

DEPARTMENT OF LABOR**Occupational Safety and Health Administration****29 CFR Part 1910****[Docket No. H-371]****RIN 1218-AB46****Occupational Exposure to Tuberculosis****AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.**ACTION:** Proposed rule; termination of rulemaking.

SUMMARY: OSHA is withdrawing its 1997 proposed standard on Occupational Exposure to Tuberculosis (TB). Because of a broad range of Federal and community initiatives, the rate of TB has declined steadily and dramatically since OSHA began work on the proposal in 1993. Hospitals, which are the settings where workers are likely to have the highest risk of exposure to TB bacteria, have come into substantial compliance with Federal guidelines for preventing the transmission of TB. Overall reductions in TB mean that all workers are much less likely now to encounter infectious TB patients in the course of their jobs.

In addition, an OSHA standard is unlikely to result in a meaningful reduction of disease transmission caused by contact with the most significant remaining source of occupational risk: exposure to individuals with undiagnosed and unsuspected TB. Particularly outside of hospitals, workers often will not identify suspect TB cases quickly enough to implement isolation procedures and other precautions before exposure occurs.

OSHA recognizes, however, that continued vigilance is necessary to maintain the gains achieved so far. OSHA intends to provide guidance to workplaces with less medical expertise and fewer resources than hospitals, and to use cooperative relationships with employers, public health experts and other government agencies to promote TB control. OSHA will also continue to enforce the General Duty Clause of the OSH Act and relevant existing standards in situations where employers' failure to implement available precautions exposes workers to the hazard of TB infection.

DATES: This withdrawal is effective December 31, 2003.

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SUPPLEMENTARY INFORMATION:**I. Background**

On August 25, 1993, the Coalition to Fight TB in the Workplace petitioned OSHA to promulgate both an Emergency Temporary Standard (ETS) under section 6(c) of the Occupational Safety and Health Act (OSH Act), and a permanent occupational health standard under section 6(b) of the Act to protect workers from occupational exposure to TB (Ex.1). 29 U.S.C. 655(b), 655(c). Citing the resurgence of TB at that time and the emergence and increasing prevalence of multi-drug resistant TB (MDR-TB), the petition argued that a mandatory standard was needed to address the hazards associated with occupational exposure to TB. According to the petition, TB Guidelines developed by the Federal Centers for Disease Control and Prevention (CDC) were not an adequate response to this hazard because the guidelines were not mandatory and were not being implemented fully or rigorously in most workplaces. The petition also requested that, as an interim measure, OSHA immediately issue nationwide enforcement guidelines.

On October 8, 1993, OSHA issued a directive governing enforcement activities to address occupational exposure to TB. (Ex. 7-1-A, updated February 9, 1996) The directive explained that, although OSHA had no standard directed specifically at occupational exposure to TB, some of its generally applicable standards provide protection from this hazard. For example, OSHA's Respiratory Protection Standard, 29 CFR 1910.134, requires employers to provide protection to workers exposed to airborne hazards. When this standard was revised in 1998, the earlier version was recodified as an interim standard governing respirators used to provide protection from TB. (29 CFR 1910.139; 63 FR 1152) (For the revocation of this rule, see the final rule published elsewhere in this separate part of the **Federal Register**) Another standard, 29 CFR 1901.145, requires accident prevention tags to warn of biological hazards. In addition, section 5(a)(1), the General Duty Clause of the Act, requires that each employer:

* * * furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

OSHA compliance personnel were directed to evaluate employers' efforts

to protect their workers from TB at health care facilities and other workplaces where CDC had identified a risk of occupational TB transmission, as well as to respond to complaints about inadequate TB control measures. The TB Directive is still in effect. OSHA has also implemented a number of National and Local 2002-2003 National Emphasis Program (NEP) for nursing and personal care facilities directed enforcement personnel to determine whether each facility where there was a suspect or confirmed TB case within the past six months had implemented appropriate infection control procedures, including isolation procedures and employee skin tests. OSHA conducted 1000 inspections under the NEP this year.

On January 26, 1994, OSHA responded to the rulemaking petition, saying that it was initiating rulemaking on a permanent standard, but would not issue an ETS. On October 17, 1997, OSHA published a Proposed Rule on Occupational Exposure to Tuberculosis (62 FR 54160). In the proposal, the Agency made a preliminary determination that workers in hospitals, nursing homes, hospices, correctional facilities, homeless shelters, and certain other work settings faced a significant risk of incurring TB infection through occupational exposure. The Agency also made a preliminary conclusion that use of established infection prevention and control measures could reduce or eliminate this significant risk. The protective measures OSHA proposed were based in large part on existing CDC guidelines, and included instituting procedures for the early identification and treatment of TB patients, isolating patients with infectious TB in rooms designed to protect others from contact with disease-causing microorganisms, requiring healthcare workers to use respirators to perform certain high-hazard procedures on infectious patients, training workers in TB recognition and control, and providing medical follow-up for occupationally exposed workers who become infected and information to their colleagues with similar exposures.

