846-464

Dräger

To:
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Medizintechnik | Medical Technology
Sicherheitstechnik | Safety Technology
Luft- und Raumfahrttechnik | Aerospace Technology
Unterwassertechnologie | Underwater Technology

From:
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10.06.96

42 CFR Part 84 : Request for comments

Dear Sir or Madam,

We have some statements on your above mentioned letter.

Best regards

Encl.

DRÄGERWERK AG
Occupational Safety
Technical Management

Pasternack
Dr. Pasternack

DRÄGERWERK AG
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Dr. Plötz

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ITEM A

Issue 2 (2)
The CEN is the standards body of the European Union and is responsible for European standards. These standards should also be acceptable to NIOSH for the testing.

The aim should be to harmonize US and CEN standards (cf. list of CEN standards).

ITEM B

Issue 1 (1)
Testing of respiratory protection apparatus can only be carried out by approved bodies, of which there is a great number in Europe (cf. enclosed list).

Issue 2 (1)
The auditors should be approved by national accreditation bodies. NIOSH should compile a list of national accreditation bodies whose audits NIOSH rates as equivalent to carrying out its own audits.

Issue 2 (2)
NIOSH should request a copy of the audit report for the puposes of approving the quality management system. The quality of the audits should be checked by means of random audits carried out by NIOSH.

Issue 1 (2+3)
Only laboratories which are approved and inspected by national supervisory authorities such as NIOSH should be used for testing respiratory protection apparatus. The device manufacturer has the right to choose between the approved testing authorities.

Issue 2 (3)
This quality check should be carried out on an annual basis and during, not in addition to, routine ISO auditing.

Issue 2 (4)
Yes

Issue 4 (1)
Spare parts must be original parts from the manufacturer of the device.

Issue 5 (1)
All manufacturers are certified in accordance with ISO 9000 and are audited on an annual basis, rendering a product audit superfluous.

Issue 6 (1)
The NIOSH certification should remain valid for an unlimited period of time. The auditing in accordance with ISO ensures that the manufacturer supplies products of consistent quality.