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From: Kline, Joann [Joann.Kline@kcc.com]
Sent: Thursday, October 08, 2009 6:55 PM
To: NIOSH Docket Office (CDC)
Subject: RIN: 0920-AA04 42 CFR Part 84 Docket Comments, Kimberly-Clark Professional
Attachments: JaxKCNIOSHQAFinal1009.docx

The comments of Kimberly-Clark Professional and Jackson Safety – A Division of Kimberly-Clark Professional are attached.

Kimberly-Clark

October 8, 2009

Via Email (niocindocket@cdc.gov)

NIOSH Docket Officer
NIOSH Docket #109
RIN 0920-AA04
National Institute for Occupational Safety and Health
Robert A. Taft Laboratories, MS-C34
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Cincinnati, OH 45226

RE: 42 CFR Part 84 Quality Assurance Requirements for Respirators

Kimberly-Clark Professional is known for innovative safety solutions for "clean" and "industrial" manufacturing settings. With the acquisition of Jackson Safety, the company offers a comprehensive line of personal protective equipment, welding and work zone safety products. The combined global safety brands of Kimberly-Clark Professional and Jackson Safety include Kleenguard, Smith & Wesson (under license) and Winchester (under license). Kimberly-Clark Professional, located in Roswell, GA, is one of the Kimberly-Clark Corporation's four business segments.

We support NIOSH's effort to update the rules governing respirator quality assurance practices and appreciate the opportunity to provide input into the rulemaking process. We offer the following comments on the proposed changes to 42 CFR Part 84.

Section 84.2(w): The definition of manufacturing facility should be revised to emphasize that the it applies only to suppliers with quality systems that are highly integrated with that of the applicant, as described by the NIOSH panel at the May 2009 Public Meeting. Without clarification, this definition and use of the word "component" to describe the relationship could be interpreted to include a supplier solely on the basis of that supplier making a key component to the applicant's assembly. NIOSH apparently intended something narrower, and the definition should be revised to more accurately reflect this intent.

Section 84.10(c): This section allows NIOSH to suspend application processing for an applicant that is noncompliant with any provisions of Subpart E. Some manufacturers have diverse

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product lines that are manufactured at unrelated facilities but are approved under a single applicant entity. A noncompliance for one respirator type should not necessarily impede the approval process for a completely different respirator from a different process or system that is not affected by the noncompliance.

A more reasonable incentive would be to suspend application processing when the applicant has missed a corrective action deadline or some similar failure that suggests a lack of commitment by the applicant. This measure would also give the applicant some control and notice over the suspension; an applicant is typically well aware of a response deadline, whereas a noncompliance can (and often does) arise unexpectedly.

If the rule does allow suspension based on pure noncompliance, then it should at least require that the noncompliance be serious or major so that minor gaffes do not delay processing for unrelated applications.

Section 84.11(d): We support the provision in this section for both registration and non-registration options for establishing conformance with ISO-based quality system requirements. Regardless of the registration status of the applicant, the rule requires the same underlying quality system. We believe that the option to be compliant to the ISO standard without registration should be available and do not agree with suggestions for a blanket registration requirement.

- The proposed rule states that NIOSH will continue to do manufacturer audits regardless of the manufacturer's ISO registration status. The rule is vague as to how the audit might specifically differ for a registered manufacturer versus one that complies but is not registered. Since this scope could be left up to a subcontracted auditing firm and possibly individual auditors, the rule could effectively require both an expensive registration process and ongoing full-scale NIOSH audits.

- Small manufacturers might prefer to have NIOSH confirm their ongoing compliance as a cheaper alternative to formal registration, especially if respirator approval is a major reason for implementing an ISO-based quality system.

- Having both options gives manufacturers some flexibility in either opening or moving manufacturing sites. If a new site were outside the scope of an applicant's existing ISO registration, it would also have to be registered before qualifying for NIOSH approval of the product. A quick audit and registration could be procedurally impossible even if all ISO systems were in place at the new operation. Allowing self-declaration of conformance would allow more seamless transfers of production processes.

We also recommend that the rule allow compliance with equivalent ISO quality system standards in addition to ISO 9000. ISO 13485 (for medical devices) might be particularly relevant since many respirators have FDA oversight in addition to NIOSH oversight, and some respirator manufacturers are currently registered to ISO 13485. Although the alternate standards

accomplish the good quality practices that NIOSH intends, these manufacturers could be required to add a second registration. At minimum, manufacturers using the non-registration option would have to add parallel but slightly different procedures to satisfy both standards.

