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The American Nurses Association thanks NIOSH for addressing a challenging and controversial issue - certification requirements for respiratory protective devices. Because of the great increase in tuberculosis cases and especially MDR-TB, this issue is of special interest to nurses, the group of care providers who spend the greatest deal of time with patients at all levels of risk. At a time when health care delivery must occur in the most effective, efficient and safe fashion, is responsive on the part of NIOSH to take action which would enable health care employers to select from a broader and more cost-effective range of certified respirators that meet the necessary performance criteria recommended by the Centers for Disease Control.

The modular approach seems the most practical approach, however ANA has concerns about implementation schedule for the different modules. The interrelatedness of the two modules which address filter testing and face seal leakage must be recognized. Although the issue to which these comments are addressed is specifically a NIOSH issue, it cannot be totally separated from the CDC recommendations or the enforcement regulations currently used by OSHA. ANA appreciates NIOSH's commitment to work collaboratively with those two agencies on this issue.

At the time that ANA submitted its comments to the CDC on the proposed TB guidelines, we were concerned about the lack of data to support the respirator recommendations. We also had concerns about face seal leakage. Preliminary results of respirator studies in progress indicated that disposable the disposable HEPA filter respirators which were tested afforded a better face seal. In order to back the economical particulate respirator, ANA needs assurance that nurses would get both the fit and filtration necessary to meet the CDC criteria. We urge NIOSH to address both the filter testing and assigned protection factor modules before implementation occurs and to continue reseach to attain definitive results.

Many of our nurses look forward to the day when TB elimination efforts have been so effective that our risk of exposure is greatly lowered. However, today, in concentrated geographic areas, exposure to TB is a reality of the nurses' everyday work. We are pushing to educate ourselves about early identification, the complicated medication regimes required for effective treatment and about correct ventilation systems. When we provide care to an active TB patient, we need quick and clear ways of knowing that respirators fit properly and that they are the correct filter medium required for protection.

Although nurses are highly motivated professionals who understand that our jobs entail some degree of risk, we feel that we do not need to accept risks for which known prevention measures exist. We support NIOSH in more clearly describing the respiratory equipment which will allow us to safely do our jobs.

ANA will confine its specific comments to Subpart K, Particulate Respirators.

84.174 Respirator containers; minimum requirements

Nurses are currently struggling with the issue of storage of disposable respirators. There are concerns about infection control and maintaining the integrity and shape of the respirator from use to use. The concern has focused mainly on the disposable HEPA filter respirators, but cost conscious hospitals may impose similar requests - to re-use particulate respirators - in the future. Some guidance about proper and safe storage from use to use, hopefully for the same patient, would be beneficial for the subset of users who are health care workers.

84.177 Inhalation and exhalation valves; minimum requirements

There is great concern about the current use of disposable HEPA filter respirators with exhalation valves when a sterile field must be maintained in front of the breathing zone of the health care worker. This is currently of special concern because of the increasing frequency of seeing TB in HIV positive patients. Because these persons are immunocompromised, they especially need to be protected from all potential sources of infection.

84.180 Particulate respirators; filter type identification

At the informal public meeting held in Washington, D.C., one of the presenters suggested that the labelling method proposed may be an opportunity for confusion if U.S. workers have been used to a European labelling system which also uses letters but for different types of masks. If the utilization of numbers or any other designation will reduce this confusion, ANA would support this change. The health care industry employs many workers who have recently immigrated from other countries or who may be obtaining health care education in this country.

84.181-2 **Isoamyl acetate tightness test:**

Implied is the fact that these are controlled testing conditions. The steps involved indicate that fit as well as filter media is being tested. ANA hopes that there will be better integration of the entire testing process throughout the different modules. Practical and safe use of respirators demands a sensible approach that can be used to assure that the entire respirator is effective.

ANA was supportive of the criteria which respiratory protective devices should meet as proposed by the CDC in their October 12, 1993 document. However, we are still concerned about practical ways to assure fit at each wearing, especially with disposable models. We are also concerned that NIOSH does not review the fit check procedures proposed by the manufacturers.

Since more respirators are being utilized in the health care environment where two protection interests are at stake, that of the patient and that of the worker, NIOSH should more thoroughly examine the issues of moisture, infection control, reuse, and storage related to respirator use in this environment.

Thank you for this opportunity to comment on this important rulemaking.

Sincerely,

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