OSHA accepted comments and held public hearings on the proposed standard in 1998. Additional comments on specific issues were also accepted in 1999 and 2002. (64 FR 32447 (June 17, 1999); 64 FR 34625 (June 28, 1999); 67 FR 3465 (January 24, 2002); 67 FR 9934 (March 5, 2002)) On the latter occasion, OSHA asked for comment on a revised risk assessment and peer reviews of that assessment, as well as on a National Academy of Sciences/Institute of Medicine (NAS/IOM) report,

"Tuberculosis in the Workplace," that Congress had commissioned in 1999. (Exs. 184; 185; 186; 187)

Rulemaking participants represented diverse constituencies, including public health organizations such as the CDC, the American Lung Association's American Thoracic Society, the Infectious Disease Society of America, the National TB Controller's Association, and state and local health departments; labor unions such as the American Federation of State, County, and Municipal Employees and the Service Employees International Union; safety and health professionals and employees working in hospitals, correctional facilities, TB clinics, nursing homes, drug treatment centers and homeless shelters; and professional and trade associations such as the Society of Healthcare Epidemiologists of America, the American Hospital Association and the Association for Professionals in Infection Control and Epidemiology. These groups have extensive experience in TB control, and provided a broad range of perspectives on the issues involved in the rulemaking.

II. Reasons for Withdrawal of the Proposed Standard

OSHA has decided not to promulgate a standard addressing occupational exposure to TB because it does not believe a standard would substantially reduce the occupational risk of TB infection. Many commenters argued forcefully that the proposed rule was based on an overestimate of this risk. In addition, existing TB control efforts, initiated by the Federal government in concert with other public health agencies, have led to a dramatic decline in TB over the past decade, greatly reducing the risk of occupational exposure to TB. Because of these TB control efforts, effective infection control measures are already in place, particularly in hospitals, which is where the occupational risk of TB exposure would be most severe.

Moreover, much of the current occupational transmission appears to occur when workers do not realize that a patient, client, or other contact has infectious TB. An OSHA standard is unlikely to be more effective than the CDC guidelines in eliminating this risk. OSHA believes that workers in many situations, particularly those with limited medical qualifications and resources, will not be able to identify or diagnose currently undiagnosed TB cases frequently and rapidly enough to prevent this transmission from occurring. Risk to workers encountering undiagnosed cases will be reduced most

effectively by reducing even further the incidence of TB in the population as a whole, and therefore in their client populations. OSHA will use technical assistance, outreach, and cooperative activities to assist employers and their workers in implementing infection control measures. In addition, OSHA will continue to use its existing enforcement tools, as appropriate, with employers who are not taking adequate action to protect their workers from exposure to TB.

TB in the United States has declined significantly since OSHA decided to propose a TB Standard.

Until 1985, the number and rate of TB cases in the United States had declined steadily for more than 30 years. Unexpectedly, however, the incidence of TB started to increase in 1986. At the peak of this resurgence in 1992, CDC reported 26,673 TB cases (10.5 per 100,000 population)—an increase of 20% over the number of cases, and of more than 12% over the case rate, reported in 1985. The situation was especially pronounced in states with historically high TB rates. In 1992, when the rate of TB for the nation as a whole was 10.5 cases per 100,000 population, New York, Florida, California, Texas and Illinois, had rates ranging from 10.9 to 25.2 per 100,000, and accounted for 58% of the total cases. In addition, by 1991 there had been a seven-fold increase in the percentage of multidrug-resistant TB (MDR-TB), TB that is resistant to both isoniazid and rifampin, the two major drug treatments for the disease. (Ex. 187, p. 13)

The Federal agency with primary responsibility for responding to the TB crisis is the CDC. In 1989, CDC published its "Strategic Plan for the Elimination of Tuberculosis in the United States." (Ex. 6-19, pp. 1-25) This plan, which had been under development since 1984, called for a comprehensive governmental and public health effort to address TB transmission. In 1992, it was supplemented by the CDC's National Action Plan to Combat Multidrug-Resistant Tuberculosis. (Ex. 7-65) These plans provided the framework for the Federal response to the TB resurgence of the late 1980s and early 1990s.

The plans prescribed a broad and multifaceted attack on TB, including infection control guidelines describing methods to reduce transmission in a number of settings; physician education programs and practice guidelines to ensure effective treatment; research into new and faster methods of identifying TB, particularly MDR-TB; the implementation and maintenance of

community-based TB control programs, and the development of alternative TB treatments. (Ex. 187, pp. 17-23) As well as beginning work on its TB proposal, OSHA's contribution to this national effort included the enforcement activities described in its 1993 directive, as well as outreach and educational activities directed at employers with workers at risk of occupational exposure to TB. As a result of all of this coordinated activity, starting in 1993, the incidence of TB began to decline again.

By 1996, as OSHA noted in the preamble to its 1997 proposal, both the number and the rate of TB cases were lower than they had been in 1985, before the resurgence began. This decline has continued, and for 2002 CDC reported 15,078 TB cases (5.2 per 100,000 population). These numbers represent a reduction of more than 50% in the rate of TB since the 1992 peak, and of 43.5% in the number of cases. (Table 1) The number of reported TB cases and the national TB case rate are now at their lowest levels since TB reporting began in 1953, with significant decreases occurring in the states where the resurgence was most severe. The most dramatic decline occurred in New York, which in 1992 had the highest TB rate in the Nation, 25.2 cases per 100,000 population. By 2002, it had experienced a 70% decline in the case rate, to 7.5 per 100,000. New York, California, Florida, Texas, and Illinois together account for fully 65% of the decrease in the number of cases since 1992. The number of TB cases in these five states was reduced by about 50% over this period, 7% more than the Nation as a whole. The number and percentage of MDR-TB cases have also declined dramatically over this period. In 2002, 138, or 1.3%, of culture-positive TB cases were resistant to isoniazid and rifampin, down from 468, or 2.7% reported in 1993, a reduction of more than 70% in the number, and 50% in the percentage, of cases that are MDR-TB. (Centers for Disease Control and Prevention, Trends in Tuberculosis Morbidity, (United States, 1992-2002), MMWR 2003; 52: 217-222).

