GREATER NEW YORK HOSPITAL ASSOCIATION
GNYHA
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NINETY YEARS OF EXCELLENCE IN HEALTH CARE

555 West 57th Street / New York, N.Y. 10019 / (212) 246-7100 / FAX (212) 262-6350
Kenneth E. Raske, President

July
Twenty
1994

Re: 42CFR Part 84 RIN - 0905 - AB58 - NIOSH Respirator Standards

To Whom it May Concern:

This letter is written on behalf of the more than 160 not-for-profit and public hospitals and nursing homes in the membership of the Greater New York Hospital Association (GNYHA) which extends throughout the five boroughs of New York City, to Westchester, Nassau and Suffolk counties in New York State. As a representative of institutions that are at the epicenter of the tuberculosis epidemic, GNYHA feels that it is imperative to comment upon the proposal from NIOSH that appears to begin to address issues related to the certification of respirators. In particular, GNYHA, as a representative of health care providers, is most interested in the government's ability to define, describe and make available (through whatever process) comfortable, easy to wear, and easy to be comprehended through respiratory protection for workers in health care settings. Additionally, of critical importance is the cost of any new device that NIOSH would chose to certify as funds for health care are increasingly constrained.

BACKGROUND

Hospitals that have some experience with attempting to comply with the OSHA Directive relative to the use of HEPA respirators for the routine care of tuberculosis patients (pursuant to current certification processes) have reported a significant number of problems. In addition to the extraordinary costs for the respirators themselves, both the reusable as well as the disposable, and the problems inherent in using a disposal as a reusable (as has been suggested by OSHA), there are a significant number of other factors of concern. They include:

1. Hospital employees report difficulty being understood.

2. Hospital employees report difficulty in wearing the respirators as the sizes are inimical to many faces and their shapes (such as nose bridges and chins).

3. Hospital employees report difficulty in breathing through the respirators, even those that provide exhale valves and claim the devices are very warm.

4. Hospital employees report difficulty in assuring a sterile field with respirators with exhale valves because to do so requires the placement of a surgical mask over the respirator itself thereby compounding breathing difficulties.

5. Hospital employees report difficulty in maintaining the integrity of the disposable respirators during their journeys throughout their institutions.

6. Hospitals' managements report difficulty in inventorying, issuing, and caring for and cleaning the reusable forms of respirators and assuring that the filters are changed on the "as recommended" basis.

In addition, hospital representatives have reported to us that full compliance by employees with the requirements to fit check and wear the respirators properly is not able to be reliably achieved.

PROPOSAL - A GENERAL CRITIQUE

It is critically important to the health care providers that whatever changes are made begin to meet the many competing demands and needs for appropriate protection based on a scientific model that is related to tuberculosis itself, its method and mode of transmission and its "concentration" in the ambient air. Therefore, in general, GNYHA would tend to be supportive of this rule if indeed it will produce the desired effect. However, the way the rule is written, it is difficult to discern whether the needs of the health care community and its workers, particularly as it relates to tuberculosis control, can be met by implementation of this new module of the standard.

First, it is extremely difficult for the non-respirator manufacturer to understand the background as well as the decision-making logic that went into the standard. Perhaps most importantly, the supplementary information appears to be especially weak so that even a trained industrial hygienist has trouble deciphering and determining the value of that section. This is, we understand, the section that should address the primary questions and issues that need to be answered by this new standard and, in the opinion of several, it did not do that.

From the point of view of the health care provider community, it would be tragic to undertake the redesign of the current crop of respirators without addressing the issues that have added "fuel to the fire" to do same -- the need for more appropriate, cost effective and comfortable respiratory protection for health care workers that address TB specifically. Therefore, although our very technical comments are brief and attached, we are not completely persuaded, in part because of the difficulty of understanding some of the information as written, that this proposal will actually look at the environment in which health care workers function and evaluate and permit the development of respiratory protection devices appropriate to that environment and appropriate to the disease at hand -- TB.

It would be most useful if there were standards that recognized that a single test is not appropriate for all particulates; and that bacterial particulates, as they occur in hospitals, are different from industrial dusts and mists. In addition, more information is needed as to what "assigned protection factors" (APF) OSHA will assign to various grades of particulate respirators and what APF OSHA will consider adequate for use with patients with infectious TB, both for routine care and high risk procedures.

