

PUBLIC SUBMISSION

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Quality Assurance Requirement for respirators

Comment On: [HHS-OS-2009-0002-0002](#)

Quality Assurance Requirements for Respirators,

Document: [HHS-OS-2009-0002-0003](#)

Comment on FR Doc # E9-04621

Submitter Information

Name: Holly Carpenter

Organization: American Nurses Association

General Comment

Please see the attached.

Attachments

[HHS-OS-2009-0002-0003.1](#) Comment on FR Doc # E9-04621

Public Submission: HHS-OS-2009-0002-0003.1

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Docket [HHS-OS-2009-0002](#)

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March 12, 2009

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To Whom It May Concern:

The American Nurses Association (ANA) welcomes this opportunity to respond to the Federal Register/Vol.74, No. 41 on March 4, 2009 notice for Department of Health and Human Services, 42 CFR Part 84, RIN 0920-AA04, Quality Assurance Requirements for Respirators; Notice of Proposed Rulemaking; Reopening of comment period.

Respirators are used to protect nurses from chemical, biological or radiological contamination. Regarding biological hazards specifically, respirators are used to prevent the transmission of certain airborne infectious diseases such as avian flu, SARS, anthrax, and TB. ANA advocates for nurses to be provided with and use protective respirators that are National Institute for Occupational Safety and Health (NIOSH)-approved, when indicated. Improving the standards in any way that would increase the protection quotient of the respirator thereby preventing harm to the users of these respirators is to be encouraged. Improved, up-dated quality assurance and quality management requirements are needed since these were last established in 1972.

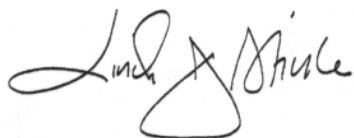
There are currently 7100 NIOSH-approved respirators on the market, 5100 which have been approved since 1995. These large numbers of respirators "have strained NIOSH resources applied to providing adequate quality assurance audits and related services" (page 75046) requiring a more efficient deployment of NIOSH auditors and what they will survey. ANA advocates for timely and adequate surveys.

Page 75046 mentions incorporation of the ISO Q9001:2000 standard: Quality Management Systems-Requirements, 3rd Edition into the proposed new rule. The purpose of this incorporation would be to "foster better quality management consistently". ANA is in agreement with higher standards that lead to a superior product.

Page 75047 defines the term manufacturing facility to include "buildings of any supplier whose quality system is a component of the applicant's quality system" and further specifies that said suppliers should "be potentially subject to NIOSH facility audits" ANA agrees that these suppliers should be required to submit to NIOSH audits when appropriate and for NIOSH approval to be withheld, denied or revoked if audits are refused by the suppliers.

Again, thank you very much for the opportunity to comment on this important issue.

Yours truly,

Handwritten signature of Linda J. Stierle in cursive script.

Linda J. Stierle, MSN, RN, NEA-BC
Chief Executive Officer
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Handwritten signature of Rebecca M. Patton in cursive script.

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