

COMMITTEE POSITION PAPER OF ABSA ON OSHA'S PROPOSED RULE ON OCCUPATIONAL EXPOSURE TO TUBERCULOSIS

On February 17, 1998, the American Biological Safety Association (ABSA) filed a Notice of Intent to Appear in the matter of the Occupational Safety and Health Administration (OSHA) proposed rule concerning the *Occupational Exposure to Tuberculosis* (Federal Register 62:54159-54308), Docket Number H-371 (proposed rule). The testimony to be delivered by an ABSA representative follows:

General Comments

ABSA believes tuberculosis (TB) is a serious public health concern and appreciates the active interest the OSHA has in controlling the impact of this disease in the workplace.

ABSA commends OSHA for incorporating sound biosafety principles currently in use and advocated by biosafety professionals into the proposed rule. Adopting principles from primary biosafety resource documents such as the Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) reinforces proven practices already in use. BMBL is re-published approximately every five years to include updated information on engineering controls, administrative procedures, and specific work practices for laboratories that work with infectious agents. ABSA commends OSHA for incorporating resources such as BMBL by reference, where practical, as that allows for future flexibility in applying recommendations published by these organizations.

ABSA believes performance-based regulations provide greater benefits for all, and applauds OSHA's effort to make this standard performance-based. ABSA believes that performance-based standards provide the flexibility needed by biological safety professionals to address workplace hazards based on the risks posed in the different work environments.

OSHA requested input regarding the need for laboratory specimens to be labeled. ABSA feels there is no need for special labeling practices for specimens from TB patients. *M. tuberculosis* will be present overwhelmingly in sputum specimens from untreated TB patients and less frequently in other

body fluids and tissues. The standard practice at most laboratories is to open any sputum specimen in a biological safety cabinet. Therefore, worker safety would not be compromised without the label. Patient confidentiality considerations should be considered if additional labeling is required.

OSHA is to be commended for not requiring the use of a respirator for employees who are using a biological safety cabinet. If the biological safety cabinet has a current certification record and the employee has been trained in the proper safe work practices, additional protection is not needed. If work is done outside the biological safety cabinet, the proposed rule requires respiratory protection for those workers. OSHA has handled this issue particularly well.

In the proposed rule preamble, OSHA recognizes that ultraviolet (UV) light is not an acceptable means of primary engineering controls for controlling aerosolized *M. tuberculosis*. The comprehensive appendix (Appendix D) on how to select and maintain UV light systems, could be misconstrued as an endorsement of UV light as a primary engineering control. In order to clarify OSHA's position, it should be stated in the proposal's text that UV light is not an acceptable primary containment system for aerosolized *M. Tuberculosis*.

Section (a) Scope

ABSA seeks clarification as to whether the scope of the proposed regulation includes industry-based first aid squads and occupational medical offices under the category of emergency medical services. Industry-based first aid squads and occupational medical offices often provide services to an employee population with a TB risk lower than that of the general population. If these groups are included under the regulation, ABSA would appreciate a further reduction in their responsibilities. ABSA recommends their responsibilities be limited to a documented risk assessment that identifies the lower risk of this employee population to demonstrate that no additional measures (e.g., exposure control plan) need be taken.

Section (b) Application

ABSA appreciates OSHA's effort to provide employers with reduced responsibilities under circumstances in which the probability of exposure to TB is reduced. However, the proposed exemption from certain provisions is currently too limited to be of real value or to really assist employers whose employees have a very low or no risk of TB exposure. In addition, the remaining requirements do not necessarily address the real risk of exposure to TB.

The current exemption still requires the employer to establish a complex written Exposure Control Plan. Such a plan is facility specific in its intent and therefore, needs to be established within a facility. However, the proposed standard includes agencies and organizations that provide external services (e.g., social work, legal services) to facilities like hospitals, long term care facilities, and so forth...(as listed in 1910.1035 Scope). How can social services, police departments, attorney offices, schools and universities establish an Exposure Control Plan for facilities for which they have no control or jurisdiction? How can these agencies determine or document the number of confirmed TB cases in such facilities when they don't operate, manage or control the hospitals or nursing homes they occasionally visit?

To require the same complex Exposure Control Plan of employers performing high risk procedures in a hospital setting as well as the attorney office providing legal services to somebody in a nursing home does nothing to address or manage the real risk of TB in the work place for the attorney.