CDC has noted, however, that even though TB is declining in all demographic groups studied, there remains substantial variation in disease incidence among these groups. (MMWR 2003; 52: 217) In 2002, for the first time, more than half of all TB cases occurred in individuals who were born outside of the United States, and CDC believes that the majority of these cases are the result of infections also incurred outside of this country. This suggests that TB transmission in the U.S. may be even

less common than the numbers in Table 1 would indicate. Even among the U.S. born population, there are substantial disparities among racial, ethnic, and economic groups, with higher TB rates

associated with lower socioeconomic status. (MMWR 2003: 52: 218) Well over half of all TB cases are in individuals who are not in the workforce, so the TB rates for workers are substantially lower

than the overall population rates. (Ex. 187, pp. 153, 154 citing MMWR 2003: 52: 222)

TABLE 1.—U.S. TUBERCULOSIS CASES AND CASE RATES PER 100,000 POPULATION

Year	Number	Rate	Percent change number	Percent change rate
1992	26,673	10.5	+1.5	+1.0
1993	25,287	9.8	−5.2	−6.7
1994	24,361	9.4	−3.7	−4.1
1995	22,860	8.7	−6.2	−7.4
1996	21,337	8.0	−6.7	−8.0
1997	19,851	7.4	−7.0	−7.5
1998	18,361	6.8	−7.5	−8.1
1999	17,531	6.4	−4.5	−5.9
2000	16,377	5.8	−6.6	−9.4
2001	15,989	5.6	−2.4	−3.4
2002	15,078	5.2	−5.7	−7.1

From CDC: "Reported Tuberculosis in the United States, 2001"; "Trends in Tuberculosis Morbidity—U.S., 1992–2002."

The occupational risk of TB infection is lower than that reflected in OSHA's proposed standard.

The proposed standard was based on OSHA's preliminary assessment that workers occupationally exposed to TB were at substantially greater risk of TB infection, and therefore of active TB disease and death, than was the general population. Both OSHA's preliminary risk assessment, and the revision released in 2000 were based in large part on published data on the number of workers in different health care and prison settings with skin tests indicating recent TB infection (the conversion rate), and on comparisons of those data to estimates of background conversion rates among comparable populations without occupational exposure. In order to determine the estimated background conversion rates, OSHA used calculations derived from the number of active TB cases reported to CDC in a given year. OSHA assumed that about 10% of infected individuals who do not undergo prophylactic treatment would eventually develop active TB, 40% of them in the first year after infection, 20% in the second year, and the remaining 40% distributed equally through the remainder of their lifetimes. The revised risk assessment estimated that, based on the existing frequency of prophylactic treatment, active TB would occur in only about 6.5% of infected individuals. OSHA also assumed that 7.8% of active TB cases would be fatal.

As both OSHA's peer reviewers and many commenters pointed out, however, there are several uncertainties associated with these calculations, and the risk assessments likely overstated the occupational risk. (Exs. 185; 186;

187, p.153; 189–21; 189–20; 189–32; 189–28; 189–25) First, for a number of reasons ranging from imprecise testing protocols to poor availability of appropriate study populations, data on conversion rates are of less than ideal reliability and estimates of increased risk among occupationally exposed workers are necessarily imprecise. Second, a number of participants pointed to data indicating that far less than 10% of infected individuals, possibly even less than 5%, will develop active TB. (Exs. 185; 187 pp. 152–153, 216–220) This most obviously affects OSHA's estimate of the number of occupationally-acquired infections that will develop into active TB. In addition, because background infection rates were derived in large part by applying this assumption about disease development to actual data on the number of active cases, the assumptions also affect the calculation of excess occupational risk of infection. If only half the assumed percentage of infected individuals develop active TB (5% instead of 10%), the number of TB infections leading to a given number of active TB cases (the background rate) would be twice as high as calculated, meaning that the excess risk of infection attributed to occupational exposure would be lower than originally assumed.

Similarly, even though the fatality rate was not a major basis for OSHA's preliminary determination of significant risk, many participants criticized the assumption that 7.8% of TB cases would be fatal. The IOM report stated that, for healthcare workers who are not immunocompromised or infected with MDR-TB, the risk of death is negligible.

