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Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
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1095 Willowdale Road
Morgantown, WV 26505-2888

June 26, 2000

LETTER TO ALL INTERESTED PARTIES

Notice of Stakeholder and Public Meetings Concerning Quality Assurance and Administrative Requirements for Approval of Respirators

The Respirator Branch, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH) would like to meet with interested stakeholders about issues and concerns related to quality assurance and administrative requirements for the approval of respirators. NIOSH is developing a proposed rule to update the present quality assurance and administrative requirements which the Institute hopes to publish in early 2001. NIOSH is seeking individual input from its stakeholders for this process and will, therefore, hold two public meetings in mid-August, 2000. In addition, NIOSH stakeholders are invited to schedule one-on-one meetings with Institute representatives. The purpose of the public meetings, as well as the additional stakeholder meetings, is to provide opportunities for an exchange of information between NIOSH and the respirator manufacturers, industry representatives, labor representatives, and others involved with respiratory protection.

NIOSH will hold two Public Meetings in mid-August 2000:

August 8th – Arlington, Virginia
Quality Hotel & Suites, Courthouse Plaza, Jefferson Room
1200 North Courthouse Rd.
Arlington, VA 22201
Phone: (888) 987-2555 or (703) 524-4000
To receive the NIOSH group rate of \$118.00, call by July 21st.

August 16th – San Francisco, California
Embassy Suites, Ambassador Ballroom
150 Anza Boulevard
Burlingame, CA 94010
Phone: (650) 340-0327
To receive the NIOSH group rate of \$164.00, call by July 24th.

These meetings will be open to the public, limited only by the space available; advance registration is not required. However, any attendee wishing to make a presentation will need to inform NIOSH of this intent by July 31, 2000. A Federal Register Notice will be published to publicly announce these meetings.

NIOSH also invites all interested parties to schedule individual stakeholder meetings with the Respirator Branch before the end of August 2000 to discuss the quality assurance and administrative improvement concepts. Meetings can be held at the stakeholders' facilities or at NIOSH, Morgantown, West Virginia. For each meeting, NIOSH will provide an overview of the quality assurance and administrative concepts under consideration. Participants will be given an opportunity to ask questions and submit verbal and written comments they wish to have included in the regulatory record and thereby provide input into potential changes to the applicable regulations. NIOSH will prepare a summary of each of these meetings which will be placed in the regulatory docket.

Requests to schedule Stakeholder Meetings can be made by email, fax or letter. Email can be sent to either the Respirator Branch (respcert@cdc.gov) or the NIOSH Docket Office (niocindocket@cdc.gov). Faxes can be sent to either the Respirator Branch [(304) 285-6030] or the NIOSH Docket Office [(513) 533-8285]. Letters can be mailed to either the Respirator Branch (NIOSH, Attn: Matt Bowyer or Roland Berry Ann, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888) or the NIOSH Docket Office (NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226)

JUSTIFICATION FOR PROPOSED CHANGES

NIOSH has not updated the administrative and quality assurance requirements for the approval of respiratory protective devices under 42 CFR Part 84 since the early 1970s.

Quality Assurance Requirements

NIOSH is in the process of developing a proposed rule to amend its existing requirements for quality control plans, site audits, and product audits and to implement quality assurance requirements consistent with international quality system standards.

An essential part of the NIOSH respirator approval requirements is the manufacturer's implementation of quality controls to limit the variability in the production of approved units. These quality controls are chosen and implemented to measure variations of specific parameters within the manufacturing process. The present regulation does not contain adequate requirements to determine that the approval holder is meeting this obligation.

The manufacturing process must be monitored to verify the adequacy and effectiveness of the implemented quality controls. There are basically three components used for monitoring. First, the process must be monitored to verify that the controls are followed. This is accomplished by in-plant audits. Second, produced units must be checked via product audits to ensure that the controlled manufacturing process produces respirators that perform as expected. Third, problem investigations must be performed for any units where user complaints are reported. All three of these components can and should be performed by the approval holder as well as the approving authority (NIOSH).

Historically, the quality monitoring NIOSH could perform has been severely limited. Nonetheless, the Institute has identified a significant number of critical findings which required stop-sale or recall requests. During the past three years, we have conducted site audits at approximately 20 facilities per year and found nonconformances in approximately 57% of these audits. Fifteen percent of these nonconformances (6 audits) were of a critical nature requiring a stop-sale letter to be issued. Other indicators of the need for increased oversight: 1) While less than 1% of the approvals were subject to a product audit, 40% of these identified a nonconformance, of which, 5% required a recall/retrofit. 2) While users have only filed an annual average of 40 complaints concerning respirator performance over the past two years, twenty-three percent (18) of them required corrective action. Nine of these involved a recall and/or retrofit of thousands of respirators. We believe it is important to strengthen the manufacturers' obligations and NIOSH's ability to perform these audits.

User Fees

Existing user fees for obtaining a NIOSH approval were based on the examination, inspection and testing of respiratory protective devices to evaluate their conformance to the regulations. These fees do not reflect current government costs for providing these services. The basis for the current fee charges is outdated: collected fees representing only 20% of actual costs incurred for the approval processing activity. Moreover, the present fee schedule does not reflect many of the services NIOSH provides to approval holders.

SUMMARY OF CONCEPTS UNDER CONSIDERATION

NIOSH has not determined the final content of its proposed rulemaking. The Institute is considering the regulatory actions listed below and is specifically asking for comments on these proposed actions. We also welcome comments on additional areas that stakeholders want to address.

NIOSH is in the process of developing the following proposals:

- 1) That quality assurance requirements for approval holders' manufacturing process be consistent with international standards - specifically the International Organization for Standards (ISO) 9000 guidelines. These standards would be supplemented by revised respirator specific quality measures, such as quality control plans and product improvement procedures.
- 2) That new quality requirements be established; e.g., mandatory pre-approval audits for new manufacturing sites, more stringent quality sampling plans, critical classification of defects for all respirator types, and records retention schedules.
- 3) That NIOSH's quality monitoring activities be enhanced by: increasing the frequency of both site and product audits; requiring approval holders to supply free product audit samples for product audits; requiring approval holders to conduct self audits of their products and convey

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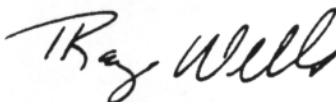
results to NIOSH; accepting ISO certification in lieu of a NIOSH performed site audit; employing contract laboratories to do certain tests for the approval program; and requiring approval holders to report all customer complaints and non-compliance findings of a serious nature to NIOSH.

4) That a new fee structure be implemented 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 audit costs [a new charge computed according to the hourly rate of government personnel (approximately \$50 per hour plus expenses)] for the chargeable services received by the applicants or approval holders.

In addition, NIOSH is requesting information and comments as to how respirator labels could be improved.

For further information, please contact Matt Bowyer or Roland Berry Ann, NIOSH, at 304-285-5907.

Sincerely yours,


for Richard W. Metzler
Chief, Respirator Branch
Division of Respirator Disease Studies