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UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

**RESPIRATORY PROTECTION USED FOR INFECTIOUS DISEASE AND ANNUAL
FIT-TESTING**

1. Background

a. **Respiratory Protection In Health Care.** Use of respiratory protection strategies have become essential to health care and occupational health since the early 1990s, when the Centers for Disease Control and Prevention (CDC) promulgated the Guidelines for Tuberculosis Control in Healthcare Facilities (see subpar. 3b). Those guidelines have become the mainstay of tuberculosis (TB) control programs in hospitals, nursing homes, and residential facilities. Essential elements included:

(1) Development of a respirator program that required initial (but not annual) fit-testing of respirators that require a face-to-facepiece seal, including elastomeric respirators equipped with cartridges and filtering facepiece respirators to evaluate the fit of the respirator on an individual,

(2) Worker training and education.

(3) Medical surveillance.

(4) Construction of negative pressure isolation rooms.

(5) Early identification (“source control”) of patients with active TB.

***NOTE:** In parallel, the National Institute for Occupational Safety and Health (NIOSH) developed a respirator classification that identified the N95 disposable respirators (Title 42 Code of Federal Regulations (CFR) Part 82).*

b. **Current Thinking on the Epidemiology of TB.** TB has decreased dramatically as an occupational disease among health care workers, even in the absence of annual fit-testing (see subpar. 3h). Where skin test conversions have occurred, several different theories pertain. First, TB exposure may occur outside of the health care setting, in the place of residence (see subpar. 3a). Second, where homogenous groups of lower income individuals have been examined, occupational exposures (prevalence of TB among clients) has been shown to correlate with skin test conversion (see subpar. 3c). Third, actual ventilation rates in the health care facilities (see subpar. 3d) appear to play a role, together with failure to identify active TB cases. Overall, the

widespread perception holds that TB transmission is no longer due to failure of existing protection strategies within health care facilities, but to exposures in the community, or a failure to implement effective identification of cases within facilities.

c. Respiratory Protection and (Severe Acute Respiratory Syndrome) (SARS) and Other Emerging Respiratory Infections. The epidemic of SARS in 2002-2003 led to the development of a formal strategy for the containment of emerging respiratory infections that are transmitted both through contact (requiring barrier precautions), droplets (requiring droplet precautions, i.e., surgical masks), or aerosols (requiring airborne precautions). This strategy requires use of respirators with at least N95 filtration capability. *NOTE: The use of N95 respirators is not required. N95s are minimum acceptable filter efficiency. N99s or N100s may also be used.* It also requires that facilities adhere to all the provisions of the respirator standard (29 CFR 1910.134), including annual fit-testing for respirators that require a face-to-facepiece seal. Powered Air Purifying Respirators (PAPRs) with loose-fitting hoods or helmets are exempt from the fit-testing requirements. PAPRs may be shared by staff if they are maintained and disinfected in accordance with OSHA regulatory requirements. Consideration needs to be given to their initial costs and maintenance needs. *NOTE: Additional strategies are described in Standard Operating Procedure 7.2.3 Infection Control in the newly revised Emergency Management Program Guidebook.*

d. Tuberculosis Standard and Facility Consequences. OSHA issued a Notice of Proposed Rule-making (NPR) based closely on CDC guidelines. OSHA's proposed standard required facilities to conduct an initial, but not annual, fit-testing of respirators that required a face-to-facepiece seal. OSHA withdrew that NPR in 2004. Withdrawal of the NPR caused respiratory protection using respirators for protection from TB to fall under the current OSHA Respiratory Protection Standard, 29 CFR 1910.134, which mandates initial and annual fit-testing of respirators that require a face-to-facepiece seal. The implementation of fit-testing as required by 29 CFR 1910.134 was controversial for several reasons. Staffing limitations made annual fit-testing burdensome. Public health agencies, professional societies, and regulatory agencies cited shifts in TB epidemiology and opined that annual fit-testing of respirators was unnecessary. Other agencies and experts felt strongly that annual fit-testing was an essential element of all respiratory protection programs and needed to be implemented. In response to the controversy, Congress passed an amendment to the 2005 Omnibus Appropriations bill that prohibited OSHA from using funds to enforce the annual fit-test provision of the respirator standard for hospital TB programs (see subpar. 3f). The language does not preclude enforcing initial fit-testing for respirators used for protection from TB or for annual fit-test provisions for other diseases and strategies. In summary, contradictory regulations exist. Title 29 CFR 1910.34 mandates annual fit-testing of respirators that require a facepiece seal. A subsequent amendment to an appropriations bill prevents the annual fit-test requirements under that regulation from being enforced for TB, but those requirements remain in force for other respiratory infections. Appropriations bills for future years may, or may not, include such a prohibition. This contradiction presents a dilemma for health care facility leadership in deciding how to implement the best respiratory program for their facilities.

2. **Decision-based Approach for VHA Facilities.** VHA staff have inquired how best to address annual fit-testing for respiratory infectious diseases, given the contradictory regulations, the new evidence on risk of in transmission of TB within health care facilities, the concern over emerging respiratory infections, and the desire to protect staff and patients while using their time efficiently. Since the greatest concerns rests on potential for serious transmissible infections like SARS and other emerging infections, the following approach is suggested:

a. Facilities may wish to identify and designate a minimum number of individuals required to support current infectious disease programs based on local needs and a clear strategy. Individuals identified to wear a respirator must undergo initial and annual fit-testing, as defined in the current OSHA standard 1910.134.

b. The number of staff included in the program may depend on the protection strategy, but is likely to include some emergency room and/or urgent care unit staff and staff to support the negative pressure rooms on all three shifts.

c. The facility preparedness plan may address how to conduct medical evaluation and fit-testing of additional needed staff on the next working day or on that same shift, either through the use of an industrial hygienist or a trained staff member, functioning as a collateral-duty respiratory fit-test technician. *NOTE: Medical evaluation and/or fit-testing must be conducted before the respirator is used for the first time. Next-day or same-shift medical evaluation and fit testing after exposure does not meet the requirements of current OSHA standard 1910.134.*

d. Collateral-duty respiratory fit-test technicians to assist in just-in time fit-testing programs could be identified.

e. To assist in prioritizing fit testing, the following questions need to be added to the mandatory respiratory protection Medical Evaluation Questionnaire (a questionnaire containing the pertinent questions as defined in OSHA 1910.134):

(1) Have you gained or lost 10 pounds or more in the last year?

(2) Have you had dental procedures with tooth removal or prostheses in the last year?

(3) Have you had jaw surgery in the last year?

(4) Have you used a respirator with a tight-fitting facepiece, such as an N95 or a PAPR, in the last 6 months at work?

(5) When were you last fit tested for the respirator(s) you are currently using?

3. **References**

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d. Menzies D, Fanning A, Yuan L, FitzGerald JM. “Hospital Ventilation and Risk for Tuberculous Infection in Canadian Health Care Workers. Canadian Collaborative Group in Nosocomial Transmission of TB,” Ann Intern Med 133:779-89: 2000.

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f. OSHA Standard Interpretations 12/22/2004 - Tuberculosis and Respiratory Protection: Prohibition of Enforcing Annual Fit Testing Requirements During 2005 Fiscal Year; Enforcement of Other OSHA Standard 1910.134 Provisions. See website at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=24977 .

g. Sepkowitz K, Discussion at OSHA-NIOSH-CDC Consensus Conference of Respiratory Protection in Healthcare, Atlanta, GA. November 30-December 1, 2004.

h. Sepkowitz KA. Tuberculosis Control in the 21st Century Emerging Infectious Diseases. 2001.

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