Comments on the NIOSH Notice of Proposed Ruulemaking on Respiratory Protective Devices, 42CFR 84, May 24, 1994

My name is Jay Parker and I am the Respiratory Protection Product Manager for Glendale Protective Technologies of Lakeland, FL. Glendale is a manufacturer of NIOSH/MSHA approved respiratory protective devices. As product manager for Glendale, I have responsibility for all aspects of our product line, including technical issues and the testing and certification process. I have twenty years of experience in the testing and certification of respirators. Glendale is a member of the Industrial Safety Equipment Association and weare in general agreement with the comments provided by ISEA at yesterday's hearing. I will therefore restrict my comments to those areas which we feel need further amplification and clarification.

As someone who has worked for many years with the silica dust test, the lead fume test, the lacquer and enamel tests I have long believed that there are better ways to test and certify particulate respirators. The fact that there is commercially available equipment to run the new particulate tests is of no small significance. The silica dust and lead fume tests are legendary for their difficulty to set up and run, due in no small part to the fact that there is no commercially available equipment or even complete equipment specfications to the best of my knowledge. Reliable and reproducible results from apparatus to apparatus are critical to the certification process. I am aware of some recent concern at NIOSH regarding differences in results between the manufacturers and NIOSH and I submit that this is partially due to the nature of the current particulate tests. The current proposal for which there apparently is commercially available

equipment to run the new particulate tests should assist the manufacturers and NIOSH to achieve better agreement in test results. Some would argue that the current tests are also a barrier to obtain approvals for particulate respirators because of the difficulty in setting up and performing these tests.

NIOSH's desire to test particulate filters against the most penetrating aerosol size is good science and I support this position. The new tests also use more monodisperse aerosols which should lead to more consistent results. It should also be mentioned that the lead fume and silica tests employ very toxic test agents which can create potential exposures to test operators.

Regarding the the proposed types or classes of filters, Glendale's position is that the types should be changed to 99.97%, 95%, and 90%. In the draft unofficial second notice of proposed rulemaking on 42 CFR 84, NIOSH proposed levels of 99.97%, 99% and 90%. I believe that it is in the best interests of the respirator users to include a 90% level which would be adequate for many of the low to moderate toxicity particulates and would allow such respirators to be relatively economical in cost. The middle level should be set at 95% in my opinion. There will not be much difference in cost or actual performance between the 99.97% class and the 99% class. The faceseal leakage factor will negate most of the improvement in efficiency between these two classes. The European CEN standard for filtering facepieces allows 1% penetration of paraffin oil for the P3 (high efficiency) class for this reason. A 95% class would be more economical in cost and would provide a true intermediate level of efficiency after allowance for face seal leakage.

The proposed grandfathering period of 2 years is too short in my opinion. The manufacturers will need sufficient time to develop new filter media and adapt it to respirator filters to meet the new requirements. Many if not most of the respirator manufacturers use media manufactured by separate companies whose priorities are not necessarily the same as ours. NIOSH itself will need time to test and certify all of the new respirators that will be submitted. Although the new tests are faster than the existing tests, there will be n avalanche of new approval applications and the sample size will go from 3 to 30. There will also be quality assurance documentation that will have to be approved. The last time there was a change in the regulations with the publication of 30 CFR 11, most of the existing Bureau of Mines approvals were grandfathered for five years, some longer, and the result was a generally orderly switchover. In my opinion, two years is not enough time to develop, test and certify the new particulate respirators. A precedent of five years was set by 30 CFR 11 when first published. I believe a minimum of four years would insure an orderly transition to the new approvals. In addition, I am in agreement with ISEA's position on two years grandfathering for extensions of approvals for currently approved particulate respirators for changes involving filter media and four years grandfathering for changes involving areas other than filter media. These changes are sometimes forced on us by circumstances not under our control, such as companies that no longer make certain media that we are using. The manufacturers need to have the ability to make modifications to their existing respirators even if they are not ready to submit to the new particulate standards. Otherwise, there may very well be a gap of availability to the users due to this scenario.

Another issue is whether the grandfathering clause affects sale or sale and distribution. The proposed rule refers to sale and distribution of respirators. Most U.S. manufacturers sell their products through distributors. In the U.S., there are thousands of small , medium and large distributors that distribute safety equipment and the manufacturers cannot control the sale of product from these distributors. The grandfathering period should cover sale and shipment from the manufacturers only. When NIOSH banned the sale of chromium-containing sorbents in chemical cartridges several years ago, the question of distributor sales did come up and NIOSH specified that distributor sales were not covered by the ban. Distributors should be allowed to continue selling particulate respirators approved under 30 CFR 11 after the grandfathering period expires. To not allow the distribution of product after the grandfathering period ends would cause utter chaos in the safety market.

Regarding respirator breathing resistance requirements, Glendale is in agreement with ISEA that the initial inhalation and exhalation resistance requirements should be increased slightly to allow the manufacturers more room to use higher efficiency media. Efficiency and resistance are related and higher efficiency usually means higher resistance. Raising the proposed limits to 35mm inhalation and 25 mm exhalation would allow more efficient media to be used and should not present any significant physiological burden. Currently, 30 CFR 11 allows initial inhalation resistance as high as 70 mm for gas masks and exhalation resistance of 25 mm for single use respirators without valves for vinyl chloride and pneumoconiosis and fibrosis producing dusts and 25 mm for supplied air respirators.

