time to develop new products, receive certification, and initiate production of the new respirators. Commenters were also concerned the use of the term distribution implied manufacturer control of the distributer system and the resale market. Several commenters recommended 4 years for NIOSHprocessing of part 11 applications, and for sale and shipment of part 11 respirators. NIOSH is expanding the phase-out period from two to three years to address these concerns.

With the effective date of part 84, MSHA and NIOSH will no longer accept applications for new approvals or extensions of approval of respirators under part 11 provisions. All applications received after the effective date of part 84 will be considered as applications for a new or extension of approval under part 84. Valid part 11 applications that were received prior to the effective data of part 84 will be processed for approval under part 11 provisions. A subpart KK containing the part 11 requirements for particulate respirators has been added to the final rule to provide continued authority for NIOSH to issue extensions of approvals needed to address respirator recall and retrofit matters that are associated with health and safety issues for workers. Respirators listed as certified under the provisions of 30 CFR part 11, subparts K or M, may not be sold or shipped by the approval holder as NIOSH/MSHA certified respirators effective July 10, 1998. Continued use of distributed particulate respirators is under the jurisdiction of OSHA and MSHA and therefore is not affected by this rule. Because certifications will not be revoked for part 11 devices sold and shipped by the approval holder prior July 10, 1998, NIOSH anticipates that OSHA and MSHA would permit continued use of those part 11 respirators.

This 3 year period was selected to ensure the timely replacement of the part 11 respirators that exhibit low initial efficiency levels while allowing an ample supply of respirators to remain available for use. This timeframe will provide sufficient time for manufacturers to have respirators approved and manufactured in quantities to meet demand. Manufacturers' comments to the proposed rule support this timeframe, as some manufacturers appear ready to provide part 84 respirators immediately. At least one commenter stated, without reservation, preparedness to submit applications to meet the new requirements. Several commenters requested that NIOSH accept applications for part 84 respirators upon

publication, rather than the effective date of part 84. One manufacturer commented that NIOSH should anticipate at least 10 applications from each manufacturer upon part 84 becoming effective. NIOSH also expects a significant number of presently certified particulate respirators, in addition to new designs, to meet the requirements of this rule. Therefore, a high initial application rate for approval of part 84 particulate respirators is expected.

Some commenters expressed concern that NIOSH would not be able to expeditiously process the part 84 applications, thereby delaying introduction of the new respirators to the marketplace. Delays in processing the part 84 applications would prolong the time needed for transition to these new respirators. Division of the NIOSH staff and resources between processing part 84 applications and pending part 11 applications, along with routine extensions of existing part 11 particulate respirator certifications, may initially slow the certification and availability of part 84 respirators. However, the Institute has determined that it cannot reject without action part 11 applications that were validly prepared and submitted while the provisions of part 11 remain in effect. NIOSH therefore will process all valid part 11 applications that were received by NIOSH before the effective date of part 84. The authority for the approval holder to sell and ship particulate respirators under any part 11 certification issued under these conditions will expire along with the other part 11 certifications on July 10, 1998.

The new technical requirements of part 84 only address air-purifying respirators. Other classes of respirators, such as self-contained breathing apparatus, gas masks, etc., are not affected by the new filter penetration test requirements. Therefore, NIOSH intends to continue issuing new and extension of approval numbers in the same format designation (TC number) as issued under existing part 11 for those respirator types whose technical requirements for approval under part 84 have not been modified from existing part 11. A new approval number series will be initiated for the products whose technical requirements have been upgraded under part 84. By checking the approval number, respirator users will be able to quickly and easily distinguish those products that have demonstrated the improved performance requirements of the new part 84 from those that have demonstrated compliance with only the

existing part 11 standards that are transferred to part 84. NIOSH further intends to issue public notices of the new approval designations to be used for products demonstrating performance to the improved standards.

VI. Discussion of Final Rule

A. Certification Fit Testing

The proposal contained two sections (§§ 84.181 and 84.182) that would have retained the existing Part 11 particulate respirator fit test protocols using isoamyl acetate. These tests were proposed to redesignate the existing §§ 11.140–1 and 11.140–2 with the tests unchanged to minimize the scope of the changes proposed in the first module.

The currently required particulate respirator facepiece fit tests of part 11 use isoamyl acetate, an organic vapor, as the test agent. Under existing part 11, such tests are required for high efficiency (HEPA) and dust, fume, and mist (DFM) respirators, but not dust/ mist (DM) respirators. Since particulate filters are not intended to filter organic vapors, the tested respirators must often be modified by the addition of an activated charcoal layer. This added charcoal layer prevents penetration of the isoamyl acetate through the filter so that the respirator-to-face fit can be evaluated. As a result, the certification program tests surrogate respirators that may have fitting characteristics that differ from the marketed (certified) respirators.

Numerous and varied comments were provided on these sections. A number of commenters suggested that NIOSH eliminate fit testing as a condition of certification. Two commenters recommended that the rule should require manufacturers to submit test data showing good fit characteristics in lieu of NIOSH conducting fit testing. Other commenters requested that NIOSH test the respirator-to-face fit, or otherwise assure that proper fitting characteristics were provided by every certified respirator. Several other commenters requested that fit testing be made a meaningful test. Several others suggested that a quantitative protocol rather than a qualitative fit protocol should be used. Two commenters stated support for the fit tests as proposed.

Several of the reasons given for eliminating fit testing were that fitting respirators to individuals in the certification program does not predict the fit of an individual wearer; fit testing of individual workers at the worksite is required by OSHA and that is the appropriate setting for fit testing; the isoamyl acetate test has not been validated; and, the isoamyl acetate test