(Ex. 187, pp. 154, 222). Several participants noted that the 7.8% mortality rate was derived from 1989 to 1991 data, and that the death rate for those years was much higher than it has been since; in fact, for 1999 and 2000, the death rate was 3%. (Exs. 187, p. 153; 185, p.12; 189–13, p. 3; 189–22, p. 3; 189–25, p. 7; 189–28, p.3)

In any event, whatever may have been the case when the proposal was issued in 1997, there is no dispute that occupational risk has declined as the incidence of TB in the population as a whole has declined. This is demonstrated by the fact that there has been a decline in TB among occupationally exposed workers that mirrors the decline in the population at large. The proposal noted that in the early 1990s, when the record shows that few employers were using infection control measures to protect their workers from exposure to TB, workplace exposures resulted in TB infections, disease and, in some cases death. (Exs. 187, pp. 95–96, 7–3; 5–16; 151–3; 151–15; 5–3; 7–136; 6–25) Healthcare workers represent the largest group of TB-exposed workers, and in the early years of TB recordkeeping, they were more likely than other workers to develop TB. (Exs. 187, pp. 105–107; 7–3; 5–16; 5–11; 151–3; 151–15) As the Society for Healthcare Epidemiologists of America (SHEA) noted, more recent data indicate that healthcare workers "represent a small proportion of all cases and are not disproportionately represented in the TB caseload compared to their presence in the workforce" (Ex. 183–15, p.1–2). IOM reported that for 1998, although healthcare workers accounted for 9% of

the working population of the U.S., these workers accounted for only 8% of TB cases among the working population, which does not appear consistent with these workers being at much higher risk of infection than the rest of the population. Moreover, from 1994 to 1998, the TB rate for health care workers declined almost 20%, from 5.6 to 4.6 per 100,000 population, while the rate for other workers remained steady at 5.2 per 100,000. (Ex. 187, p.89)

Because TB rates among healthcare workers vary demographically in a manner similar to rates among the general population, and because it is very difficult to determine whether any individual case was transmitted occupationally, many participants believed that much of the risk to these workers likely arises outside of work. For example, the Infectious Disease Society of America pointed to data "suggest[ing] that community exposure was responsible for most conversions even at a hospital which cares for a large number of TB patients." (Ex. 183-1, p.2) IOM pointed out that foreign-born workers account for a very high percentage of TB cases in healthcare workers. (Ex. 187, p. 89) Many of these workers are from countries such as India and the Philippines, which have very high TB rates.

Increased implementation of TB controls has reduced TB levels.

The record contains virtually unanimous agreement on two crucial points. First, along with the spread of AIDS and an influx of immigrants from areas where TB is common, widespread complacency about TB and a consequent lack of resources focused on TB prevention contributed significantly to the 1985-1992 resurgence of the disease. (62 FR 54173, 54175; NY TR, p. 211) Second, the post-1992 decline in TB has resulted from public health and infection control measures taken as part

of the intense Federally-coordinated response to the resurgence. (62 FR 54175, 54176; DC TR, pp. 767, 884) Primarily because of this CDC-coordinated anti-TB campaign, the public and occupational health communities better understand the factors creating risk of TB transmission and disease, are more knowledgeable about TB containment strategies, and are more aware of the importance of implementing those strategies. (Exs. 187, pp. 13-22, 82; 183-15, p. 1; TR NY p. 212)

Prominent among these TB control strategies are the recommendations in several CDC guidelines for preventing the transmission of TB. CDC updated its TB guidelines for health care settings (first issued in 1982) in 1990 and 1994. (Ex. 4B) The guidelines recommend measures such as early identification and isolation of individuals with infectious TB, prompt initiation of therapy for these individuals, the use of negative pressure ventilation in TB isolation rooms, the use of respiratory protection for health care workers performing high-hazard procedures or working in TB isolation rooms, and employee tuberculin skin testing and training. CDC issued additional guidelines for long term care facilities in 1990, for facilities dealing with homeless persons in 1992, and for correctional facilities in 1996, all locations where the resident populations have relatively high levels of infectious TB. (Exs. 3-35; 6-15; 7-284) As part of its outreach and compliance assistance efforts, OSHA notifies employers of these guidelines, and provides links to them on its own Web site.

Because TB is an airborne hazard, the CDC guidelines have recommended that exposed workers wear respirators. OSHA requires the use of respirators

certified by CDC's National Institute for Occupational Safety and Health (NIOSH). See 29 CFR 1910.134; 29 CFR 1910.139 (1997)(to be revoked). In 1992, NIOSH recommended specific types of respirators for health care workers working around TB patients, and CDC's 1994 guidelines listed specific performance criteria that a respirator needed to meet to provide protection against TB. (Exs. 7-64; 4B) In 1995, NIOSH issued a new certification protocol for respirators, creating new classes of respirators that meet the CDC performance criteria. One new type of respirator is the N95, now the most frequently used respirator for TB protection. (Ex. 7-261)

The record shows that compliance with CDC's TB guidelines has increased significantly since OSHA began work on a TB standard in 1993. Compliance is most extensive in hospitals. Hospitals are where the greatest risk of TB exposure occurs, because most TB cases are diagnosed and treated in a hospital setting, and this diagnosis and treatment often involves the use of cough-inducing procedures such as sputum induction and bronchoscopies that are likely to expose workers to high concentrations of infectious material. During the rulemaking, the American Hospital Association (AHA) relied on the results of 1992 and 1996 surveys that it conducted in conjunction with CDC to show that "hospitals have made significant progress in implementing control measures to prevent transmission of TB consistent with the 1994 CDC guidelines." (Ex. 17-454) As shown in Table 2, by 1996, the vast majority of hospitals were using isolation rooms meeting CDC's criteria, providing appropriate respiratory protection, and performing periodic skin testing of potentially exposed workers.