GNYHA appreciates the fact that NIOSH has gone forward with a modular approach to this change to respirators. This modular process should expedite the entire undertaking and enable people with specific interests to focus on their areas of concern. It would be important to assure that there is consistency between the modules with overlapping or interconnecting issues. Some representatives

of GNYHA have raised the issue of the need for addressing the issue of fit testing, especially for single use respirators, in this regard.

Finally, those who are capable of critiquing this document from a technical standpoint felt strongly that it should assure that the class "C" respirator, if intended for use in hospital environments for tuberculosis, with its 95% proposed filter efficiency, is acceptable to OSHA. There were many who were concerned that this standard would not become the underpinning of any further actions on the part of OSHA.

CONCLUSION

On behalf of the members of the Greater New York Hospital Association, GNYHA is encouraged that this proposal has surfaced although there are many questions remaining with particular reference as to how this proposal would affect the use of respirators and the kinds of respiratory protection utilized in health care facilities. There are telling experiences about use of types and levels of protection (other than the HEPA currently required by OSHA) that are documented and show safe environments without nosocomial transmission or massive, unexplained PPD conversions by workers. It is because of this last statement that GNYHA remains concerned that any new standard adequately reflect the kind of environment in which health care is conducted and other engineering, administrative and other environmental activities have already been undertaken to better assure a safe environment.

GNYHA is also attaching the Association's oral testimony delivered at the hearings which makes the point that there have been outbreaks that have been resolved without the use of current requirements and there have been institutions, (many, in fact,) that have not had any massive, unexplained PPD conversions or nosocomial transmissions without the use of currently required respirators.

Therefore, we would argue that the current requirements are excessive when taken in conjunction with engineering and administrative controls and that any new requirements must adequately reflect the scientific information and evidence available from institutions on the current situation relative to TB control in hospitals. In fact, we would very strongly argue that facilities without outbreaks and massive unexplained PPD conversions should be permitted to utilize the least restrictive, most comfortable, perhaps less "high tech" respirator such as the current DM, as long as they can demonstrate a good outcome. No one should be required to raise the level of protection of respiratory protection if it, in conjunction with other engineering and administrative controls, is working.

Yours truly,

Elizabeth Sommers Strevey
Senior Vice President
Regulatory and Professional Affairs

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attachments

GNYHA COMMENTS ON SPECIFIC SECTIONS OF NIOSH PROPOSAL

Fit Testing

[84.181] There is concern with this section. Given that disposable respirators are the respirator of choice for most hospital settings, it is essential that workers and management are confident that these types of respirators provide adequate protection. The greatest concern about disposables is the ability to get a good fit. This section perpetuates two different sets of criteria for fit testing disposables compared to replaceable filter respirators (84.182). "Talking" should be added to the protocol to provide better simulation to health care workers' environment.

In addition, in order to meet the CDC draft guidelines, the respirator must also be able to be capable of reliable fit testing as well as able to be reliably fit checked. This issue should be addressed. A requirement of the standard might be to have the manufacturer develop acceptable methods for fit testing and checking by the user. This should be part of the certification process. (Why put the burden of determining adequate fit testing and checking on the employer and worker? It should be up to NIOSH to establish effective standards for fit testing and checking disposables and up to the manufacturers to show they can meet this standard.)

Methodology

There are many questions relating to the correlation between the particle testing being proposed and the efficiency of respirators to remove bacterium and droplet nuclei. Some are unconvinced by this document that a single test for all particulates is reasonable. From the conservative side, the following is raised:

- The new certification would employ either a sodium chloride aerosol (mean particle size = 0.06-0.11 micrometers, or a dioctyl phthalate aerosol (mean particle diameter = 0.17-0.22 micrometers). At the lowest level of certification a particulate respirator would filter at least 95% of the sodium chloride aerosol. It is not clear that one can infer from the data obtained in the certification test, the filtration efficiency of the filter against a larger particle, such as bacterium or droplet nucleus. One could only say that it will be at least the efficiency shown against the smaller particle.

- Do all particles of various shapes and sizes behave the same? (Asbestos are fibers. Droplet nuclei are large, wet somewhat spherical particles. Any impact of shape on filtration?)

- Is a droplet nuclei considered a liquid or a solid?

- Is there anything about a bacterium that would impact on the filtration ability of the respirator?

All of these questions should have been addressed in the supplementary information section.

