846-461

TECNOL

The Innovation Company

August 6, 1996

NIOSH Docket Office
Robert A. Taft Laboratories
M/S C34
4676 Columbia Parkway
Cincinnati, Ohio 45226

Dear Madam or Sir:

Tecnol Medical Products, Inc., 7201 Industrial Park Blvd., Ft. Worth, Tx. 76180, submits the following comments to Docket No. 96- in the Thursday, May 16, 1996 issue of the Federal Register/ Vol. 61, No. 96 Department of Heath and Human Services, Centers for Disease Control and Prevention, 42 CFR Part 84, National Institute for Occupational Safety and Health (NIOSH); Public Meeting.

Comments on Public Meetings

III. Matters to be Discussed

A. Priority of Technical Modules

*Issue - NIOSH will inform the respirator community of regulatory priorities to allow research and planning to be coordinated with the development of new standards. How these priorities may change as new needs are identified. NIOSH can readily notify respirator manufacturers directly about these changes.*

(1) How should NIOSH notify respirator purchasers and users of revised priorities?

Response:

Publish Articles in Industrial and Professional Journals. Sales and marketing managers who work in this industry can also notify their customers and owners/purchasing managers at new accounts.

B. Administrative/Quality Assurance Module

*Issue - Independent laboratories should be capable of performing routing testing required for respirator certification.*

(1) Are private sector testing laboratories capable of conducting the respiratory testing currently performed by NIOSH?

Response:

There are currently not enough labs with the equipment and experience needed to conduct this testing. A change from in-house testing by NIOSH to independent laboratories would be detrimental to the respirator industry for the following reasons:





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1) Testing in the respirator market is highly specialized and often requires custom built equipment. Special training and technique has to be developed to assure proper testing and accurate results. If testing is not performed properly, an incorrect failures could result.

2) New laboratory equipment investments could increase the price of the product submission.

3) We have a serious concern that an independent laboratory would not provide the same confidentiality and security that we currently have with the NIOSH government system and employees.

4) If independent laboratories are used, NIOSH can minimize the opportunity for inadvertent bias by receiving the products from the manufacturers and selecting the laboratory for testing on a random, rotating basis.

This step, however, could cause a delay in testing and increase the chance of sample loss or damage.

5) The requirements to monitor and audit independent laboratories could increase the registration fees for the manufacturers which may prevent the manufacturer from being able to justify the cost of new product development and registrations.

We recognize that giving NIOSH the ability to outsource testing by private laboratories may be a future option which would give NIOSH the ability to do more compliance testing, but at this point no laboratories have the equipment, expertise, or security measures to support this change. In addition, the industry currently does not have the business base to assure that testing would be performed at an acceptable quality level and at an acceptable cost.

(2) What qualification requirements should NIOSH require of private laboratories who perform certification and product audit testing under NIOSH guidance?

Response: See Comments in 1 above.

(3) Should NIOSH assign the testing of a manufacturer's respirators to laboratories approved by NIOSH or should the manufacturer be permitted to use the laboratory of choice among approved laboratories?

Response: See Comment #4 in 1 above.

(4) What type of monitoring should NIOSH perform to assure that private sector laboratories continue to provide quality service?

Response: See Comments in 1

*Issue - Quality Auditors with international certification are authorized to conduct audits for International Organization of Standardization certification.*

1) What qualification requirements should NIOSH require for the acceptance of independent quality auditors to perform manufacturing site audits under NIOSH guidance?

Response:

Companies that are ISO 9001 or 9002 certified by an accredited notified body and who maintain their certification should be allowed to forward copies of their ISO certification to NIOSH on a 6 month basis and these facilities would not require auditing by any other quality auditor or NIOSH.

2) What measures should NIOSH use to ensure the integrity of the program using private quality auditors?

Response:

Require that copies of the ISO certification from an accredited notified body be sent to NIOSH following each certification re-evaluation.

3) What frequency of audits would be considered a minimum to provided assurance that only quality products are distributed?

Response:

If a manufacturer has chosen to use ISO standards, they will be required to send a certified copy of their recertification to NIOSH every 6 months. For those manufactures who have not chosen to become ISO certified, NIOSH should audit the facility every two years.

4) Should manufacturing sites be audited prior to the issuance of a NIOSH certification?

Response:

NIOSH should do an audit prior to the issuance of the first NIOSH certification unless the facility is ISO certified..

