

Copyright Warning & Restrictions

The copyright law of the United States (Title 17, United States Code) governs the making of photocopies or other reproductions of copyrighted material.

Under certain conditions specified in the law, libraries and archives are authorized to furnish a photocopy or other reproduction. One of these specified conditions is that the photocopy or reproduction is not to be “used for any purpose other than private study, scholarship, or research.” If a user makes a request for, or later uses, a photocopy or reproduction for purposes in excess of “fair use” that user may be liable for copyright infringement,

This institution reserves the right to refuse to accept a copying order if, in its judgment, fulfillment of the order would involve violation of copyright law.

Please Note: The author retains the copyright while the New Jersey Institute of Technology reserves the right to distribute this thesis or dissertation

Printing note: If you do not wish to print this page, then select “Pages from: first page # to: last page #” on the print dialog screen

The Van Houten library has removed some of the personal information and all signatures from the approval page and biographical sketches of theses and dissertations in order to protect the identity of NJIT graduates and faculty.

ABSTRACT

PREVENTION OF OCCUPATIONAL EXPOSURE OF TUBERCULOSIS TO HEALTH CARE WORKERS

by
Thomas C. Carle

The resurgence of tuberculosis in the United States within the past decade has prompted the health care community to develop tuberculosis elimination policies. However, recent outbreaks of tuberculosis have proved to be resistant to multiple antibiotics. Tuberculosis infections among health care workers is also rising. This increase in occupational exposures has prompted the examination of current exposure control measures.

The occupational exposure to tuberculosis is prevented by the use of administrative policies, engineering controls and personal protective equipment. Each control measure has inherent strengths and weaknesses and when implemented through an exposure control plan the risk of occupational exposure can be reduced. Control techniques currently utilized may benefit from additional research and development. The research will not be squandered if tuberculosis is ultimately eliminated, as the knowledge gained may prove beneficial for exposure protection from future bio-hazardous aerosols.

**PREVENTION OF OCCUPATIONAL EXPOSURE
OF TUBERCULOSIS
TO HEALTH CARE WORKERS**

by
Thomas C. Carle

**A Thesis
Submitted to the Faculty of
New Jersey Institute of Technology
in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Occupational Safety and Health Engineering**

Department of Mechanical and Industrial Engineering

May 1994

NEW JERSEY INSTITUTE OF TECHNOLOGY
RESEARCH LIBRARY

APPROVAL PAGE

PREVENTION OF OCCUPATIONAL EXPOSURE
OF TUBERCULOSIS
TO HEALTH CARE WORKERS

Thomas C. Carle

Dr. Howard Gage, Thesis Advisor Date
Associate Professor of Industrial Engineering
Director of the Occupational Safety and Health Engineering Program, NJIT

Dr. David Kristol Date
Professor of Chemistry
Director of the Biomedical Engineering Program, NJIT

Dr. Peter Engler Date
Associate Professor of Electrical Engineering, NJIT

BIOGRAPHICAL SKETCH

Author: Thomas C. Carle

Degree: Master of Science in Occupational Safety and Health Engineering

Date: May 1994

Undergraduate and Graduate Education:

- Master of Science Occupational Safety and Health Engineering,
New Jersey Institute of Technology, Newark, New Jersey, 1994
- Bachelor of Science in Engineering Technology,
New Jersey Institute of Technology, Newark, New Jersey, 1988
- Associate in Applied Science in Mechanical Technology,
Union County Technical Institute, Scotch Plains, New Jersey, 1982

Major: Occupational Safety and Health Engineering

TABLE OF CONTENTS

Chapter	Page
1 THE TUBERCULOSIS BACILLI	1
1.1 Introduction	1
1.2 History	2
1.3 Etiology	4
1.4 Epidemiology	5
1.5 Pathology	8
1.6 Signs and Symptoms	10
1.7 Diagnosis	11
1.8 Summary	12
2 THE NEED FOR CONCERN	14
2.1 Introduction	14
2.2 Resurgence of Tuberculosis in the United States	15
2.2.1 The HIV Epidemic	16
2.2.2 Multidrug Resistant Tuberculosis	17
2.2.3 Foreign Born Persons Entering the United States	19
2.2.4 Health Care Infrastructure	23
3 TREATMENT OF TUBERCULOSIS	25
3.1 Historical View and Early Treatments	25
3.2 The Sanatorium	26

3.3 Early Surgery	28
3.4 Modern Chemotherapy and the Development of Streptomycin . . .	29
3.5 Other Antibiotics	30
3.6 Multidrug Resistant Tuberculosis	32
3.7 Summary.	34
4 TRANSMISSION PREVENTION	36
4.1 Historic Methods	36
4.2 The United States Public Health Service	39
4.3 Occupation Exposure Control	41
5 ADMINISTRATIVE CONTROLS	45
5.1 Introduction	45
5.2 Screening for Early Detection and Preventative Therapy.	45
5.3 Education and Training of Health Care Workers	46
5.3.1 Recognition of Signs and Symptoms	48
5.3.2 Evaluation of Infection Communicability	49
5.3.3 Isolation Procedures	51
5.4 High Hazard Procedures	52
5.5 Medical Surveillance	53
5.6 Summary	55
6 PERSONAL PROTECTIVE EQUIPMENT	57
6.1 Airborne TB Hazards	57
6.1.1 Particulate Respirators.	58

6.1.2 Respirator Training Program	61
6.2 Universal Precautions	62
7 ENGINEERING CONTROLS	64
7.1 Introduction	64
7.2 Modern Ventilation	67
7.2.1 Dilution and Removal	69
7.2.2 Air Mixing	71
7.2.3 Flow Direction	72
7.3 Filtering and Irradiation	73
7.3.1 High Efficiency Particulate Air Filters	74
7.3.2 Germicidal UV Radiation	76
7.4 The TB Isolation Room	77
7.4.1 Retrofit of Existing Facilities.	79
7.5 Special Areas.	80
7.6 Summary.	83
8 FUTURE TRENDS	84
8.1 Introduction	84
8.2 Medical Research	85
8.3 Occupational Safety and Health Research	87
8.3.1 Administrative Controls	88
8.3.2 Engineering Controls	89
8.3.3 Personal Protective Equipment	92

9 CONCLUSIONS AND RECOMMENDATIONS.	93
APPENDIX A Respiratory Protection 1910.134.	100
APPENDIX B Respiratory Protection 1915.152.	108
APPENDIX C Bloodborne Pathogens 1910.1030.	112
WORKS CITED.	131
GLOSSARY.	134

LIST OF TABLES

Table	Page
1 Reported Cases and Rates of Tuberculosis in the United States. . .	facing 8
2 Tuberculosis Morbidity and Mortality in the United States.	15
3 HIV Mortality Data.	facing 16
4 Regimen Options for Initial Treatment of TB among Children and Adults.	33
5 Criteria for Preventative Therapy	facing 46
6 Contaminant Removal Efficiencies per Air Changes per Hour . . .	facing 70
7 Selected Pressure and Ventilation Relationship of of Hospital Areas	facing 71
8 APPENDIX A Table I-1	106

LIST OF FIGURES

Figure	Page
1 The Mycobacteria Tuberculosis	5
2 Graph of Expected Cases of TB vs. Actual Cases	16
3 The Ventilation System at a Viel Loge in Salpêtrière, France . . .	facing 64
4 Hospital Ward Design for Johns Hopkins Hospital, 1875	facing 64
5 Pressure Drop Test For HEPA filter Operation	facing 75

CHAPTER 1

THE TUBERCULOSIS BACILLI

1.1 Introduction

Tuberculosis has been acknowledged as a major health threat throughout the history of mankind. Despite the decline of new cases experienced during the middle of this century, it has again become a serious threat in the United States. Once again research and technology have been applied towards the prevention and cure of tuberculosis. Tuberculosis is caused by a bacteria called the *Mycobacterium tuberculosis* also known as tubercle bacillus (TB) which is coined from the Latin word tubercle, meaning small lump or nodule. The lungs are the predominate site of the infection; however, any body tissue is susceptible. When a significant infection develops in the lung, necrosis may occur, often the size of a nut or small egg, that heals either by fibrosis, encapsulation, calcification or scar formation. When these lesions soften and break down through liquidification, the characteristic cavity within the lung associated with TB remains. Despite the constant decline of new cases since 1953, TB has realized a resurgence in the U.S. beginning in 1985. To discuss the implications and the contributing factors of this increase and its impact on the health care community, it is necessary to first understand the history, etiology, epidemiology and pathogenesis of TB.

1.2 History

TB ravaged skeletons from pre-historic times have been discovered and pre-biblical references made of a human illness similar to TB in the pre-2000 BC *Code of Hammurabi*, demonstrating that TB has had a long history with mankind. This scourge was known as "phthisis" by the Greeks, "consumption" in the Bible, the "great white plague" in the Victorian era, and finally, as "tuberculosis" beginning with the age of modern medicine. Hippocrates (460-377 BC) considered TB to be the gravest of all the diseases at that time, the most difficult to cure and the most fatal (1). That sentiment followed for hundreds of years as physicians were discouraged from treating advanced cases of TB since the patient would surely die and damage their reputation, that is until the age of modern medicine.

The modern discoveries initiated by René Théophile Laënnec who invented the stethoscope in 1816 and L. Auenbrugger who re-developed chest percussion from the ancient Greek technique in the late 1700's, allowed clinical diagnosis and the physical signs and morbid anatomy of TB to be defined. Also proposed was evidence that this single disease which originated in the lung could have a systemic effect on other body tissues. Laënnec never believed that TB was contagious or transmissible. However, he ironically infected himself when sawing a cadaver skeleton during an autopsy in what was described as one of the first documented accounts of transference of TB (2). In 1868, Jean-Antoine Villemin proposed that TB was an inoculable agent or germ and was transferable from

man or cow and that TB never originates spontaneously and is perpetuated only by transmission through society (3). In 1882, Robert Koch isolated the tubercle bacillus by use of a staining process. Koch's discovery finally ended the assumptions made for thousands of years that the disease was hereditary and attributed to "bad blood" or "bad hereditary" (4). The invention of the microscope, allowed a detailed examination of sputum cultures with staining techniques. The discovery of X-rays in 1885 by Roentgen revealed the presence of cavity formations in the lung enabling an accurate diagnosis to be made. Typically, those who were identified as being infected with TB often convalesced at sanatoria where bed rest, good food and moderate exercise along with surgery in the more severe cases served as the only relief of the disease's symptoms. Surgical techniques relieved suffering and put diseased portions of the lung at rest and collapsing the lung by artificial pneumothorax or removal of portions of the lung resection or lobectomy. Finally, with the development of streptomycin by Selman A. Waksman, the first chemotherapy was made available for the treatment of TB.

In 1945, the first attempts at chemotherapy with Waksman's streptomycin were made. Streptomycin is an antibacterial antibiotic which was combined later with another antibiotic called para-aminosalicylic acid (PAS). This combination of drugs delayed the emergence of streptomycin resistant strains of TB. With the introduction of isoniazid (INH), another antibiotic in 1952, three drugs were now available for the treatment of TB. PAS and INH were given orally,

typically for a course of 18 to 24 months. In 1962, PAS was replaced by Ethambutol which had fewer adverse side effects. Chemotherapy was extremely effective and had practically forced the closing of the sanatoriums in the US by 1960. In 1966, rifampin (RIF) was added to the chemotherapy regimen which allowed the treatment period to be nearly cut in half.

1.3 Etiology

The ground work for the modern etiology of TB was proposed by Robert Koch in his paper *The Etiology of Tuberculosis* (5) that was presented before the Physiological Society of Berlin on March 24, 1881 leaving the audience in utter silence as he struck down the beliefs of many of his opponents in attendance. Koch understood from Villemin's and the research of others that TB was transmissible and that some nature of a parasite or bacteria was responsible for its transmission. Koch systematically analyzed suspected tuberculosis microorganisms and, through the development of a specific staining process, was able to isolate the *Mycobacterium tuberculosis*. Koch was able to subsequently grow the bacteria in an artificial medium and inoculate laboratory animals which resulted in TB infections. There was nothing extraordinary with regards to his methodology; however, he received much world acclaim for being the first to isolate the previously unseen "greatest killer of mankind".

Mycobacterium tuberculosis is an obligate intracellular parasite or nonmotile rod as shown in Figure 1. TB shares a particular staining quality with other acid

fast aerobic bacilli (AFB). After staining with a carbol-fuchsin compound and then washing with nitric acid, the cell walls that contain lipids absorb the stains and form a stable complex with the cells allowing the identification of the organism by turning the AFB red and all other tissue blue.



Figure 1 The Mycobacterium tuberculosis (X 90,000 by electron microscope)

Various strains of TB have occurred and taxonomists disagree as to whether to divide the genus Mycobacterium tuberculosis into three complexes: M. tuberculosis, M. bovis and M. africanum where others would consider M. tuberculosis to be the only complex with subclassifications for the M. bovine or M. african type.

1.4 Epidemiology

As indicated in his 1865 paper, *On the Cause and Nature of Tuberculosis and Its Inoculation From Man to Rabbit*, (6) Villemin demonstrated that TB could be transferred among animals with the injection of sputum or blood from

infections, utilizing control experiments. He further concluded that TB was a specific virus (although TB is actually a bacterium) which did not occur spontaneously and was not the product of emaciation, misery, atmospheric disturbances, heredity, occupations nor progressive maladies (6). Three years later in his book *Etudes sur la Tuberculose*, (3) Villemin further proposed that TB was more prevalent among medical personnel, soldiers stationed in barracks than among troops in the field, prisoners, industrial workers and members of cloistered religious orders. Villemin found that TB was less prevalent at higher altitudes and among those groups that live in the open air in a nomadic state, and more prevalent in cities and among groups that are confined indoors (3). His recommendations for combating TB included the improvement of working conditions, ventilation and the disinfection of things and places occupied by consumptive patients.

