to ask questions; submit verbal and written comments they wish to have included in the regulatory record; and provide individual input into potential changes to the applicable regulations and policies.

Discussion and Comment Topics

NIOSH has not determined the final content of its proposed rulemaking but is considering the regulatory actions listed below. NIOSH is specifically asking for comments on these proposed actions, but would also welcome comments on additional areas that the commenters believe may need to be addressed.

**NIOSH is Considering**

1. Proposing quality assurance requirements for the approval holder’s manufacturing process that are consistent with international standards, specifically the International Organization for Standards (ISO) 9000 guidelines. These international standards would be supplemented by respirator-specific quality measures.

2. Proposing new quality requirements, such as mandatory pre-approval audits for new manufacturing sites, more stringent quality sampling plans, critical classification of defects for all types of respirators, and records retention schedules;

3. Proposing to enhance quality monitoring activities by NIOSH by increasing the frequency of both site and product audits, requiring an approval holder to supply free product audit samples for product audits, requiring approval holders to self-audit their product and present those results to NIOSH, accepting ISO certification in lieu of a NIOSH-performed site audit, employing contract laboratories to do certain tests for the approval program, and requiring the approval holder to report all customer complaints and non-compliance findings to NIOSH; and

4. Implementing a new fee structure to recover costs of approval application processing (approximately a 2.5 times increase over the current application fees), approval records maintenance (a new annual fee of approximately $36 per approval), and auditing costs (a new charge computed based on the hourly rate of government personnel [approximately $50 per hour] plus expenses) for the chargeable services received by the applicant or approval holder.

Comments on the concepts presented in this notice should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513–533–8450, fax 513–533–8285, or e-mail to NIOCINDOCKET@CDC.GOV on or before July 30, 2000.

**SUMMARY**

The National Institute for Occupational Safety and Health (NIOSH) is in the process of developing a proposed rule on the quality assurance and administrative requirements for the approval of respirators and is seeking individual stakeholder input for this process. The purpose of these meetings is to provide an opportunity for an exchange of information between the Agency and respirator manufacturers, industry representatives, labor representatives, and others with an interest in respiratory protection. Attendees will be given an opportunity to ask questions; submit verbal and written comments they wish to have included in the regulatory record; and provide individual input into potential changes to the applicable regulations and policies.