an average APF of] 12, with the difference, [an APF of] 18 for FFR. They believe that FFR and elastomeric are the same. Mr. Bevis is talking about the past and today the FF respirators are the same as elastomeric; FF respirators are ½ face respirators. 3M supports the OSHA findings of an APF of 10 for FFR and elastomeric ½ face respirators.

Horowitz noted, given the data points and the variables in the other studies for the elastomeric, and given the difference in the way the masks fit against the face, there was a statement that generally the elastomeric fits better than a FFR.

Weber responded that the data doesn't show that, that is just an opinion. The data says that the devices are equal. Bottom line is they are both ten. These studies were done in very dirty and harsh atmospheres, in CA, Kansas, and other states, in workplaces including foundries and other extreme environments. 3M would challenge the statement that they don't fit as well.

Horowitz asked for others comments.

Goran Berndtsson from Australia asked about the data points that were used in the studies. He noted that it is not part of normal use to have a fit test the same day as a study is done.

Weber said the pass/fail criterion was 100.

Goran Berndtsson asked if that is the normal use situation. He asked if it is part of normal use to have a fit test the same day as a study is performed. It is important that the data is not constrained.

Weber said that you want to see if the people who passed the fit test get the same protection on two, three or four days, and deferred to Larry Janssen to give a more complete response.

Janssen said they tested people Monday morning, some were tested again later in week or some new people were included, but there was no difference in the results. Fit is only one component. The seal is dynamic in real use, compared to lab situations, large particles get in the seal. What happens in the workplace is different. See lower workplace protection factors in more severe environments, maybe less jostling.

Horowitz said the concern is if employees are getting sufficient protection.

Janssen said that he had not seen this before, found lower exposures in worse atmospheres.

Jim Johnson (retired from Livermore) said that most OSHA data is on respirators that are now not in use. Look at NIOSH certifications, from 1999, there are 3903 certifications currently. Look at 31C, 675 particulate respirators certified, 479 withdrawn, 107 current. In one study: 92 available, 52 elastomeric, study shows variability in these types. There were some that could give repeatable results. FFR as a class of respirator, there are a lot that don't perform, and there are many that cannot be field tested. There is a significant difference with half masks between FFR and elastomerics.

Horowitz wanted to clarify if fit testing the elastomeric is easier.

Jansen said that in a published article in 2002 in the AIHA journal, subjects were told to don, perform check. A pool of people was tested 30 to 40 times a year. But the author observed that most were able to make the respirators fit too well.

Janssen: used a unique population that knew too well
Johnson said he would hope an experienced user knows that.

Berndtsson said that there is no way to insure on a daily basis that a disposable would be used properly at work.

Chris Anaya is an end user, a firefighter, and he did a survey informally. Some fire departments don't bother with FFR fit test, can't get it to pass. Have to do the test over and over to get a pass after adjusting nosepiece. Different positions, some guys pass, some don't... how can you duplicate that in the field? Find that with heavy use, outpace the amount of air that can go through the filter, it will collapse, and you can see this in field use because the dust streaks show underneath it. The air goes along soft edge of mask. He learned a lot in last few years about harmful particulates, related to cardiac and lung disease and he recommends we not allow Federal OSHA to sway this process.

Jeff Birkner said that a seal check is just one part of the program, need to be cognizant of where to put the respirator. Regardless of the type of respirator, the seal check is but one element of the necessary program, he said. He commented about the fit check cup, but said there is the same problem with the elastomeric respirator. We'd never want to see anyone wearing a respirator if it is not fitting properly. Respirators have come a long way. In regard to Dr. Johnson's point about 30 CFR vs. 42 CFR, Birkner said he believed the latter were better respirators—for example, with the newer respirators having flanges, etc, making many of the FFR have features that make them equivalent to elastomeric respirators.

Horowitz noted that ten years ago the testing changed to 42 CFR, and how it was done is different from now.

Mr. Bevis commented that he agreed that substantive change has been made to the filters, but we are not talking about the filter media, but about fit, face piece to face seal. Bevis said the 3 commenters said that those FFR passed under 42 CFR are better, and the filtration is better, but this is really about how the devices seal to the face. Don't really see the difference in the construction or material of the sealing surface from before. How were the tests made to find the people who passed? Saccharin?