In addition, OSHA fails to provide any information on occupational exposure rates for these groups. Rather OSHA states "Thus, although the data on employee conversion rates in other work settings cannot be used to directly quantify the occupational risk of infection for those work settings, there is strong evidence that employees in various work settings other than hospitals can reasonably be anticipated to have exposure to aerosolized *M. tuberculosis* and that TB can be transmitted in these workplaces when appropriate TB infections control programs are not implemented."

This statement not only reemphasizes the difficulty of assessing the real risk to social workers, attorneys, police officers and others, it also clearly

identifies the responsibility as being facility specific. For example, the hospital has the responsibility for providing a safe work environment, the nursing home has the responsibility for ensuring the appropriate management, etc. This also includes providing the necessary information to outside agencies and services who may be performing work in those facilities.

ABSA recommends that OSHA establish a clearly defined exemption category with its own unique minimal requirements which addresses the real risk of exposure for employees from social services agencies, police departments and others. If a written plan is deemed necessary, it should be limited to post-exposure follow-up and initial training/information without annual retraining requirements. One challenge for the protection of these individuals is how to protect the police officer, or social worker that has to question a patient with suspected TB sitting in an acid fast bacilli (AFB) isolation room. The primary protection for these individuals in this situation is the proper signage of and the procedures in place for the AFB isolation room which address personal protective equipment needs prior to entry.

Exemption should be granted to all employers whose employees do not perform or are not involved in high hazard procedures and do not admit or provide medical services to individuals with suspected or confirmed infectious TB. All additional requirements such as no confirmed TB cases and certain county TB rates are unnecessary, since they do not take the real risk of exposure into consideration. What difference does it make for the attorney if the county had 0 or 1 confirmed infectious TB case in a certain year? What difference does it make to a social worker visiting a certain nursing home if another social worker from the same agency acquired TB at home and is on medical leave?

The key to protecting these workers is to establish appropriate procedures at the facilities they are visiting.

Section (c) (2) Exposure Control Plan

It is not clear in whether the Tuberculosis Exposure Control Plan may be combined with a facility's Bloodborne Pathogen Exposure Control Plan or whether it must be a separate Plan. ABSA recommends that employers be allowed to establish and

maintain a single Exposure Control Plan. This would reduce unnecessary duplication of information for multiple Exposure Control Plans.

Section (e) Clinical and Research Laboratories

This section identifies requirements that pertain to both clinical and research laboratories and establishes additional requirements for research laboratories. The requirements are a subset of the guidance provided in BMBL for Biosafety Level 2 and Biosafety Level 3. BMBL offers the following guidance for determining the appropriate biosafety level:

The recommended biosafety level(s) for the organisms in Section VII (Agent Summary Statements) represent those conditions under which the agent can ordinarily be safely handled. The laboratory director is specifically and primarily responsible for assessing risks and for appropriately applying the recommended biosafety levels. Generally, work with known agents should be conducted at the biosafety level recommended in Section VII. When specific information is available to suggest that virulence, pathogenicity, antibiotic resistance patterns, vaccine and treatment availability, or other factors are significantly altered, more (or less) stringent practices may be specified.

Following that guidance, ABSA recommends that section (e) of the proposed rule be modified as follows in order to ensure laboratories adopt the complete, proper biosafety level(s) for their specific activities:

(e) (1): No change.

(e) (2): No change.

(e) (2) (i) - (e) (2) (ii) (E): Replace with the following:

(i) The laboratory director is specifically and primarily responsible for assessing risks and for implementing the biosafety level(s) identified in the Exposure Control Plan. The laboratory director shall prepare or adopt a biosafety manual which meets the following criteria:

(A) Provides the identification and assessment of the special hazards posed by the laboratory activities involving *M. tuberculosis*.

(B) Adopts a combination of standard and special practices, safety equipment and facility requirements that are specifically appropriate for the operations performed, the routes of infection, and the laboratory function or activity per the biosafety level identified in the Exposure Control Plan.

(e) (2) (iii) (A): Change to allow the use of a certified Class 2 or Class 3 biological safety cabinet.

(e) (2) (iii) (B): ABSA supports the certification requirements of this section but recommends the adoption of the following statement based on the CDC document *Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets*:

The operational integrity of a BSC shall be validated by certification before it is put into service and after a cabinet has been repaired or relocated. Relocating a BSC may break the HEPA filter seals or otherwise damage the filters or the cabinet. Each BSC shall be tested and certified at least annually to ensure continued proper operation.

