

Guidelines & Regulations

Multiple TB outbreaks occurred in healthcare facilities in the late 1980s and early 1990s. In response, guidelines and regulations were developed and implemented to help ensure safe TB control practices. Investigations of these outbreaks found lapses in administrative, environmental, and respiratory protection control measures.

Highlights from TB-related guidelines and regulations are included below. While guidelines are not requirements nor are they binding by law, regulations are required by law and often refer to and rely on guidelines. Refer to your state and local regulations for requirements that are binding by law.

Centers for Disease Control and Prevention (CDC) Guidelines

The most comprehensive TB control guideline for healthcare facilities published to date is the CDC document, “Guidelines for Preventing the Transmission of *M. tuberculosis* in Health-Care Settings 2005.” The CDC guidelines include a supplement called “Environmental Controls,” which contains recommendations for AIIRs. Much of this Infection Control Manual is based on the CDC Guidelines.

Environmental control recommendations for the design of TB patient rooms include exhausting air to create negative pressure (see page 26 “What is Negative Pressure?”). For AIIR exhaust, the preferred practice is to directly exhaust to the outdoors. If recirculation is unavoidable, then HEPA filters are recommended.

A minimum ventilation rate of 12 air changes per hour (ACH) is recommended for AIIRs that are being renovated or newly constructed, and where HEPA filter units are used to supplement the central ventilation system.

For existing AIIRs, the CDC Guidelines are less restrictive. Increasing the AIIR air change rate to 12 ACH is recommended where feasible, but a minimum of 6 ACH is acceptable.

The CDC Guidelines also include recommendations for testing and monitoring AIIRs. The recommendations address testing methods and frequency of testing.

American Institute of Architects (AIA)

The AIA has published a revision of its guideline titled “Guidelines for Design and Construction of Health Care Facilities.” These guidelines apply to the design and construction of new health care facilities and major renovations in existing facilities.

Recommendations of the 2006 AIA guidelines include the following: 12 ACH in AIIRs, negative pressure, and daily confirmation of negative pressure when a room is used for isolation.

These guidelines also recommend that air from AIIRs be either exhausted outdoors or HEPA-filtered before recirculation.

A separation of 25 feet is recommended between exhaust from AIIRs and other ventilation system intakes or occupied areas.

ASHRAE

The American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE), Inc. published a handbook in a series of four volumes, one of which is revised each year to ensure that no volume is older than 4 years. The 2004 Handbook covered “HVAC Systems and Equipment,” and the 2003 Handbook addressed “HVAC Applications.”

Occupational Safety and Health Administration (OSHA)

On October 17, 1997, OSHA published a proposed standard for occupational exposure to *M. tuberculosis*. In May 2003, OSHA announced the termination of rulemaking for a TB standard. Effective December 31, 2003, OSHA revoked 29 CFR 1910.139 which had regulated the use of respirators to protect against exposures, and placed this use of respirators under the general standard, 29 CFR 134.

The compliance directive issued in 1996 remains in place: CPL 2.106 – Enforcement Procedures and Scheduling Occupational Exposure to Tuberculosis. OSHA will enforce the most current CDC TB Guidelines.

California Division of Occupational Safety and Health (Cal/OSHA)

Interim Tuberculosis Control Enforcement Guidelines

Cal/OSHA has published and enforces Interim Tuberculosis Control Enforcement Guidelines. These were published in 1992 and have been updated periodically. The most recent update was in March 1997.

In 2004, Cal/OSHA took the equivalent action to OSHA, in repealing Title 8 California Code of Regulations, Section 5147, that had applied to the use of respirators against tuberculosis, and placed this use under Section 5144.

Cal/OSHA is working on an aerosol transmissible disease standard, which would include tuberculosis. If that standard is adopted, the Enforcement Guidelines will be revised to reflect that standard. The Cal/OSHA website should be monitored for further information and updates: www.dir.ca.gov.

Environmental controls mandated for AIIRs include negative pressure and an air change rate of 12 ACH, which can be achieved by a combination of building ventilation and HEPA filtration. The agency also mandates that ventilation systems be tested at least annually and that records of each test be kept for at least 5 years.

Office of Statewide Health Planning and Development (OSHPD)

The California Mechanical Code (CMC)

The CMC regulates the construction of new and renovated AIIRs in California hospitals. The current version is the 2001 CMC and consists of the 1997 Uniform Building Code (UBC) combined with amendments specific to California. The CMC is enforced by OSHPD.

The California amendments include detailed requirements for the mechanical design of many hospital spaces, including AIIRs. Requirements for AIIRs include negative pressure and a minimum ventilation rate of 10 ACH. OSHPD also mandates that each new and renovated AIIR be equipped with an anteroom and a permanent room pressure monitor.