When you do qualitative fit testing, there is no fit factor, but with quantitative fit testing, you do get a fit factor. Qualitative testing is positive error prone, they were pressed to find another. Quantitative testing takes out the error, so the results are different, not testing the seal.

Edward Garcia, CC Myers, said he agrees with everyone. Not considering human behavior, when you look at instructions, still see that workers complain, the people in the field do not always shave, etc. The true use is not the way it is intended.

Horowitz noted that the Federal OSHA process focused on the filtering media performance. The Federal OSHA standard setting process did not consider real world use problems. Should CA go with the Federal OSHA approach or is there another factor that needs to be considered?

Ray Trujillo said that the firefighter said it well, a lot of times people have facial hair, bulk buyers will not have different types. Construction workers often put them on hardhats, stretch out the strap, and have other user errors.

Janice Bradley said if the user does not pass the fit test, should not use that respirator. No manufacturer controls the use. There are training requirements that employers need to be doing in their programs.

Anne Katten said that the user cannot do the negative check each time. In agriculture, people sweat and that changes the fitting, several hours later the worker will have removed the respirator at least once. So the fit check doesn't show the real use, and many workers don't use FFR with the exhalation valve, so the sweating problem is more severe. Research shows a problem with small particulates.

Horowitz wanted to move on to petition issue #2:

Tim Roberts: people can see how they are used and the importance of this issue. He has experience with training including Cal/OSHA, but there are other issues. FFR are very commonly used now. The second point is that there have been more recent studies on FFR, one about microorganisms/particulate sizes. The smaller the particle, the more likely it is to get by the seal. This was substantiated by research. Older research was done with larger particles, so they may not really apply. Also there is variability in design and construction. Second study shows that the variability is so great that you cannot have a class like this uniformly approved.

Lisa Brousseau, Consultant to the ISEA, said she has reviewed the papers that Tim mentioned: Shu-An Lee and Auld, and it appears that OSHA received it from other sources also. They thought the finding unusual, for organisms to have higher penetration than inorganic material. Her experience is that the particles should penetrate the same way. The factors are complicated, she is not persuaded by this study and thinks it is wrong. The second one by Don Hee Han included workers who did not pass the fit test, so this study actually evaluated how the program performed, so the problems the study identified were from the program not the respirator. It has been generally accepted that a qualitative fit test that there is a fit protection factor of 100, do not get a number. The focus should be on data, should rest entirely on data. There are a number that don't, which rests with a problem with NIOSH.

Bevis asked if this covers false positives.

She responded that it is important to focus on whether the factor should be five or ten, and this should rely on data. If you look at the Lawrence study, it is interesting that it shows that some FFR do not fit as well as hoped. The focus should be on data, should rest entirely on data. There are a number that don't, and this is a problem with the NIOSH protocol, these should have been screened out.

Horowitz said that 3M felt it was controversial and would be a long time before NIOSH resolved that issue. But this group needs to act on what evidence is presented, and not wait.

Weber said NIOSH is looking at total inward leakage

Jeff Birkner said that the fit test they validated was a fit factor of 100 which gives PF of 10. Talking about fit test, quantitative fit test has problems. Relying on that number may be just as inaccurate. Need to have annual testing, and need to have employees buy in, to use them correctly.

Berndtsson said the problem is that you cannot use a concept based on just if something covers the nose and mouth, and not the real factors that make a respirator work well. Need to get a new system. In five or six years there will be a new European standard that is based on performance.

Weber did not agree.

Bevis said the protection factor of 5 is important not only to industry but also the health care industry. They assume that FFR are as good as elastomeric. Bevis had asked for TB testing data, found that the people testing positive for TB are higher for FFR users than general respirator users.

Horowitz noted there is no standard for levels of TB etc, but there may be data in the future, e.g., the nanotech industry that would bear this out.

Bevis noted that his point was more that the users of FFR are more at risk.

Adrian McCambridge of SCIF said that when policy holders use FFR, she finds that people use them until they are ragged, past the point when they should have been replaced.

Jeff Birkner said you are overlooking practicality. OSHA should be cautious about downgrading the APF for FFR when not many employers will be able to comply, e.g., in health care, where people want to use surgical masks instead of respirators, industry provides something that works that is cheap enough for employers to provide.