TABLE 2.—COMPARISON OF TUBERCULOSIS CONTROL MEASURES FOR 103 HOSPITALS THAT REPORTED MORE THAN SIX ADMISSIONS OF PATIENTS WITH TUBERCULOSIS IN 1992 CDC SURVEY AND THAT ALSO RESPONDED TO 1996 CDC SURVEY (EX. 187, P. 111)

	1992 number (%)	1996 number (%)
Engineering Controls:		
• Isolation rooms meeting CDC criteria	59/92 (64)	99/103 (96)
• Routine check of negative air pressure	42/85 (49)	96/99 (97)
• Monthly check of negative air pressure	5/35 (14)	76/90 (84)
Respiratory Protection¹:		
• Nonfitted surgical mask	69/101 (68)	1/103 (1)
• Soft mask, molded or fitted	34/101 (34)	NA
• Particulate respirator	8/101 (8)	40/103 (39)
• N95	NA	85/103 (83)
Tuberculin Skin Testing:		
<i>Testing by Worker Category:</i>		
• Nurses	103/103 (100)	103/103 (100)
• Respiratory therapists	102/103 (99)	103/103 (100)
• House staff	65/81 (69)	65/73 (89)

TABLE 2.—COMPARISON OF TUBERCULOSIS CONTROL MEASURES FOR 103 HOSPITALS THAT REPORTED MORE THAN SIX ADMISSIONS OF PATIENTS WITH TUBERCULOSIS IN 1992 CDC SURVEY AND THAT ALSO RESPONDED TO 1996 CDC SURVEY (EX. 187, P. 111)—Continued

	1992 number (%)	1996 number (%)
• Attending physicians	43/86 (69)	65/94 (69)
• Students	55/95 (58)	74/97 (76)
<i>Testing Elements:</i>		
• After exposure incident	98/101 (97)	102/103 (99)
• Two-step testing	NA	77/98 (79)
• Maintain yearly reports	64/98 (65)	93/98 (95)

¹ Numbers add to more than one hundred because facilities may use more than one type of mask.

The record also shows increased compliance with TB control procedures in prisons and other correctional facilities. CDC published TB control guidelines for these facilities in June 1996, and surveys it conducted with National Institute of Justice between 1992 and 1997 showed an increasing implementation of TB control measures in correctional facilities. The surveys examined the implementation of recommended control provisions in the Federal Bureau of Prisons facilities, all 50 state systems, and a number of large local jail systems. Results showed that 90% of facilities screened new employees for TB, and 75% of those included periodic tuberculin skin testing. The use of negative pressure isolation rooms increased from 30% in 1993 to nearly 98% in 1997 (for Federal and State systems) and 85% (for local jail systems). The use of directly observed therapy for inmates with active TB disease increased from 77% to 98% for Federal and State systems and 84% to 95% for local jail systems (Ex. 187, p. 113–114). Although an AFSCME report of a 1997 survey of correctional facilities where its members were employed showed “a wide variation of adherence to CDC guidelines from departments that had instituted rigorous programs throughout prison systems to those that had done very little,” the survey covered a “very small, nonrandom set” of facilities, and does not contradict the conclusion that compliance in correctional facilities is increasing. (Ex. 189–23, p. 4; 187 p. 116) The evidence in the record indicates that both hospitals and correctional facilities improved their TB control practices significantly over the 1990s.

Taken together, survey results suggest, at a minimum, two conclusions. First, institutional departures from recommended tuberculosis control policies and procedures were common, if not the norm, in the late 1980s and early 1990s. Second, institutions—at least hospitals and correctional facilities—were taking tuberculosis

control measures more seriously and reporting substantially higher rates of implementation of recommended measures in later years. (Ex. 187, p. 116).

Evidence about the use of infection control procedures in other types of settings also showed increasing levels of compliance, although generally not as high a level of compliance with CDC guidelines as was occurring in hospitals. (Ex. 187, pp. 114–117; DC TR, p. 676) AFSCME reported that, “in non-hospital healthcare settings, [its] survey revealed inadequate to virtually non-existent TB control programs.” (Ex. 189–23, p. 4) As noted above, however, IOM pointed out that this survey was of a “very small, nonrandom set of respondents,” only 23 long-term care facilities, 28 mental health facilities, and 28 social service agencies, and that its results “must be viewed with considerable caution.” (Ex. 187, p. 116) In contrast to the AFSCME survey, a number of participants provided evidence that voluntary implementation of the CDC TB guidelines had increased dramatically since 1994, even outside of hospitals. For example, Barbara Hood, testifying on behalf of the California Association of Homes and Services for the Aging stated:

* * * many health care employers have implemented key control measures as recommended in CDC’s 1994 TB guidelines and have incorporated these recommendations in their policies and procedures. This has improved screening and surveillance protocols for both residents and staff. As a result, nursing facility providers have significantly reduced the level of TB in long-term care organizations. (LA TR, pp. 124–125)

AHCA also asserted that many nursing and long-term care facilities have protected their workers effectively by implementing many of the CDC recommendations, even though these facilities are not necessarily complying with all the provisions in OSHA’s proposal. (Ex. 17–756)

