

# PUBLIC SUBMISSION

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**Docket:** [HHS-OS-2009-0002](#)  
Quality Assurance Requirement for respirators

**Comment On:** [HHS-OS-2009-0002-0002](#)  
Quality Assurance Requirements for Respirators,

**Document:** [HHS-OS-2009-0002-0005](#)  
Comment on FR Doc # E9-04621

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## Submitter Information

**Name:** Angela Werner  
**Organization:** The George Washington University School of Public Health and Health Services

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## General Comment

Please see my attached comment. Thank you.


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## Attachments

[HHS-OS-2009-0002-0005.1](#) Comment on FR Doc # E9-04621

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**Submitter Information**

**Comment Tracking Number** 8094ad46  
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**General Comment**

**Comment** Please see my attached comment. Thank you.

April 8, 2009

Department of Health and Human Services  
Charles E. Johnson  
Acting Secretary  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary and Staff,

I am writing in response to the proposed rule from the Department of Health and Human Services on improving quality assurance standards for all respirators approved by the National Institute for Occupational Safety and Health (NIOSH). The proposed rule (*Quality Assurance Requirements for Respirators; Notice of Proposed Rulemaking*) was originally published in the Federal Register on December 10, 2008.<sup>1</sup> The proposed rule was then republished, with the comment period being reopened, on March 4, 2009.<sup>2</sup>

I believe that the proposed rule is necessary and will be beneficial for workforces around the world. I hope that my comments will demonstrate how this rule will help improve the health and safety of workers throughout the United States, as well as in other countries. I will also review some questions that arose while reading the proposed rule, which I hope can be addressed by your staff.

#### Importance of an Updated Rule

The use of personal protective equipment in protecting workers from various occupational exposures is very important. As mentioned in the background section, some occupational diseases, including lung diseases and cancer, can take years to develop after exposure to toxic dusts, particles, or other substances. With many occupational diseases and cancers having a long latency period, it is difficult to determine the exact cause of the exposure and how to prevent the problem once it has already occurred. For example, asbestosis and other asbestos-related diseases can have a latency of up to 40 years before the onset of symptoms.<sup>3</sup> There are approximately 1.3 million workers, mostly construction and general laborers, who are potentially exposed to asbestos each year.<sup>3</sup> This is very important to consider, as this is just one example, where many people have the potential to develop a life-threatening disease decades after their exposure. It is necessary to ensure people have *properly functioning* protection with the *highest quality standards* to reduce morbidity and mortality in future years.

The existing rule requiring quality control plans from respiratory protection equipment manufacturers is over three decades old and many practices have changed over time, indicating the need for amendments to the regulation. As indicated in the proposed rule, nearly 40 percent of product audits in nearly the past decade have shown some nonconformance with certification.<sup>1</sup> I think that this is unacceptable because this equates to approximately 2,800 products that do not meet requirements one way or another. In addition, as already mentioned, five percent of products have been recalled or had similar

action taken, meaning over 350 products are included in this category. While this may not seem like a large number over a decade, what happens to the workers if they were wearing respirators that did not function properly and they will not know it until twenty or thirty years from now? I am glad all of these factors have been recognized and that the need for an updated rule has been acknowledged.

### Sections of Proposed Rule

I will now continue through sections of the proposed rule to comment on aspects of the rule that I think are important and also bring up questions or concerns. I look forward to reading other comments addressing these issues.

#### *Subpart B*

It is important that manufacturers have some type of incentive, even if it is not tangible. This is addressed by paragraph (c) in that previously certified applicants who do not comply can have new applications suspended.<sup>1</sup> This will help companies to ensure their product meets the quality standards promoted in ISO standards. It seems as though having the NIOSH certification would be an incentive itself, helping the companies to improve or maintain strong reputations for quality products and, in turn, increase their presence and popularity in the respiratory protection market. It is also logical to assume that higher quality assurance and control standards would result in less liability for manufacturers.

#### *Subpart D*

Applicants who do not maintain the standards of quality assurance can have their certification revoked, as stated in Section 84.34 of the proposed rule.<sup>1</sup> Is there a certain time frame that the applicants have to reapply for their Certificate of Approval or do they have to undergo additional steps before reapplying for failure to maintain quality assurance or quality control requirements? In addition to this, does the applicant have any right to challenge a decision or does NIOSH automatically have the final word on a decision?

