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National Center for Infectious Diseases
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MESSAGE

Attached are comments from Walter J. Hierholzer, Jr., M.D., Chair, Hospital Infection Control Practices Advisory Committee (HICPAC) regarding proposal for certification of particulate respirators.

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CDC

COMMENT DELIVERED TO NIOSH
ON BEHALF OF HICPAC CONCERNING
PROPOSAL FOR CERTIFICATION OF PARTICULATE RESPIRATORS
W. J. HIERHOLZER, JR. MD. - CHAIR HICPAC

Good Morning. I am Dr. Walter Hierholzer the Hospital Epidemiologist at Yale New Haven Hospital in New Haven Connecticut. I am here today as the Chairman of the Hospital Infection Control Practices Advisory Committee (HICPAC) to offer support and comment on the proposed rule for certification of respiratory protective devices.

HICPAC is a 12-member Federal 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 thanks NIOSH for the opportunity to comment on the Notice of Proposed Rule-making on Respiratory Protective Devices.

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 earlier this month, HICPAC began the process of developing the organization for the 5th 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 today's discussion, HICPAC is especially interested 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 describe 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 most portions of the proposed draft 1993 revision and has we have 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 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 those recommended in the 1993 draft proposal.

We are especially gratified that NIOSH is recommending in the current document that certification of the particulate respirators applicable to TB 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. 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 force 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 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 content of the 1993 draft proposal. The difference in cost between the currently available HEPA devices and the 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 to 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 paticnts 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. None the less, we are willing, and feel that we must handle each potential case appropriately including respiratory protection 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.

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 mancuvers to assist the Health Care Worker with the appropriate seating (or fitting) of the mask at each use.

Finally, 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, our other collaborators at the CDC, and other professional groups in this and other projects in the areas of infection control.

HICPAC again thanks NIOSH for the opportunity to comment at this time. I would be pleased to answer any brief questions that you might have. We will deliver these comments in written form within the next two weeks.