Additionally,

1. Will the 95% filter efficiency meet OSHA standards? It is not clear if this testing protocol includes leakage.

2. It is important to get clarification on the relationship between the Assigned Protection Factors (APFs) and the three proposed filtration efficiency levels. If OSHA requires a high APF for infectious tuberculosis, perhaps the 95% efficiency level respirator would not be adequate although that appeared to be the intent.

STATEMENT OF THE
GREATER NEW YORK HOSPITAL ASSOCIATION
ON NIOSH'S PROPOSED RULE
ON RESPIRATORY PROTECTION DEVICES AT THE NIOSH
INFORMAL PUBLIC HEARING
Friday, June 24, 1994

Good morning. My name is Elizabeth Sommers Strevey, and I am the Senior Vice President for Regulatory and Professional Affairs of the Greater New York Hospital Association. The Greater New York Hospital Association (GNYHA) represents the interests of 167 not-for-profit voluntary and public hospitals and nursing homes in New York City and surrounding suburbs. On any given day, GNYHA's members care for more than 800 adults and children with confirmed or suspected tuberculosis (TB). GNYHA's members employ more than 200,000 health care workers (HCW), many of whom come in contact with these 889 patients in variety of ways. Questions of the level of proper protection and HCW comfort and compliance have been raised with implementation of the recent HEPA respirator requirements by OSHA. We come, therefore, to this hearing on behalf of our patients and our workers to discuss what would appear to be a new positive direction in terms of patient care, worker safety and cost effectiveness relative to the quality of the respiratory protection to be utilized in our members' facilities.

As you likely know, New York State, and particularly New York City, have been at the epi-center of the TB epidemic, and, as such, have been grappling with issues related to infection control and TB transmission for some time. Unfortunately, over time, there have been instances of nosocomial TB transmission both to other patients as well as to employees in New York and elsewhere. In the incidents that have been documented, enhanced, rigorous adherence to traditional infection control practices relative to reducing and mitigating transmission of air-borne diseases have proved effective in combating and eliminating nosocomial transmission. To our

knowledge, in none of the outbreaks that have been controlled was the use of the currently required HEPA respirator undertaken as a control measure. In point of fact, we have gone back to the basics that we have known about for some period of time, and by employing the basics in a rigorous and consistent manner, have broken the backs of outbreaks both in New York and elsewhere.

Therefore, the hospitals, on behalf of their patients and employees, greet NIOSH's new proposed regulatory requirements with very positive and significant interest. As hospitals have attempted to comply with OSHA's requirement for HEPA respirators, they have encountered a series of problems in effecting legitimate and comprehensible communication with patients while wearing the respirator and have also encountered many, many complaints and concerns from employees who find the respirators constraining, difficult to breath through, and otherwise hot and uncomfortable. Additionally, many employees have been forced to shave facial hair or to utilize higher levels of protection (with other attendant problems) given the current situation and the rules.

As relates to the cost, the expenditures being incurred when mounting a fully functional respiratory protection program that includes the use of either reusable or disposable HEPA filtered particular respirators are extremely high. While GNYHA had originally estimated an incremental cost of 40 million dollars or more for its members, the cost is more likely to be around 65 million dollars. The funds come from hospitals with negative or barely break-even margins. These expenses have diverted and will continue to divert resources from proven techniques for mitigation of disease transmission such as engineering and administrative controls. Hospitals that spend one-half million or 1 million dollars more for respirators cannot dedicate that money for re-engineering and re-ventilating presumable risky emergency departments and their waiting rooms, for example.

NIOSH's new proposal offers the manufacturers an opportunity to develop respirators that meet the needs of the health care community in terms of disease prevention, ease of use, comfort, and cost. While we have not yet critiqued the proposed rule from a technical standpoint, the initiative itself and its stated intent are sufficient to suggest to us that NIOSH and the Federal

Government are heading in the direction of reinserting science into this equation while continuing to protect health care workers and marshalling scarce resources for the proven techniques of disease transmission control. We are, therefore, extremely supportive of this change in direction.

GNYHA plans to submit more formal technical comments by the July 22, 1994 deadline, but wanted to be sure that, as we have historically voiced loud complaints about the current OSHA requirements, we are now heard voicing encouragement in moving forward toward more science, more comfort, more compliance, less cost and more sanity in this area.

We continue to stand ready to work collegially and cooperatively with any and all organizations to ensure that the ultimate result of this process, hopefully expedited, will better ensure worker safety, high quality patient care and cost effective use of limited resources.

Thank you for the opportunity to share our views.