Particularly in nursing homes and other long-term care facilities, this trend has probably been accelerated by the need to comply with requirements for Medicare and Medicaid eligibility. A regulation that took effect in October 1992 requires each of these facilities “to establish and maintain an infection control program * * * to help prevent the development and transmission of disease and infection.” (42 CFR 483.65) IOM reports that, at least as of 2000, the guidelines used by state inspectors to determine compliance in nursing homes “specifically require that facilities demonstrate procedures for early detection and management of residents with signs and symptoms of infectious tuberculosis, screening of residents and workers for tuberculosis infection and disease, and evaluation of workers exposed to tuberculosis in the workplace.” (Exs. 187, p. 58, n. 3; 17–756) Moreover, the Centers for Medicare and Medicaid Services (CMS) recently inaugurated a new Program of All-inclusive Care for the Elderly (PACE), which requires participants to “follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.” (42 CFR 460.74)

The national efforts to reduce the incidence of TB in the general population have also protected workers by reducing the likelihood that they will encounter infectious TB at work. As the IOM points out, “Overall, fewer cases of tuberculosis and less multidrug-resistant disease means less risk for nurses, doctors, correctional officers, and others who work for organizations that serve people who have tuberculosis or who are at increased risk for the disease.” (Ex. 187, p. 104) The Society of Healthcare Epidemiologists of America (SHEA) also credits the efforts of public health officials, government agencies, professional organizations and clinicians for “clearly put[ting] the United States back on the road to TB

elimination.” (Ex. 183–15, p. 1) The effectiveness of all of these measures is demonstrated by a decline in TB among occupationally exposed workers that has exceeded the decline in the population at large. (Exs. 7–147; 7–148; 7–149; 7–173; 7–167; 151–15; 18–49A; 181–3; 18–53; 187, p. 89)

An OSHA standard would not substantially reduce transmission of TB from undiagnosed sources.

Finally, evidence in the rulemaking record indicates that, with the current level of compliance with CDC guidelines, the “primary risk” of occupational exposure to TB is from individuals with unsuspected and undiagnosed infectious TB. (Ex. 187, p. 2) One commenter, St. Joseph Mercy Hospital, called these exposures the “Achilles heel” of TB control efforts. (Ex. 17–881, p. 3) Although OSHA’s proposed standard called for early identification and isolation of infectious TB patients, this early identification can be extremely difficult. (Exs. 5–4; 5–18; 6–27; 7–76; 7–77; 7–78; 7–79; 5–12) An OSHA standard must substantially reduce a significant risk, and OSHA believes it is unlikely that employers will identify enough of the currently undiagnosed TB cases their workers come in contact with to reduce the remaining occupational risk of TB infection substantially. *Industrial Union Department, AFL–CIO v. American Petroleum Institute, et al.*, 448 U.S. 607, 642, 653 (1980).

The record shows that there are a number of reasons that a client’s or patient’s infectious TB may not be recognized. (Exs. 17–11; 17–12; 17–36; 17–458) In some situations, the infectious person may not manifest evident signs and symptoms of TB. And even after receiving training, a worker who is not expecting to see TB, which is especially likely in an area where the disease is uncommon, may not recognize the significance of TB signs and symptoms. In other cases, an exposed employee may lack the clinical expertise or resources to identify a patient or client as a suspect TB case and make a referral for diagnosis.

Lack of recognition may also occur where a worker has contact with many patients or clients who have coughs or other possible TB symptoms. Also, workplaces such as drug treatment centers and homeless shelters operate with unique limitations, and rarely possess either the resources or the clinical expertise to identify and isolate TB cases in a timely manner. (Exs. 187, p. 132; 17–53; 17–76; 17–58; 17–12; DC TR, pp. 2019–2020, 2113, 2131; NY TR, pp. 610, 612; LA TR, pp. 598, 600, 601, 617, 630) They are also less likely to be

able to distinguish between active TB disease and other medical conditions with similar symptoms.

As the Association for Professionals in Infection Control and Epidemiology (APIC) put it:

Obviously, protecting workers against exposure to TB from patients is contingent upon suspecting that the patients have TB in the first place. Patients may initially enter a hospital for a different reason or show only vague symptoms of TB. Until diagnosed, these patients unwittingly expose probably dozens of individuals to their illness. (Ex. 17–671, p. 3)

APIC then reported on 17 outbreaks since 1960 where transmission to healthcare workers was reported, pointing out that 75.6% of the workers were infected by an undiagnosed and unsuspected TB patient. (Id.) The Home Health Services and Staffing Association (HHSSA) also asserted that 75% of TB transmissions from patients to healthcare workers are not preventable because, at the time of transmission, the patient’s TB could not be readily identified or even suspected. (Ex. 17–673, p. 3) To the extent that these reports do not reflect advances made in infection control over the last decade, they may overstate the percentage of undiagnosable cases, but HHSSA’s and APIC’s conclusions about the significance of these cases are consistent with those of the IOM. Moreover, the case reports APIC submitted describe situations where transmissions have occurred, and OSHA’s own review of these reports indicates that, even with a modern TB infection control program, a number of the source patients would still not have been diagnosed before healthcare workers were exposed to them.

These reports also show that occupational exposures to undiagnosed TB and potential disease transmission can occur in all settings, including hospitals that have implemented the CDC Guidelines. The IOM pointed out that, in locations such as hospital emergency rooms, exposure may occur before infectious individuals are recognized and isolated, and that infectious individuals may remain asymptomatic for some time. (Ex. 187, p. 135) Consistent with CDC guidelines, the proposal called for treating contacts as having suspected infectious TB if they had both a persistent cough lasting at least three weeks, and at least two of the following additional symptoms: bloody sputum, night sweats, weight loss, fever, and anorexia. (62 FR 54292–3).