Janssen does not agree with many of the statements presented and wants to see the data supported in writing. First the fit check performance. The Lee study didn't say what outside concentrations were, close to background means you cannot get a clear measurement. The opposite has been demonstrated three times. Also the comment about smaller particle penetration, it is not true in the workplace. The NIOSH testing method can't separate fit and test leakage (pg, 13 of handout). The result is due to penetration, not leakage. NIOSH Total Inward Leakage (TIL) test, relies on facial shapes, a recent study of anthropometric factors did not support any tendency.

Bevis noted that the 3M studies had pictures of specific workplaces (they said they were the places used in the study). Study included lead and Bevis asked if the photos are showing places that are representative for all workplaces?

No, what workplace should they go to? Weber said 3M just did a cross section.

Horowitz asked how many studies were 5 over PEL

Janssen said that PEL is not important, just the relative presence of contaminants.

Horowitz asked Mark Nicas to discuss variability of user exposure using a Powerpoint presentation.

Nicas said in 1995 he had an OSHA contract to develop factors for respirator testing. Finkel wanted a different type of approach to testing. More research followed but Finkel left OSHA and the research stopped. More recently there was an approach to analyze aggregate data, one researcher suggested looking at the Nicas data.

Issue 1: should account for variability between wearers of same respirator. Looking at a couple of people, see great differences. Wrong way to look at data as aggregate of all the WPF measurements, but that is the way it has been done. This is interpreted as every wearer's factor, which is not true.

Scenario: 10 wearers with log normal consistency: (look at chart of Workplace Protection Factors WPFs) if you aggregate the data, it looks log normally distributed, but 30 percent are really out of log normal distribution. Does represent every wearer's 5th percentile. Should use ANOVA analysis, as Neuhaus did for OSHA.

Issue 2, most analyze only for particle associated contaminants, got rid of others. Particles tend to get lost. The size distribution inside the respirator would probably show a higher small particle concentration inside. No studies have been done, no testing of the small particles for deposition near the seal, or in the respiratory tract. In the recent 3M studies, there is no adjustment for respiratory tract deposition. Nicas presented this source of error to Federal OSHA, but they ignored it. Studies should correct for deposition in the tract and say it is about 50%. Or assume all of that is lost.

Issue 3, what is acceptable WPF distribution? No one has said what that is. People accept 5%, hence fifth percentile. Let's make that assumption.

The respirator approval process needs to specify what percent is acceptable to not have acceptable fit. Like the PEL process. It is implicit now in the present approval process that more than 5% of respirator users will not have acceptable fits.

Also, no one ever applies confidence limits. Nicas quoted an article by Crump which supported Nicas' approach; there are statistical confidence limits that should be applied. OSHA seemed to intend to adopt incorrect size factor criteria.

Lisa Brousseau of the University of Minnesota asked if Nicas did other types of respirators; Nicas said he did only old PAPRs. Would all respirator protection factors go down with his approach to measuring fit? (Probably, Nicas thought).

Janssen said that 3M looked at the TWA associated with the WPF, they tried to do that but it didn't work.

Mark Nicas said to think about the long term average contaminant level and see if they are related. This gets into the realm of toxicology, and the statistical assumptions of PELs.

Larry Janssen said that one of their studies showed that workers were protected even when the exposures were high. Mark declined to get into the toxicology of the exposures.

After lunch, discussion began with a report on the status of other respirator committees' work, e.g. ANSI Z88.2. There are appeals that can be made. For example, there was an appeal in 1991 of the ANSI Z88.2 revision of that year. James Johnson reported that in the current ANSI Z88.2 revision process, there were three appeals to the parent body of subcommittee reports. One of these appeals has been finalized with two others pending.

Anne Katten asked if the ANSI documents were now in progress. Horowitz answered that these are independent, Z88 includes some government.

Janice Bradley said the current draft is under appeal and has not been published

Ray Trujillo, reiterated that they have not changed their position, want 5 as a PF for FFR.

Tim Roberts, in regard to petition item #3: a number of the studies presented by 3M may represent better performing devices, but there is not data to show that other FFR all perform as well as 3M's FFR. Most of the studies have been done on the dup style, and some on the duckbill, which can't be seal checked. So if there is peer reviewed study data he hasn't seen it.

So, if you consider the 2006 Lee study which did look at a lot of brands, there was a tremendous amount of variability. This used WPF (simulated workplace fit factor), not as good in field in some ways, but may actually account for extreme variability in the workplaces and allow for uniform comparison and be more reproducible.