Today, it's understood that TB is transmitted via airborne aerosols 1-5 microns in diameter which are generated by persons infected with pulmonary or laryngeal TB where active bacteria are expelled when they cough, sneeze, speak or sing (8). The aerosolized particles may be suspended in air or travel on ambient air currents for long periods. Those infected in extrapulmonary sites are not contagious via the airborne route, however, care must be utilized when handling infected human tissue. TB thrives in dark, moist places and dies on exposure to sunlight and drying (9). Linens, eating utensils and bed clothes are not considered viable routes of infection. Other less frequent routes of exposure

include injection through the skin by laboratory workers who may be cut by glass containing actively growing TB cultures, surgeons and nurses in operating theaters who aerolize TB infected tissue during surgery and pathologists conducting postmortems on TB infected corpses. In the days of unpasteurized milk *M. bovis* was transmitted causing TB of the tonsils and submandibular lymph nodes of humans.

Other contributing factors in susceptibility to TB include concentration of aerosol droplet nuclei in the air and length of exposure. Once infected, only 5% to 10% of persons not HIV+ will show clinical signs of the disease in their lifetime (10). Pulmonary sites account for 85% of cases of TB while extrapulmonary sites such as blood, central nervous system, pleura, pericardium, genitourinary, gastrointestinal tract, adrenal, liver, mouth, middle ear, larynx, bronchial tree, lymph, bones and joints represent the remaining 15%.

The Center for Disease Control (CDC) has recently classified the following groups as high risk for developing TB. This group includes persons who are HIV+ or who are suspected of being HIV+; those in close contact with newly diagnosed infectious TB patients; recent converters of TB skin tests; persons with chest X-rays indicative of old healed TB; intravenous drug users or persons with other medical conditions known to be susceptible to TB. Other risk factors identified include foreign-born persons from high prevalence countries, medically underserved low-income populations and residents of long term care facilities (11). Other investigators believe that health care workers also

Table 1 Reported Cases and Rates of Tuberculosis in the United States

	<u>CASES</u>			<u>RATE per 100,000 persons</u>		
	1985	1990	%	1985	1990	%
Totals	22,201	25,701	+15.8	9.3	10.3	+10.8
Sex						
males	14,496	16,966	+17.0	12.5	14.0	+12.0
female	7,704	8,729	+13.3	6.3	6.8	+7.9
unknown	1	6		-	-	-
Age						
0-4	789	936	+18.6	4.4	5.1	+15.9
5-14	472	660	+39.8	1.4	1.9	+35.7
15-24	1,672	1,867	+11.7	4.2	5.1	+21.4
25-44	6,758	9,730	+44.0	9.2	12.0	+30.4
45-64	6,138	6,365	+3.7	13.7	13.7	0.0
>64	6,356	6,115	-3.8	22.3	19.6	-12.1
unknown	16	28	-	NA	NA	-
Race/Ethnicity						
White	8,453	7,836	-7.3	4.5	4.2	-6.7
Black	7,592	9,634	+26.9	27.1	33.0	+21.8
Hispanic	3,092	4,782	+54.7	17.3	21.4	+23.7
Asian/Pacific						
Islander	2,530	3,027	+19.6	46.0	41.6	-9.6
Native Alaskan/ American	397	371	-6.5	24.9	18.9	-24.1
Other	137	51	-	NA	NA	-
Country of Origin						
Foreign	4,925	6,626	+27.1	NA	NA	-
US-born	17,712	18,997	+7.3	NA	NA	-
Unknown	131	442	-	NA	NA	-

Source: Center for Disease Control. 1990. "Tuberculosis Morbidity in the United States Final Data, 1990" *Morbidity and Mortality Weekly Report*. 40 SS-3.

represent a high risk group. The CDC recognizes the potential for the spread of TB among health care workers and patients alike within health care facilities and has prepared recommendations outlining a set of guidelines for the prevention of contamination.

The latest published data by the CDC from 1990, shown in Table 1, indicates the greatest rise in new cases of TB to be among the age group between 25 to 44 with a 44% increase over the 1985 data. The rise in new cases of 39.8% among the 5 to 14 year old's is attributed to the fact that most often, an older family member in the 25 to 44 age group has contracted the illness and transfers the TB bacteria by virtue of living in the same household (12). The only declines among new cases were found in members of the groups belonging to the white non-hispanic and Native American or Alaskan groups. Increases in new TB cases also have been shown to parallel those of new cases within the HIV epidemic mainly occurring in males within the 25 to 44 year old age group.

1.5 Pathology

In the primary phase of TB, assuming the bacteria are airborne and able to pass through the upper airways defenses of the mucosal membranes or cilia, the 1-2 micron diameter organisms will lodge in the alveoli of the lungs, usually in the lower or mid lung fields, while those larger than 3-5 microns in size deposit higher in the respiratory tract. Once trapped, the bacteria multiply and spread through the lymph system and blood stream, quickly infecting other organs,

typically those high in oxygen concentration. Inflammation occurs at the site of initial deposition in the lung forming granulomas consisting of epithelioid cells, macrophages and giant cells. As the infected person's immune system becomes sensitized and recognizes the bacteria, macrophages attack, not destroying, but engulfing and surrounding the TB organism and walling them off in tiny hard capsules called tubercles throughout the body (13). Depending on the concentration, virulence of the bacteria and effectiveness of the immune system, these granulomas in the lung (if they are large enough) may cause a form of necrosis called caseation, which has the consistency of soft cheese (14). The caseum softens and liquifies when attacked by the toxin emitting cytotoxic lymphocyte macrophage of the immune system. A cavity will form in the lung when this liquid material and lung tissue is expelled. In less serious infections, the initial site may heal completely without any cavitation. The secondary stage consists of the healing process of the primary infection which includes the formation of cavities and scar tissue in the lung.

During the third stage, the bacilli remain encapsulated by the macrophage. They may remain encapsulated for the lifetime of the patient, and may never cause a reactivation of the disease. However, should the immune system become depressed and the macrophages weaken, a fourth stage will occur when the bacteria reactivate and multiply. This process occurs in a relatively small population of normally healthy persons not infected with an immunosuppressant illness like HIV. This multiplication often will occur in the lung usually at the

apex, or at other extrapulmonary sites. A fifth stage occurs if a previously infected person becomes again infected with a variant bacilli of drug sensitivity different from that of the primary infection.

1.6 Signs and Symptoms

The early medical community unknowingly often placed TB within a general class of illness with similar characteristics. The early Greeks utilized the word *phthisis* meaning "wasting of the body" to describe the fluid losses of the body from diarrhea in the latter stages of the illness, and from drenching sweats (4). Later, *consumption* was used to describe the burning up or wasting of the body. Finally, *tuberculosis* was used to describe the illness from the Latin word *tuberculum*, meaning lump.

One of the earliest and most encompassing descriptions of the disease was by the early Roman physician Caelius Aurelianus who stated:

The symptoms of the disease are as follows: there is a latent fever, which generally begins toward the end of the day and is relieved by the coming of the new day; this is accompanied by much coughing at the beginning and end of the night, with discharge of sanious sputa... The voice is either hoarse or high pitched, breathing difficult, cheeks flushed, and the rest of the body ashen colored. The eyes have a worn appearance, and the patient is emaciated, a fact more obvious from the appearance of the naked body. In some cases there is a hissing sound or wheezing in the chest; and, as the disease spreads, there is sweating in the upper parts down to the end of the chest.(15)

Pulmonary tuberculosis, as previously indicated, is asymptomatic at first. The initial signs of fever, weakness and weight loss are very subtle and often

unnoticed. Signs become more apparent once the lesion in the lung is visible on X-ray. A cough occurs as secretions are drained from necrotic lung tissue into the bronchi. The cough is more productive usually in the morning from the accumulation of secretions overnight while sleeping. The expectorate or sputum produced from the cough is green and purulent and is minimal at first, increasing as cavitation occurs. As cavitation ends and the illness enters a more chronic stage, the expectorant becomes yellowish. Hemoptysis, or the coughing of blood, may occur as cavitation erodes an arterial wall, or inflammation of the endobronchial tree develops. Bleeding may range from slight streaking in the sputum to massive bleeding, but is rarely fatal. Chest wall pain may occur as the pleural lining of the lung may become inflamed by effusion of fluids. Dyspnea, or shortness of breath, may occur from spontaneous pneumothorax or pleural effusion (16).

1.7 Diagnosis

The tuberculin skin test is useful in determining if a patient is infected, however, a negative test should not exclude a diagnosis of TB (16). Several tests have been developed, all of which utilize a purified protein derivative (PPD) antigen which is introduced to challenge the immune system. The most effective method is an intradermal injection called Mantoux's Test. Other methods include a scratch method called Pirquet's Test or a multipuncture tine test. Typically five tuberculin units (TU) are administered, however, one TU may be

utilized for young children. A positive test results in a palpable induration or upwelling of the injection site over 10mm in 48 hours.

As the skin test is not a definitive indicator if a patient is infected, the importance of taking a careful history and conducting a thorough physical examination by the physician cannot be mitigated. When suspicion of TB exists, the patient should be asked if contact has been made with known TB infected patients or members of high risk groups. Chest X-rays may be useful for showing cavitation; however, this may not always be diagnosed by the radiologist who may interpret the finding as another malady. Bacterial examination of sputum samples which test positive for staining AFB also will prove effective; however, other AFB's besides TB cannot be ruled out by this method.

Definitive diagnosis can only be made with the cultural identification of the sputum samples. This process currently takes three to six weeks and entails the growing of the bacteria in a culture medium. One advantage to this technique is the capability of determining the varying degree of resistance to antibiotics utilized in combating TB should a new drug resistant strain be present.

1.8 Summary

Modern medicine prevailed during the middle of this century in the war against TB. Thousands of lives were saved as the result of the development of antibiotics. The advent of multidrug resistant TB strains has made the potential for cure more difficult. This has increased the importance of understanding the

pathology, epidemiology and etiology of TB in order to prevent its unnecessary transmission through society. The public health service must disseminate their knowledge to make the general public, and health care workers in particular, aware of the need for concern.

CHAPTER 2

THE NEED FOR CONCERN

2.1 Introduction

Once known to be the leading cause of death among young adults during the industrial revolution in both Europe and the United States, and once commonly called the "great white plague", the tuberculosis bacilli is again showing a resurgence in new cases in the US. These outbreaks have prompted the Public Health Service's, Advisory Committee for Elimination of Tuberculosis (ACET) to propose as a goal the elimination of TB in the US by year 2010. The diseases resurgence has been attributed to several factors: the increase in multidrug-resistant strains of TB, susceptibility of patients infected with HIV to TB, immigration of infected persons into the US, and the weakening of the healthcare infrastructure. Ironically, the health care system which is charged with the task of caring for the sick, may unknowingly bring patient's with active TB together with those with depressed immunosystems, such as, HIV. This new resurgence has made it essential for the health care community to examine its existing infrastructure to insure that additional exposures do not occur among health care workers and patients alike. A discussion of each causative factor and its implication related to the recent increase in outbreak of tuberculosis follows in this chapter.

2.2 Resurgence of Tuberculosis in the United States

On the world wide level, particularly in third world countries, TB has continued at epidemic levels for decades despite the development of antibiotics. The World Health Organization estimates that 8 million new cases and 3 million deaths occur annually (17). Fortunately, these massive epidemic levels have not reached the US, but a resurgence nevertheless is occurring here. The total number of TB cases began declining in the US following the clinical introduction of streptomycin in 1947. As shown in Table 2, the death rate also decreased significantly with the introduction of antibiotics.

Table 2 Tuberculosis Morbidity an Mortality in the United States

<u>YEAR</u>	<u>NEW CASES</u>	<u>TB DEATHS</u>	<u>DEATH RATE</u> <u>per 100,000</u>
1930	124,940	88,010	71.0
1947	134,946	48,064	33.0
1950	121,742	33,959	22.0
1953	106,925	19,393	12.0
1959	*****	11,429	6.5

Source: Selman A. Waksman *The Conquest of Tuberculosis*. Berkeley and Los Angeles: The University of California Press 1964, 23.

The CDC began collecting TB data nation wide in a standardized manner in 1953. The data indicated that from 1953 and until 1985, the rate of new cases has declined steadily by 5% to 6% each year. However, from the period between 1985 to 1991 an 18% increase in new cases was reported. This represents 39,000 additional cases beyond those normally expected (10). Figure

Table 3 HIV Mortality Data for 1990

1990 CASES	
<u>Totals</u>	43352
<u>Sex</u>	
males	38094
female	5258
<u>Age</u>	
0-4	626
5-12	162
13-19	170
20-29	8334
30-39	19728
40-49	10023
50-59	3020
>60	1289
<u>Race/Ethnicity</u>	
White	22326
Black	13211
Hispanic	7353
Asian/Pacific Islander	271
Native Alaskan/ American	79

Source: Center for Disease Control. 1992. "Update, Acquired Immunodeficiency Syndrome United States 1991 " *Morbidity and Mortality Weekly Report*. 41: No 26.

2 shows the graph of the increase over the projected decline.

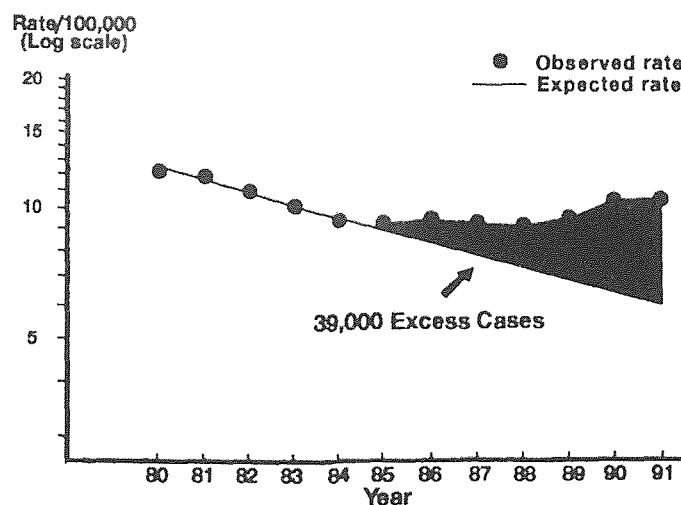


Figure 2 Graph of Expected Cases of TB vs Actual Cases

Source: Snider, Dixie E. and Dooley, Samuel W. 1993. Nosocomial Tuberculosis in the AIDS Era With a Emphasis on Multidrug Resistant Disease." *Heart and Lung*. 22:366.

