



Inchcape Testing Services

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August 14, 1996

NIOSH Docket Office
Robert A. Taft Laboratories
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4676 Columbia Parkway
Cincinnati, OH 45226

Dear Sir or Madame:

We would like to offer the following comments in response to the Federal Register Notice at **61 Fed. Reg. 24740 (Thursday, May 16, 1996)** regarding rulemaking to revise current NIOSH procedures for certifying respiratory devices. These procedures appear at 42 CFR Part 84.

If you have any questions regarding this response please do not hesitate to contact me at (508) 681-6608.

Sincerely,

Steven G. Roll
Vice President

R E C E I V E D

AUG 15 1996

NIOSH DOCKET OFFICE

Inchcape Testing Services (ITS) response to Federal Register Notice at **61 Fed. Reg. 24740 (Thursday, May 16, 1996)** regarding rulemaking to revise current NIOSH procedures for certifying respiratory devices. These procedures appear at 42 CFR Part 84.

B. Administrative /Quality Assurance Module

2. Issues for Comment

Issue 1

Item (1)

Inchcape Testing Services (formerly ETL Testing Laboratories) strongly advocates the use of independent third party certification agencies to verify compliance to the appropriate NIOSH standards and requirements. In addition, we believe that certification organizations should be accredited by established independent organizations such as ANSI and A2LA.

ITS (Inchcape Testing Services) currently has the ability to perform a majority of the work that would be required by a respirator testing program. ITS has a broad range of experience providing third party testing for a variety of industries and their certification programs, in both the public and private sector. We currently provide various levels of testing and certification for approximately 50 organizations, with over 100 different programs. Some of these include: the Occupational Safety and Health Administration (OSHA), Federal Aviation Administration (FAA), National Highway Transportation Safety Administration (NHTSA), Safety Equipment Institute (SEI), Air Conditioning and Refrigeration Institute (ARI), Association of Home Appliance Manufacturers (AHAM), and Certified Ballast Manufacturers (CBM). Each of these groups requires a dedicated laboratory with specialized equipment, as well as extensive industry knowledge.

Item (2)

Many laboratory accreditation schemes currently exist. We do not believe that it would be necessary to create additional systems such as a NVLAP to handle accreditation. A current independent accreditation program such as ANSI or A2LA should be able to handle a category expansion that would cover this type of equipment.

Item (3)

Independent laboratories are selected by manufacturers to provide a service. When NIOSH chooses to select as qualified more than one independent laboratory to provide this testing service, the market will dictate which agency has the ability to provide the required service in the best manner for each individual manufacturer. We believe that the choice of which NIOSH approved laboratory to use should be solely the equipment manufacturers.

Item (4)

To insure that NIOSH approved laboratories continue to be able to provide the appropriate testing we would recommend that there be a periodic review of the testing agency to the standards established in ISO guide 25 and/or 28. This procedure would verify the ongoing quality of the work being performed by the independent laboratory.

Issue 2

The complexity of a respirator requires that an individual with an intimate knowledge of these products be available to handle the Initial Plant Inspection of a manufacturing site.

Item (1)

Independent quality auditors should be certified by an independent accrediting service such as ASQC/RAB (American Society for Quality Control/Registrar Accreditation Board).

Item (2)

The current NIOSH check list along with continuing certification of qualified auditors who will provide the required information to NIOSH should insure the integrity of the program.

Item (3)

The current industry practice of two audits per year, as supported by NFPA and SEI, would be appropriate for this type of program.

Item (4)

Manufacturing sites should be audited by a qualified inspector (Initial Plant Inspection) prior to NIOSH issuing certification. The facility should show compliance to NIOSH program requirements.

Issue 3**Item (1)**

Fees for testing and certification are based on numerous factors, including, but not limited to: testing volume, capital investment, labor, and overhead. The independent laboratory will determine what they would need to charge to perform the required testing. NIOSH administrative fees (if necessary) should be determined by NIOSH.

Item (2)

As with other certification programs, manufacturers should pay fees for the services that they receive. This would include periodic inspections and audits.

Item (3)

Many certification programs have challenge procedures. These are generally structured to collect a fee for the complaint that a product is in violation from the party that is on the losing side of the investigation.

Issue 4**Item (1)**

Replacement parts that would be used other than the parts specified by the manufacturer would act to change the original product. A change in the original product would require a new certification, as it would be a "new" product.

Item (2)

Effectiveness of replacement parts could only be verified by 100% testing of each model intended to receive the replacement part. The manufacturer of the replacement part would supply the respirators and would also install the components prior to testing. Annual retesting should be required.

Item (3)

Yes.

Item (4)

If NIOSH would chose to certify replacement parts they would have to be certified and evaluated with the respirator.

Item (5)

NFPA does allow for replacement parts by other than the OEM, although we are unaware of any cases where this has occurred.

Issue 5**Item (2)**

Samples should be randomly selected by a representative from NIOSH, an independent auditor, or the testing laboratory.

Item (3)

Certification program and testing fees can be determined when the program is initiated. Fees for audits can be structured either within the program fees, or separately.

Issue 6

Item (1)

Product certifications should be valid for a specific period of time. Annual retesting is generally the norm in certification programs.

Item (2)

Satisfactory quality audits and annual retests should justify certification renewal.

Item (3)

Products of this type generally have a 1-5 year renewable certification, then requalification of the product is needed.

Item (4)

NIOSH should control the use of their label and require manufacturers to maintain records on the use of their labels. This will address the production volume issues.

Item (5)

Certification of units in the field is valid for the standard revision used at the time that specific equipment was shipped from the factory. Units in the field would not be affected by loss of a certification, unless the loss was the result of a quality or performance issue that required products to be recalled.

We appreciate the opportunity to offer comments regarding the rulemaking revision of the current respirator certification procedures.

If you have any questions please do not hesitate to contact me at (508) 681-6608.

Sincerely,



Steven G. Roll
Vice President