*Issue - The fees and free structure for activities conducted in the certification program are based on the fee schedule contained in 42 CFR Part 84.*

1) Should certification fees be structured and calculated to recoup the cost of the certification process?

Response:

Manufacturers should be required to pay the actual costs associated with certification.

2) Should manufacturers be required to pay for manufacturing site and product audits?

Response:

Manufacturers should not be required to pay for manufacturing site and product audits. This should be included in the cost of government enforcement activities.

*Issue - The certifications standards currently limit NIOSH to certify only complete respirators.*

1) Should NIOSH allow replacement parts for respirators by manufacturers other than the original manufacturer of the respirator?

Response: YES

2) How should the effectiveness of replacement parts be assured?

Response:

NIOSH can certify the parts just as they do the new respirator. The filing representative must supply the parts to NIOSH for certification. The representative would be required to provide NIOSH with the dimensions and data indicating that the parts for submission are equivalent to the existing parts in form, fit, and function. NIOSH would be responsible to check both the part and the part with the entire unit for confirmation.

3) Would NIOSH need to adopt or develop component-specific certification requirements to allow alternate supplies for replacement parts?

Response: YES

4) Should NIOSH consider certifying respirator components in addition to, or instead of, complete respirator?

Response: YES

5) Do other certifying agencies or standards organizations allow suppliers other than the original manufacturer to provide replacement parts for certified units?

Response: YES

6) If suppliers other than the original manufacturer were permitted to provide replacements parts, how should NIOSH monitor these alternate suppliers?

Response:

In the same manner as NIOSH monitors manufacturers who manufacture the whole units.

7) If suppliers other than the original manufacturer were permitted to provide replacement parts, how should NIOSH monitor those parts?

Response:

Suppliers of replacement parts should be monitored the same as the primary manufacturers of the parts.

8) Would NIOSH need to adopt design specifications to ensure that interchangeability of parts is safe?

Response:

Parts must be in compliance with current regulations and must be equivalent to the same specifications as the entire unit. In addition, standards need to be formalized within the respirator market in order to help facilitate interchangability of same parts. This would allow the market forces to lower the cost of respirators and their associated disposable parts.

*Issue - Products auditing is an ongoing NIOSH activity involving the acquisition of respirators to assure compliance with NIOSH certification requirements.*

1) What would be the maximum number of respirators per year, aside from problem investigations, that NIOSH should request from a manufacturer, at no charge to NIOSH?

Response: As many as they need for disposable respirators.

2) How should NIOSH acquire products for audit?

Response:

NIOSH should acquire products for audit at the distributor level. To acquire products from the manufacturer, would give the manufacturer the opportunity to prescreen product for functionality and specification prior to NIOSH receipt. If NIOSH were to give the distributor a voucher to send to the manufacturer for replacement units, this would eliminate the cost to NIOSH and return it to the manufacturer.

3) Should manufacturer be charged for these product audits, since they are a condition of certification?

Response:

Manufacturers should not be charged for product audits.

*Issue - The NIOSH certificate is issued for an unlimited number of units, without an expiration date.*

1) Should the NIOSH certification be valid for a limited time?

Response:

NIOSH certifications should not be time-limited.

2) What conditions should be met for a time-limited NIOSH certificate to be renewable?

Response: See Comments in 1.

3) What time limits should be used for a NIOSH certification and renewal?

Response: See Comments in 1.

4) Should certification holders be required to notify NIOSH of changes in production status and the number of produced units when production is halted?

Response:

Periodic updates to indicate new or obsolete equipment may be the optimal way to handle monitoring manufacturer status.

5) How would purchasers and users be affected if the certification of their respirator expires?

Response: See Comments in 1.

6) Would an expired certification benefit purchasers and users by informing them that their respirator is longer produced?

Response: See Comments in 1.

7) Could information on the number of respirators produced under a certificate be used to benefit purchasers and users?

Response:

There is no benefit to informing the purchasers and users of the number of respirators produced under a certification.

Thank you for allowing comment on the above issues. To date, Tecnol has enjoyed a good working relationship NIOSH, and we feel that NIOSH has been able to meet our needs in a most timely, efficient, and cost effective manner.

Sincerely,

Ruth L. Jones
Director of Regulatory Affairs
Tecnol Medical Products, Inc.