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3 July 1996

Dear Rich,

Re: NIOSH Certification

I have received a copy of pages 24740 - 24743 of Volume 61, Number 96 of the Federal Register, which sets out a number of issues concerning proposed changes and asks for comments.

I have read through the document and where our experience is relevant, made comments; I have enclosed these as a separate document.

I hope you find the comments useful in your deliberations and I look forward to receiving details of the outcome.

Yours sincerely,

Kevin Warren
Certification Manager.

IC QUALITY MARK

NIOSH Certification of Respirators

Reference	Comment
B. Admin/Quality Assurance Module	
2.1 Laboratories	
(1)	There is nothing in principle to stop a laboratory from being able to perform testing in accordance with NIOSH procedures. There may not be any current capability, but once the use of such laboratories was permitted I am sure that the required facilities would become available.
(2)	Compliance with an internationally recognised standard (e.g. ISO guide 25) independently confirmed either by accreditation recognised by NIOSH or by direct assessment by NIOSH. NIOSH would need to investigate how they would judge an accreditation acceptable - this is by no means a straightforward task, especially as NIOSH would demand specific expertise of sub-contract laboratories.
(3)	Once a list of approved laboratories is available, manufacturers should be free to choose - NIOSH's main role would be to ensure that the sample selection method was acceptable and that the necessary level of testing was conducted. Also, NIOSH would need to be responsible for commissioning the test programme and reviewing the test report(s).
(4)	Annual review to cover such items as (a) test fees (b) customer complaints (c) timescales (d) adherence to NIOSH commissions (e) continuing acceptable accreditation (f) NIOSH annual surveillance where a laboratory does not hold acceptable accreditation.
2.2 Auditors	
(1)	There are no qualification schemes currently in operation that would ensure auditor competence for NIOSH. A system would need to be operated by NIOSH for either individual auditor approval or direct recognition of specific auditing bodies. I would suggest that clear auditor qualifications would need to be established by NIOSH to cover both general auditing skills and product specific knowledge. This would result in a limited list of individuals and organisations approved by NIOSH to perform sub-contracted audits.

(2) A monitoring scheme should be established to cover (a) auditor training (b) witnessed on-site audits (c) audit report review (d) manufacturers comments.

(3) A minimum of one audit every 12 months should be established.

(4) Yes, most definitely.

2.3 Fees

(1) The fees should be split and assigned to each identifiable, separate, process e.g. Application/type testing/pre-certification audit/annual administration fee/routine audits/routine testing. The calculation should be based upon the overall time required for each discrete phase and be subject to annual review and adjustment. These fees should be available to manufacturers.

(2) Yes; if not, the moves to use external organisations will be wasted.

(3) This is rather contentious, especially if the complaint is not valid. Perhaps a policy of manufacturers covering the cost of investigations following valid complaints could be established.

2.4 Components

(1) Yes, provided there is agreement between both parties and satisfactory testing has been conducted.

(2) By independent testing of the combined product.

(3) This should be able to be covered by the general scheme, and might involve the original certification being endorsed with details of the alternative components.

(4) Only if there was no effect on the final product's performance - generally complete items need to be tested at some stage in order to ensure overall compliance.

(5) Yes; there are separate ENs for filters and masks and corresponding certification. However, this does not extend to components within a certified product e.g. valves within a half-mask.

(6) (7) The same certification requirements should apply i.e. testing, audits etc.

(8) This would be one route. Alternatively, NIOSH could insist upon agreements between the original manufacturer and alternative supplier.

2.5 Product Audits

(1) One model sampled per certified product family once a year; the quantity sampled would depend upon the testing required and would need to be specified e.g. 20 filters/10 half-masks/2 complete SCBA etc.

(2) Selection during the on-site audits.

(3) Yes

2.6 Certification

(1) Certification should be subject to annual renewal based upon continuing compliance with certification requirements and payment of an annual administration fee.

(2) Maintenance of acceptable quality system/satisfactory quality audits/satisfactory product audits/correct claims with regard to NIOSH certification/lack of major, valid, complaints.

(3) Annual

(4) If a system of annual quality audits is implemented, a standard form could be included in the report format covering all pertinent production information. This would keep NIOSH up to date with each manufacturer's production details with regard to NIOSH approved products.