Tim Roberts said that the newer filtration efficiencies are better, the elastomeric respirators when they test them, the seal is made very well to exclude that problem. The factor that is a problem now is more related to particle size.

Jeff Birkner said that as far as fit testing disposables with the N-95 companion, measure leakage with 40 nanometer particles, and if you get a high fit factor with a disposable respirator, then you probably are getting real protection, higher particles would not pass through.

Darrel Bevis said that ½ half face respirators did have a good seal but they were also required to have organic vapor cartridges to confirm the fit testing but when disposables came along, this was stopped.

Tim Roberts NIOSH looking at elastomeric, if it is a cartridge, goes through ten person tests.

Larry Janssen said the Han study only had 10 of 42, good fits; this reflects the bad respirator program.

Bob Weber said one should not look at if qualitative or quantitative fit testing is better. With qualitative, there are aggregate of testing, must total 100, but with qualitative you fail if you smell something. Should not use that argument, if you pass a fit test, you should be able to wear that respirator, if not, get new one. With individual, get different results throughout the week, or day, and all they use is the seal check to confirm. (This shown by workplace studies, but also commenting that user field checks are valid.) They confirm the respirator is worn correctly with the user seal check

Berndtsson said the sensitivity of smell or taste is not measurable, and the other thing that there is a problem with is that the WPF studies have not been following a common acknowledged accepted protocol. Another ignored factor is the size of the wearer, which

is not reported, and which reflects metabolic differences, etc. Studies should take the entire population into account.

Weber said that 3M encourages others to do workplace studies, to see that the people tested are of all different sizes, etc.

Anaya said fit testing is important but not real world. Methods are flawed; they seem designed to save money, like PCM for asbestos. Some of the studies for respirators, use weight comparison inside and outside. Weight should not be the issue, some lighter particles can be very toxic. E.g., asbestiform particles, bypass the seal, get in the respiratory tract. Why not give the best protection?

Horowitz noted that people have said that it is just as protective.

Anaya continued that it isn't as protective, if you look at the pictures of the workplace, the places are not clean. Another problem, shown by 9/11, is that if the respirator had a good fit, they filled up and people couldn't breathe so they took them off, and if they could breathe, it meant there was bypassing through the face seal.

Lisa Brousseau said simulated workplace studies might have information about work protection factors, but the NIOSH studies with 6 redonnings is a misuse of the term... the definition is not for 6 fit tests. But the data in some, like Lawrence 2006, they looked at flat folding and cup, got similar results for the cup and folding, so it may not be necessary to study all the respirators to make decisions.

Bevis said it seems that everything here is predicated on a fit factor of 100, but not much to correlate fit factor to protection factor. There is no specific correlation. Fit factor of 100 for a half mask is atrocious. If fit test with Portacount, test elastomerics, get fit factor of 10,000 and up. Same thing with filtering facepiece, get lucky if you get 500.

Berndtsson remarked that it is sad that only 3M funds the studies. OSHA failed to find other research. Unbiased research should have done that. He asked Larry Janssen how many models were studied, and there were about 3000 tested (actually 3900 respirators.)

Janssen answered that there were 92 N95s . Bevis asked if the 92 are all FFR. Janssen said 3M started from a pool of N95 FFR... and there were 56 elastomeric that could have N95 cartridges. There are also a lot of imported N95s.

Adrienne McCambridge, asked an article, Horowitz said that the concern was they were not simulated workplaces.

Horowitz wanted to move on to petition issue #4.

Tim Roberts noted for issue #3 to look at NIOSH selection process. Thinks the Han study showed that the effect was small particles. Should look at welding fume, nano-particles, etc

Larry Janssen said small particles agglomerate and are easy to remove, like welding.

Roberts said that for petition item #4, the test data is not reflective.

Mark Nicas, the focus should be on gases and vapors, which are not exhaled again, not going to have an exhalation problem due to deposition. Problem is that you are talking about elastomeric mostly. The response to his paper for OSHA says that they should look at the performance with gases and vapors.

Berndtsson said that is what they do in Europe.

Brousseau said selection of representative conditions affected performance, question if any respiratory would offer anything; it's not good to limit the set of environmental conditions; the conditions should not be set for one class of respirators.

