DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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LETTER TO TESTING LABORATORIES AND ACCREDITED REGISTRAR ACCREDITATION BOARD AUDITORS

Subject: Meeting Announcement Concerning the Utilization of Private Sector Laboratories and Auditors as part of the Quality Assurance and Administrative Improvement Concepts for the Approval of Respirators

The Respirator Branch (RB) of the Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH) would like to meet with interested testing laboratories and Registrar Accreditation Board (RAB) accredited auditors on issues and concerns related to quality assurance and administrative requirements for the approval of respirators. NIOSH is in the process of developing a proposed rule to update the present quality assurance and administrative requirements which it hopes to publish early 2001. The agency is seeking individual input from its stakeholders for this process. To get this input, NIOSH will be holding two public meetings in mid August 2000. In addition, NIOSH is inviting all interested laboratories and auditors to attend meetings at NIOSH, in Morgantown, West Virginia, on July 25-26, 2000. The purpose of the public meetings, as well as the laboratory and auditor specific meetings, is to provide an opportunity for an exchange of information between the Agency and the respirator manufacturers, industry representatives, labor representatives, and others involved with respiratory protection.

The Public Meetings will be held for one day each, on August 8, 2000, in the Washington, D.C. and on August 16, 2000, in the San Francisco, California areas. They will be open to the public, limited only by the space available. Advance registration for the Public Meetings is not required. However, any attendee wishing to make a presentation at one of these public meetings will need to inform NIOSH of this intent by July 31, 2000. The forthcoming Federal Register Notice provides additional information on these meetings.

NIOSH invites all interested testing laboratories to attend a meeting on July 25, 2000, at NIOSH, 1095 Willowdale Rd, Morgantown, West Virginia, Room L-2A, at 8:30 a.m. to 11:30 a.m. The afternoon will be made available for anyone interested in one-on-one sessions. These sessions will be time limited and will be on a first-come first-serve basis.

NIOSH invites all interested auditors to attend a meeting on July 26, 2000, at NIOSH, 1095 Willowdale Road, Morgantown, West Virginia, Room L-1C & D, 8:30 a.m. to 11:30 a.m. The afternoon will be made available for anyone interested in one-on-one sessions. These sessions will be time limited and will be on a first-come first-serve basis.

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, as well as submit verbal and written comments they wish to have included in the regulatory record to 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.

NIOSH is requesting that those Laboratories and/or Auditors planning to attend one or both meetings please notify Matt Bowyer or Roland Berry Ann at (304) 285-5907 or fax (304) 285-6030 by July 19, 2000.

Laboratories and Auditors may provide comments to the docket via 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 Change:

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.

1. Quality Assurance Requirements

NIOSH is considering proposing 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 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 quality controls put in place. There are basically three components used for this monitoring. First, the process must be monitored to verify that the planned controls are in place and being followed. This is accomplished by in-plant audits. Second, produced units must be checked via product audits to assure 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).

NIOSH has historically been severely limited in the amount of quality monitoring that we could perform. Even with this limited monitoring, NIOSH has identified a significant number of critical findings requiring stop sale or recall requests. NIOSH has conducted site audits at approximately 20 facilities per year for the past three years. NIOSH has found nonconformances in approximately 57% of these audits. In addition, 15% of these nonconformance (6 audits) were of a critical nature requiring a stop-sale letter to be issued. Other indicators of the need for greater oversight are: 1) less than 1% of the approvals were subject to a product audit. However, 40% of these identified a nonconformance, of which, 5% require a recall/retrofit, and 2) the Institute averages 40 field problem investigations per year, of which 45% (18 investigations) required corrective action. Of these, 8 involved a recall and 1 required a stop-sale request. We believe it is important to strengthen the manufacturers' obligations and NIOSH's ability to perform these audits.

2. Fees

The 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 regulation. These fees do not reflect the current cost to the government for providing these services. The basis for the present fee charges is outdated, with collected fees representing only 20% of actual costs incurred today 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:

We want to emphasize that NIOSH has not determined the final content of its proposed rulemaking. However, the agency 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 stakeholders 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 revised respirator specific quality measures, such as quality control plans and product improvement procedures.

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 type 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 conduct self audits

of their products 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 approval holder to report all customer complaints and non-compliance findings of a serious nature to NIOSH.

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 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.

In addition, NIOSH is requesting information and comments to improve respirator labels.

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 Respiratory Disease Studies