occupational disease or injury. In most circumstances the respirator user has no way of knowing if respirator performance is substandard. Except for the most acute responses to substandard respirator performance, it is not possible to attribute health effects to a failure of respiratory protection. Most of the serious occupational diseases have long latency periods, so respirator users typically would not know if they used an inferior device. Even the relationship to workplace exposures can be obscured because of the presumption that respirators provide effective protection.

Respriator purchasers and users expect and deserve to be able to select respirators with complete confidence that they will perform with a specific efficiency for a specific purpose. They rely on the NIOSH, formerly MSHA/NIOSH, performance standards and certification program to assure them that they can have that confidence.

These new particulate filter efficiency tests are needed to reduce potential health risks that may result from leakage of small particulates through some filters certified under the current regulations (30 CFR part 11). For over a decade the filter penetration tests contained in 30 CFR part 11 have been known to be deficient. Leakage of small aerosols has been recognized as a problem that could be corrected only by revising that regulation.

The magnitude of the filter leakage problem came into sharper focus in the early 1990's when NIOSH and other researchers used modern methods not available under the provisions of part 11 to measure performance over a range of particle sizes. For certain models, leakages higher than 50% were found. Not all respirator models exhibit this high level of leakage, but 30 CFR part 11 testing does not distinguish adequate from inadequate filters.

The respirator community acknowledges filter leakage to be a problem. The American National Standards Institute (ANSI) Z88.2–1992 national standard, for example, states that 2 of the 3 types of particulate respirators certified under 30 CFR part 11 should be used only when the workplace particulate contaminant is know to have a mass median aerodynamic diameter (MMAD) greater that 2 micrometer.

Compliance with aerosol size limitations such as those of the ANSI Z88.2 would represent a major technologic and economic burden for respirator users. Those burdens are great even for the largest employers and exceed the capacity of smaller employers. Adequate worker protection with DM and DFM respirators certified under 30 CFR part 11 can be assured only if employers conduct sophisticated and expensive measurements of the size distribution of the aerosol in each workplace. This is simply too expensive for the great majority of respirator users, who may elect to use DM or DFM respirators without evaluating aerosols in their workplaces, thereby placing their workers at increased risk of occupational disease or disability. The only alternative at present is for those employers to provide costly high efficiency (HEPA) filters. The difficult and costly aerosol size measurements are not needed when HEPA filters are used because they are tested with the most penetrating size of aerosol. HEPA filters are therefore known to be effective against any aerosol regardless of size.

The new 42 CFR part 84 filter efficiency tests use only the most penetrating aerosol size, so all filters certified under these new procedures will be effective against any size aerosol. This new rule thereby corrects an acknowledged deficiency in existing filter efficiency tests, removes from the workplace respirators that fail to deliver the expected degree of worker protection, relieves employers of the need to perform costly and difficult measurements of aerosol size distribution, and provides alternatives to the expensive HEPA filters in workplaces where the aerosol size is either unknown or is known to be small.

This new rule continues to limit, as does the current 30 CFR part 11, the breathing resistance (inhalation and exhalation resistance) of the respirator. Breathing resistance is significant to respirator wearers in three ways. First, higher breathing resistance increases leakage at the face seal of the respirator. Face seal leakage is directly proportional to breathing resistance, other factors being equal. Second, respirators with lower breathing resistance are more comfortable and more acceptable to wearers. If a respirator is uncomfortable to wear, workers are less inclined to use their respirator as often as they should. Third, high breathing resistance can be an unacceptable physiological burden on some workers. For a worker with impaired pulmonary or cardiovascular function, high breathing resistance may make respirator use impossible. In this rule, NIOSH has increased the allowable inhalation and exhalation resistance in consideration of minimizing economic impact, but NIOSH has maintained the breathing resistance at a level that still will minimize adverse impacts on the respirator user.

E.O. 12866 further requires the agency to determine whether the proposed rule is ''economically significant'' (e.g., it does not have an annual effect on the economy of $100 million). NIOSH generally prepares a regulatory flexibility analysis, in accordance with the Act, if the rule is expected to have a significant impact on a substantial number of small entities. NIOSH does not believe that this final rule will have an annual impact on the economy of $100 million, nor does NIOSH believe that the rule will have a significant impact on a substantial number of small firms.

This regulatory change affects only particulate respirators. A total of 56 manufacturers hold respirator approvals, and 33 of these hold approvals for particulate respirators. Based on inquiries received, NIOSH believes that several additional manufacturers are planning to submit applications for particulate filter products under this new regulation.

Data are not available to define company size, market share, or diversity of products for the current approval-holders. Projections of impact are based on an understanding of manufacturers—dependence on existing approved particulate respirators. Of the 33 manufacturers that have particulate filer approvals, 24 hold additional approvals for devices other than particulate respirators, and nine have only particulate filter approvals. One of these manufacturer holds approvals for DM, DFM and HEPA respirators, while the remaining eight each hold only a single particulate filter approval. Because all existing HEPA filters are expected to pass the new certification tests, it appears that only eight of 56 respirator manufacturers might be dependent upon particulate filter respirators possibly at risk of not passing the new certification tests without redesign. At least one of these eight manufacturers commented favorably on this proposed rule, indicating readiness to meet these new criteria.

Any manufacturer that cannot meet the new criteria immediately will have three years in which to develop new products or face removal from the approved respirator market. However, loss of approved respirator status does not prohibit sales of the devices as non-approved units. The non-approved respirator market appears to be very lucrative, with several of the larger manufacturers participating. Non-approved respirators are sold in many retail outlets including hardware, auto supply, and department stores. Consumers purchase these devices for use against nuisance dusts while