With the recent upward trend in new cases, the CDC realized that the war against TB was not over. Greater emphasis was now placed on the identification of the predisposing factors leading to this increase.

2.2.1 The HIV Epidemic

The increase in new TB infections correlated with those population groups which experienced increases in HIV. The socio-economic, age and geographic location factors of those groups which have the greatest growth of TB are similar to those with HIV. Table 3 shows the latest data concerning the growth of HIV.

A comparison of Tables 1 and 3, confirms the parallel increasing growth of TB and HIV within the same groupings. The male sex and the middle age groupings show the greatest number of new cases in both TB and HIV infection in the United States. As TB is a disease which becomes reactivated when the natural immunosuppressant system weakens, these correlations between HIV & TB are to be expected.

One study conducted by the CDC in 1990 and 1991 examined multidrug resistant TB outbreaks in six hospitals. Of a total of 200 patients, most had HIV or AIDS and showed the clinical signs of active TB varying from two weeks to several months. The mortality was 72% to 89%, death usually resulted in four to 16 weeks following diagnosis of TB (10).

The CDC recognized the immunological association between HIV and TB and added TB to its list of AIDS indicator diseases in December 1992. With this addition, TB joined 24 other diseases found to be prevalent in AIDS cases. This correlation will further enhance collaboration between TB and HIV/AIDS programs and allow preventative therapy to be provided to HIV contact individuals who test TB positive (18).

2.2.2 Multidrug Resistant Tuberculosis

A study conducted in New York City in 1991 indicated that 33% of TB cases were resistant to at least one antibiotic and 19% were resistant to both isoniazid and rifampin (19). One strain was found to be resistant to seven drugs (10). Of

the total cases in 1991, multidrug resistant TB (MRTB) accounted for 6.9% of cases, a increase from 3% for the period between 1982 and 1986 (19). This significant increase of a bacterial mutated strain during such a short time frame has the public health community concerned.

MRTB is a result of a spontaneous genetic mutation. The cause of resistant strains is most often the result of the non-compliance with patient's medications, which allows the mutated strains to multiply while antibiotics, which may still be effective, are not taken. The drug resistant property is unknown at the start of a treatment regiment and can only be determined following an in-vitro culture examination which may take several weeks. A study of the infection rates of MRTB vs TB found the rates to be approximately the same (19). The CDC has recommended an initial treatment course of four different antibiotics to combat the current strains of TB.

The impact of these MRTB strains upon the resurgence of TB in general is two-fold. First, the MRTB's are more difficult to cure as multiple drug regimens are required, and close supervision is needed to assure that the patient consumes all required medications so as not to permit the evolution of another drug resistant strain. Second, the economic impact associated with the administration of these drug programs deprive other areas of funds which may be utilized in education and/or prevention. The impact of MRTB will be discussed in a future chapter.

2.2.3 Foreign Born Persons Entering the United States

The Advisory Committee for the Elimination of Tuberculosis has recognized the impact of foreign born individuals entering the US who have TB or who come from countries which have a high prevalence of TB. This development has prompted the CDC to issue a set of recommendations in December 1990. In 1989, the CDC projected that the TB incidence rate for the overall US population was 9.5 persons per 100,000 and the incidence rate among foreign born persons entering the US to be 124 persons per 100,000. Most of these individuals immigrated from one of six countries: Mexico, Philippines, Vietnam, South Korea, Haiti or China. Data available on illegal aliens is not available; however, it is estimated that a high prevalence also exists within that population group since they often stem from the lower socioeconomic groups of their home countries which also tend to have a higher prevalence of TB similar to those in the US.

Currently, a physical examination conducted by physicians appointed by the local consulate is required for those who wish to immigrate permanently to the United States. The examination includes the taking of a medical history, a chest X-ray for those 15 years of age or older (or a TB skin test for those younger than 15 if the adolescent's family member has active TB or if the child is ill). If the immigrant is determined to have TB, the physician may classify the patient either as Class A or Class B depending upon the disease's communicability. Class B, "Tuberculosis, not considered active" is given if the

comparison of a old chest X-ray from at least three months ago shows no changes or, Class A, "Tuberculosis active, non-communicable for travel purposes" for those individuals who do not have a previous X-ray and who test negative for AFB in two consecutive sputum smears. Class B individuals may receive their visas, but Class A must receive a waiver from the local consulate to enter the US. Both classes must follow up with visits to the local public health boards if permitted to travel to the US. The philosophy of the current procedure is to exclude those who are actively contagious and begin treatment until a time when they are no longer communicable, and to help manage the illness once they arrive in the US. The CDC has identified several areas of the present policy which are problematic.

Various problems cited include several aspects of the procedure. The misdiagnosis of the condition as a result of incorrect interpretation of the chest X-ray, clerical errors, fraud by the applicant in providing "doctored" or purchased normal X-rays, or failure to produce sputum samples when requested. The physical exam is valid for one year, which would tend to exclude identifying those individuals who may have contracted TB some time after their physical exam. The failure of immigrants to report for follow up exams with domestic health departments upon arrival in the US has been identified to be as large as one third for both Class A or Class B infected individuals. When follow-up was made in the US, it was found the classification between A's and B's was often in error, possibly as a result of crude techniques utilized overseas. Those

treated in their home countries may have developed multi-drug resistant TB as a result of inadequate treatment because of the limited resources available. Only immigrants who desire permanent residence are required to submit to a physical. This step excludes most students or those with temporary visas. Cases were found where some immigrants entered the US on a temporary basis specifically for TB treatment. This further taxes the health care system. Finally, the problems associated with increasing numbers of illegal aliens and the language barriers which exist between the health officials further hamper the proper management of the illness in the US. For these reasons, the CDC has proposed a number of modifications to the current system.

In order to mitigate many of the problems described above, various recommendations were made. The CDC still recommends that chest X-rays and skin testing should still be required for immigrants; and those who test positive should all be considered Class A, thus eliminating the Class B diagnosis overseas. This allows public health authorities in the US to further classify the illness and recommend appropriate treatment. For those individuals who have positive AFB sputum smears, treatment should begin overseas until negative smears are obtained in two consecutive days, and only then should a waiver be granted to travel. Advanced arrangements with a local health department or private physician in the US who will agree to treat the illness or make the required follow-up examination will be required for those entering on waivers. Quarantine officers at ports of entry will continue to notify local public health

departments of the arrival of such immigrants and to anticipate a follow-up within ten days with the prearranged health care provider. Private physicians treating patients must notify the local health department within 30 days if the immigrant has not reported for evaluation. Those who refuse treatment should be quarantined as provided by law. Finally, a quality assurance program should be established and overseas physicians conducting screening exams for local consulates given a standard written procedure for the exam. Corrective action against the physician could be taken if these procedures are not followed.

Refugees who seek political asylum in the US share many of the same infection problems as those who immigrate via regular channels. For refugees entering the United States from high prevalence countries in Southeast Asia, all ages must also undergo a TB skin test in addition to chest radiographs. They too must receive preventive TB therapy if their skin test is positive. All refugees from these areas must also follow up with local health departments upon arrival in the US. Refugees from other countries will follow the same procedures as other immigrants, but they must still follow up with local health departments even if X-ray abnormalities are not uncovered.

In both scenarios the local health departments play a key role in controlling both the immigrant and refugee populations residing in the US. These departments have been charged with the task of screening, prevention and treatment of many of these immigrants. Needless to say, the economic resources required to fulfill these requirements are substantial. With three

quarters of foreign born arrivals settling in New York, New Jersey, California, Florida, Texas and Illinois, these regions are especially hard hit. In order for the ACET to realize their proposal to eliminate TB in the US by 2010, the entire health care infrastructure must be examined.

2.2.4 Health Care Infrastructure

The health care infrastructure encompasses a broad spectrum which includes the facilities and personnel of hospitals, clinics, private offices, dental offices, emergency medical services, the public health service, administrative policies, governmental legislation, private accreditation and even the training and education provided to employee and patient alike. As with any chain, it is only as strong as its weakest link. One of the weaker links within the system appears to be the inability to diagnose active TB early. Late detection enables the illness to be needlessly transmitted to other persons including family members, hospitalized patients or health care workers.

The data suggest that the highest populations of new cases of TB have occurred within those socio-economic groups which belong to the lower classes and who live in urban areas where the local hospital emergency department (ED) serves as the primary care facility. Most of these facilities are over taxed caring for the normal emergency case load. The early symptoms of TB are very subtle and even when noticed, may be confused with many other maladies. In a busy ED, the likelihood of a misdiagnosis is multiplied causing other patients

and health care workers to be exposed to a communicable aerosol. Recent attempts to prevent such over-crowding of ED's in urban areas include the establishment of satellite clinics where a continuity of care may be provided. In these settings preventative medicine may also be applied, and a more rapid diagnosis of TB established with routine testing. Once identified, those diagnosed with TB may be referred to special clinics for those diagnosed with HIV or TB. These facilities assure that the most current and continuous level of care may be provided for such patients.

CHAPTER 3

TREATMENT OF TUBERCULOSIS

3.1 Historical View and Early Treatments

The Romans believed climate influenced the prognosis of phthisis and the cure was to be found only in a warm dry climate. Hence those afflicted that have financial means would travel to Egypt or Sicily. Long sea voyages and the warm ocean air inhaled by the patients was thought to be a cure. The Greeks believed that nutrition and fluid intake played a key role in the cure of phthisis. Galen, early in the first century indicated that consumptive patients should occupy a cool, well ventilated underground room (4). Many believed that sunshine was the surest cure and recommended habitation in sunny southern climates. This theory was later justified by scientific evidence as Koch demonstrated that the *Mycobacteria tuberculosis* in culture form was shown to die when exposed to sunlight. Diet and absolute bed rest was stressed by others, contrary to those who believed the consumptive patient should exercise regularly.

Obscure cures utilized prior to the age of modern medicine included the drinking of woman's, goat's, cow's or ass' milk. The remedies of an early Roman naturalist named Pliny, suggested the intake of a wolf's liver boiled in wine, inhaling smoke of burning cowdung through a reed, the drinking of elephant's blood mixed with the milk of a woman or ass or the eating of mice

boiled in salt and oil (2). Cold bathing and "breathing into a hole fresh cut into the earth" was recommended by John Wesley in the eighteenth century. Primitive attempts at early chemotherapy included treating patients with salt compounds of iron, sodium chloride, chlorine gas, digitalis, creosote, iodine and preparations of gold and silver. All of these compounds proved ineffective against curing TB and in many cases, actually caused complications (4).

In retrospect the most effective of these early treatments proved to be convalescence in better climates, good nutrition and the advocacy of proper rest augmented with slight exercise. These methods were combined leading to the eventual development of the sanatoria, after the Latin word sanare meaning to cure or heal.

3.2 The Sanatorium

In the early 1800's a young botanical student named Hermann Brehmann suffered from TB and was told by his doctor to convalesce in a better climate. Brehmann left Germany for the Himalaya Mountains where he conducted botanical research. He ultimately recovered and returned to Germany to study medicine. He presented his findings regarding TB to the medical community in 1854 in his thesis entitled *Tuberculosis is Curable* (5) and settled in Görbersdorf. There he built a house in the middle of a pine forest where he treated TB patients with nourishment and life in the open air. Although sanatoria were established prior to Görbersdorf, the techniques Brehmann utilized

met with success and became the model for sanatoria for many years. The typical treatment utilized was to first rest the patient until the fever subsided. Once the fever broke, exercise was introduced, gradually at first, and then increased to a level allowing for completion of a day's normal activities.

Edward Trudeau MD, said to be the American pioneer of TB, was one of the first to successfully develop a sanatorium philosophy domestically. Trudeau, who himself was infected with TB, was not satisfied with his grave prognosis and set out to find a successful treatment. He left for the Adirondack Mountains near Saranac Lake, New York where he could rest and "lead a open-air life in the great forest, alone with nature". In 1885, he established the Adirondack Cottage Sanatorium and committed himself to the study of TB. The sanatoria and specialized hospitals spread quickly across the US in the late nineteenth century. One of the first specialized hospitals established in the United States was the Chestnut Hill Hospital in Philadelphia in 1886. Specialized wards previously had been established at Bellevue Hospital and City Hospital in New York City.

The period of the sanatorium lasted for many decades. The quality of life for many improved because of the rest and fresh air provided at the sanatorium. Perhaps the greatest contribution of the sanatorium system, was the consolidation of resources and sharing of knowledge towards the research and care for those inflicted with TB. The establishment of professional societies like the National Tuberculosis Association and the sponsoring of International

Conferences enhanced cooperation among the medical community. Work stemming from these organizations aided in public health campaigns, early detection through the use of X-rays, and public education.

With the advent of chemotherapy, the need for long convalescence at sanatoria or specialized hospitals ended. Initial therapy would now be started at general hospitals followed by care given at home. Where once long waiting lists existed at the turn of the century, beds were now vacant at TB sanatoria. By 1960, most of these facilities were closed or converted into old age convalescent centers.

3.3 Early Surgery

Surgical methods introduced at the sanatorium included the artificial pneumothorax, thoracoplasty, lobectomy or pneumonectomy. These techniques were performed for more difficult cases where rest and fresh air did not relieve the symptoms. Surgeons typically developed new techniques in the military and passed this knowledge on when returning to private practice.

The artificial pneumothorax developed by Carlo Forlanini in 1888 introduced a pressurized gas between the layers of the pleura which would cause the lung to collapse. The theory was to induce a forced rest of the lung. The artificial pneumothorax could only be performed on one lung at a time and was not sustained for long periods since the lung would tend to reinflate. The thoracoplasty perfected later would collapse the rib cage by removing portions

of the ribs thereby making the pneumothorax more permanent.

