This interpretation led to two conclusions that increased the cost estimates. The first conclusion was that all disposable filter respirators would need to be redesigned to include a costly elastomeric facepiece. The estimated increased costs of disposable respirators led to the second conclusion that the currently inexpensive and widely used disposable particulate respirators would be replaced by costly reusable elastomeric cartridge masks. This increased use of reusable masks was estimated to increase users' costs of respirator maintenance and training programs not associated with disposable respirators. The costs associated with the use of an isoamyl acetate represented a substantial portion of the projected cost impact of the proposed rule.

As discussed earlier, NIOSH has reconsidered the proposed requirement for isoamyl acetate fit-testing of these respirators. Based on technical considerations, the isoamyl acetate tests have not been included in the final rule. NIOSH anticipates that currently accepted, fit-testing procedures will continue to be used to assure a proper respirator-to-face seal for each respirator user. Based on prior experience with currently certified disposable respirators using these procedures, no redesign of the facepiece seal of disposable respirators will be required as a result of this final rule. Therefore, the cost implications attributed to the isoamyl acetate fit tests are not applicable to this final rule.

It is our understanding that substituting better filter material will have negligible effects on the costs of filters, over the long run. The material costs may be slightly increased, but are relatively small compared to those estimates for statistical evaluation and fit testing. The costs associated with these latter two have been greatly reduced by the requirements in the final rule.

The demonstrated level of performance for filters will be substantially more effective. Instead of an efficiency rate of 95 percent for removing particles sized at 1 to 2 micrometers in diameter, they will demonstrate the ability to remove particles of less than 1 micrometer in diameter at a typical efficiency rate of 95 to 99.97 percent. The importance of this change will vary considerably from workplace setting to setting. However, in at least some settings the benefits will be considerable.

For example, the classes of particulate filter respirators certified under this rule will meet or exceed the recommendations for respiratory protective devices used for M. tuberculosis. Of the currently NIOSH-certified respirators, only high-efficiency particulate air (HEPA) filters meet or exceed these recommendations. The certification to an enhanced performance level will create options for the choice of respirators that adhere to the recommendations at reduced expense. A disposable (one-time use) HEPA filter respirator generally sells for around $7 to $10 and replaceable respirators equipped with HEPA filters can cost $20 or more, with replacement filters costing about $5 each. Replacement non-HEPA filters cost about $1 to $2 each. Disposable non-HEPA filters cost about $1 to $8 each when purchased in bulk. Costs for a N95 filter are expected to be less than those of a current HEPA filter. Applications of new filter technologies and market competition is expected to generally have the impact of reducing the cost of the new respirators. At least one commenter has already indicated that the 95% efficiency level respirators will be priced not exceeding the cost of 30 CFR part 11 disposable DFM respirators, $5 to $8 each.

NIOSH would expect similar effects—both improved health and cost avoidance—in many other settings. NIOSH estimates that as many as seven million workers use respirators at some time each year. NIOSH estimates that employers annually purchase over 110 million disposable respirators.

There are approximately 35 manufacturers of these respiratory devices. Most of these already possess or have access to test equipment needed to perform the new filter tests. As is currently required under 30 CFR part 11, NIOSH will continue to require that applicants conduct or have conducted examinations, inspections, and tests of respirator performance at least equivalent to those set by the respirator certification tests. This is to assure that all necessary research and development is conducted by the applicant prior to submitting an application to the Federal Government for testing of the respirator by NIOSH. For those manufacturers that do not currently possess this capability, NIOSH estimates that the purchase of this equipment represents an investment of approximately $60,000. Amortized over time, this would not represent a significant cost for most manufacturers.

Commenters indicated that the projected costs of new, updated test instruments for the filter efficiency testing contributed significantly to the costs reported to be attributable to the proposed rule. NIOSH agrees that if manufacturers opt to purchase newly developed instruments, this represents a significant investment. As discussed previously, the filter efficiency tests of this final rule can be conducted using the instrumentation previously specified for the testing of high efficiency filters under 30 CFR part 11. Therefore, the purchase of new test instruments is not required for most manufacturers. Further, the purchase of test instruments represents a capital investment amortized over time, not an annual recurring cost.

Filter materials are currently available that can be substituted into present filter designs with minimal redesign (if any) to meet the performance requirements of the new tests. Some currently NIOSH-certified respirators have, when tested using the new standards, demonstrated acceptable performance. Therefore, little or no cost will be needed to develop suitable filtration materials or redesign existing devices. However, NIOSH does realize that additional development and redesign costs may be incurred to augment the presently available products. NIOSH specifically requested relevant data and comments on projected costs of redesign of respirators.

One commenter cited the cost of commercially available filter media to meet the proposed standards as dramatically increased over the present cost of the existing 30 CFR part 11 disposable dust/mist requirements. The cost of present dust/mist media was stated as between 60 cents and one dollar per square yard, whereas the cost of commercially available filter media to meet the proposed 42 CFR part 84 requirements is between 12 dollars and 17 dollars per square yard, depending on the type (A, B, or C), and whether it is for the ''solids'' or ''liquid/solids'' category. Two other commenters indicated the availability of prototype respirators and filters that could be marketed for little or no cost increase from existing dust/fume/mist respirators and filters.

Several comments were received stating that the combination of proposed initial inhalation and exhalation resistance limits and efficiency levels might require increasing the surface area of filters. It was asserted that an increase in filter surface area to meet these requirements would ''increase substantially the raw material and manufacturing costs of respirator protection.'' For the technical reasons discussed previously, the initial inhalation and exhalation resistances have been increased in the final rule to the values recommended by these commenters. Adoption of these values will allow ''latitude to develop filters at