

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### National Institute for Occupational Safety and Health; Approval of Respiratory Devices Used to Protect Workers in Hazardous Environments

**AGENCY:** Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (DHHS).

**ACTION:** Notice of public meetings concerning quality assurance and administrative approval requirements for respiratory protective devices.

**DATES:** August 8, 2000, 9 a.m.–5 p.m., in the Washington DC Area. August 16, 2000, 9 a.m.–5 p.m., in the San Francisco, CA Area.

**PLACES:**

Washington DC Area—Quality Hotel & Suites; Courthouse Plaza, Jefferson Room, 1200 N. Courthouse Road, Arlington, VA 22201. Phone: 1-888-987-2555 or 703-524-4000. Phone by July 21, 2000 to receive the NIOSH group rate of \$118.00.

San Francisco, CA Area—Embassy Suites, Ambassador Ballroom, 150 Anza Boulevard, Burlingame, California 94010. Phone: 650-340-0327. Phone by July 24, 2000 to receive the NIOSH group rate of \$164.00.

The meetings will be open to the public, limited only by the space available. Each meeting room accommodates approximately 120 people.

Requests to make presentations at the public meetings should be mailed to the NIOSH Docket Officer, 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.

#### 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. Comments may also be submitted by e-mail to: NIOCINDOCKET@CDC.GOV. E-mail attachments should be formatted as WordPerfect 6/7/8/9 or Microsoft Word. Submitted comments should reference docket number, NIOSH-001, in the subject heading.

**FOR FURTHER INFORMATION CONTACT:** Matt Bowyer or Roland BerryAnn, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888, telephone 304-285-5907, fax 304-285-6030 and/or E-mail: respcert@cdc.gov.

In addition to these public meetings, NIOSH invites individuals, organizations and companies to meet with the staff of its Respirator Branch. Requests for such meetings should be made on or before July 31, 2000 to Matt Bowyer or Roland BerryAnn. NIOSH will prepare summaries of these meetings and place them in the regulatory docket.

#### **Linda Rosenstock,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1359]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Affirmation of Generally Recognized as Safe (GRAS) Status

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reporting and recordkeeping, general and specific requirements, and availability of sample electronic product for manufacturers and distributors of electronic products.