Other procedures such as lobectomy and pneumonectomies were developed as advanced surgical techniques advanced. These techniques would facilitate the removal of a diseased lung or portions of diseased lungs and relieve some symptoms in the more serious cases. However, these procedures were not available to all, nor did they provide a cure for TB. Only with the advent of modern chemotherapy was a cure for TB found.

3.4 Modern Chemotherapy and the Development of Streptomycin

Research in the late 1800's demonstrated that tuberculocidal agents exist in fresh unsterile soil. Bacteria, actinomyces or fungi in the soil were identified as the possible agents. Experiments conducted in Europe had TB patients inhale these microbes, where others injected the microbes randomly into rabbits. Veudremer, in 1910, injected 200 patients with an extract of a fungus in Paris. The results showed evidence that *Mycobacteria tuberculosis* is sensitive to some products of fungi. However, the medical community at the time did not exploit the findings.

Selman Waksman, a soil microbiologist, confirmed the *Mycobacteria tuberculosis* consumption process occurring in soil in 1935. Further research by Waksman was delayed for eight years due to a lack of funding and interest in the area. In June 1943, Waksman met with representatives from various pharmaceutical companies, the Saranac Laboratories and the National

Tuberculosis Association. The scientific interest and financial backing was now in place for research and development in effective chemotherapy.

Waksman systematically analyzed the various organisms found in soils and dusts. He concentrated on actinomycetes as he had conducted research in this area as an undergraduate at Rutgers and as a graduate student at the University of California. Waksman and his staff isolated several antibiotics from specimens during his research; however, they were found to be too toxic when administered to laboratory animals. Finally, in September 1943, streptomycin (SM) was isolated and was found to be less toxic than previous strains. Streptomycin was used in the control of various infections and was confirmed to be effective against TB in humans at the Mayo Clinic.

Clinical tests were conducted in 1944 in conjunction with the Merck Company and the Mayo Clinic. The clinical results confirmed that streptomycin was effective against TB with a low toxicity to man. In 1947, the drug was marketed nationwide for use against TB. The death rate decreased and the end of TB could now be foreseen; however, Waksman warned the medical community that resistant strains of TB would develop and additional antibiotics would be needed.

3.5 Other Antibiotics

The development of additional antibiotics was necessitated soon after the distribution of streptomycin for several reasons. Streptomycin did not kill the

medications available, home treatment could now be seriously considered.

Other antibiotics developed included pyrazinamide (PZA), ethambutol (EMB), ethionamide, capreomycin and kanamycin. When given in varying combinations and dose regimens, existing TB cases were cured and new cases decreased. Typically sputum would clear of AFB within six months if the suggested treatment regimen was followed. Few drug resistant strains developed as a result of using multiple antibiotics and increased public awareness. However, resistant strains have developed in this decade as a result of inappropriate treatment overseas, the spread of the HIV virus and a weakening of the health care infrastructure. These resistant strains proved to be most difficult to cure and may require even more powerful antibiotics to combat them.

3.6 Multidrug Resistant Tuberculosis

Between 1990 and 1992, the CDC studied several outbreaks of MRTB that were isolated within hospitals or correctional facilities. One strain in particular was found to be resistant to seven antibiotics. Typically, these outbreaks were found in persons that were HIV positive, or in health care workers who cared for the patients (20).

The pathology and mode of transmission of MRTB vs TB are the same. However, MRTB tends to remain infectious for longer periods, as resistance to treatment is initially unknown. Only through invitro cultures could the actual

resistance be measured and the appropriate treatment selected. This culturing may take several weeks, which leaves the susceptibility of the bacteria to the initial course of medication in question during this period.

The CDC recognized the potential danger of MRTB strains developing and recently revised their recommendations regarding the initial treatment regimes for TB. As shown in Table 4, one of four options is recommended.

Table 4 Regiment Options for Initial Treatment of TB Among Children and Adults

<u>OPTION 1</u>	<u>OPTION 2</u>	<u>OPTION 3</u>	<u>TB with HIV</u>
Administer daily INH, RIF, and PZA for 8 weeks followed by 16 weeks of INH and RIF daily or 2-3 times a week.... EMB or SM should be added to the initial regiment until susceptibility to INH and RIF is demonstrated. Continue treatment for at least 6 months and 3 months beyond culture conversion...	Administer daily INH, RIF, PZA, and SM or EMB for 2 weeks followed by 2 times/week administration of the same drug for 6 weeks, and subsequently, with 2 times/week administration of INH and RIF for 16 weeks...	Treat by DOT, 3 times /week with INH, RIF, PZA, and EMB or SM for 6 months...	Options 1,2,3 can be used, but treatment regimens should continue for a total of 9 months and at least 6 months beyond culture conversion.

Source: Center for Disease Control. 1993. "Initial Therapy for Tuberculosis in the Era of Multidrug Resistance Recommendations of the Advisory Council for the Elimination of Tuberculosis" *Morbidity and Mortality Weekly Report*. 42 RR-7.

Each option includes the recommendation that a TB medical expert be consulted if the patient remains symptomatic or has AFB positive sputum smears after three months of treatment.

Noncompliance with medications has been recognized as a leading cause of MRTB. The CDC recommended that patient needs, living conditions, employment status and personal preferences be considered when deciding if direct observed therapy (DOT) should be utilized. DOT is more typically applied in lower socio-economic classes where the availability of a stable life style may not be possible because of homelessness or unemployment. Typical settings where DOT is administered are at TB clinics, community health clinics, migrant clinics, homeless shelters, prisons, nursing homes, drug treatment centers, hospitals, HIV/AIDS clinics, and occupational health clinics (10).

3.7 Summary

Waksman summarized in his book *The Conquest of Tuberculosis* published in 1964, the five stages that occurred in the search for the cure a TB:

1. The health resort era where patients would convalesce at sanatoriums typically located in a country atmosphere or in pine forests where the patients could inhale fresh air was the first stage.
2. The bed rest era initially rested the lung, then slowly exercised the patient to a level where they could at least perform to a level of limited activity.
3. The collapsing theory era provided the means to induce rest on effected lungs by a pneumothorax.
4. The resection era followed where removal of the effected area of the lung was accomplished by lobectomy or resection.
5. The chemotherapy era evolved providing effective treatment and the ultimate decline and cure of TB. (4)

Advances in technology or understanding would cause the advancement to the next phase. Each of these five eras overlapped in some degree as acceptance to the next stage was gained. Usually, patient prognosis would improve with each development; however, with a new era of increasing infection rates, this may not be the case. If Waksman were to propose his theory today, would he include MRTB?

CHAPTER 4

TRANSMISSION PREVENTION

4.1 Historic Methods

Debate ensued within the medical community as to the cause and communicability of TB, even after Koch's isolation and identification of the *Mycobacterium tuberculosis*. As late as 1952, some still believed that heredity played a major role in a person's relative susceptibility to TB. One of the earliest published commentaries regarding the highly contagious nature of TB was Girolamo Fracastoro's book *De Morbis Contagiosis* published in 1546 (4). Girolamo cited the analogy that TB was transmitted like a seed, remaining virulent for great lengths of time on the beds, clothing, and in rooms of phthisis patients. Girolamo proposed the use of caustics as a disinfectant wherever possible to destroy these seeds. Although he gave the virulence of TB more credit than warranted, his theory was the most contemporary of the day. Even the Bible describes the infectious nature of some diseases and the necessity for the burning or destruction of clothing and dwellings that contagious patients occupied.

Sylvius, later in the sixteenth century, more accurately described the infectious nature of TB. He cautioned that those brought close to the air expired through the nose or mouth of consumptive patients may become

infected. Those in close contact were advised to "protect themselves against those who are afflicted" (21). In 1720, Benjamin Marten proposed that TB may be caused by "minute, living creatures". Marten indicated that casual contact should not be feared, but close association with a consumptive patient where "drawing in part of the breath he emits" should be avoided (22). Although many of the theories were widely published during their time, factions within the medical community chose not to heed the warnings and the number of physicians and scientists who became afflicted with TB were numerous.

The potential communicability of TB was recognized by some national and local authorities. The earliest and most progressive measures taken to prevent further contamination within the general population were enacted in Southern Europe. In the Republic of Lucca, laws were enacted in 1699 which required the names of those infected to be reported, to permit disinfectant measures to be taken and to destroy certain possessions upon the patient's death. Physicians were required to perform autopsies upon death and families were advised to leave the front door open to allow an exchange of fresh air. All utensils, clothing and bedding were to be cleaned with lye. The rooms of consumptive patients were to be cleaned thoroughly and freshly painted upon death (4).

In England, the tuberculosis dispensary system was founded in 1887. It was realized that TB patients who were released from sanatoria would soon relapse upon returning home. The dispensary provided a location where the patient could be given minor treatment instead of returning to the sanatorium. Nurses

were trained to visit the patient at home and recommend changes in life style which might improve their medical condition. By visiting the home, the nurse could also monitor the health of other family members of the household and facilitate rapid recognition and treatment of TB should anyone become infected.

In 1911, when the National Health Insurance Act was enacted in England, the numbers of new tuberculosis dispensaries increased significantly. The appointment of Tuberculosis Officers to monitor and administer TB care in a regional manner also solidified the efforts of the nation.

One of the more encompassing laws was passed in Italy in 1782. Salvatore de Rensi recounted the following:

1. That household goods not susceptible of contamination shall immediately be cleansed and that which is susceptible shall at once be burned and destroyed.
2. That the authorities make an inventory of the clothing in the patients room to be identified after his death; and if any opposition shall be made the person doing so, if he belongs to the lower class shall have three years in the galleys or in prison, and if of the nobility, three years in the castle and a penalty of three hundred ducats.
3. The physician shall report a consumptive patient when ulceration of the lungs has been establish under penalty of three hundred ducats for the first offence and banishment for ten years for repetition of it.
4. That the authorities themselves shall tear out and replaster the house from cellar to garret, carry away and burn the wooded doors and windows and put in new ones.
5. That the poor sick shall at once be removed to a hospital.

6. That newly built houses shall not be inhabited within one year after their completion and six months after the plastering has been done and everything about the building operation has been finished.
7. Superintendents of hospitals must keep clothing and linens for use of consumptive patients in a separate place. (21)

4.2 The United States Public Health Service

Much of the early organized work in the United States regarding the eradication of TB was performed by voluntary organizations and later by official agencies. The National Tuberculosis Association, one of the oldest voluntary health organizations, worked closely with the United States Public Health Service. The Public Health Service formed the Surgeon General's Task Force on Tuberculosis Control in 1963. Both agencies recognized the complexity involved in the eradication of TB within the United States. The stubbornness of the TB bacteria was the major cause. TB will often remain dormant for long periods and exhibit no symptoms until in advanced stages, thus providing a longer period for the illness to spread among others.

With the stubbornness of TB in mind, the Public Health Service in the early 1960's recommended a two point approach at first. The first recommendation was to aggressively combat existing infections and achieve the maximum number of cures as possible. Second, dormant TB should not be allowed to develop into active TB by providing prophylactic treatment and requiring follow up by

regional health authorities for those individuals classified at greatest risk.

The systematic elimination of TB in children was recommended in order to reduce the epidemic. TB skin testing of all children upon entering school and investigating all family contacts of children who tested positive was recommended. All teachers and school employees also had to be tested annually, and those testing positive should subsequently have chest X-rays taken.

To prevent the spread of TB among adolescents, recommendations were made that all children of fourteen years of age should be screened for TB. The adult population was to be screened by a chest X-ray when admission into a general hospital in urban centers was required for any illness. The annual cost for this two point plan and its screening procedures was estimated at approximately 65 billion dollars.

A program of this nature would need to be continued for a minimum of ten years. Six recommendations were made to achieve this goal:

1. The United States Public Health Service should allocate the funding to all programs on a sliding scale.
2. All services should be provided without discrimination with regards to ability to pay or legal residence of the patient.
3. Funds should be provided by the way of teaching fellowships to medical schools in the areas of medicine and nursing to improve professional skill levels.
4. A system utilizing the most current technology should be established to provide a accurate record keeping method regarding TB infections.
5. Manner in which to finance the previous two items.

6. The continuation of the study of the epidemiologic outbreaks with regards to geographic location and frequency should be continued. (23)

The public health programs of the 1950's and 60's met with success, as shown by the decline of new TB cases. However, outbreaks of additional cases in the mid 1980's may have been a result of decreased funding for combatting TB. Unfortunately the impact of budget cuts ten years ago are being offset by increased expenditures required in the present decade. Today, disease control on the Federal level continues through the US Department of Health and Human Services, via the Public Health Service's Centers for Disease Control in Atlanta.

4.3 Occupation Exposure Control

The responsibility for occupational exposure control, research, regulation and enforcement in the United States falls upon the Department of Labor's Occupational Safety and Health Administration (OSHA) and the Department Health and Human Service's National Institute for Occupational Safety and Health (NIOSH). The reports of various MRTB outbreaks and the occupational exposure of 16 health care works to MRTB resulting in the death of at least five workers, prompted OSHA to develop a policy regarding TB exposure. In May 1992, OSHA Region II in conjunction with the NY State Public Employee Safety Act and Health Program, developed guidelines for the

enforcement of TB exposure regulations. The guidelines provided OSHA compliance officers information regarding their own protection during inspections as well as procedures for the inspection process itself. Many questions arose from this document, promoting the drafting of a memorandum to regional administrators in October 1993 clarifying OSHA's intent. These recommendations are to be enforced as a minimum in those states which have their own OSHA programs.

The ability to enforce tuberculosis exposure regulations on employers is promulgated under several Federal laws. Employer responsibilities are cited in the Occupational Safety and Health Act of 1970. Sections which have been applied to TB exposure enforcement include: the *General Duty Provision* section 5(a)(1); *Accident Signs and Tags* 29 CFR 1910.145; *Respiratory Protection* 29 CFR 1910.134; *Access to Employee Exposure and Medical Records* 29 CFR 1910.20 and *Log and Summary of Occupational Injuries and Illness* 29 CFR 1904. The CDC document entitled *Guidelines for Preventing the Transmission of Tuberculosis in Health Care Settings with Special Focus on HIV Related Issues* has been used as a widely accepted standard by OSHA.