Katten said the FFR were more affected by movement, and if you do have a good seal, it is important to consider filter loading but this would be very difficult to enforce. There is no guidance on when to change FFR. In the absence of such recommendations, OSHA should give a lower protection factor for FFR.

Janssen said that in one study, in one place, the people tested had a lot of sweat, and they could wear the FFR all day, or ½ a day.

Anaya said firefighters work in humid environments. EPA estimates a normal breathing rate of 0.8 cubic meters of air, but the harder you work, the quicker you fill the filters up, or get leakage. With heavy activity, in two to three hours you have bypass; you have to change the FFR frequently.

Bevis noted that sweat in the facepieces is not that important compared to water on the facepiece. N95 filters are degradable. N95s are affected by electrostatic charges, and high humidity. My experience is N95s and elastomerics are not equivalent. Morning and afternoon. NIOSH said humidity alone degraded filters, including cartridge. Degradation is not due to organic vapors; NIOSH separated ¼ masks because of the electrostatic effect.

Horowitz: N95s also?

Janice Bradley wanted to see the research.

Janssen said that there is a range of media and some are not affected by humidity, that the new N95s are not as sensitive to moisture, oil, etc.

Edna de Medeiros asked Chris Anaya if the FFR are used for firefighting.

Anaya said that they use them for knockdown after the fire is out, firefighters are prohibited from using elastomeric respirators even if they buy their own.

Birkner said that if you put an N95 in an organic solvent, it will degrade, said that Ernie Moyers had to actually saturate filters in a solvent to degrade them. I hate to make blanket statements, but ours were tested with solvent, found that it didn't have an effect.

Bevis said that he dipped it because he tested a P100.

Janssen said that there are papers on degradation of N95s, conclude only see effects with saturated environments. They also tried saturation in workplaces, got good performance,

Roberts said petition item #5 was about there being no published factors for efficiency of the different styles of FF respirators. Johnson saw performance differences.

Horowitz said that 3M was critical of OSHA finding, most of the studies relied on were based on 30 CFR testing,

Roberts said it is hard to extrapolate; respirators were not tested as well under the earlier protocol.

Janssen said that OSHA looked at one their studies, performance same ditto with flat fold style. Don't see performance difference.

Horowitz summarized.

Weber said Janssen has degraded them with radiation to be out of 42 CFR but the filters still work well. The filter doesn't matter.

Janssen said the variable was the valve or lack of. No real conclusion about different cup shapes.

Johnson said filter media is a snake pit; it varies greatly between respirators. So it is interesting to show what a person could do with a lot of respirators. He found the difference with results was due to the different filtering media used, for example, whether or not the filtering was based on a mechanical process. There are multiple ways to put charges on media, and these vary among manufacturers. Right now you can't rely on a P100 to be a mechanical process. The whole filter issue is due to what NIOSH allows, can't see any information about the process, same for FFR and elastomeric. The whole class of filters has a problem. Filter media is questionable unless he knows it is a mechanical filter.

Janssen said that NIOSH addresses that concern with the information on the P100. Like instruction to throw out the item for time exposed to oil or something else.

Edward Garcia asked if NIOSH does the testing in secret.

No, he was told

Garcia asked, "Can 3M do a public test?" He was told 3M is trying to do one with NIOSH, may happen in 2008.

Bradley said that the sponsor should be NIOSH and should fund it even though manufacturers are willing to pay for it.

Bevis asked if the ISCA allows participation.

Bradley said that members can do what they want. Anyone with interest can do research and publish.

Janssen said peer review of studies is the only mechanism for doing

Garcia noted that CalTrans had a lot of people test concrete by having them watch it in the field test.

Horowitz noted the conclusion of OSHA, that not all respirators were tested.

David Smith said that is typical of OSHA, to use the best available data.

Bevis said the variable for the typical FFR is that the user has to shape the nose bar and has anyone ever quantified that?

Weinberg said the CDPH based on experience with respirators, supports the petitioner and an APF of 5 for FFR.

Anaya said that he has done fit testing for many years, what is the rationale for the lawsuits against manufacturers if the fit test was okay?

Weber declined to respond but Hornstein (Moldex General Counsel) said there were 40,000 claims were filed in Mississippi and Texas over asbestos, and then silicosis. Federal judge in Texas threw it out, most litigants didn't get a fit test or use Moldex.

Katten stated that the lack of data for many models is a big concern, argues for using lowest common denominator of the class of respirator.