Section 84.34: This section allows NIOSH to revoke any certificate of approval and includes failure to maintain the quality assurance requirements as one basis for revocation. Most quality assurance requirements apply across a broad range of respirators, while the other listed examples of reasons for revocation tend to be specific to a particular respirator or type of respirator. The rule should describe the scope of devices for which NIOSH may revoke certification based on failures in the quality assurance area. It should also only allow revocation where the applicant has had an opportunity to cure the failure and has not reasonably or effectively responded.

Section 84.36: This section governs changes in device or applicant ownership and disallows any manufacture after the date of ownership change until NIOSH has issued the modified certificates of approval. This is not workable in light of how changes in ownership typically occur. These changes, particularly to applicant ownership, almost always require strict confidentiality (even within the parties' organizations) during the run-up stages. There is no opportunity to begin working on NIOSH applications prior to the change so that the modified certifications could be available on the date of the acquisition. This guarantees a hard stop in production in almost all cases. The stop could be lengthy depending on how many devices are certified, how long it takes to prepare the applications and how long it takes NIOSH to turn around the modified certificates.

We suggest that the rule be written so that manufacturing and shipping may continue under existing approvals provided that the new owner certifies to NIOSH that the processes, materials and designs for all affected devices have not changed with the ownership change. This type of letter could be done in a matter of days.

The rule should then allow a defined period for the applicant to submit the Application for Modification of Certificate of Approval for all devices. If the new owner changed a material, design or process within that period, then the modified certificate would have to be sought and issued before manufacturing the revised version of the respirator.

Section 84.37(a) and (b): Section (a) requires that an applicant notify NIOSH of a decision to make "any substantive change in the *quality system* …" associated with manufacture of certified devices. Section (b) then requires that NIOSH approve the change before implementation. Section 84.2(gg) defines "Quality System" as

> *"The entire organizational structure, responsibilities, procedures, specifications, processes and resources used or required for quality assurance and control."*

These two sections, read together, require that a manufacturer notify NIOSH of essentially any non-editorial (substantive) change in systems, process and possibly even the organization, and get NIOSH approval prior to proceeding. A change in reporting relationships within the QC department could be subject to NIOSH review and approval. A change in how nonconforming tags throughout a plant are issued and filed could be subject to NIOSH review and approval. Changes to job descriptions that affect certain responsibilities could be subject to NIOSH review and approval. Since modern quality systems – including ISO 9000 - reach most of an organization, this clause essentially gives NIOSH some approval authority over much of the operation. Although this scope is probably unintended, it is fairly clear that the rule as written could subject all of these examples to the submit-and-approve requirement of 84.37(b).

This section should be rewritten to more clearly describe the types of changes that must be submitted and approved.

Sections 84.42(a)(2), (a)(3) and (a)(4)(i): These sections address the requirements for Drawings, Inspection/Test Procedures and CTQC Classifications, respectively. Each section says that the described documents must be made available to NIOSH on request. However, 84.42(a) says that each of these is required content in a control plan and 84.43 says that a control plan must be submitted to NIOSH for approval.

The rule should be revised so that it is clear that these items, while part of the control plan, are not subject to the automatic submission and approval requirements.

Section 84.42(a)(4)(iii) and (a)(5)(i)-(ii): We agree with and support the detailed comments to this docket of the International Safety Equipment Association (ISEA) concerning the change in the basis for sample plan selection. These changes result in a de facto requirement for manufacturers to improve process averages en masse with no clearly demonstrated need for such widespread changes.

Without almost instantaneous improvements in process averages, the sudden increase in batch rejections could dramatically reduce the number of available devices as manufacturers must sort more rejected batches than usual. In the case of destructive inspection, these batches would become permanently unusable. Reduced shipments could lead to shortages that require users to continue to use devices after they should be replaced or available but less appropriate devices.

Section 84.42(a)(5): This section says that sampling must conform to one of the listed sampling plans. Does the word "sampling" in the first sentence imply that the requirement applies only where sampling exists, or does it mean that a sampling process (as opposed to alternate methods such as supplier data) is expressly required for incoming, in-process and final inspections? The rule should clarify the requirement here, and consider that there are many viable assurance techniques besides sampling.

Section 84.42(a)(7): We are concerned with the ambiguity in this section as to NIOSH's overall intent in granting approval to alternate sampling approaches for destructive testing. If NIOSH

intends to approve plans that are submitted based on current sampling approaches and plans, then there is no effect. If NIOSH intends to restrict approval to those plans that have also switched to a consumer-protection approach, even if they are reduced from the 1916 levels, then we cannot accurately predict or comment on any increased cost of test scrap.

Again, we appreciate the opportunity to comment on the proposed rule.

Sincerely,

/s/ Joann Kline

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