The *General Duty Provision* of the OSHA Act is applicable since TB is a recognized health hazard and feasible abatement methods exist. Citations will be issued by OSHA to employers at certain facilities classified by the CDC where higher incidence of TB exposures have occurred. Occupational exposure is said to occur by two types of methods. First, exposure may occur when the

possibility of inhaling the exhaled air of an individual with suspected TB or confirmed TB exists. A suspected case may be assumed, when the patient has the symptoms of a productive cough, coughing up blood, weight loss, loss of appetite, weakness and night sweats from fever. The second type of exposure occurs during high risk procedures where an infected or potentially infected individual has a high probability of producing airborne respiratory secretions.

The *Respiratory Protection Regulations* of 29 CFR 1910.134 require the guarding of employees against airborne health hazards. The legislation is primarily concerned with the provision of respirators for the workers; however, engineering control measures such as improved ventilation are recommended to be utilized first where feasible. The CDC recommends that particulate respirators should be used when entering rooms of individuals with suspected or confirmed cases of TB or when performing high hazard procedures like aerosolizing medication, bronchoscopy, sputum induction, endotracheal intubation, suctioning, autopsies and when emergency medical personnel transport an individual with suspected or confirmed TB. Respirators must be NIOSH approved high efficiency particulate air respirators (HEPA). Disposable respirators may be reused if their structural and functional integrity are maintained. A program which includes training in the proper use and care of the respirator must also be established.

Warning signs shall be posted as per requirements of 29 CFR 1910.145 *Accident Prevention Sign and Tags*. The sign shall be prominently displayed and

be posted outside all AFB isolation rooms. The message typically shall warn of "SPECIAL RESPIRATORY ISOLATION", or "AFB ISOLATION", or provide other similar warning.

Employee exposure and medical records shall be maintained as per 29 CFR 1910.20 *Access to Employee Exposure and Medical Records*. A record of TB testing and results shall be maintained and a subsequent evaluation or treatment provided must also be recorded. These records shall also be provided to the OSHA compliance officer on request under 29 CFR 1913.10

TB infections and positive TB skin tests should be reported on the OSHA 200 Log as per 29 CFR 1904, *Log and Summary of Occupational Injuries and Illness*. All routine baseline testing evaluations with positive results should be reported on the 200 Log with the exception of pre-employment testing. Should active TB develop after a positive skin test, the log should be updated to include this information but a new entry should not be made so as to avoid double counting.

TB compliance inspections will occur as a result of employee complaints or be included as part of routine industrial hygiene compliance inspection. These inspections will occur at facilities identified by the CDC as having the greatest incidence of infections among workers. Such locations include health care settings, correctional institutions, homeless shelters, long term care facilities for the elderly and drug treatment centers.

CHAPTER 5

ADMINISTRATIVE CONTROLS

5.1 Introduction

Administrative controls are the least desirable type to utilize in the occupational health and safety field since they do not act passively as engineering controls, but require active participation by the individuals involved. However, in the prevention of occupational exposure to TB the use of administrative controls is essential as it provides a basis to identify those infected and to initiate the other forms of exposure control. The education of health care workers to recognize early signs and symptoms of active TB is essential to prevent needless exposure to airborne TB bacilli prior to a clinical diagnosis of TB. When identified, the patient may be placed on isolation procedures if active TB is suspected. Patient education, employee medical surveillance, pre-employment screening, isolation guidelines, early detection, employee education and follow up of patient contacts are all administrative controls which should be included in a facilities infection control plan.

5.2 Screening for Early Detection and Preventative Therapy

The ideal scenario is to detect latent TB and prevent the needless exposure to airborne TB bacilli before it develops to a point where it becomes contagious

Table 5 Criteria for Preventative Therapy

Category	Age group (years)	
	<35	≥35
With risk factor* ≥5 mm	Treat all ages if reaction to 5 TU PPD ≥10 mm (or patient is recent contact, HIV infected, or has radiographic evidence of old TB)	
No risk factor High-incidence group†	Treat if PPD ≥10 mm!	Do not Treat
No risk factor Low-incidence group	Treat if PPD ≥15 mm‡	Do not treat

* Risk factors include HIV infection, recent contact with infectious person, recent skin test conversion, abnormal chest radiograph, intravenous drug abuse, and certain medical risk factors.

† High incidence groups include foreign born-persons, medically undeserved low income populations and residence of long term care facilities.

‡ Lower or higher cut off points may be used for identifying positive reactions, depending on the relative prevalence of TB infection and non specific cross-reactivity in the population

! Measurement in millimeters of induration (upwelling or hardening, approximate size of a of pencil eraser)

Source: Center for Disease Control. 1990. "The Use of Preventative Therapy for Tuberculosis Infection in the United States" *Morbidity and Mortality Weekly Report*. 39 RR-8.

to others. The CDC estimates that approximately 10 to 15 million persons in the United States may be latently infected with TB (11). Efforts made to identify and treat the latently infected through the use of Mantoux skin testing of high risk groups has been attempted. If early detection indicates the presence of TB, preventative treatment by oral antibiotics may be indicated. Usually, treatment may be completed at home or given on an out patient basis at a local clinic. Only the most serious cases would be admitted to a hospital where continuous medical monitoring would be required. Currently the CDC recommends that a preventative therapy of INH be given. Dose ranges are from 10 mg/kg per day for children to 300 mg daily for adults for a duration of 6 to 12 months. The CDC established the criteria shown in Table 5 to aid physicians in determining if preventative therapy is warranted.

Patients treated at home would be educated to the importance of taking their medication regularly in order to prevent a resistant strain of TB or symptomatic disease from developing. Follow up exams would be conducted monthly to insure compliance with medication and to identify the presence of active TB should it develop.

5.3 Education and Training of Health Care Workers

When left undetected, those of lower socio-economic classes will often develop the clinical signs and symptoms of active TB and seek treatment at a busy hospital emergency room. In order to prevent these unrecognized exposures

from occurring, health care workers should be well versed in the signs and symptoms of TB. The early identification of a potentially infectious person is still paramount to the success of any infection control program. Much the same way that early medicine classified TB within a group of similar illnesses, the same occurs today as signs and symptoms may be mistaken for other diseases like pneumonia or bronchitis. The recognition of the potential for infectious TB to exist in a patient entering a health care facility must be established. When identified, appropriate isolation measures should be taken as to prevent the nosocomial transmission of the disease and physicians should order the appropriate diagnostic tests to confirm the clinical diagnosis. Once the diagnostic tests are completed and the results returned, the decision may be made if the patient is required to remain in AFB isolation.

The clinical findings and pathology of TB is taught in medical and nursing schools. The decline of new cases within the United States in the past decades may have caused the medical community to be less suspicious of TB infections in some communities. Within the past five years numerous papers have been published in medical journals discussing the resurgence of MRTB and its association with HIV. Those employed in high risk urban settings have, of necessity, become familiar with the clinical signs and hazards associated with TB. Therefore inservice education should be provided to familiarize medical personnel of the signs and symptoms of TB, infection control policies and isolation procedures. Additional training regarding the use of personal

protection equipment and the condition of the physical plant to isolate patients should be reviewed.

5.3.1 Recognition of Signs and Symptoms

The Center for Disease Control recommends the diagnosis of active TB should be vigorously pursued for those patients who demonstrate the clinical signs and symptoms. Those patients (particularly those belonging to high risk groups) which exhibit a persistent cough, weight loss, anorexia and fever should be considered suspect TB cases until further clinical testing proves otherwise. Diagnostic tests ordered for suspected TB patients should include a PPD skin test, chest X-ray and microscopic examination of sputum cultures for AFB's. The history and physical exam by the physician should reveal if the patient is a member of a high risk group or has been exposed to an individual who is a member of a high risk group.

Ironically, one risk group that has had increased outbreaks of TB is also more difficult to diagnose as having TB. HIV positive patients often will have a normal chest X-ray without the presence of cavitation, and the percentage of false negatives associated with the PPD skin testing has also increased as the HIV disease progresses in an individual (8). For this reason, those who are known to be HIV positive are considered to have TB positive skin tests if the updwelling is greater than five mm as opposed to the ten mm for non HIV persons.

As of this date, the only method to positively confirm the presence of pulmonary TB is through culture examination of sputum samples. This process may take several weeks; however, new technologies are being developed which would provide a more rapid identification such as radiometric and genetic probes. Isolation procedures should not be withheld until lab results return for those suspected to have a high level of communicability of the illness. Patients treated for other respiratory maladies who did not respond to therapy should be considered as suspected TB infected and have the appropriate tests ordered and treatment initiated. If the patient had not been previously placed on isolation procedures, they should be implemented immediately.

5.3.2 Evaluation of Infection Communicability

Once a suspected case of TB is presumed, the health care provider must determine the level of communicability. A patient found to be infected with TB after testing positive to a skin test after routine screening, who has no symptoms or productive cough is obviously less contagious (if at all) than a symptomatic patient with a productive cough who arrives at a hospital emergency room because of shortness of breath. For this reason, a heightened level of suspicion should be maintained when initially triaging patients entering the emergency department. Proper initial placement of the patient may substantially decrease the unrecognized exposure of the staff and other patients alike.

The Center for Disease Control has established a list of eight criteria to help

determine the communicability of TB as related by the number of potentially airborne bacilli expelled. These factors are:

1. Anatomic site of disease (pulmonary or laryngeal TB, extrapulmonary site which includes a open lesion in which concentration of organisms is high or non pulmonary disease located in the respiratory tract.
2. Presence of cough or other forceful expirational maneuvers.
3. Presence of AFB in the sputum smears.
4. Willingness or ability of the patient to cover his mouth when coughing.
5. Presence of cavitation on the chest radiograph.
6. Length of time the patient has been on adequate chemotherapy.
7. Duration of symptoms.
8. Administration of procedures that can enhance coughing. (8)

The most contagious of patients are those with a productive cough, positive AFB smears and cavitation. Patients who respond to chemotherapy usually become less infectious within two to three weeks. For health care workers treating these patients, isolation procedures should be utilized until the sputum smears show fewer bacilli and the cough decreases. However, some patients remain highly infectious for the length of the illness and must remain isolated for longer periods. Each case must be reviewed individually as no two patients are alike. The above criteria are to be only used as a guideline for determining the infectiousness.

5.3.3 Isolation Procedures

Protocols should be established for the criteria required to isolate potentially infectious TB patients. Typically, these procedures should be immediately imposed on patient's with suspected TB. Patients requiring isolation and admission to the hospital should be admitted to private rooms. When available, isolation rooms with special ventilation systems should be utilized. The patient should be instructed not to leave the room unless wearing an approved mask. The patient may be instructed to wear appropriate masks even when occupying the isolation room except when eating or drinking. Those caring for contagious TB patients must also wear approved personal respirators when occupying the same room. Visitors should be limited to family who have been instructed on isolation procedures and training on use of the appropriate respirator.

Isolation rooms should be well identified with signs stating "AFB ISOLATION" or "SPECIAL RESPIRATORY ISOLATION". Visitors should be required to stop at the nursing station for any special instructions prior to entering the room. Those exposed to patient body fluids should follow the appropriate precautions for blood borne pathogens. The appropriate gloves, face shields and gowns should be worn when appropriate. OSHA *Bloodborne Pathogens Standard* CFR 1910.1030 shown in Appendix C of this document outline the requirements for protection from infectious fluids and substances.

5.4 High Hazard Procedures

The CDC has recognized several medical procedures which are potentially high risk ones for the medical professional to perform without being exposed to respiratory tract secretions. Special recommendations have been provided to insure that the health care provider is protected from these potentially infectious secretions.

Diagnostic sputum induction is used to collect deep sputum samples to test for AFB or other culture examinations. The patient is instructed to inhale and exhale deeply three times, then inhale swiftly and cough forcefully and expectorate into a sputum container. This technique allows only the deepest secretions and potentially the most contagious to be expectorated. The patient should be instructed to cover his mouth and nose and when he coughs during the procedure to further limit bacilli from entering the room air. The ideal setting for this procedure is in a special negative pressure ventilation booth or isolation room. The patient should remain in that area until any residual coughing has been resolved after the procedure. The health care worker, typically a nurse should wear an approved personal respirator if required to be in attendance during the procedure.

Patients receiving aerosolized medication via nebulizer are also subject to expelling bacilli into the air. Several medications are given in this manner requiring the patient to deeply inhale and exhale in order to absorb the medication deeply into the lungs. Typically these procedures are also conducted

in special booths or isolation rooms. Personal respirators should be worn by the health care worker if in close proximity. Bronchoscopy, endotracheal intubation and endotracheal suctioning should also be conducted in areas which have the appropriate ventilation. These procedures often cause the patient to cough forcefully, creating the possible expulsion of TB bacilli during and after the procedure, thus requiring the necessity for masks and eye protection to be utilized by those in contact with the patient.

5.5 Medical Surveillance

The maintenance of medical surveillance of the employees of health care facilities cannot be mitigated. The benefits are two fold: the pre-employment PPD screening identifies the base line result of the employees's TB status and second, it serves as a means to screen personnel during employment and control outbreaks.

Initial pre-employment Mantoux skin testing should be conducted for all employees at the initial physical exam. Annual testing should be provided at no cost to employees whose responsibilities include patient contact. Those individuals who have high risk exposure by caring for known TB patients should be tested bi-annually. Employees previously found to have tested positive to a PPD test, or who are currently receiving oral antibiotic TB treatment may be exempted from annual skin testing. However, these persons should be closely monitored for the appearance of clinical signs and symptoms should the latent

TB become active and require treatment.

The data collected on employee and patient outbreaks should be reviewed frequently to identify and stem any outbreaks within the facility. When outbreaks occur, exposure control policies should also be reviewed to identify if new policies should be established, or existing policies modified or more rigidly enforced.

Special testing should be provided for those employees who had contact with patients who were found to have contagious TB, but were not on AFB isolation. A Mantoux test should be administered immediately to the employee upon discovery of the unprotected exposure and repeated twelve weeks later. When indurations greater than five mm occur or the signs and symptoms of TB are present, a chest X-ray should be taken. For those employees who test positive, preventative therapy should begin immediately and counseling regarding HIV antibody testing provided, as TB has been found more frequently in HIV positive persons.

