Miller, Diane M.

From: Robert.Sell@Draeger.net
Sent: Friday, August 29, 2003 4:43 PM
To: NIOSH Docket Office
Cc: Steven.Meyer@Draeger.net; Bodo_Heins@DRAEGER_ST_US.draeger.net; angus.donaldson@draeger.com
Subject: NIOSH Docket #001 - Quality Assurance Module Concept

NIOSH Docket ¥001.doc (171 KB)..

To Whom it May Concern:

Attached please find Draeger Safety's comments on the above Docket Number.

(See attached file: NIOSH Docket #001.doc)

Regards

Robert Sell
Technical Product Mgr, Respiratory

Dräger
SAFETY

August 27, 2003

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

Subject: NIOSH Docket #001 – Quality Assurance Module Concept

To Whom It May Concern:

This letter is a compilation of comments from Draeger Safety (Draeger Safety AG & Co. KgaA [Germany], Draeger Limited [England], and Draeger Safety, Inc. [USA]) concerning the Quality Assurance Module Concept dated July 21, 2003. Draeger Safety would like to thank NIOSH for the opportunity to provide our comments on respirator quality and administrative improvements. Draeger Safety's comments are:

1.2 Quality Assurance Requirements:

Section (a):
This requires a quality system that embraces the specific requirements of ASQ / ANSI / ISO 9001:2000. Draeger Safety would like to recommend that addition of "or equal national body for non-US approval holders" to this statement. One of the registrars being used by Draeger Safety for accreditation is Lloyd's Registrar Quality Assurance (LRQL) which is an international certification body.

Section (d):
If no significant changes have been made to the Quality System Manual (QSM), would a letter from the manufacturer suffice as a notification instead of submitting the manual at the four year point?

Section (g):
Draeger Safety would like a clarification of what "Servicing records" are because we have several interpretations. In addition, what is the purpose of having this requirement? ISO 9001:2000 requires the retention of quality records and some of these records are kept by the manufacturer for life of the product.

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1.3 Quality Control Requirements:

Section (a) (2) (b):
Part numbers for the major sub-assemblies that are permanently marked on the component can present problems if they are not molded or etched into the component. The use of a label is the predominate method for labeling components as are other methods that can be worn off over time or by the user. In case where the component is large labeling is easy, whereas smaller components may be difficult. Draeger Safety would like to recommend the following two items:

1. Include additional wording: "Part numbers shall be clearly and permanently marked on the component or evidence of its removal is apparent to the user."
2. NIOSH to consider on a case-by-case basis the exclusion of the part number if there is sufficient reason to warrant it.

Section (a) (5):
Evaluation, changing, implementation, and training to put into place a new sampling plan requirement will require some extensive time and effort to establish even for new approvals. Draeger Safety would recommend a longer implementation period; i.e. five years.

1.4 Audit Programs:

Section (c) (2):
The Quality Control and NIOSH Specific Requirements Audit seems to be an additional audit that may not be required and only adds an expense for the manufacturers. Draeger Safety would recommend that the Quality Management System Audit coupled with a product audit should be sufficient, particularly for those manufacturers who are certified to ISO 9001:2000.

1.6 Use of External Resources by NIOSH:

Draeger Safety endorses the use of external resources to supplement existing staff and laboratories. This practice is currently experienced through the NFPA certification programs for Personal Protective Equipment. In addition, our experience with SBCCOM and their system has been favorable.

The one downside for outside laboratories would be in gearing up to perform tests in accordance with the current NIOSH protocols where some of the test equipment is specific to NIOSH.

The accreditation requirements for 3rd party labs is sufficient, but Draeger Safety would like to know what accreditation's NIOSH / NPPTL currently holds?

Finally, with our experience with CBRN certifications, we would like test data to be available for our use during the certification phase. We understand that this data is "unofficial" until the certification has been granted, but the information is useful for the manufacturer.

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1.7 Approval Holder Audit, Inspection, and Reporting Requirements:

Section (b):
Prior to submitting for an extension of approval, Draeger Safety performs an evaluation of the change based upon the customer requirements and the performance requirements as listed in 42 CFR, Part 84. The records, that are maintained, are for internal justification. Draeger Safety does not understand the benefits that can be gained from this requirement.

Section (c):
Draeger Safety believes that first piece inspection and restart inspection is a common manufacturing practice and that parts are inspected throughout the assembly during regular production. We would recommend that this requirement be removed.

Section (d):
Draeger Safety continually performs internal audits and inspections of all products whether they are NIOSH approved or not. Any findings found that were of a concern to respiratory protection products has been voluntarily been reported by Draeger Safety to NIOSH resulting with a resolution and closing of the investigation. We would recommend that this requirement be removed.

2.1 Application Procedures:

Section (a):
The July 14, 2003 draft document included the option of "Electronic Transfer of Funds" in several of sections of the draft and Draeger Safety would recommend that this remain an available option. We understand that this can be the manufacturer's problem, but it does become difficult to obtain funds in order to make a submittal and there are concerns over the check getting lost.

2.2 Application Contents:

Section (b) (c) (d) (e):
Draeger Safety feels that these requirements are redundant since this is the same information that is contained in the Standard Application Procedures and is a requirement for the submittal of product.

2.4 Voluntary Withdrawal of Approval:

The decision to voluntarily withdraw an approval is not taken lightly and Draeger Safety does have an internal process for product obsolescence where stock, literature, customers, etc. are reviewed. Draeger Safety does not understand why NIOSH would be interested in this other than to know that the product is no longer being offered.

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2.5 Fees for Approvals:

Draeger Safety understands that it has been some time since the fees have been raised and this is now considered a cost-of-doing business. The assessment of indirect costs by NIOSH should also be considered a cost-of -doing business and should be removed from consideration. With the fee proposal for various NIOSH activities, this will become a more expensive endeavor for manufacturers and future budgets and approval activities will need to be reassessed. How will the request for payment be notified to the manufacturer for fees other than certification fees?

2.6 Administration of Fees:

Section (2):
Draeger Safety would request that ample notification be provided to the manufacturers prior to implementation of maintenance fees in order that we may reduce this fee by voluntarily withdrawing approvals that are no longer being offered to the market.

General:

In reviewing the draft, it was noticed that there was no requirements concerning Intrinsic Safety. With the integration of electronic components to respirators this should be considered as to what these requirements should be or would this be addressed in future modules for specific respiratory equipment.

Draeger Safety again thanks NIOSH for the opportunity to provide comments on this module. If there should be any questions concerning the above items, please do not hesitate to contact me 412-788-5685 or via e-mail at robert.sell@draeger.net.

Sincerely,

Robert Sell

Robert Sell
Technical Product Mgr. Respiratory

cc: Steven Meyer – DSI
Angus Donaldson – DLtd
Bodo Heins - DST

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