Concerning the issue of test statistics, Glendale is in agreement with the ISEA position that the one-sided tolerance limit should be based on 95% confidence of 90% conformance as was used in the 1987 proposal. The purpose of this statistical test is for the manufacturers and NIOSH to have more confidence in the results obtained when testing respirators for certification. Under the current system, three samples are tested and if they pass, approval is granted. The three results could all be borderline, but approval is still granted. It is therefore understandable for NIOSH to require statistical treatment of the data. The proposed criteria of 95% probability of 95% conformance is unneceessarily strict, in my opinion, and will resuslt in additonal costs that will be transferred to the end user, with little benefit. Glendale would like to see 95% confidence of 90% conformance because we believe this is sufficiently stringent for the purpose of these tests.

In regard to NIOSH's modular approach to the rulemaking, Glendale understands the benefits to be achieved by such a process. However, there are potential difficulties such as combination respirators for gases and particulates which have to be modified to achieve the new particulate regulations and may have to be modified again to meet the new requirements of afuture module on chemical cartridges. The facepiece fit testing or simulated workplace protection factor testing module may also require further modifications. Therefore, the modular approach will result in numerous modifications of respirators which will cause confusion, delays and expense for the manufacturers and the government. The respirator users may be totally confused by the endless parade of new approvals to new requirements. However, the benefits of being able to change certain parts of the regulations with speed are not be overlooked. I would recommend that the

modules be carefully prioritized to achieve the least disruption and to address the areas of greatest concern first. Glendale is willing to assist in this process in any way possible.

Another issue is the addition of isoamyl acetate fit tests for all particulate respirators. Glendale is concerning with the feasibility of testing filtering facepiece type respirators since the addition of an activated carbon cartridge to allow the test to be performed can have a significant effect on the fit of this type of respirator. It may be meaningless to run a fit test on a respirator that is modified in such a way as to profoundly change the weight and fit characteristics of the respirator, which is what would occur with a typical lightweight disposable respirator.

It should be mentioned that the cost of test equipment needed to run the new tests will be over $100,000, not $60,000. as stated in the suppplementary information. The test equipment for running the sodium chloride and DOP tests is about $45K per unit and the scanning mobility particle sizer required in the proposal about $60K. More than one test unit may be required for production testing. I would also question the the increased material cost for filters projected by NIOSH as only "pennies per filter." I would argue that these pennies are going to add up fast - I have seen some pretty expensive mediia out there when one gets up into the higher efficiency levels. There may be quite a few pennies there! NIOSH also refers to the cost of replacement non-HEPA filters as about $1 to $2 each and disposable non-HEPA filters at about $1 to $8 each. I think the new types of filters, especially for a 99% efficiency level, may be considerably more expensive than existing non-HEPA filters. NIOSH states that some currently certified respirators have demosnstrated acceptable performance when tested using the new standards. Is

this data available? A NIOSH study published in the American Industrial Hygiene Journal in May, 1989, showed that dust, mist type, paint spray type and dust, fume and mist type filters from four different manufacturers had initial penetrations of sodium chloride and DOP above 5% using test aerosols with a range of particle sizes that extend down lower than the proposed tests. There was no preconditioning in these tests. These data from 1989 are initial readings only and the proposed rule requires testing until a certain load has been placed on the filters and the efficiency level must be maintained. NIOSH must also consider the research and development costs of these new respirators and increased manufacturing costs to make them.

Another huge concern is the selection of respirators with these new classes replacing the existing dusts, mists, fumes, radionuclides, radon daughters, asbestos, paint spray and pesticide classifications. Who is going to decide which class to use? Does NIOSH intend on publishing a guide listing all common air contaminants and what class to use? Will OSHA do this? How about existing OSHA and other federal standards (EPA, NRC, MSHA) that require certain types of current particulate respirators, such as the OSHA cotton, asbestos and lead standards? A system must be put in place to address this issue of user guidance in the selection and use of these new classes of filters. This point is of the utmost importance because without the user guidance, the new classes will not serve the purpose for which they are intended, mainly to provide respirator wearers with improved respiratory protection and cost avoidance.

On the subject of assigned protection factors, NIOSH is intending to publish a Respirator User's Notice at the time of publication of the final rule to provide respirator users with new assigned

protection factors for the new classes of particulate respirators. This notice will not go through the public rulemaking process. I understand that assigned protetction factors are the next scheduled module and this notice will apply only in the interim period bettween passage of the final rule affecting particualte respirators and the final rule on assigned protection factors, I still think that the public should be able to have input in this important area. This can serve as a quick start on the module for assigned protection factors and provide a base for this section. This would make final rulemaking easier on assigned protection factors.

In summary, Glendale Protective Technnologies as a respirator manufacturer is concerning with this proposal which has many good points but which really needs to be modified as I've explained in order to provide the end users with an improved product at a small increase in cost. Let's not rush into a new regulation that will cause undue hardship to the respirator manufacturers and still not provide end users with affordable improved particulate respirators. I'd like to thank NIOSH for offering me the opportuunity to address you all today. Thank you.