Work restrictions should be evaluated on a case by case basis as to the communicability potential of the employee. Those with infectious TB should be permitted to return to work only after the cough is resolved and the sputum is free of bacilli on smears conducted in three consecutive days. The employee should be closely monitored regarding the recurrence of symptoms and completion of prescribed treatments. Those refusing to complete the preventative therapy and who are otherwise healthy may still return to work, but

should be counseled as to the possible occurrence of a drug resistant strain of TB (8).

Employee medical records should be maintained as per 29 CFR 1910.20 *Access to Employee Exposure and Medical Records*. Records of treatment provided and PPD test results should be documented. The OSHA 200 log must be regularly updated for positive PPD tests which occur during employment. Positive tests occurring at the time of the pre-employment screening are not considered as an occupational exposure and need not be logged. Only those employees who initially tested negative and then test positive PPD during employment should be documented. If active TB develops, the initial log entry of positive testing should be updated. A new entry should not be made so as to avoid double counting.

All outbreaks of communicable diseases are reportable to the local Boards of Health as the law requires. The Board of Health will identify and notify suspected exposure contacts. The infection control personnel at the appropriate facility should assist the authorities with information regarding known contacts.

5.6 Summary

The CDC has recognized the importance of the administrative regulations required to prevent the spread of TB. In the CDC document entitled *Guidelines for Prevention of Transmission of Tuberculosis in Health Care Settings*, seven fundamentals are cited to reduce the transmission of TB.

1. Screening patients for active TB and TB infection.
2. Providing rapid diagnostic services.
3. Prescribing appropriate curative and preventative therapy.
4. Maintaining physical measures to reduce microbial contamination of air.
5. Providing isolation rooms for persons with, or suspected of, having infectious TB.
6. Screening health care facility personnel for TB infection and TB.
7. Promptly investigating and controlling outbreaks. (8)

All but items four and five may be considered as administrative controls. The provision of isolation rooms and the physical measures to reduce contamination of the air will be discussed in the next two chapters *Personal Protective Equipment* and *Engineering Controls*.

CHAPTER 6

PERSONNEL PROTECTIVE EQUIPMENT

6.1 Airborne TB Hazards

Tuberculosis is primarily transmitted via the airborne route, although blood borne exposures have occurred. Microscopic aerosols of one to five microns in diameter may remain airborne and travel on air currents for long periods within a facility (10). Administrative controls play an important role in the identification of suspected or infected persons and placement of the patient on isolation procedures. Most outbreaks of nosocomial transmission of TB occurred as a result of contact with patients with unrecognized TB. Transmissions occurred between patient to patient and also patient to health care worker in one study (20). The personal respirator serves as the only protection before the patient is placed in an isolation room. This is the last line of protection against infectious pulmonary TB occupying an AFB isolation room.

As with all types respiratory exposures, the likelihood of contracting TB is related to the concentration of the bacilli in the air and the duration of the exposure by the health care worker. Theoretically, only one TB microbe need be inhaled to contract TB and the probability of this occurring increases as the concentration of the microbes is increased. Administrative controls are utilized

to identify those infected with the bacteria, and placing the patient in isolation to reduce these concentrations by the other types of controls. Engineering controls attempt to alter the path of the bacilli by exhausting or filtering the room air thereby reducing their concentration. The use of personnel protective equipment, i.e., personal respirators (PR) constitute receiver control as they do not alter the path but only protect the wearer, provided they are utilized properly and worn at the appropriate times.

The CDC guidelines for wearing a PR when possible TB exposure occurs in three circumstances:

1. When entering rooms housing individuals with suspected or confirmed infectious TB.
2. When employees perform high hazard procedures on individuals who have suspected or confirmed TB disease. Examples of high hazard procedures include aerosolized medication treatment, bronchoscopy, sputum induction, endotracheal intubation, suctioning procedures and autopsies.
3. When emergency medical response personnel or others must transport, in a closed vehicle, an individual with suspected or confirmed TB. (8)

The PR's utilized must be NIOSH approved high efficiency particulate air (HEPA) respirators as a minimum standard.

6.1.1 Particulate Respirators

Although the CDC guidelines are vague with respect to the type of personal respirator to be utilized, OSHA requires HEPA respirators be provided as the

minimum protection under 29 CFR 1910.134. A respirator protection program must also be established at the facility under the same code. Because TB is considered a biological hazard, there is no permissible exposure limit (PEL) defined, as any exposure is considered hazardous. NIOSH therefore recommends that powered air-purified respirators (PAPR) be utilized for a minimum protection level. However, OSHA recognized that PAPR's could interfere with patient care and therefore authorized the use of HEPA respirators as an acceptable standard. Both devices utilize paper element HEPA filtration; however, the PAPR is equipped with a powered fan which blows filtered air into the face piece of the user to provide further protection by positive pressurization.

This option to authorize HEPA respirators by OSHA was justified for several reasons. There is no published data regarding the efficiency of HEPA in filtering TB; however, tests have been conducted by NIOSH for particulate matter associated with a similar diameter. The aerosolized mycobacteria tuberculosis ranges in diameter from one to five microns. Tests conducted in the three respirator classes of dust/mist, dust/mist/fume and HEPA indicated that only the HEPA filter met the filtering requirements of particulate matter similar in diameter to TB in low concentration environments.

The typical surgical mask utilized in many hospital settings is not approved for employee use for protection against TB. Although the cup shaped surgical mask may have a similar appearance to the HEPA mask, the same filtration

effect or fit will not be achieved. Disposable HEPA PR's may be utilized and reused if they retain their original cup shape after reuse. The mask may be fitted with one way valves to release expired air; however this type of mask would not be appropriate for patient use.

Even the best mask will be ineffective if not worn or fitted properly. Employee training must be conducted in the use of PR's which includes fit testing. Either a qualitative fit testing (QLFT) or a quantitative fit testing (QNFT) technique may be utilized. QLFT relies on the employee to have a sensory response to a irritant introduced into the proximate atmosphere of the mask. If the employee has a response to the irritant or "tastes" the test material, the fit is not considered "tight" and is less effective. Less offensive fumes may be utilized provided they are similar in diameter to the hazard material. Common test materials utilized for TB testing would be either aerosolized sodium saccharin at three microns in diameter or isoamyl acetate. QLFT is a fast, inexpensive and relatively easy to perform test; however, it relies upon a subjective response by the individual being tested to the test material.

The QNFT requires that the employee be exposed to a detectable non-toxic atmosphere. The employee dons a respirator fitted with a probe attached to a special instrument that measures the amount of leakage into the mask. Rather than a subjective response as required with the QLFT test, the instrument detects and measures the amount leaked yielding a quantitative fit factor as a result. Special equipment and training is required to conduct QNFT causing this

method to be more expensive. A common rule of thumb regarding fit testing is: the greater the difficulty of inspiration, the "tighter" the fit and the better the respirator.

Several shortcomings are associated with the use of personal protection equipment. The hazard is not eliminated by their use, and the receiver would realize the full effect of the hazard if the PR fails or is not fitted properly. PRs often are not utilized because they are cumbersome, therefore enforcement policies must be enacted. Facial hair may drastically effect the fit of the device on the face requiring the enforcement of grooming codes. Through proper education and training, the employee is introduced to the hazards of TB and the importance of using personal respirators.

6.1.2 Respirator Training Program

OSHA requires that respirator training be provided under 29 CFR 1910.134. The training should include the pathology of TB, its signs and symptoms, a review of the medical surveillance program, as well as therapies and specific written protocols in the use of controls. The National Safety Council outlines a typical respiratory training program as follows:

1. An explanation of the respiratory hazard and what happens if the respirator is not used properly.
2. A discussion of what engineering and administrative controls are being used and why respirators must still be used.
3. An explanation why a particular type of respirator is used.

4. A discussion of the function, capabilities and limitations of the selected respirator
5. Instructions on how to don the respirator and how to check it's fit and operation.
6. Instruction of the proper wearing of the respirator.
7. Instruction in respirator maintenance.
8. Instruction in recognizing and handling emergency situations.
9. Instruction as needed for special respirator use.
10. Regulations regarding respirator use. (24)

If facilities are reusing disposable respirators, the training programs should address the point at which the respirator is considered contaminated or deformed and must be disposed. Although TB is predominantly transmitted via the airborne route, employees should be instructed that TB may also be transmitted by the blood borne route and universal precautions should be used.

6.2 Universal Precautions

The term universal precautions refers to the philosophy that all human body fluids are considered to be infectious and therefore should be treated with certain precautions. Originally adopted as a response to HIV and Hepatitis B (HBV) infections, the universal precautions concept encompass a broad spectrum that include work practice controls, personal protective equipment and engineering controls. Since a high percentage of those infected with TB are also

HIV positive, the use of these standards as promulgated by the Blood Borne Pathogens Standard CFR 1910.1030 are highly recommended and often required for all patients regardless of their HIV status. One valuable asset to the regulations included the requirement of providing a hepatitis vaccination free of charge to all employees by their employer. Disposal and marking of regulated biohazard waste, employee education and the use of personal protective equipment were also included in the regulations.

Personal protective equipment typically includes latex gloves, gowns, masks, as well as eye or face shields. As a PR is required to be worn by the health care workers when caring for those infected with TB, these additional items should be utilized whenever the health care worker reasonably anticipates contact with body fluids. Eye protection and gowns are also needed whenever gross contamination may occur as during autopsies or arterial bleeding control.

The health care worker must always remain suspicious and treat all patients as if they are infected with a contagious illness. Latex gloves should be worn when contact with any body fluid is anticipated. Drawing blood, starting IV's, changing bed pans and handling soiled linen are situations where barrier protection in the form of gloves should be utilized. Frequent hand washing after patient or cultural contact has been made also decreases the risk of cross infection. Accidental needle sticks or splashing of body fluids onto unprotected health care providers should be reported so that the required prophylactic treatment or examination may be initiated.

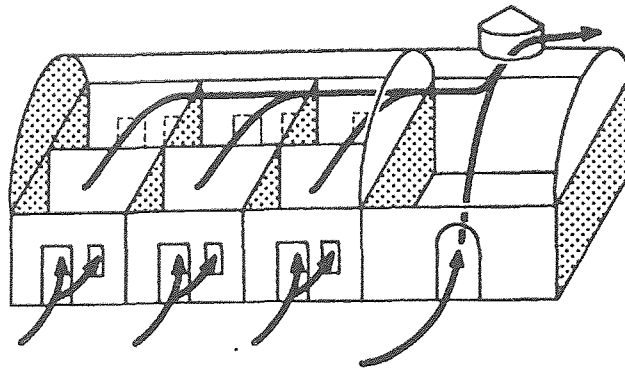


Figure 3 The Ventilation system at a Viel loge in Salpêtrière, France

Source: Thompson John D. and Goldin Grace. 1975. *The Hospital: A Social and Architectural History*. New Haven & London. Yale University Press.

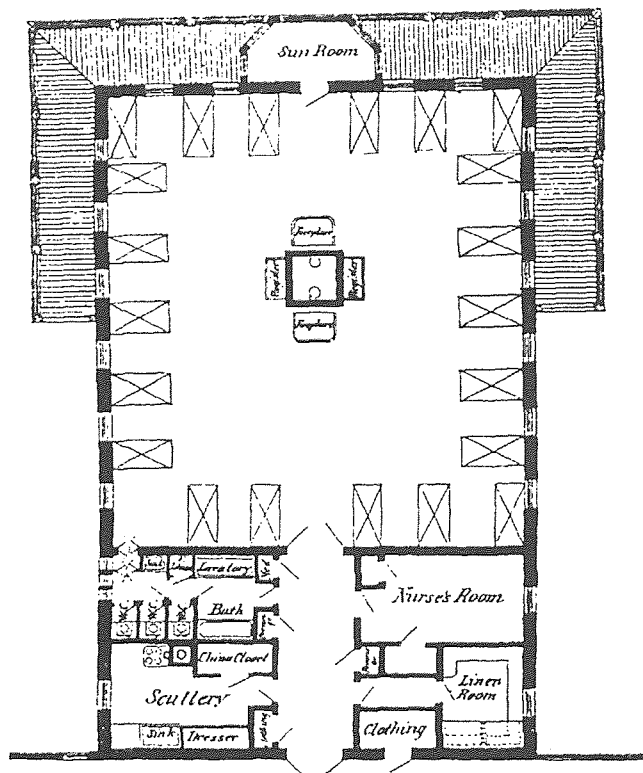


Figure 4 Hospital ward design for Johns Hopkins Hospital, 1875.

Source: Thompson John D. and Goldin Grace. 1975. *The Hospital: A Social and Architectural History*. New Haven & London. Yale University Press.

CHAPTER 7

ENGINEERING CONTROLS

7.1 Introduction

Ventilation within hospitals wards was recognized early in medical practice as a method to combat the spread of infection and aid in the cure of some diseases. Florence Nightingale recognized the adverse effects that the poor natural ventilation provided in her book entitled *Notes on Hospitals* (25). Patients were housed in large pavilions and treated in wards with perhaps a dozen other patients during her time. Ventilation was provided by opening large windows permitting natural outside breezes to blow through or out a central vent in the ceiling. More progressive designs allowed for the air currents within the structure to be drawn into a vaulted attic and out through the ventilation dome in the roof. Figure 3 shows the ventilation system of smaller "loges" designed by Charles François Viel in France in the 1780's where fresh air was drawn through the doors and windows and exhausted through the dome on the roof

Other designs provided a central fireplace which would draw the ward air up the chimney on warm currents. This fire would burn year round regardless of weather conditions outside, for ventilation purposes and hot water. Figure 4 shows the floor plan of a hospital ward, note the centrally located fireplace

and numerous windows between each bed side.

