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From: Bodo Heins [Bodo.Heins@draeger.com]
Sent: Thursday, November 27, 2003 2:21 AM
To: NIOSH Docket Office
Cc: Boord, Leslie F.; BerryAnn, Roland; Stein, Robert; waho@cdc.gov; Szalajda, Jonathan V.
Subject: Comments Docket #001
Importance: High

Please find attached Dräger Safety's comments for the above mentioned docket number to the QA Modul Concept (status July 21, 2003)

If there should be any questions, please contact me at +49 451 882 2678 or by E-mail.

Mit freundlichen Gruessen / With friendly regards,

Bodo Heins

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November 21, 2003

NIOSH Docket Office
Robert A. Taft Laboratories
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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:

Goals

- 1. Update the Quality Assurance and Quality Control portions of 42 CFR Part 84 to promote improved respirator quality and reliability
  For manufacturers which have and follow a (already required) certified Quality system there will be no improvement, only more costs. We recommend, that NIOSH force the minority of manufacturers not following the existing regulations to follow them, instead of installing more redundant requirements in the module.

- 1.2(d) Submit a copy of the Quality Manual to NIOSH whenever the Manual is significantly revised or, **no less than once every four (4) years**
  If nothing has been changed in the manual (which is seldom), a letter should be enough. Any changes are already required to be submitted.

- 1.3 (2)(a) Engineering drawings which present pictorial representation(s) of the respiratory device shall be generated and shall include views, dimensions, material(s) requirements
  Scaled drawings and BOM's should be sufficient. Materials are shown in lower level drawings of the single part.
  Drawings
  It should be enough, to submit scaled drawings of the main components and the assembly of the respirator, if the applicant is a QA certified company. Every detail of the respirator is shown in (lower level) drawings including tolerances, dimensions, material and special notes (i.e. free of oil).
  The simplified drawings required for the Assembly Matrix are additional work only and does not show anything that is binding.

- 1.3 (5) move away from Acceptable Quality Level (AQL)
  As long as the respirator meet all requirements, it should belong to the manufacturer

including his QA system. NIOSH should not dictate the way in which a manufacturer ensures that their products meet all applicable requirements.

- 1.4 (a) level of monitoring activities shall be determined by the Institute, but in the case of manufacturing facilities, shall not be less than 6 months between on-site compliance audits
  This is not necessary if the manufacturer is ISO/NIOSH certified; every 2 years would be enough.
  This will be costly for the manufacturers. It makes sense to audit those that need audits more often than those that have had no problems, but all manufacturers are being held liable because some are not good enough or do not follow the regulations.

- 1.4 (b) Pre-approval Audits
  not necessary if the manufacturer is ISO/NIOSH certified.

- **1.4(2) Quality Control and NIOSH Specific Requirements Audit**. This audit will determine compliance with quality control and specific product test requirements of NIOSH. These audits will be performed by a NIOSH authorized representative
  Instead of doing another audit, the specific NIOSH requirements should also be certified/audited together with the ISO certification by national bodies

- 1.4 (d) ..audit samples (per approval issued) at a rate of no more than once per calendar year
  This is not necessary if NIOSH would believe the certification

- 1.4 (d) ..the requirements of 42 CFR 84 could be grounds for action outlined in § 84.37.
  Section D ends at 84.36 and Sect E starts with 84.40 ! § 84.37 ?? does not exist.

- 1.6 (b)(2) The choice of using a NIOSH or non-NIOSH auditor * will be at the discretion of the Institute
  *We recommend, to insert "or equivalent national body for non-US approval holders"

- 1.6 (c)(3) External testing laboratories will be qualified by the Institute
  We recommend, that also European Test labs be included .

- 1.7 c perform first piece inspections
  This is included and self-evident of any QA system and belongs to the manufacturer

- 1.7 d NIOSH will be notified within 3 working days of a non-conformance or failure.
  As long as the QA system prevents such parts going out to customers, it is privacy of the manufacturer. This belongs directly to a manufacturers established quality system and serves no purpose since the manufacturer has already inspected and tested these products IAW his QA system.

- 1.7 e (4)(b) Any substantiated complaint.... Communicated in writing to the Institute within 3 working days
  Please change to within 3 days after the manufacturers internal investigation shows a substantiated complaint. These types of documents could have some legal implications

- **2.1 Application procedures** ..(a) shall be accompanied by a check..

The July 14, 2003 draft document included the option of "Electronic Transfer of Funds" in several of sections of the draft and Dräger Safety would recommend that this remain an available option. There are many different ways to control the payment before the application will be handled, so it could not be the reason for the paper check.

Manufacturers will have to plan accordingly, as many budgets and R&D activities are developed several years in advance.
This will become more important now with the increased fees. Especially having no invoice or receipt from the institute, makes it very difficult to get a check from the financial accounting of a company.
This is absolutely unusual in bigger companies and **against any commercial rules**.

The amount specified in subpart C is very difficult to calculate in the new version. It does not show up in the SAP software, especially in the German version of MSWindows 2000.
Because it becomes more difficult to calculate the approval fees, NIOSH should consider to send an invoice after initial review, which can be paid cashless. That would make it much easier to get money out.
Suggestion : Only after the money is billed to the NIOSH account (easy to find IAW the AAR#), the manufacturer can receive his TC-number for his product.