Horowitz said that filing at OSHA was an open question at the time, OSHA rejected the petition, but item 6 has been answered in part that there should always be more information.

David Smith offered to send Horowitz the OSHA response.

Roberts said that he filed the petition with two others; they were on the ANSI committee at the time and they never saw the Federal OSHA response. My concern is point 6A, I filed a Freedom of Information request (FIFRA) for statements at hearing and

subsequently had OSHA/NIOSH exchanges, but I got no response. Apparently in the record. Also, the selection of the data for rulemaking seemed incomplete, never looked at. Also, unclear was if Office of Management and the Budget (OMB) studied the impact of protection factors.

Roberts noted that the cotton dust APF number of 5 had been considered...

David Smith said in the Federal OSHA response addresses this by saying that FFR can be appropriately fit tested.

Horowitz said that it also seems that it may not be done because it may not go anywhere.

Roberts said petition point #5 was that worker protection studies shouldn't be used to set PF if the studies were not used in certification of the respirator. Point #6 raised the question of nano and other small particles not being considered by Federal OSHA in their determination of APF.

Petition point # 7 is concerned with avian flu, which is not considered, though OSHA had some discussion of respirator sealing to the face.

Horowitz talked about a letter in the Federal Docket from 1986; the letter said that the construction of the old 8710 makes uncertain close fit, so PF of 5 was chosen then.

David Smith said it is on page 4 of that letter. Techniques and procedures have been developed to assure seal in the replacements for the 8710.

Janssen said it was things like the Portacount, bitrex, etc. that had improved ability to evaluate individual respirator fit.

Bevis wanted to clarify if this is the OSHA response, that it was never sent to Tim Roberts.

Smith said no one filed for court review, but OSHA was asked for a stay.

Janssen said the reason NIOSH said they were not going to use Workplace Protection studies 20 years ago, manufacturers said it was impractical to field test them all. Nano testing, no testing has been done.

Jim Hornstein said NIOSH saw no hope in using field testing

Weber said that the issue of small (nano) particle atmospheres was addressed by the company who said that the particles do not follow the air stream the way that inhalable particles would, they are more subject to Brownian motion, and they do not remain in the air as particles, but agglomerate rapidly, within seconds.

Mike Horowitz read part of the OSHA letter on the subject.

Mr. Bevis said that during his time doing the research at Los Alamos, the research being done was intended to set the SWPFs, not the WPFs.

Janssen said that some of those numbers held up over time and some didn't. The numbers for the PAPRs did not.

Mr. Bevis said that only some of the numbers were derived by actual research, some of them were extrapolated at best.

Jim Hornstein added that some of the studies showed higher protection factors, but the adopted numbers were lowered to 1000.

Mike Horowitz directed the group to the User Field check, asked Mr. Roberts to explain.

Mr. Roberts said that part of the original petition is no longer applicable but the bottom line is that it is easier to do a fit check with an elastomeric than with an FFR.

Janssen said that it is easy to teach people to do the field check. There is no data to show the relationship of the field check with the fit factor. Janssen said we don't have any data that field checks are efficacious.

Brousseau added that a good respiratory protection program requires good selection procedures for finding a respirator that fits. Selection may be more important than fit testing.

Katten asked how you could verify a good fit without fit testing.

Mike Horowitz responded.

Johnson noted that the NIOSH site has a page for disposable respirators and it has many of the manufacturer's user and seal check instructions. Some of these instructions are useless, so you can only expect limited assistance for employees using FFR. On page 35 of the NIOSH Guide to Respiratory Protection are the certified respirator use instructions. This is what's provided, some of this data is poor but it is at best what the employer is telling the workers.

Horowitz asked the group for data about what proportion of FFR are used for varying percentages or multiples of the PEL.

Weber responded that most of the places where they are used are not above any PEL, and a very low percentage even approach the PEL.

Johnson disagreed noting that you could look at concrete workers who have a lot of high exposures to silica during the various tasks they do.

Horowitz noted that for many vertical OSHA standards, the application of the other requirements for engineering controls would seemingly tend to drop the exposures below the PEL, but he had the experience of having an IH monitor the exposure of people doing granite finishing outdoors on a windy day. The employees were using half-face respirators and had exposures 13x the PEL.