The ventilation within any health care facility serves two basic purposes. First, the system must protect the patient from the contaminated air of others and second the system must protect the air supply from an infectious patient. Early attempts to achieve these measures involved removing highly infectious patients from the general wards to crude isolated rooms which were freely ventilated. When isolated rooms were unavailable, infectious patients were often moved closer to the fire so the infectious vapors could be pulled up the draft through the chimney (26).

Dr. Stephen Smith of New York realized that patients should be separated by their degree of contagiousness as well as by sex and age. As the pavilion style hospital grew and multiple wings were built, each housed one particular type of patient. Ventilation technology also progressed as hospitals grew. The Johns Hopkins Hospital built in 1877 utilized several types of ventilation techniques. One method facilitated the drawing of fresh air from a well ventilated basement by convection across heated coils mounted on the basement walls, through a duct venting at the patient's bedside. The foul air in the ward was removed through vents located under the patient's bed which conveyed the air through an iron tube mounted across the basement ceiling to the ventilating chimney. A coil of heated tubing at the end of this vent near the chimney accelerated the air to provide a draft. A crude heat exchange would occur as the iron tube warmed the fresh air in the basement without mixing with the foul

exhausted ward air. In the ceiling of the ward, six 2' x 2' vents leading into a 12" tube conveyed the foul air across the ceiling into the chimney to draw off the air. These ceiling vents usually remained closed during the winter to retain the heat.

As the wards were stacked in several stories, the technology to ventilate them also advanced. The central ventilation chimney still remained with an open fire but additional ventilation shafts and tubes were constructed in the main chimney to facilitate the drawing of foul air from the additional wards. Elevators and other direct shafts between floors were purposely avoided to prevent the movement of air from ward to ward.

As advances in architecture and mechanical ventilation systems developed, the hospital evolved into a skyscraper to provide more efficient use of central services. The Beaujon Hospital constructed in Paris in 1935 was one of the first skyscrapers built. The central fire and ventilating chimneys once commonplace in a hospital ward were replaced with mechanical fans and elaborate duct systems to provide fresh air and exhaust the foul air. At the Beaujon facility, the TB ward was located at the top of a twelve story structure. Patients could be placed on sun drenched balconies specially constructed for the sunshine cure without obstruction from the facade of the building.

As a result of modern ventilation, special rooms could now be constructed to isolate highly infectious patients. The evolution of central heating and air-conditioning now provided rooms with a comfortable environment to convalesce.

7.2 Modern Ventilation

The move away from natural breezes and thermal drafts to ventilate hospitals gave way to forced air as developments in mechanical systems were made. The ability to ventilate areas without reliance on weather conditions allowed the interior design of hospitals to change and permitted the construction of windowless central areas. Specialized ventilation systems would provide clean air for the operating theater and exhaust the harmful fumes from labs and isolation rooms.

A ventilation system may be utilized to heat, cool and supply make-up air or remove a contaminant to improve air quality. The simplest system consists of an air moving device, (a fan) and a distribution system (a duct). Humidifiers, air conditioning, heaters, air cleaning and filtering devices may be added to upgrade the simplest system. Typical temperature ranges within a hospital are maintained between 68 and 80°F with a 30 to 60% relative humidity.

A modern hospital ventilation system must be able to complete the following four criteria:

1. heating and cooling
2. contamination removal
3. contamination dilution
4. make-up air supply (27)

When these criteria are achieved, and the system is well maintained it will protect the patients from exposure to contaminated air and also protect the

hospital from its contaminated patients. In order to understand what is entailed in a simple ventilation system a brief discussion of some basic principals is required.

The movement of air by a ventilation system requires an expenditure of energy. This energy is transformed into wind velocity which may be measured by means of the increase in pressure across two points. Both kinetic and potential energy are the components of this pressure. The energy relationship is expressed as in equation 7.1 below.

$$TP = SP_1 + VP_1 = SP_2 + VP_2 + LOSSES \quad (7.1)$$

TP = Total Pressure

SP = Static Pressure

VP = Velocity Pressure

1 & 2 are measurement points, 2 being down stream

Static pressure is defined as a force which is said to "blow" in a duct in a positive pressure system; or the force to "collapse" a duct in a negative pressure system. Velocity pressure is the energy that causes air in the system to flow much like kinetic energy. Static pressure is easily measured by tapping a duct with a manometer and directly reading the pressure. Total pressure is measured by use of an impact tube which allows direct reading of the pressure value. The velocity pressure may be calculated from equation 7.1 or directly determined with the use of a pitot tube. Once the VP is known it may be converted into the more functional value of velocity by the following relationship shown in

equation 7.2.

$$V=4005\sqrt{VP} \quad (7.2)$$

V = Velocity (feet per second)
VP = Velocity Pressure (inches of water)

The velocity may also be measured directly with thermal anemometers. With this value now calculated, the air flow in the duct can be measured by equation 7.3.

$$Q=A \times V \quad (7.3)$$

Q = Air Flow (cubic feet per minute)
A = Area of Duct (square feet)
V = Air Velocity (feet per minute)

Once the air flow in the duct is known, the existing capacity and effectiveness of a hospital system may be determined. The dilution and removal rates of room air are expressed in air changes per hour by dividing the value calculated as air flow, by the room volume and multiplying by 60.

7.2.1 Dilution and Removal

Most industrial ventilation systems were designed without the removal of contaminants as a design criteria. Recent concerns about indoor air quality have prompted consideration of this factor during design and subsequent application of the technology required. Today, most new ventilation systems

Table 6 Contaminant Removal Efficiencies per Air Changes per Hour

<u>Air Changes/hr</u>	<u>Mins. required for a removal efficiency of</u>		
	<u>90%</u>	<u>99%</u>	<u>99.9%</u>
1	138	276	414
2	69	138	207
3	46	92	138
4	35	69	104
5	28	55	83
6	23	46	69
7	20	39	59
8	17	35	52
9	15	31	46
10	14	28	41
11	13	25	38
12	12	23	35
13	11	21	32
14	10	20	30
15	9	18	28
16	9	17	26
17	8	16	24
18	8	15	23
19	7	15	22
20	7	14	21
25	6	11	17
30	5	9	14
35	4	8	12
40	3	7	10
45	3	6	9
50	3	6	8

Source: Center for Disease Control. 1990. "Guidelines for Preventing the Transmission of TB in Health Care Settings" *Morbidity and Mortality Weekly Report*. 39 RR-17.

provide some type of mechanism to insure the quality of the indoor air, particularly in closed buildings like modern office buildings or skyscrapers.

One of the simplest methods to achieve this goal is by dilution. Dilution provides addition of fresh uncontaminated air into the ventilation system rather than recirculating the same air. A percentage of the stale air is exhausted outside, while the remaining is mixed with fresh intake air. The objective of this technique is to reduce the level of concentration of a contaminant or toxin to acceptable threshold limit values (TLV's in ppm). A mathematical model shown in equation 7.4 does exist to calculate the required ventilation rate given a value for the TLV assuming the returning air is free of contaminants.

$$Q = \frac{403 \times \alpha \times 10^6 \times ER}{MW \times TLV} \times K \quad (7.4)$$

Q = Ventilation Rate (cubic feet per minute) α = Specific Gravity
ER = Evaporation Rate (pt/hr) MW = Molecular Weight
K = Safety Factor

As with all biological hazards, the TLV for TB is zero, meaning that there is no acceptable level, and all contaminants must be removed, making equation 7.4 inapplicable. Special systems which exhaust all room air to the outside for isolation rooms containing biohazards like TB. Tabulations have been made regarding the efficiency of air borne contaminants removed as expressed in air changes per hour. Table 6 shows the theoretical data assuming perfect mixing of air as presented by the CDC in their Guidelines for TB Prevention.

Table 7 Selected Pressure & Ventilation Relationships of Hospital Areas

<u>Functional Space</u>	<u>Pressure Relationships to Adjacent Areas</u>	<u>Minimum Air Changes Of Outdoor Air per Hour</u>	<u>Minimum Total Air Changes per Hour</u>	<u>All Air Exhausted Directly to Outdoors</u>	<u>Recirculated Within Room Units</u>
<u>Surgery and Critical Care</u>					
Operating room					
(all outdoor air)	P	15	15	YES	NO
(recirculating air)	P	5	25	OPT	NO
Delivery room					
(all outdoor air)	P	15	15		
(recirculating air)	P	5	25		
Recovery room	E	2	6	OPT	NO
Nursery suite	P	5	12	OPT	NO
Trauma room †	P	5	12	OPT	NO
<u>Nursing</u>					
Patient room*	±	2	4	OPT	OPT
Toilet room	N	OPT	10	YES	NO
Intensive care	P	2	6	OPT	NO
Isolation‡	±	2	6	YES	NO
Isolation alcove‡	±	2	10	YES	NO
Labor and delivery	E	2	4	OPT	OPT
Patient Corridor*	E	2	4	OPT	OPT
<u>Ancillary</u>					
Lab, general	N	2	6	YES	NO
Lab, bacteriological	N	2	6	YES	NO
Lab, pathology	N	2	6	YES	NO
Autopsy	N	2	12	YES	NO
<u>Diagnostic and Treatment</u>					
Exam room*	±	2	6	OPT	OPT
Medication room	P	2	4	OPT	OPT
Treatment room*	±	2	6	OPT	OPT
<u>Service</u>					
Laundry	N	2	10	YES	NO
Soiled linen sorting	N	OPT	10	YES	NO

P = Positive N = Negative ± = Continuous directional control not required* OPT = Optional

† The term trauma room as used here is the first aid room/and or emergency room used for general initial treatment of accident victims. The operating room within a trauma center that is routinely used for emergency surgery should be treated as a operating room.

‡ The isolation rooms described in these standards are those that might be used for infectious patients in the average community hospital. The rooms are either positively or negatively pressurized depending on the patient...

* Although continuous directional control is not required, variations should be minimized and in no case should a lack of directional control allow the spread of infection from one area to another. Boundaries between functional areas should have directional control.

Source: American Society of Heating, Refrigeration and Air-Conditioning Engineers. 1991. *1991 ASHRAE Handbook*. Atlanta.

The CDC recognizes the recommendations for the minimum number of air changes per hospital area by the American Society of Heating and Refrigeration and Air-Conditioning Engineers (ASHRAE) shown in Table 7. The emergency department, including its waiting area, is recognized as being one of the highest contaminated areas of the hospital. This results from the contaminated condition of many patients and the high traffic volume (28). The classification of trauma rooms is deemed similar in nature to the emergency treatment area of a hospital requiring a minimum of twelve air changes per hour. ASHRAE recommends a minimum of ten air changes per hour be provided hourly for the waiting room and the area to be negatively pressured to prevent the contamination of other hospital areas.

7.2.2 Air Mixing

Another component of ventilation relates to the air mixing which must occur in the ventilated room. Air mixing refers to the movement of air currents within the room which prevent foul, stagnant air from collecting in poorly circulated spaces within a room. The most ideal air supply is overhead with the exhaust at the floor level. This method allows the freshest air to be provided in the breathing or working zone and the contaminants to be pulled downward.

Some experts believe that the movement of air within some isolation rooms should be laminar and not turbulent flow (29). The flow in most hospital and industrial settings is turbulent with the exception of operating rooms and ultra-

clean rooms utilized in some types of demanding manufacturing. A dimensionless quantity called the Reynolds number is derived by equation 7.5 and utilized to determine the type of flow characteristic.

$$Re = \frac{DVe}{\mu} \quad (7.5)$$

*Re = Reynolds Number, D = Duct Diameter (feet)
e = Fluid Density (lb/ft³), μ = Fluid Viscosity (pound seconds per square feet)*

Once this value is calculated, the flow type is determined by the following criteria:

$$\begin{aligned} Re < 2100 & \text{ Laminar flow} \\ 2100 < Re < 4000 & \text{ Transition flow} \\ Re > 4000 & \text{ Turbulent flow} \end{aligned}$$

The transition flow refers to a region where the flow may be laminar at times while periodically returning to a turbulent type of flow.

7.2.3 Flow Direction

The direction of flow refers to the movement of air from rooms or areas occupied by patients in adjacent areas. Isolation rooms which are used by TB patients are typically designed to protect the hospital air supply. To achieve this goal, a negative pressure is induced in the patient's room which would cause the air to flow from adjacent areas into the room. This effect is created by supplying less air into the room via the ventilation system and exhausting a greater volume thereby creating a negative pressure by drawing air from outside

sources such as corridors or alcove rooms.

However, simply drawing air from a corridor into an isolation room may be introducing unwanted contaminants into the isolation room. TB patients are often infected with HIV and potentially contaminated air drawn from a common corridor may expose the patient with immunodeficiency to other potentially lethal infectious bacteria. Most modern isolation room designs have a specially ventilated ante-room or alcove at the room exit to the corridor. This room is usually ventilated with opposite pressurization from the isolation room. Larger urban teaching hospitals often have special isolation wards established with elaborate ventilation systems which may allow the adjustment of the pressurization of the isolation room, the ante room and the corridor depending on the type of isolation desired.

Proper ventilation is difficult to maintain and must be closely monitored. The opening of doors and windows or changes in temperature can drastically effect the pressure differentials. Modern control systems utilizing automatic digital technology and continuous closed loop system monitoring requiring no human intervention are the ideal.

7.3 Filtering and Irradiation

Air exhausted from a TB isolation room must be vented directly to the outside and not be recirculated. Filtering may be provided for exhaust air to limit the outside concentrations of contaminated air from being too great if required by

local regulations. The outside vent should never be located near other patient areas, air intakes, animals or plants.

Areas like the emergency department or X-ray department may sometimes be occupied by TB infected personnel. A percentage of the exhaust from these areas is usually recirculated into the hospital ventilation system and not completely exhausted. A filter or irradiation device may be placed in the exhaust vents from these areas to insure that infectious material is not recirculated through the return air system into other hospital areas. The use of high efficiency particulate air (HEPA) filters are approved for such a use.

7.3.1 High Efficiency Particulate Air Filters

HEPA filters have been demonstrated to filter particulate matter greater than 0.3 microns in diameter with 99.97% completion (28). Although no specific data exists regarding the efficiency of HEPA filters in removing tuberculosis bacilli, studies have proven these filters to be effective at removing aspergillus spores which have the same diameter as TB (30).

