county). Five commenters represented respiratory protection experts. Three commenters represented workers' organizations. Two commenters represented test instrument manufacturers. One commenter represented industrial hygiene professionals. One commenter represented a Federal Advisory Committee. These figures include the 18 presenters at the Public Meeting held in Washington, D.C. on June 23 and 24, 1994.

IV. Summary of Major Changes in Response to Comments

The requirements of the final rule differ from those proposed (59 FR 26850) in 8 major areas. These changes, discussed in sections V. Administrative and Procedural Matters of Final Rule and VI. Discussion of Final Rule, are summarized as follows:

1. Three categories (series) of particulate filters (N-, R-, and P-series) are included rather than two (solid and liquid and solid);

2. Maximum allowable inhalation and exhalation airflow resistance values have been slightly increased and labelling changes are included to identify the certified efficiency level to users;

3. The new certification categories apply only to non-powered air-purifying respirators. Powered air-purifying particulate respirators (PAPRs) will be approved only with filters meeting the requirements for 30 CFR part 11 high-efficiency filters;

4. A new subpart KK has been added for the issuance of extensions of existing 30 CFR part 11 approvals to address respirator non-conformances when there is a demonstrated safety or health need during the transition period and for the approval of PAPRs;

5. Fit testing during the certification process is not included for particulate respirators;

6. The number of tested units has been reduced and the test data will no longer be treated statistically;

7. The period for sale and shipment of 30 CFR part 11 certified particulate respirators has been increased. The period for processing part 11 applications has been eliminated, except for demonstrated need; and

8. Testing parameters are stated more explicitly.

A summary listing of the section-by-section changes from the proposal to this final rule is provided in Appendix A—Comparison of Technical Requirements Final Rule to Proposed Rule. Each of these changes is discussed in detail in the following preamble.

V. Administrative and Procedural Matters of Final Rule

A. Modular Approach

The proposed rule explained the intent to promulgate modifications to the requirements of 30 CFR part 11 in a series of modules. There are numerous benefits to utilizing a modular approach to promulgate changes to the existing requirements. Among these are the following considerations:

1. Improvements can be implemented on a priority basis, assuring that those expected to contribute most to improving worker protection are implemented first;

2. Incremental promulgation of improvements should facilitate adaptation to new requirements by the respirator manufacturer and user communities, minimizing the potential for any disruption in the supply of certified respirators;

3. Public participation in the rulemaking process will be facilitated by proposing important regulatory changes in individual segments of separate rulemaking; and

4. Improvements made to limited segments of the rule can be implemented in a much shorter time period than comprehensive revisions to the entire rule. Therefore implementation of technological advancements and response to emerging hazards will be expedited.

Comments overwhelmingly endorsed the concept of the modular approach with only two comments specifically opposed to this approach. More than 250 comments supported the proposal's approach and approximately 40 specifically endorsed and offered recommendations for changes in the modular scheduling. Some commenters expressed concerns about this new rulemaking procedure. These predominantly questioned the interaction of modules and implementation schedules. Module interaction concerns included added costs, confusion, transition periods (grandfathering) of interrelated modules, and redesign of respirators due to effects of multiple modules. Concerns of scheduling included the priority of modules, additional module topics, transition periods for products to meet prior requirements, timetable for completion of revisions, and availability of NIOSH resources to support work on multiple modules simultaneously.

The modular approach represents a continuous improvement strategy for rulemaking. With this process, NIOSH expects regulations and products to be incrementally improved and updated to address worker health concerns and prevent any disruption in the supply of respirators. Each module will constitute a separate rulemaking activity. The modular approach undertaken by NIOSH provides clear advantages over the comprehensive approach to rulemaking. No specific time period has been identified in which all certification standards will be revised. The Institute recognizes that a predetermined revision cycle could ensure the periodic re-examination of standards. However, a requirement of this type would also diminish the capability of the Institute, with its limited resources, to address priority respiratory protection needs. The Institute has determined that a flexible approach is required that will permit expeditious responses to emerging respiratory protection priorities. These can change rapidly as technological advancements, international harmonization, changed working conditions, or the emergence of new hazards make current standards obsolete. As discussed below the Institute will balance industry's need for planning and adjustment time associated with future modules by having ample public involvement in setting the priorities for module selection and with judicious selection of transition periods.

NIOSH is aware of the needs of the respirator community to be able to plan future production and purchasing needs. This is true for consumers as well as manufacturers of respirators. NIOSH announced at the informal public meeting its intention to hold ample public meetings in advance of any proposed future modules so that these concerns could be addressed. The concerns expressed in the comments can be addressed in these informal public meetings and with the use of appropriate transition periods.

NIOSH intends to establish transition periods for implementing the requirements of each module. These transition periods will be determined by an assessment of the industry's ability to adopt the new requirements, ongoing transition periods from prior modules, and the public health implications of the changes.

Anticipated subjects and sequence of the NIOSH rulemaking were outlined in the proposed rule. Numerous comments were received providing suggestions for additional module subjects and their priority. Suggested additional subjects included powered air-purifying respirators, smoke masks, fit testing, supplied air respirators, gas masks, and combination respirators. Suggestions on scheduling priorities indicated a diversity in perceived needs. Based on the public interest in the future module