Dragon, Karen E.

From: Jeff.Gutshall@MSANET.COM
Sent: Friday, December 08, 2000 3:25 PM
To: Bowyer, Matt E.; NIOSH Docket Office
Subject: Docket Number, NIOSH-001

Mac Word 3.0 (116 KB)

Matt,

Please review the attached and contact me if you have any questions.

Jeff G

(See attached file: MSADocketComment8Dec00.doc)

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December 8, 2000

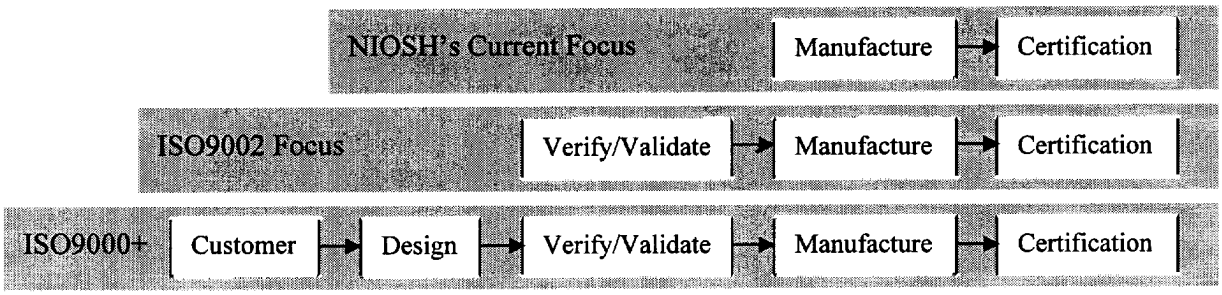
Mr. Matt Bowyer
NIOSH DRDS MS35
CQAB
1095 Willowdale Rd.
Morgantown, WV 26505-2888

Re: Docket Number NIOSH-001

Dear Mr. Bowyer:

With this rulemaking, NIOSH has the opportunity to improve the quality of this industry, and the proposed "ISO9000+" system is a good approach. ISO 9000 is all about continuous improvement. The program that NIOSH has envisioned as "ISO9000+" can specifically apply that spirit to NIOSH approved products.

NIOSH has recognized that an ISO9000 requirement alone does not necessarily produce quality products. However, we want to emphasize that a focus on end-item sampling is a diversion from the search for a healthy industry and quality products. A quality product is one that meets the requirements of the customer. In regards to respirators, these requirements most often include NIOSH certification. Because it is impossible to codify requirements that address all requirements for all users, NIOSH must look beyond minimum product performance standards as the focus of the new QA Regulatory Module.



A fully capable production process cannot assure a successful product without an equally capable design process. We cannot imagine a manufacturer of safety products that would not be involved in design engineering process, and all production variances have their roots in design engineering. Only a product that has been designed according to valid customer

requirements, and is focused on continuous improvement has a high probability of satisfying the user. In this way, the role of production end-item sampling is reduced to a control verification tool.

Table 1

Demonstrated Capability	**Associated Requirement**
ISO Registration	NIOSH Facility Audits
Production Processes	Sampling Standards, Status Reports
Design Engineering Processes	Submission Review

The evolution of a system that consistently produces a successful product is not immediate, and involves a commitment to continuous improvement. If NIOSH issues minimum requirements without some incentives for improvement, theses minimum requirements can become maximum performance targets. In order to encourage continuous improvement, we are recommending a tiered system that encourages the use of these techniques by balancing demonstrated capabilities against associated requirements.

A potential tier design that uses these balances to encourage improvement is shown below in Table 2. Changes to the requirements for facility audits, sampling plans, end-item sampling requirements, and production status reports result from a change in designation. In this way, NIOSH can issue a uniform set of requirements that do not penalize a manufacturer, nor will the requirements discourage improvement.

Because a manufacturer may have multiple facilities with varying capabilities, the tiers must apply to the specific location even though all facilities may use a common Design Engineering and/or QA manual. During the implementation of the new QA regulations module, each manufacturer would demonstrate compliance to the applicable tier for each facility.

Through this approach, a manufacturer can initially select a tier that most closely matches their current QA system. The manufacturer can then make changes to a facility's tier designation if they choose to benefit from that change.

Table 2

Tier Designation	Production Quality System Characteristics	Design Quality System Characteristics	Requirements Profile
Standard	Meets the intent of ISO9000	Not Documented	• NIOSH audits per base schedule, • C=0 sampling levels • End-item sampling, • Re-certification of products not produced for a defined period
Registered	ISO9001 registered (w/design engineering in the new edition)		• NIOSH audits per a reduced schedule, • C=0 sampling levels • End-item sampling, • Re-certification of products not produced for a defined period
Tracking	Registered Characteristics *PLUS* NIOSH receives periodic reports regarding production process capabilities and training		• NIOSH audits per a reduced schedule, • Sampling plans per ANSI or other accepted plans • End-item sampling, • No production based re-certification
Enhanced	Standard Characteristics *PLUS* Submission package includes CPS, QTP, TDR** (For Example)	Not Documented	• NIOSH audits per basic schedule, • C=0 sampling plans • Limited end-item sampling, • No production based re-certification • Accelerated submission testing considerations
Enhanced (T)	Tracking Characteristics *PLUS* Submission package includes PCS, QTP, TDR** (For Example)		• NIOSH audits per a reduced schedule, • Sampling plans per ANSI whatever • Limited end-item sampling, • No production based re-certification • Accelerated submission testing considerations

**PCS: Process Capability Studies
QTP: Qualification Test Plan
TDR: Technical Design Reviews

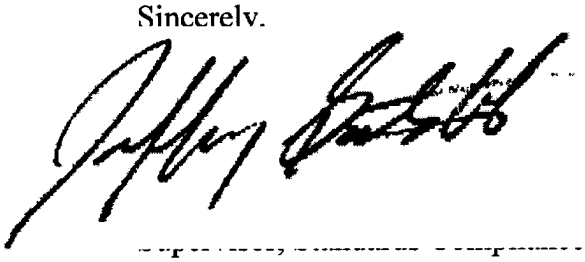
The "standard" designation reflects the requirements envisioned by NIOSH. That is, a QA system that meets the intent of ISO 9000. An incentive to gain ISO9001 registration would be a reduced NIOSH facility audit schedule. ISO 9001 compliance would allow NIOSH to consider issuing a "registered" designation to that facility. It is important to note that this change in designation would also signal that they are committed to continuous improvement, and are implementing tools such as six-sigma.

A "tracking" designation would add to the registered level of compliance through a NIOSH notification process regarding the facility's production process capabilities. By providing such data, the facility demonstrates that a C=0 sampling requirement gains nothing statistically, and the facility is able to use another NIOSH approved sampling plan.

Any facility that is designated "tracking" or "registered" can opt to pursue an "enhanced" designation. This tier would provide an opportunity to reduce the load at NIOSH, as well as reduce approval-processing time. With this designation, the manufacturer can choose to include process capability studies, technical design reviews, quality validation and verification reviews, etc., that were created during the design process. NIOSH's review effort could be reduced when this type of data is available, and a "fast-track" review process can be designed for this case.

This type of a tiered system is an initial effort to define a system that will avoid reducing the performance of the industry to a single codified target. We welcome the opportunity to work with NIOSH and industry to complete its design.

Sincerely,



Safety Products Division