differential mobility particle sizer that was specified in the proposal. This reference to the newer technology was added in response to comments from the public. NIOSH will accept manufacturer's size verification data determined by SPMS or an equivalent particle sizing instrument that provides particle sizing information consistent with an SPMS.

Paragraph (h) requires the efficiency of the filter (i.e., the amount of aerosol particles that pass through the filter) to be monitored and recorded throughout the test period by a suitable forward-light-scattering photometer or equivalent instrumentation.

Paragraph (i) requires the minimum filter efficiency for each of the 20 filters to be determined and recorded. The minimum efficiency of each tested filter is to be greater than or equal to 99.97% for P100, R100 and N100 filters; 99% for P99, R99 and N99 filters; and 95% for P95, R95 and N95 filters.

Many comments were received on all aspects of the testing requirements. Comments were received regarding the proposed loading levels, test agents, preconditioning requirements, number of filters to be tested, and test equipment specifications.

The proposal included a statistical treatment of the filter efficiency test results (U statistic). Thirty filter samples were to be tested for each certification application. The number of samples tested and the test statistic used in the treatment of the data was intended to provide a 95% confidence interval of 95% conformance (95% tolerance interval) of manufacturers' product to the certification criterion. These methods rely on the applicability of the ''normal'' or Gaussian distribution for test data. A similar statistical treatment of the test data was included in the 1987 NIOSH proposal.

A number of commenters expressed concern with the use of a NIOSH proposed U statistic (based on a 95% tolerance interval for the 95th percentile) to determine if the performance of filters submitted by manufacturers meet the requirements for requested classification (type). Comments concerned the use of the constant 2.22 for the calculation of the U statistic, suggesting that this is too strict a criterion for manufacturers to meet and implying that 95% tolerance intervals based on some lower percentile (e.g., 90th) would be more appropriate. Other comments concerned the distribution assumptions inherent in the calculation of the U statistic. Commenters expressed concern that the assumption that test data represent a sample from a Gaussian distribution is incorrect and that the application of tolerance interval methods for this data is inappropriate.

Other commenters questioned NIOSH's justification to ''knowingly'' allow the certification of respirators that do not meet the performance requirements. They interpreted the statistical criterion as NIOSH accepting up to 5% of the distributed respirators to be less than the stated class minimum. This analysis of the data would imply that some of the distributed certified respirators perform below the inferred minimum performance level of its class. The commenters expressed concern that this would cause an unacceptably large number of workers to have inadequate respirator protection.

One commenter pointed out that the use of the U statistic was an attempt to predict future production variability. This commenter further asserted that respirators submitted for certification testing do not constitute a random sample of a manufacturer's product. Production variability, this commenter continued, is to be controlled by the separate quality control program.

NIOSH concurs with the commenter that the proposed statistical approach addressing pre-market production samples is inconsistent with determining product quality in a controlled process. NIOSH further agrees that the samples submitted for certification testing are not random samples. Therefore, the final rule does not include an acceptance criterion based upon the statistical treatment of test data.

A significant portion of the cost attributed to the proposed regulations (25 to 30% of the cost, by one estimate) resulted from the statistical treatment of data. Manufacturers stated that this cost impact would be reduced if a 95% tolerance interval based on a 90 percentile (i.e., 95% confidence of 90% conformance) were used. Manufacturers and others suggested that a pass/fail criterion should be offered. Several commenters suggested reducing the number of test samples and using a pass/fail criterion.

A pass/fail criterion is consistent with the current respirator acceptance criterion, and is generally accepted as appropriate for a certification program with testing of pre-production units. The pass/fail criterion presents another advantage in that it establishes the minimum acceptable performance level consistent with the class definition. A member of a 95% class will not be in compliance with the certification if it has an efficiency below that level when tested. The statistical test criterion could allow some individual units to have performance test measurements below 95% but still meet certification requirements.

Based on these comments, NIOSH has reconsidered the use of the tolerance interval approach for the analysis of respirator performance data. NIOSH agrees that the application of the tolerance interval approach is inconsistent with type approval and recognizes that respirators submitted for certification do not constitute a random sample of a manufacturer's product. Consequently, the final rule has been modified to test 20 respirators for laboratory performance, with certification if all 20 units meet the specifications.

The proposal specified both sodium chloride (NaCl) as the solid test aerosol and dioctyl phthalate (DOP) as the liquid test aerosol. Although DOP is a suspected carcinogen, the set up of the test instruments precludes laboratory personnel exposure to the aerosol. Sodium chloride does not pose a suspected health hazard. Dioctyl phthalate is the most severe liquid, or degrading test aerosol known. It has been used for decades as the test aerosol for certification of the best (HEPA) part 11 filters. Sodium chloride is a solid test aerosol that provides some degrading characteristics. Sodium chloride has also been used for years as the solid test agent in the European (CEN) certification standards.

No comments were received against the use of NaCl as the solid test aerosol for non-powered respirators. One commenter, a former employee of the Department of Defense, questioned its use because the military does not use it in their mask testing. Another commenter, accepting the use of NaCl, stated that part 84 should allow equivalent test aerosols as well. The only negative comments received to the NaCl test aerosol were due to the difficulties associated with the testing of powered air-purifying respirators (PAPRs). The requirements for PAPRs was discussed previously in V. Discussion of Final Rule, B. Powered Air-Purifying Particulate Respirators.

Commenters interested in the use of certified respirators for protection against TB suggested the use of biological agents (bioaerosols) for the certification testing. It is not necessary to subject filter respirators to a bioaerosol as a condition of certification. By using test aerosols of the most penetrating size range, the efficiency-level determination of the certification testing will be the lowest obtainable for any size aerosol. Therefore, the efficiency level against