First, for workers in residential settings such as nursing homes and correctional facilities, this criterion does

not provide any protection in the first three weeks that a resident has symptoms and is not recognized as having TB. In some other settings, identification of infectious individuals depends on the self-reports of patients or clients to determine whether almost any of the symptoms are present. Several participants pointed out that, outside of health care settings, potentially infectious individuals who fear they will be denied a benefit (such as a shelter bed or substance abuse treatment), or be compelled to enter a coercive treatment situation, may feel a strong incentive not to respond honestly to questions about symptoms. (Exs. 18–22A, 18–57A; 183–15, p. 4; NY TR, p. 615; DC TR, pp. 2009; 2034; 2069)

Homeless shelters are a prime example of a population where many clients have the coughs, fevers, night sweats, weight loss, and other symptoms associated with TB. (NY TR, pp. 607–608; Chicago TR, pp. 710–711, 768, 789) These non-hospital settings do not diagnose, treat, or isolate individuals with active TB disease; at most, they screen clients for symptoms of infectious disease and transfer or refer those with suspect symptoms to facilities with appropriate diagnostic and isolation capabilities. (Exs. 17–50; NY TR, p. 697; Chicago TR, pp. 789–790; DC TR, pp. 1867–1868) They rarely possess any means to identify asymptomatic individuals. They often lack the resources even to provide all the services they believe their clients need, and may well resist transferring any of their limited resources to a TB screening program, particularly when, as noted above, the screening may engender fear or hostility in their clients. (Exs. 18–22A, 18–57A; 17–50; 183–15, p. 3, NY TR, p. 703; Chicago TR, pp. 701–702, 713; DC TR, pp. 1910, 2046, 2069)

The bottom line is that no infection control regime, including that in OSHA’s proposed standard, would have much effect on workplaces where the greatest source of exposure and risk is unsuspected and undiagnosed active TB disease.

The Need for an OSHA Standard

The major issue in the rulemaking was whether, in light of the ongoing decline in the national incidence of TB, the steps that employers were already taking, and the difficulty in identifying many infectious TB patients, there is a current justification for an OSHA rule on occupational exposure to TB. Many participants argued that the rule would not result in a meaningful additional reduction in risk. According to these commenters, the problem addressed by

OSHA's proposed standard has already largely been solved. APIC testified, "Clearly, the TB crisis that OSHA is attempting to address has passed." (DC TR, p. 722). This sentiment was echoed by other commenters, such as the American Medical Association, Infectious Disease Society of America, Home Health Service Staffing Association, American Health Care Association, Society of Healthcare Epidemiologists of America, American Association of Homes and Services for the Aging, who also questioned the need for an OSHA standard in an era of declining TB cases. (Exs. 17-719; 183-1; 17-673; 18-61; 17-666; 17-673). The American Lung Association's American Thoracic Society, stated:

The [proposed] OSHA * * * TB standard, is based heavily on the CDC's 1994 guidelines. * * * The CDC guidelines were an appropriate response at the time they were formulated but the proposed OSHA standard will be far out of proportion to the risk by the time it is implemented and increasingly inappropriate and burdensome with each passing year if the current epidemiologic trends continue. (DC TR, pp. 1035-36)

In contrast, other commenters, such as the United Food and Commercial Workers Union and the Service Employees International Union (SEIU), argued that, because CDC's TB guidelines are not directly enforceable, there remain employers who have placed their workers at risk by failing to implement them fully. (DC TR, p. 676; Ex. 17-1089, p. 1-2; DC TR, pp. 635-636). Some of these commenters, such as SEIU, pointed to the geographic variation in TB rates to support the argument that a standard is needed because not all employers are taking appropriate protective action. (Tr LA, pp. 245-246)

In response to these arguments, OSHA acknowledges that a standard is often the most efficient way of assuring that employers reduce their employees' exposure to specific hazards. TB is primarily a public health hazard, however, and occupational exposure at this time is in large part a function of the prevalence of active TB in the population at large. There has been a decade-long decline in TB prevalence, resulting in large part from the Federal resources devoted to public health and infection control measures that were implemented without an OSHA standard in effect.

OSHA believes this shows that, in the unique case of TB, there are powerful incentives for employers to continue to provide appropriate protection even without an OSHA TB standard. The ongoing Federal commitment to TB control provides them with a wealth of

information and expert resources to assist in TB control efforts. Among other incentives, hospitals and nursing homes must have infection control plans to qualify for Medicaid and Medicare reimbursement, and are subject to annual reviews to verify their continuing compliance. (Ex. 17-756, 42 CFR 482.42; 42 CFR 483.65) Facilities participating in CMS's PACE program must comply with "at least" the CDC guidelines. (42 CFR 460.74) The Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), which many hospitals and nursing homes use to demonstrate qualification for Medicare and Medicaid reimbursement, also requires an infection control plan as a condition of accreditation. (Exs. 17-756; 187, p. 58; Chicago TR, p. 931) The record also shows, as does CDC's new TB elimination plan, that the sobering memory of the 1985-1992 TB resurgence is not likely to fade anytime soon, and that the complacency that led to that resurgence is unlikely to recur. (Ex. 187, p. 21; NY TR, p. 212)