(e) (2) (iv): As written, there is some question as to how "as near as feasible" may be interpreted. BMBL provides packaging recommendations that allows either decontamination outside the immediate laboratory or decontamination off-site. This provides flexibility in the development of waste management procedures at a facility. ABSA recommends that this strategy be adopted by OSHA. The fact that the U.S. Department of Transportation, in granting its 1996 packaging exemption, recognized that current medical waste packaging and transportation practices for *untreated* discarded cultures and stocks of Biological Safety Level 3 agents such as *M. tuberculosis* pose no adverse risk to human health or the environment supports this strategy.

(e) (3): This section would not be necessary under the ABSA proposed (e) (2) (i) (B) above.

(e) (3) (i) (A): As a point of information

ABSA recommends that all laboratory doors be kept closed when work involving *M. tuberculosis* is in progress, and not just limit this requirement to research laboratories. Voluntary standards (National Fire Protection Association and the American Society of Heating, Refrigerating and Conditioning Engineers) indicate biological and chemical laboratories should be negative to the corridor and have single-pass air. In the event of a laboratory mishap, occupants in areas surrounding the laboratories will be protected if the doors remain closed. An expansion of OSHA's proposed requirements to include all clinical and research laboratories will provide greater employee protection.

Section (f) Respiratory Protection

(3) (i): This requires employers to "select and provide properly fitted negative pressure or more protective respirators." ABSA believes there is an opportunity for misinterpretation of "more protective respirators." Alternative wording that would provide clarification would be "N95 respirators which have met the NIOSH certification criteria detailed in 42 CFR Part 84 or powered, air-purifying (positive pressure) respirator."

Section (g) Medical Surveillance

The proposed rule indicates that medical surveillance is to be done in accordance with CDC recommendations. OSHA recognizes in the preamble that medical knowledge of TB disease is dynamic. OSHA states that it believes that it is the employer's responsibility to inform health care professionals of the medical surveillance requirements of the proposed rule. However, TB is a disease with which many health care professionals may lack real experience or education on its management. The OSHA bloodborne pathogen standard (29 CFR 1910.1030) requires employers to provide copies of CDC recommendations to health care professionals performing medical surveillance under the provisions of that standard. This proposed rule should have a similar provision. Such a provision would increase the level of awareness of the employer and it would help to improve the level of medical surveillance provided. Provision of only the pro-

posed rule would not provide enough technical detail to ensure the desired quality of the medical surveillance would be achieved.

Section (g) (3) (i) (E)

ABSA appreciates OSHA's intent behind the requirement for a TB skin test within 30 days of termination of employment. However, this is unenforceable on the part of the employer once an employee has resigned or been terminated. ABSA recommends that OSHA require an employer to provide TB testing within 30 days of employment only if the former employee requests or agrees to be tested.

Section (h) Communications of Hazards and Training

(1) (ii): The use of the universal biohazard symbol is noted as needed to address labeling requirements of the proposed rule. However, a graphic of this symbol is not provided. A graphic or reference to 29 CFR 1910.1030 (g) (1) (B) should be provided for anyone unfamiliar with the universal biohazard symbol.

(2) (iii): The "STOP" sign noted in the proposal will get the attention of people about to enter a patient's room. Trained employees at risk of TB infection should recognize what a respirator is and for what it is used. However, the signage provides no indication as to the type and nature of the hazard within the room. Some employers may have employees on staff who do not go into TB patient isolation rooms. Employers may train only their workers at risk of TB infection. Untrained workers may not recognize the hazards within the room posted in this manner. A posting such as "Airborne Infection Hazard" (or an equivalent) would enhance hazard communication and could prevent exposure events.

(3) (ii) (C): ABSA appreciates OSHA's flexibility in accepting a demonstration of employee knowledge and skill in lieu of an automatic annual re-training requirement. This allowance will enable employers to utilize newer, more efficient and more flexible technologies to demonstrate employee understanding.

(3) (vii): This section is missing the requirements for spill clean-up and decontamination training for an accidental spill of *M. tuberculosis*. This is a critical oversight. Spill training is mentioned in Section (e)(2)(ii)(D) and states "All spills shall be contained and cleaned up by employees who are properly trained and equipped to work with potentially concentrated *M. tuberculosis*." Since it is required, it should be identified in this section.

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Appendix G to Sec. 1910.1035—Smoke-trail Testing Method for Negative Pressure Isolation Rooms or Areas

OSHA has not indicated whether or not this appendix is a mandatory or a non-mandatory appendix. This needs to be clarified.

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