Section 84.36 addresses any type of ownership change and addresses timeliness as a key factor.<sup>1</sup> If a company does change ownership, is there a deadline to submit an Application for Modification of Certificate of Approval? A deadline would provide companies with a timeframe to work within. If they do not submit an application by a certain date and are attempting to sell certified respirators under the old owner's certificate, then their certificate may be revoked and they will have to go through the entire process from the beginning.

#### *Subpart E*

Implementing the ISO standard is an excellent idea and will help to create more consistent quality management in companies across the United States and in other countries. There are currently more than 100 manufacturing sites for NIOSH approved devices in countries around the world.<sup>4</sup> It is important to have a standard for these manufacturers to ensure the highest quality assurance and quality control in their

products. While the use of ISO 9001:2000 is important, ISO 9001:2008 should be implemented in the rule instead. ISO 9001:2008 (4<sup>th</sup> edition) has been published and has replaced ISO 9001:2000.<sup>5</sup> It would make sense to incorporate this updated standard so that the proposed rule can be as current as possible.

It is very important to include the need for rapid reporting of device complaints because these could include incidents like product malfunctions, which would result in product recalls. It imperative that manufacturers are required to report these cases (Section 84.44) so that the health of those who use the respirators is a top priority. However, is there any type of penalty or consequence to manufacturers if they would not, for some reason, report any type of complaint?

Section 85.45 addresses audit programs conducted by NIOSH. The section states that audits shall not be conducted more than once per calendar year per approved device or more than once within six months.<sup>1</sup> In the case of a facility changing ownership, does the new six month or year period start upon change to the new owner or continue through the previous owner's time frame for an audit?

### Conclusions

The current rule is outdated and it needs to be updated to allow for better quality assurance. The new rule will reflect the newer capabilities of manufacturers to produce more products, as well as having better process control and design. The proposed rule does a good job at updating and addressing important factors that NIOSH must consider when determining if a manufacturer can be certified. Having a stronger, standardized system will also help to save time during NIOSH manufacturer audits for those companies that are guaranteeing their process meets ISO standards (as specified in their requirements for certification). While the proposed rule should be effective, there are still some concerns that should be addressed. Two of these main concerns are the need for implementing the *updated* ISO standard (ISO 9001:2008) and penalties for manufacturers not submitting information on product complaints.

I hope that my comments have helped to strengthen support for this proposed rule, as well as bringing up certain points that may need to be addressed before the final rule is issued. Everyone, including NIOSH, manufacturers, and workers in the United States, as well as in other countries will benefit from greater quality assurance and control measures. Thank you for your time.

Sincerely,

Angela Werner

Master of Public Health Candidate, 2010

Department of Environmental and Occupational Health

The George Washington University School of Public Health and Health Services

## References

- <sup>1</sup> U.S. Department of Health and Human Services. 42 CFR Part 84: Quality Assurance Requirements for Respirators; Notice of Proposed Rulemaking. In: Federal Register, Vol. 73, No. 238, December 10, 2008. Available at: <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=09000064807d5702>
- <sup>2</sup> U.S. Department of Health and Human Services. 42 CFR Part 84: Quality Assurance Requirements for Respirators. In: Federal Register, Vol. 74, No. 41, March 4, 2009. Available at: <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=09000064808e9c7b>
- <sup>3</sup> U.S. Centers for Disease Control and Prevention. (2008). Asbestosis-related years of potential life lost before age 65 years – United States- 1968-2005. MMWR Weekly. 57(49), pp. 1321-1325. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5749a1.htm>
- <sup>4</sup> National Personal Protective Technology Laboratory, Institute of Medicine. (2007). Workshop on personal protective equipment for healthcare workers in the event of pandemic influenza. Available at: <http://www.iom.edu/File.aspx?ID=40760>
- <sup>5</sup> International Organization for Standardization. ISO 9001:2008 Quality Management Systems - Requirements. Available at: [http://www.iso.org/iso/iso\\_catalogue/catalogue\\_tc/catalogue\\_detail.htm?csnumber=46486](http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=46486)