Nor does OSHA believe that the facts that there are pockets of TB prevalence and a few states where TB rates have increased require it to promulgate a standard. First, the states with the highest levels of TB during the resurgence are also states that have been aggressive in implementing control measures, and are among the states where the most significant recent declines have occurred. From 1992 to 2002, only three states reported an increase in their TB rates, and these increases represent only an additional 106 TB cases (which is less than 1% of the total TB cases in the U.S.). (Centers for Disease Control and Prevention, Trends in Tuberculosis Morbidity—United States, 1992-2002, MMWR 2003; 52: 217-222) These increases do not detract from the fact that, nationally, there are fewer TB cases and lower TB rates being reported each year. CDC's new plan for TB elimination, CDC's Response to *Ending Neglect*, directs resources specifically at localized areas and population groups who remain at higher risk for TB. (Centers for Disease Control and Prevention. *CDC's Response to Ending Neglect: The Elimination of Tuberculosis in the United States*. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2002) Even without a standard, OSHA can take appropriate enforcement action to address those situations where employers are not taking adequate steps to reduce their workers' TB exposure.

OSHA has additionally concluded that, as a practical matter, early identification of infectious TB patients

will not occur enough more often than it already does to justify adoption of a standard. The fact that TB symptoms are neither universal nor unique to TB could also make OSHA enforcement of an early identification provision highly problematic. As the proposal recognized, identification of suspect cases requires the exercise of judgment. (62 FR 54247) Unless an employer simply fails to implement any identification criteria at all, it would be very difficult to establish when a violation occurs. As noted above, however, the record shows that most affected workplaces with the expertise and other resources to do so have already adopted programs to control exposure, including early identification of infectious TB patients, and OSHA will continue to use its general duty clause to require others to follow suit.

For employers without these resources, OSHA believes that providing assistance in exercising the judgment necessary for an effective early identification program can best be accomplished through outreach, consultation, and education efforts, and OSHA intends to provide this type of assistance. CDC's targeted guidelines already provide some guidance, and OSHA believes that the most effective approaches are likely to be the integrated ones that build on the CDC guidelines and target occupational TB transmission as part of a broader TB control program.

As noted above, workers are exposed to TB when they serve patients or clients who have infectious disease, and one of the most straightforward ways to reduce that exposure is to reduce the number of such contacts that occur by reducing the rate of infectious TB in the patient or client population. As CDC's most recent prevalence data show, ongoing TB reduction efforts have been remarkably effective in achieving this goal.

Nor is there any indication that this success is leading to the type of complacency and inattention that contributed to the last TB resurgence. CDC's new TB control plan takes full account of the "scientific, programmatic, and health-sector developments of the last decade." This plan is focused strongly on the current demographic and epidemiological profile of TB, with one of its major goals being to reduce the global burden of TB. In *CDC's Response to Ending Neglect*, CDC explained that "the heavy impact of TB in foreign-born persons living in this country" is a major factor tempering its recent success in TB control." (CDC; 2002, p. 13) Now that foreign-born residents account for more than half the

incidence of TB in the United States, reducing TB in this population is more critical than ever to controlling TB domestically. CDC is much better suited than OSHA, which has authority only over domestic workplaces and employers, to address this increasingly important aspect of TB control.

OSHA believes its role in this process should be to continue with the initiatives that have already contributed to reducing the occupational risk of TB infection. OSHA will continue to provide both industry- and workplace-specific TB control information and guidance, through its website as well as targeted outreach activities. OSHA will also continue the successful enforcement policy, described in its TB Enforcement Directive and in several national, local and regional emphasis programs targeting TB risks, to make sure that employers protect their employees from TB infection. In fact, OSHA's experience in these programs has helped convince it of the high level of compliance with TB exposure safeguards. When appropriate, however, OSHA has cited these employers for violations of the general duty clause, the TB-specific respirator standard, or other

applicable requirements. These citations, (32 of the general duty clause and 92 of the TB-specific respirator standard since the proposal was issued), have provided protection to a broad range of workers, including ambulance drivers, physicians, therapists, lab personnel, health care social workers, emergency medical technicians, support personnel, and morticians. The availability of this enforcement mechanism, coupled with OSHA's ongoing monitoring of TB-control efforts, will help prevent the widespread complacency of the mid-1980s from recurring, and will allow an expeditious response to any backsliding that does occur.

In summary, OSHA has concluded that the success of existing Federal and community programs to control TB has significantly diminished the need for a standard, and that promulgating a standard will not reduce the remaining occupational risk substantially. Under the leadership of the CDC, community, institutional, and occupational public health efforts, including OSHA's own continuing outreach and enforcement, have increased worker and employer awareness of the factors leading to TB

infection and disease and led to an increased implementation of CDC's TB guidelines. OSHA also intends to continue to use its enforcement, outreach, and education resources to ensure that employers' TB control efforts remain effective.

Review Under Executive Order

This document has been reviewed by OMB pursuant to E.O. 12866.

Authority and Signature

This document was prepared under the direction of John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC, 20210. It is issued pursuant to sections 4, 6, and 8 of the Occupational and Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary's Order 3-2000, and 29 CFR part 1911.

Signed at Washington, DC, this 19th day of December, 2003.

John L. Henshaw,

Assistant Secretary of Labor.

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