In response to the resurgence of TB, and recognizing the expense of constructing a new CMC-compliant AIIR, OSHPD provides a less expensive option for the isolation of TB patients in existing AIIRs or patient rooms. These requirements were published as Policy Intent Notice (PIN) Number 4 in 1996. PIN Number 4 allows the use of portable HEPA filter units to create negative pressure and increase the effective ventilation rate in TB AIIRs. The requirements for such rooms include negative pressure, a minimum ventilation air change rate of 12 ACH to match Cal/OSHA requirements, and provision of a permanent room pressure monitor.

TABLE 1.

Comparison of Regulations and Guidelines At-A-Glance

An At-A-Glance table comparing selected environmental controls for AIIRS of five prominent Federal and California regulations and guidelines follows:

	REGULATIONS		GUIDELINES		
	OSHPD ¹	CAL/OSHA ²	CDC ³	ASHRAE ⁴	AIA ⁵
Room designation	Negative-pressure isolation room	Atmospheric isolation	Airborne infection isolation room	Airborne infection isolation room	Airborne infection isolation room
Applies to	New & renovated	All	All	New & renovated	New & renovated
Total air changes per hour (ACH)	≥10	≥12	Prefer ≥12, minimum >6 for facilities existing pre-1994; >12 for post 1994 new & renovated	>12	≥12 May be reduced if room unoccupied
In-room HEPA recirculation allowed?	Only for remodel under (PIN) 4, dated 2/16/96	Yes	Yes, if used to achieve 12 ACH in existing pre-1994 facilities	No	No
Total ACH can include HEPA recirculation?	No	Yes	Yes, if used to achieve 12 ACH in existing pre-1994 facilities	No	No
HEPA-filtered recirculation to other areas?	No	Yes	Only if unavoidable Single pass recommended	No	No Exhaust to outside, if not possible recirculate to air handling unit exclusively serving AIIR
Minimum outside air change rate (OSA ACH)	2	Section 5142 requires employers to maintain the minimum amount of outside air required by the building code at the time the system was permitted.	See table 2 of CDC guidelines	2	2
Minimum exhaust air excess airflow (offset)	75 CFM	Not addressed	See page 64 of CDC guidelines	Not addressed	Not addressed
Minimum room pressure differential	0.001" W.G.	Not addressed	≥0.01" W.G.	≥0.01" W.G.	≥0.01" W.G.

1 2001 California Mechanical Code. Title 24, Part 4, Chapter 4: Ventilation Air Supply.

2 California Division of Occupational Safety and Health (Cal/OSHA). Interim Tuberculosis Control Enforcement Guidelines, revised March 1, 1997. Policy and Procedure C-47.

3 Centers for Disease Control and Prevention. Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings, 2005. MMWR 2005; 54 (No.RR-17),

4 American Society of Heating, Refrigerating and Air Conditioning Engineers. Chapter 7: Healthcare Facilities. In: 2003 HVAC Applications handbook. Atlanta: American Society of Heating, Refrigerating and Air Conditioning Engineers, Inc., 2003.

5 American Institute of Architects, 2006 Guidelines for Design and Construction of Hospitals and Health Care Facilities published by the American Institute of Architects Academy of Architecture for Health, with assistance from the Department of Health and Human Services (DHHS).

	REGULATIONS		GUIDELINES		
	OSHPD ¹	CAL/OSHA ²	CDC ³	ASHRAE ⁴	AIA ⁵
Minimum air velocity under door	100 FPM	Not addressed	Not addressed	Not addressed	Not addressed
Air distribution	Supply high, exhaust low, specific arrangement	Not addressed	See figure 3 on page 63 of CDC Guidelines	From clean (ceiling) to less clean (floor) areas	From clean to less clean areas
Upper-air or in-duct UVGI allowed?	Not addressed	Yes, but not in lieu of ventilation	Yes, but not in lieu of ventilation	Not addressed	Yes, but not in lieu of ventilation
Variable air volume ventilation allowed	No	Not addressed	Yes, must maintain negative pressure at all times, minimum set point must be adequate to maintain the recommended mechanical and outdoor ACH and a negative pressure >0.01" W.G. compared with adjacent areas	Not addressed	Yes, but maintain minimum code ACH and pressurization
Anteroom required?	Yes	No	No	"May be desirable"	Noted as general option, required for PE isolation rooms for airborne infection isolation
Minimum anteroom ACH	10	Not addressed	Mechanical 10 ACH See Table 2 of CDC guidelines	10	10
Minimum anteroom outside air change rate (OSA ACH)	2	Section 5142 requires employers to maintain the minimum amount of outside air required by the building code at the time the system was permitted	Defers to ANSI/ASHRAE Std 62.1-2004	2	Defers to ASHRAE & 100% exhaust to outside
Anteroom pressurization?	Positive to isolation room, neutral to corridor	Not addressed	Positive or negative See table 2 of CDC guidelines	Not addressed	Positive or negative See table 2.1-1 of AIA guidelines
Monitoring of negative pressure	Continuous, alarmed	Test annually	Check daily while being used for isolation	Not addressed	Not addressed