has to be performed on modified respirators.

The comments requesting that fit testing be made a meaningful test were based on reasoning similar to those suggesting elimination of the test. In lieu of elimination, they suggested that some inadequacies could be resolved with modification of the test protocol to use a particulate aerosol, such as Bitrex, as the test agent. Changing the test protocol to test with a particulate would at least permit the tested respirator filters to be as certified, thereby eliminating specially-made surrogates.

Commenters endorsing NIOSH continuation of fit testing believed that the present certification process provides an assurance that the respirator will properly fit a given worker when use of the respirator is needed in the workplace.

The problems associated with testing the facepiece-fit in a certification program have been recognized for years. Efforts have been made to seek more meaningful test results; nevertheless, the validity of the test results remain questionable.

Successful fit testing in the certification process provides no assurance that the respirator will properly fit a given worker when used in the workplace. The only means presently available to assess the fit achieved on the worker is a respirator-to-face fit test conducted on that individual with the chosen respirator. Even this test procedure, conducted on the individual, cannot assure that the respirator will maintain a proper fit when use of the respirator is needed in the workplace. This concern is compounded when the fit is determined with a surrogate respirator.

During review of this rule, both OSHA and MSHA favored inclusion of respirator fit testing and fit checking procedures as part of NIOSH respirator certifications under the new part 84 particulate filter classifications. Both agencies accepted the determination by NIOSH that these issues cannot be properly addressed in this first module. Both agencies therefore urged NIOSH to develop a face fit module to include respirator fit testing and fit checking procedures for all respirators.

The purpose of face fit testing in the certification program has been to assure that respirators have generally good face fitting characteristics. However, at this time NIOSH does not have studies that define the effectiveness of either the isoamyl acetate or American National Standards Institute (ANSI)/OSHA accepted fit tests in predicting actual workplace protection provided to workers. NIOSH is presently conducting research for this purpose. In the interim, lacking validation and correlation of testing protocols, workers' health concerns are best served through the application of fit-testing and fit-checking procedures on individual workers in a quality respirator program. Therefore, the isoamyl acetate fit tests proposed in §§ 84.181 and 84.182 are not included in this final rule. NIOSH will address issues associated with face-fit efficacy in a separate module upon completion of the necessary research.

B. Powered Air-purifying Particulate Respirators

The proposed regulation included filter efficiency requirements for powered air-purifying respirators (PAPRs). The solid and liquid and solid categories were to be tested with sodium chloride (NaCl) and dioctyl phthalate (DOP), respectively. The classes to be certified were the 99.97 and 99% efficiency levels. The remaining design and test parameters for PAPRs were retained from part 11 without change.

Commenters questioned why the efficiency levels proposed for PAPRs were not the same as non-powered respirators. The proposal specified three efficiency levels for non-powered (95, 99, 99.97) and only two levels for PAPRs (99 and 99.97). Commenters indicated many present filter cartridges are interchangeable between the non-powered and PAPR units, recommending corresponding filter efficiencies between the non-powered and PAPR units to retain this broader market for a filter design.

Numerous commenters stated a concern that the proposed requirements of subpart K did not adequately address PAPRs. These commenters indicated that the respiratory protection provided by PAPRs is dependent on the respirator components working together as a system. The proposed rule, focusing on filter efficiency, did not address the system requirements for these respirators. These commenters reasoned that the performance of these complicated respirator systems deserves special consideration because of unique problems addressing airflow, filter efficiency, and fit. These commenters suggested that the requirements for powered units be removed from subpart K, to be addressed in a separate module.

Other commenters addressing PAPR requirements stated concerns over sodium chloride (NaCl) filter test instrumentation capabilities. With the present state-of-the-art capabilities, the proposed PAPR loading requirements are difficult to achieve. This leads to a number of testing difficulties including instrumentation availability, time consuming tests, reproducibility of results, and system costs. NIOSH agrees with these concerns and will address them in the forthcoming module.

Commenters to the proposal also acknowledged that the resultant part 84 filters would be a significant improvement over those currently certified and marketed under part 11. Two commenters recognized the concern over the performance of part 11 powered dust, fume, mist respirators. They indicated that this concern could be addressed by incorporating only part 11 high-efficiency filter requirements for PAPRs approved under part 84. NIOSH agrees and has revised the rule to permit the continued use of part 11 high efficiency filters for PAPRs approved under part 84.

NIOSH also agrees with commenters that the proposed filter efficiency requirements alone do not adequately address the operational parameters of PAPRs that should be revised. The sections of subpart K have therefore been modified to be applicable only to non-powered air-purifying particulate respirators. The requirements for the powered units will be addressed in a forthcoming module. In the interim, powered air-purifying particulate respirators equipped with HEPA filters will be approved under the provisions of subpart KK.

C. Filter Classification

The proposal provided for six classes of filters in a filter classification system with three filter efficiency levels and two categories of filter degradation resistance. The three efficiency levels (99.97, 99, and 95%) were determined by testing with the most penetrating aerosol size until a maximum loading of 200 mg was reached. The two degradation resistance categories were established by the choice of either NaCl or DOP as the test challenge aerosol. Sodium Chloride is only mildly degrading to filter media while DOP is a liquid oil that is highly degrading. Accordingly, filters tested with the NaCl aerosol were recognized as not highly resistant to degradation and only appropriate for use with solid aerosols in the workplace. Filters tested with the liquid DOP oil were recognized as highly resistant to degradation and considered appropriate for both liquid and solid workplace aerosols.

The categories and classes of filters that would have been certified under the proposal are summarized below:

Category	Class	Efficiency	Test agent
Solid and liquid	A	99.97	DOP