Horowitz said that in the APF Final Rule Federal OSHA asked the same question and noted that 3M looked at worksites for 20 years but couldn't find worksites to study that met the criteria of over five times the PEL. OSHA looked at the IMIS records and found 9000 samples that were above the PEL, and 13% were 5-10 X the PEL. So, how significant for worker protection would it be to change the allowed PF to 5?

Heather Borman said that her 19 years of field work experience with small employers she rarely saw exposures at 10x PEL, and most were below the PEL. However, she does not recommend FFR for silica, and if the assigned PF is 10, it gives the employers a false sense of security.

Weber responded that it is irrelevant how many workplaces have exposures over the PEL. The record shows that there is no difference between a FFR and a half-face elastomeric. So you should drop all the half-face to 5; it makes no sense but it would be better than just dropping the factor for the FFR.

Johnson noted that the theory is that we can rely on the market and following the OSHA program to weed out poor performing respirators. But a 2001 BLS study showed 60-70% of employers don't have respiratory protection programs. So if you have to rely on a good program, the weeding out won't happen. So, NIOSH is saying that there needs to be a change for assessing this class of respirator.

Adrienne McCambridge added that in her experience, you never see an employee do a seal check with the FFR. They say it doesn't work, and then begin to doubt the program works, and laugh at the written instructions that come with the FFR.

Anaya said there is a significant failure rate of negative vs. positive pressures. With the elastomeric half face respirator, the semi-rigid seal holds up against pressure better.

Bevis said there is tremendous variation among FFR and NIOSH suggested individual ratings.

Weber said that proposal was outdated.

Bevis responded that it was but you need to be conservative in the selection process because of what happens in the workplace.

Tim Roberts said you may be able to say that 10 is good with enough documentation; for example, with the case of the air supplied helmets the rating is 25 unless there is evidence of better performance to support 1000. Recall that this was done because one model of

that class of respirators didn't provide that much protection. Maybe this process could be applied to FFR since it has been pretty well shown that not all FFR are made the same. Roberts proposed that perhaps there could be a compromise between the two positions by having a note in the table as for the air supplied helmets. Similarly, if an FFR manufacture could document that their FFR could achieve an APF of 10, this would be allowed, otherwise not.

Berndtsson asked how they would prove that.

Weber said the manufacturer just has to prove it; there is precedent with the end of service indicators on cartridges.

Janssen said that this 5 or 10 idea would be more of an issue as use increases in response to the hex chrome standard, and for beryllium exposures. Within the NIOSH logic, the idea of using fit testing to correct for bad programs, you would still have to test everyone, even if it passes at NIOSH.

Borman noted that for fit checking before each donning, have to rely on the quality control of the respirator. Some have adjustable straps, others may not stay on the same the whole time. Fed/OSHA says it is okay to fit check the FFR because the manufacturer says it works, but we need independent findings to support that.

Horowitz noted that the objection from labor groups is that the fit check is often not done in real world settings.

Bevis noted that in his experience, some N95s have a quality control issue, he found some of the head bands failed the check. He had an experience of attempting to fit test an individual on three FFR from the same box. All had the same problem, it seemed to be a quality control problem. NIOSH should use a different test procedure. The Z88.7 committee of 1987 represented many interested parties, and set up evaluation procedures. Something like that could be done so that manufacturers can submit useable documentation.

Berndtsson said that there are some really bad respirators that just don't work. Development of a FFR protocol to really fit the human face needs to be done by NIOSH.

Janssen disagreed that NIOSH should do any fit testing of that type.

McCambridge asked why 3M hasn't done more basic research on these subjects. Janssen responded that 3M doesn't think it is necessary, the seal check is adequate.

Horowitz summarized the key points of the day's discussion. He said the DOSH staff would digest the information and comments from the meeting and a recommendation would be developed for the Standards Board. He explained the steps that go into rulemaking noting that the actual proposal from the Division would go through a 45 day comment period and successive 15 day comment periods until a final proposed regulation

was presented to the Board for a vote. He noted that in the process, formal comments made about the proposal would receive a response that would be in the documentation of the rulemaking process.

Someone noted that testing of the FFR for the European agencies is already being done, so there is a precedent and model.

Johnson noted the NIOSH inward leakage research, and asked if the manufacturer doesn't submit any data, what rating would it get?

The answer was the rating would be 5.

Meeting adjourned at 4:10.