performing various home and hobby-related activities.

While some current respirator manufacturers may experience negative impacts, other manufacturers that are not now approval holders have indicated an intention to enter this market. The new rule thus will stimulate competition as new technologies are introduced and new markets are developed. Furthermore, this rule enhances the ability of domestic manufacturers to compete globally, especially in the European Community. NIOSH expects to see more new approval holders develop as a result of the new rule.

A high percentage of the respirator manufacturers are large corporations or subsidiaries and are international in nature, although several employ 100 or fewer persons. NIOSH does not have an estimate of the total number employed by the 33 manufacturers of particulate respirators. Neither does NIOSH have any indication of how many employees are engaged solely in the manufacture of particulate respirators. However, the respirator manufacturing industry in general is mature and stable. A 1982 survey of the industry performed for NIOSH covered 29 firms that were active at that time, the majority of which continue to manufacture respirators in 1995. Of these, 12 were subsidiaries of larger firms. Median total employment was 375. A large portion of these workers were believed to be engaged in activities unrelated to particulate respirator manufacturing. Sales figures indicated respirator sales ranged from less than 1% to 10–15% of total corporate sales.

NIOSH believes the industry profile remains basically the same it was in 1982. That is, respirators do not represent the primary source of sales income for any of the manufacturers that will be affected. Because respirators represent a low percentage of overall sales, the percentage of total employees involved in the manufacture of respirators is believed also to be low. Therefore, few employees are likely to be severely impacted by the new rule. Indeed, the increased competition and opening of markets expected to result from the rule may well enhance aggregate employment for both current and new approval holders.

Most employers rely on government standards to determine acceptable levels of respirator performance. It would be inefficient and unreasonably costly for each of millions of occasional purchasers of these inexpensive devices to independently attempt to determine which devices operate effectively to filter out submicron toxic particles.

This rule removes a regulatory impediment to the improved design of respirators by substituting a performance standard for an obsolete specifications standard. The practical effect of this will be to enable firms to substitute a more effective and efficient filter material in lower-cost respirators. Respirators already using high efficiency filters meeting 30 CFR part 11 requirements will not be affected by this proposal. These respirators will not require modification to be certified under this final rule, although the certification may not be at the new P100 efficiency level. Although the category of performance may be reduced from the previous HEPA rating, no design or development costs are associated with the certification of these products.

NIOSH received limited responses to its request for comments and data for projected estimates of cost for materials and labor for these improved respirators. Several respirator manufacturers referred to a survey conducted by their trade association as suggesting that costs of this module would exceed $100 million, but specific cost estimates for this module were not provided. The trade association reported that their estimate was based largely on the surveyed manufacturers' projections of procuring new equipment, procuring new materials, plant retooling, and the like. The largest manufacturer of respirators did not project the same cost impact on its products, even though that manufacturer recommended changing the proposed rule to eliminate the least costly class of proposed respirators and to increase the severity of two testing parameters. Another manufacturer stated that the ''projected increased user cost for disposables of 42 CFR part 84 would be between $440 and $990 million,'' based solely on impacts to that manufacturer's products. This manufacturer forecast that prices to end users would rise by 1.7- to 2.9-fold or 9- to 16-fold depending on filter type.

Very limited data were submitted in support of any of these estimates, but it appears that the large discrepancy between NIOSH and industry cost estimates are attributable to 3 principal factors:

(1) Cost estimates by industry included many capital investmet costs rather than recurring annual costs, inclusion of which improperly inflated the annual cost projections.

(2) An erroneous assumption made by the manufacturer projecting the greatest cost impact. That manufacturer assumed that the proposed fit test would require all disposable respirators to have an elastomeric flange. Additional costs attributed to consumer reaction to this assumption were:

(a) expensive reusable elastomeric cartridge respirators replacing inexpensive disposable models, and

(b) costly respirator maintenance and training programs associated with reusable respirators.

Neither NIOSH nor other manufacturers projected either of these as a consequence of the fit testing. In any event, the requirement for fit testing was eliminated from the final rule. That represents a cost saving in itself but this change also renders moot the question of elastomeric flanges for disposable respirators.

(3) Two additional elements of the proposed rule were identified as having significant cost impact: statistical evaluation of certification test results and limitations on inhalation/exhalation resistance. These were changed in the final rule to eliminate the statistical criterion and to adopt the inhalation/exhalation resistance levels requested by the manufacturers. As a result and as discussed below under specific topics, NIOSH does not believe that this rule will approach the $100 million threshold. In fact, NIOSH believes that over time manufacturers' costs and prices to users will fall.

Commenters stated that the statistical treatment of test data as included in the proposal would ''add greatly to the cost of filters and respirators.'' One commenter estimated that the added manufacturing and waste costs attributable to this provision would be 25–30% of the costs attributable to the proposal. According to the commenters, the replacement of the proposed statistical treatment of test data with the less stringent statistical treatment proposed by NIOSH in 1987 or a pass/fail criterion would remove the added cost implications of the proposed rule.

As discussed previously, NIOSH has replaced the proposed requirement for the statistical treatment of test data with the recommended pass-fail criterion. Twenty filters are to be tested, reduced from 30 to be required under the proposal. This change in the final rule, based on technical concerns discussed previously, will significantly reduce the cost implications of the final rule from the estimated costs of the proposal.

The fit test requirements proposed under §§ 84.181 and 84.182 were identified as another source of a significant portion of the costs attributed to the proposed rule. The increased costs resulted from the interpretation that the isoamyl acetate testing would necessitate elastomeric inner flanges to be added to all certified disposable respirators in all categories.