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July 14, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, OH 45226

Dear Colleagues:

I am herewith submitting to you in my role as Chairman of the Hospital Infection Control Practices Advisory Committee (HICPAC) our comments concerning the NIOSH proposed rule on respiratory protection devices. If I may be of further assistance, please do not hesitate to be in touch with me. Thank you very much.

Yours sincerely,



Walter J. Hierholzer, Jr., M.D.
Chairman, HICPAC

cbm
Enclosure
NIOSHREM

JUL 18 1994

**STATEMENT OF HICPAC ON
NIOSH'S PROPOSED RULE ON RESPIRATORY PROTECTION DEVICES**

As the Chairman of the Hospital Infection Control Practices Advisory Committee (HICPAC), I would like to offer support and comment on the proposed rule for certification of respiratory protective devices. Comments have been added to our presentation made at the Washington meeting. These are in great part to address issues raised by other individuals and groups presenting at that meeting. HICPAC thanks NIOSH for the opportunity to comment on the notice of proposed rule-making on respiratory protective devices.

HICPAC is a 12-member Advisory Committee chartered in 1990 by the Secretary of the Department of Health and Human Services to provide advice and guidance to the Director, CDC, and the Director, National Center of Infectious Diseases regarding the practice of hospital infection control and strategies for the surveillance, prevention, and control of nosocomial infections in U. S. Hospitals. HICPAC activities include the preparation, review, and publication of Guidelines, information exchange with CDC staff and other CDC advisory committees, concept reviews of education and research initiatives relative to hospital infections, and assistance in strategic planning and program review.

HICPAC would note that Nosocomial Infection Control Programs have always been concerned not only with the transmission of infectious diseases between patients but also with the bi-directional spread between patients and health care workers.

At its recent meeting in June, 1994, HICPAC began the process of developing organization for the fifth of its current Guideline reviews. This Guideline will be devoted to the issues

of infection control and the health care worker. We look forward to NIOSH assistance with that document.

For the purposes of the present discussion, HICPAC is especially interested in and concerned with those portions of the proposal which reflect on the personal respiratory protective devices applicable to use in the care of patients with infectious pulmonary tuberculosis. The resurgence of this airborne disease and the increase in its multi-drug resistant forms has led to several well-described epidemics of nosocomial spread of this disease to other patients and to health care workers with resultant serious disease and, in some cases, death.

HICPAC strongly supports the routine use of the CDC 1990 Guideline for the Control of Tuberculosis and with major portions of the proposed draft 1993 revision and has joined in the review and comment on that revision. HICPAC is of the consensus opinion that the Respiratory Protection recommendations detailed in Section G of the October 12, 1993 Draft Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities and the Performance Criteria, and other technical specifications in Supplement 4 (Respiratory Protection) of the same document, not only meet but probably exceed the requirements for respiratory protection and personal safety for health care workers caring for patients with infectious pulmonary tuberculosis. This is especially so when these features of a Personal Respiratory Protection Program are combined with the appropriate Administrative and Engineering Controls outlined in the same document. HICPAC feels that this opinion is supported by evidence in the historical information of several institutions (which is just beginning to appear in published form) and in the

successful, documented control of several of the epidemic outbreaks of tuberculosis investigated and reported by the CDC, wherein transmission to health care workers was controlled by appropriate application of the 1990 Guidelines using disposable personal respirators, which are less efficient than the 1993 draft proposal.

We are concerned, based on other testimony, that the technical specifications of the TB or "type C" respirator mask not exceed those required for use in the care of patients with transmissible pulmonary tuberculosis. While added technical specifications to provide a combined solid/liquid capability for the "type C" respirator mask may increase the probability of appropriate use in some industries, it apparently would not add value for TB control but would add appreciably to certification and purchase costs for the health care industry. The concern for appropriate use in other industries might be better dealt with by special coloring or other marking for a respirator limited to health care use. We were also made aware in the discussions that the protective value of a respirator mask (APF's) might be best served by indicating a range of efficiencies and particle sizes to allow equivalent protection, since the cost of media for the respirators (and the final respirator cost) might be optimized through this method.

We are especially gratified that NIOSH is recommending in the current document that certification of the particulate respirators applicable to the TB guideline technical recommendations be given some priority in hope that the time line to manufacture and certification of a disposable personal protective respirator for use in the care of TB patients will be as short as possible. We were alarmed at the suggestion in the Washington presentations that times to implementation might be as long as two to four years.

Currently we are caught in a difficult situation in health care. In order to protect our health care workers, (based on the 1993 draft TB recommendations) and to meet the requirements of the law under OSHA standards, we are forced to obtain and use a form of protective respirator that is technically excessive, not designed for clinical use, expensive, limited in configuration, and in inadequate supply. Obviously, it is a solution that is not well suited to our needs. As you know, this has come about since OSHA, under its general duty clause, is now requiring the routine use of HEPA-filtered respirator protective devices since, unfortunately, they are the only NIOSH-certified devices meeting the intent of the 1993 draft proposal. The difference in cost between the currently available HEPA devices and projected costs of simpler devices meeting the technical specifications of the Draft 1993 TB guidelines would appear to be 3 to 5 fold. For an institution of the size of Yale-New Haven Hospital (approximately 900 beds), evaluating over 70 patients each month for TB, that difference in cost will range between \$150,00 and \$600,000 per year. Fortunately, in our environment only one of these 70 patients is confirmed to have active, potentially infectious pulmonary TB at the end of our diagnostic evaluations. The expense to adequately protect ourselves from infection during the care of that single TB patient is obviously high. Nonetheless, we are willing and feel that we must handle each potential case appropriately, including respiratory protection, as though they present a risk situation until the diagnosis is excluded. However, we must do so efficiently and with optimum methods if we are to avoid excessive costs and needless transfers of critical funds from other programs, including the critical administrative and engineering controls that are the most productive features of TB control. Following the presentations in Washington, we

have residual concern that the "type C" respirator mask specifications would be widened to improve its use in other industries and that these added specifications would both add to the cost and delay the implementation of certification.

With the production and certification of an "appropriate TB respirator mask," we would ask for assistance in developing highly efficient and easily implemented training and fit-testing protocols. These protocols should not only provide details for the initial training and fit testing of health care workers but also guidance or easily applied maneuvers to assist the health care worker with the appropriate seating of the mask at each use. If these protocols are not to be a part of the certification process, they must be immediately available from OSHA in order not to have a replication of the designation of a respirator mask which cannot be used for lack of availability or administrative detail to allow its correct use.

As with the introduction of all new devices, we would argue for at least a brief period of appropriate field testing at pilot institutions before final introduction. This testing should include both the fit testing and proposed in-use protocols and should continue in some form of post-marketing surveillance to identify potential problems and improvements. We do NOT suggest a significant delay in introduction as a result of this evaluation but wish to avoid potential accidents within our user populations as a result of unrecognized product dysfunction or misuse.

HICPAC will be delighted to continue to work with NIOSH and our other collaborators at the CDC in this and other projects in the areas of infection control and again thanks NIOSH for the opportunity to comment at this time.