Statement of the Society for Healthcare Epidemiology of America on the Rule Proposed by the National Institute of Occupational Safety and Health (NIOSH) Concerning Respiratory Protection Devices at the NIOSH Informal Public Hearing June 23, 24, 1994 Washington, D.C.

Mr. Chairman, Ladies and Gentlemen, I am David Henderson and I am the Associate Director of the Warren G. Magnuson Clinical Center – the hospital – at the National Institutes of Health in Bethesda, Maryland. I am here today to represent The AIDS and Tuberculosis Committees of the Society for Healthcare Epidemiology of America (SHEA), chaired by Dr. Michael Tapper from Lenox Hill Hospital in New York City. SHEA is an organization composed of several hundred individuals trained at the doctoral level who are responsible for hospital epidemiology and infection control programs in hospitals and clinics across America. As is the case for the other speakers here this morning, I come to speak about the proposed rule that discusses certification requirements for respiratory protection devices, specifically as the rule would apply to devices used in the healthcare environment.

Whereas SHEA shares the concern of the U.S. Public Health Service and other organizations about the marked rise in reported cases of tuberculosis in the United States, and we specifically are concerned about the dramatic increase in reported cases of multiply drug-resistant tuberculosis in the cities of the United States, we also have substantial concern about the face of healthcare in the United States in the 1990's and beyond. Any strategy that we, as a country, develop for the control of tuberculosis in the United States must be grounded firmly in science and must, I believe, be broadly applicable to all healthcare institutions throughout our country. Among the strategies that appeal most to us as an organization focusing on hospital epidemiology is the concept of risk assessment. Because of the complexity of the problem presented by the airborne spread of drug-resistant tuberculosis and because of the non-homogeneity of the problem throughout our country, a sensible approach to risk-assessment, modeling prevention strategies appropriate to the various levels of risk for each institution, appears most sensible to us. Applying a broad-based, "one-size-fits-all" set of recommendations to all healthcare establishments in the country seems needlessly expensive, quite labor-intensive, and virtually impractical. We believe fervently in fitting the appropriate prevention strategy to a carefully evaluated, definitively determined level of risk.

We concur with the approach, initially presented several years ago by the National Institute of Occupational Safety and Health (NIOSH) basing tuberculosis prevention efforts on the implementation of a hierarchy of controls in the healthcare environment. We concur with the previously published hierarchy: that is, that administrative controls remain the most important, engineering controls next most important, and that the use of personal protective devices represent the third most important strategy to reduce the risk for transmission of tuberculosis in the healthcare setting. Primary efforts simply must be expended on identifying cases of tuberculosis, managing such cases appropriately, and making certain that therapy for active tuberculosis is completed appropriately.

SHEA has been vitally interested in the Draft Guidelines for control of tuberculosis in healthcare settings, published in October of 1993 in the Federal Register by the Centers for Disease Control. We have felt that – despite the fact that the guidelines emphasize the two crucial concepts of a hierarchy of controls and a risk-assessment-based prevention strategy – these guidelines nonetheless overemphasize the importance of respiratory protection devices as a primary prevention strategy. Further, we have been concerned that only respiratory protection devices that employ high efficiency particulate air (i.e., HEPA) filters would meet the criteria published earlier by NIOSH. We endorse the concept that the Centers for Disease Control has proffered that respiratory protection devices should provide 95% filter efficacy of particles 1.0 micron and larger, and note that previous testing procedures for other respiratory protection devices (e.g., so-called dust-mist, and dust-mist-fume protection devices) were not specifically designed for use this type of use nor were they designed for use in the healthcare setting.

We enthusiastically endorse the adoption of these new proposed regulations which would result in the establishment of a new class (i.e., Class C) of respiratory protection devices that would meet or exceed the CDC's published performance characteristics. Should this regulation be adopted, we believe that a much broader variety of respiratory protection devices – each of which offers an appropriate, effective level of respiratory protection – would meet these testing requirements and therefore would become available for use in the healthcare setting.

At a time when all of us are focusing on the dramatically increasing costs of healthcare, implementation of these cost-effective, sensible guidelines seems both prudent and highly advisable.