Fee
The fee is still required as a piece of paper, and it should be possible to pay the fee by international banking and paperless.
There are several possibilities to do that :
1. The applicant transfers the expected money to the NIOSH bank account. After the money is received, NIOSH could start working/send out the TC#.
2. With the application NIOSH receives a direct debit and starts working after getting the money into their bank account
3. The manufacturer is building up an amount of money in a bank account, on which NIOSH has access.
4. NIOSH is **sending out an invoice**. No manufacturer would take the risk of not paying the bill. NIOSH has tools available to force the payment, as it is shown in
Failure to make payment of any fee by due date, specified in the final rule, will result in (as appropriate):
Delayed initiation of processing for new approvals or extensions.
Rejection of further applications for approval until payment is received.
Initiation of debt collection procedures that will include interest, penalties and administrative costs.
Curtailment of any further processing of applications in-house at NIOSH.
Notification from NIOSH that the Institute will list the approved product as obsolete on the CEL until the delinquent payment is received.

- 2.1 (b) Except as provided in 42 CFR part 84, the examination, inspection, and testing of all respirators shall be conducted by NIOSH.
  We recommend that it should become possible, to do it at accredited test labs in other countries (as MSHA is already doing), which would solve the problem with the long turn around time of approvals.

Fit Test..... $5,000

does not apply to particulate respirators

Why is the fit test only for extensions and then so expensive ?
A fit test (made in a different test as IAA) will be necessary for particulate respirators too (i.e. asbestos)

- **2.5 Fees for Approvals**
  All costs, which do not appear directly with the application cannot, following international commercial regulations, be billed i.e. once a year. In Germany i.e. these regulations are published in the German Code (HGB = HandelsGesetzBuch) and the Civil Code (BGB=Bürgerliches GesetzBuch). We suggest to include these indirect costs into the flat rates for examination etc., even when they at the moment appear to be very high.
  All manufacturers are merchants, which have to calculate their products for loss or profit at the beginning of a development. Unforeseeable costs will change the calculation.

  Most of the manufacturers, at least the bigger ones, also have to create their budgets mostly i.e. in September of the actual year for the next year.
  Annually billed maintenance and administration fees would not fit into this budget, they are unforeseeable.
  We recommend, that NIOSH, since it has now also to follow commercial rules, is following these international valid rules. In Germany i.e. these regulations are published in the German Commen Code (HGB) and the Civil Code (BGB).

  The German approval authority (DMT, now EXAM, BBG Prüf- und Zertifizier GmbH, Am Technologiepark 1, D-45307 Essen, phone 011 49 201 172 1181 , Fax 011 49 201 172 1193) has been in a similar situation as NIOSH is now.
  In the past they have been a government / employers' liability insurance company paid organization and they had to change to cost-covering organization.
  They are doing it in a way, that all costs (direct and indirect) will be calculated for a year and divided by the billable hours of available persons working for manufacturers. This then provides a flat rate for all work to be done for a specific purchase order / certification request. As long as the institute is booked up completely, it will work well, and there is no doubt, that the institute is not booked up.

Some comments on the Turn-around time:
The turn around time we and other manufacturers have experienced as much too long. The promised time of 90 calendar days is sometimes up to 180 days.
This is also an issue of planning in (bigger) companies. Materials, documents, resources etc. have to be planned at least months or more ahead. If the calculated day of beginning manufacturing / operations after receiving the approval letter is not observed, these calculations have to be changed and that means that resources/people have to be shifted to other jobs, and budgets and market share are not met, etc.

The actual possibility of watching the approval status on the homepage is not very helpful. The information is usually weeks behind reality and it is not showing the **expected date** of the approval letter which is the **most important information** for the manufacturer.
This is a **missing column** in that tool and **we suggest to include it**.
It is the only important information for a manufacturer , which he actually has to calculate for his own out of the data's from the homepage.

The tool should be reworked, to become interactive. If the manufacturer is looking for a special TN, they should only type this number in and then the required table (or date of expected approval) should appear on the screen, independent of Air Supplying or Air Purifying.

At least the headline of the existing table should be repeated on each page when printed out, to prevent several pages that have to be printed, although I only want to see 1 line and headline.

We suggest also, to give the applicant the final **approval number after Laboratory Testing** is passed (and the bill is paid).
All remaining work is administrative / organisational paperwork, which should not prevent the manufacturer from beginning production, like ordering the label, IFU's etc. which are also time costly activities. The permission to bring the product into the market can remain until they received approval letter.
NIOSH has tools enough, to force manufacturers to make required possible changes to the paperwork. (see **Failure to make payment of any fee)**

NIOSH should accept outside test results from sources which should be approved by an accredited agency to perform laboratory testing and a separate accreditation or certification for auditors IAW special NIOSH 42CFR84 requirements.
The maximum would be, that NIOSH does accept foreign approvals, if these approvals contain such NIOSH specific requirements.
This would automatically **solve the time problem**.

Draeger Safety 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 us

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