HEPA filters are constructed of pleated paper or other filter material, bonded to a housing or frame. The intent of this filter is to trap the smallest of micro-particles; thus the smallest puncture or slightest separation between the filter material and frame reduces the efficiency of the filtering effect significantly. Proper manufacture, installation and testing are each essential to achieve the desired effect of the system. Installation should only be performed

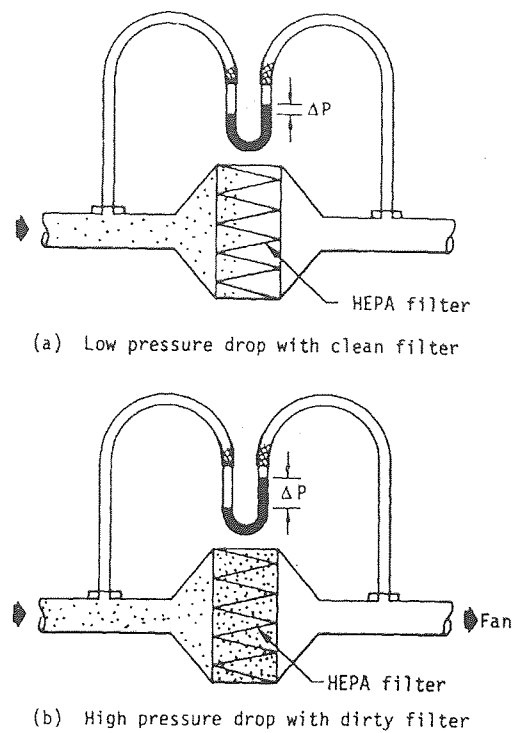


Figure 5 Pressure drop tests for HEPA filter operation.

Source: McDermott, Henry J. 1977. *Handbook of Ventilation for Contaminant Control*. Ann Arbor, Michigan. Ann Arbor Press. p.245.

by qualified personnel familiar with the use of these specialized filters.

As HEPA filters trap nearly every particle over 0.3 microns in diameter, they become clogged quickly by average room dusts or other microscopic contaminants. Some installations may require the use of a non HEPA type prefilter to prevent the HEPA filter from being clogged with larger particles. Clogged or dirty filters may be easily detected by measuring the pressure differentials across the filter. ASHRAE recommends the installation of manometers across filtering banks so as to provide a quantitative method to determine the need to change filters when dirty, as opposed to direct visualization. As shown in Figure 5, a minimal drop in pressure occurs across a clean filter, with a higher differential across a dirty filter. Sudden changes in pressure may indicate the presence of a damaged or leaking filter. A maintenance program designed for the particular use should be prepared by the manufacturer and installer. It should detail the frequency of filter changes and testing.

The ventilation system should be designed to allow the changing of HEPA filters without introducing contaminants into the system. Contaminated filters should be disposed of in accordance with local codes and legislation regarding regulated medical waste. ASHRAE further recommends that the high replacement costs for HEPA filters should not be overlooked in operating budgets. *Means Open Shop Building Construction* estimates the cost of HEPA filters to be eight times more than expensive than standard paper type filters.

7.3.2 Germicidal UV Radiation

The use of UV lamps having a wave length of 100 to 290 nm for destroying TB bacilli has met with some success and also controversy. As Koch demonstrated soon after his isolation of the mycobacteria bacillus in 1882, sun light was shown to destroy TB bacteria. The use of these lamps provided an artificial method to reproduce this effect at a more concentrated level. In the early 1960's, Richard Riley of Johns Hopkins University, showed by a controlled experiment that UV lamps placed in ventilation ducts from rooms occupied by TB patients to cages occupied by guinea pigs had a lower incidence of contracting TB (31). Although no strong human data exists, and the same results have not been repeated, this technique has been utilized for decades but not without controversy.

The use of UV lamps in patient rooms has been controversial because of safety concerns. Short term adverse health effects with UV lamps is caused by the direct exposure of humans to the damaging wavelengths with short term exposure causing erythema of the skin and keratoconjunctivitis. Long term exposure effects include basal cell carcinoma and cataracts. These effects are only realized if the lamp is installed in the patient's room.

A wall or ceiling mounted unit may be placed in the patient's room in order to disinfect the room air. These lamps are typically mounted high near the ceiling to have the greatest effect in the breathing zone. The effectiveness of these lamps is also influenced by the movement of air within the room. The lamps must be left on day and night in order to achieve the desired effect.

When the lamps are placed directly in the ventilation ducts, the exposure to humans is eliminated. The UV light utilized in this area may be of higher intensity as there is no human exposure except during required maintenance at which time the lamp may be shut off. Warning signs should be placed on duct access doors to warn maintenance worker of the presence and dangers of UV light exposure. Obviously, lamps placed in the exhaust ducts will not protect the persons occupying the same area as the TB patient and only disinfect the exhaust air.

The UV lamps should be routinely cleaned of dusts and tested as to their efficiency in the appropriate wave lengths. Bulbs should be replaced at the end of their recommended life. The CDC recommends that a timing device be installed as to indicate the end of the bulb life at a remote monitoring station.

7.4 The TB Isolation Room

The cornerstone of TB transmission prevention in a hospital setting is the AFB isolation room. Reserved for those with active infectious TB, these rooms are specially ventilated as previously described to achieve isolation by ventilation. Suspected or confirmed cases of infectious TB should be admitted and moved to these areas at the earliest possible moment. Patients should be fitted with approved valveless masks until the transfer to these areas is completed.

Rooms must be single occupancy with private bath facilities and shower if available. At teaching hospitals, the rooms should be large enough to

accommodate a variety of medical equipment including a ventilator, and be able to hold five to seven students without anyone touching the bed. A separate wash basin may be provided in the ante-room or near the door for the health care workers to utilize upon entering and exiting the room. As uncomplicated cases of TB may remain infectious for two to three weeks, a window, TV and phone may help to alleviate the sense of confinement. Electrical service of 120 and 208 volts should be provided in a convenient location for medical equipment. Medical grade oxygen, compressed air, and suction should also be provided at bedside.

Windows should be sealed and locked shut, doors must be fitted with automatic closure devices to insure that they remain closed thereby preventing changes in room pressurization. When used for AFB isolation, negative pressurization is required; however, more versatile isolation rooms will permit the pressurization to be changed between negative and positive dependent of the patient's isolation requirement.

ASHRAE recommends that six air changes per hour including two fresh outside air changes must be provided in isolation rooms. A monitoring station should be set up to alarm the staff if any fluctuations in pressurization or flow rate occur. A fail safe system which automatically activates backup power sources should a power failure occur should be included in the design. One such system would provide full exhaust on system failure with no make up ventilation supplied. Supply air ducts should also be fitted with HEPA filters

to prevent reverse migration during system failure and to filter the supply air provided to the room. HEPA filtration would also be required when the room is positively pressurized and used for non AFB isolation but for immunosuppressant patients. Flutter strips placed near vents and frequent testing with smoke tubes or smoke sticks are non mechanical methods to insure the desired flow direction.

The AFB isolation rooms will often be located in separate isolation wards in larger teaching hospitals or clustered in the medical-surgical floor of smaller hospitals. The isolation rooms should be adequately identified by appropriate signs. The nursing station serving these rooms should be ideally located within view of the room to prevent unauthorized entry or exit from the area.

Once the patient's symptoms have subsided and he or she is improving clinically, the patient may be moved to a private room. This usually occurs after three weeks of effective treatment. When the patient's sputum is free of bacilli for three consecutive days, he or she may be placed in a semi-private room with others (32). The housekeeping staff may clean the isolation rooms in the same manner as other hospital areas, but should wear PRs when in a AFB isolation room whenever the patient is present.

7.4.1 Retrofit of Existing Facilities

Hospitals located in smaller communities may not have any specially designed isolation rooms, and if so, they are usually very few in number. Existing patient

rooms or wards may have to be converted into isolation areas because of the increased demand, or to conform with state or local regulations. The greatest difficulty in converting these areas is installing the necessary ventilation. Existing exhaust vents must be sealed if they return to the general air supply of the hospital. Walls, cracks, windows, floors and doors should also be sealed to prevent unwanted infiltration.

A new ventilation system may have to be installed which is solely dedicated to the space. Exhaust vents should also be located near the floor with the supply near the ceiling to provide desired air mixing. UV lamps installed in the rooms may be utilized as a secondary measure but should not replace the use of negative pressurization to prevent migration of airborne bacilli to other hospital areas. The use of alcoves or ante-rooms may permit pressurization to be maintained for difficult retrofits. All systems installed should also be equipped with fail safe monitoring systems similar to those used in new construction.

7.5 Special Areas

The CDC also recognizes the importance of maintaining proper engineering controls in other health care areas. Hospices, nursing homes, correctional facilities, ambulatory care facilities, emergency medical services and home health services should all adhere to the TB transmission precautions outlined above.

Ambulatory care facilities which care for both patients who may suffer from TB and HIV must use special caution when caring for these individuals. Patients should be firmly instructed to cover their mouths when coughing in common areas like waiting rooms in such clinics. Ventilation systems should be enhanced to provide frequent air changes and filtration by HEPA filters or irradiation with UV lighting. When special high hazard procedures are performed, they should be completed in isolation booths similar to those used at inpatient facilities. The medical staff should be familiar with the administrative procedures and the use of PPE in hospitals.

Emergency medical services must also be concerned with transporting active TB patients. Often EMS will be the first to contact a patient who may have active TB. Recognition of the signs and symptoms of TB by the pre-hospital care providers is essential towards utilizing the proper prevention measures to be taken during transport and arrival at the ED. Ambulance personnel should wear HEPA PR's when transporting suspected cases of active TB. Rear windows of the ambulance should be opened if possible; the air conditioning or heating unit should not be on a recycle setting and the rear exhaust vent should be switched on. EMS personnel, when giving reports to the medical staff at the receiving facility, should express their concern as to any suspicion of infectious TB.

Home health care workers should also be familiar with the hazards associated with TB. HEPA PR's should be worn whenever caring for patients

with active infectious TB. If children or immuno-compromised persons live in the same household, measures to relocate these individuals should be considered. In reality, the home is an excellent setting to receive therapy as exposure to others is limited. With proper patient and family education, the quantity of airborne bacilli may be reduced by simply covering one's mouth with a tissue when coughing. As family members are screened for TB during the initial investigation, the home care worker should also monitor such individuals for any the signs and symptom within the family.

Nursing homes and correctional facilities both contain populations which are high risk groups or have immunosuppressant illnesses. The medical departments at correctional facilities should adhere to the guidelines established for inpatient facilities regarding administrative controls, PPE and engineering controls. The primary concern regarding nursing homes relates to increased surveillance. New residents and employees should be tested upon admission or employment at these facilities. The CDC recommends that two Mantoux skin tests should be performed for a more reliable baseline result as the percentage of false negative results is high. Outbreaks should be reported to the local boards of health and identified early to stem epidemic levels which may occur swiftly in these confined residential settings. Local boards of health should investigate all TB exposure contacts where outbreaks occur as described in the CDC document *Prevention and Control of Tuberculosis in Facilities Providing Long Term Care to The Elderly*.

7.6 Summary

Engineering controls serve as the best method to prevent the transmission of TB. These controls act passively and provide protection for employees and other patients alike. The microbial concentration of TB in the air is reduced thus decreasing the likelihood for exposure and preventing nosocomial transmission. When installed during new construction, as opposed to retrofitting old facilities, the higher costs of these special systems are significantly reduced. However, the need for improved ventilation within common areas and the construction of isolation rooms may only be realized as the TB epidemic grows. Other engineering methods may be developed as a result of research currently being conducted to help decrease the spread of TB among health care workers in the near future.

CHAPTER 8

FUTURE TRENDS

8.1 Introduction

The CDC has recognized that discontinuities exist in our current understanding of TB transmission in the workplace. The document entitled: *Guidelines for Preventing the Transmission of Tuberculosis in Health-care Settings, With a Special Focus on HIV - Related Issues* prepared by the CDC cited the need for research in the following three areas:

1. Better quantifying the risk of tuberculosis transmission in a variety of health care settings.
2. Assessing the acceptability, efficacy, adverse impact, and cost effectiveness of currently available methods for preventing transmission.
3. Developing better methods for preventing transmission. (8)

To increase knowledge in the three areas cited above, research in two separately distinct fields needs to be conducted. The medical community must further strive to explore the causes of the new resistant strains and search for a method to rapidly identify and treat these TB strains. The occupational safety and health community must analyze the value of the present transmission prevention techniques and research new methods. Published material from the occupational health community is minimal; however, the medical community has

made some advances in identifying drug resistant strains of TB.

8.2 Medical Research

The use of multiple antibiotics to treat TB has again become commonplace in the past decade. The combinations of these medications were often selected by the physician from past experience of success from the eleven available tuberculocidal medications. This "blind" selection was necessitated because the cultural examination required to identify the particular drug resistance of any given TB strain takes several weeks or months, primarily because of the slow growth of the bacilli in producing enough culture to test susceptibility. New techniques are urgently needed to identify MRTB.

One new technique developed at the Albert Einstein College of Medicine and the University of Pittsburgh (33) has shown promise in pinpointing drug resistance quickly. The introduction of firefly luciferase into the Mycobacterium tuberculosis by means of a bacterial virus called a "phage", allows the drug sensitivity of tuberculocidal antibiotics to be measured. The luciferase will literally "glow" when combined with luciferin and adenosine triphosphate (ATP) as an energy source. ATP is found abundantly in healthy organisms including mycobacterium Tuberculosis at the cellular level and less abundantly in unhealthy or dying cells. TB bacilli, which are dying as a result of being treated with an effective antibiotic, will have less ATP available for energy consumption. A device called a luminometer is used to measure the light emitted by various

culture samples treated with an individual antibiotic. The degree of drug susceptibility may then be determined. As William Jacobs, who is a member of the research team stated "If the sample was drug sensitive, the lights were out; and if it was resistant, the lights would go on" (34).

Genetic modifications are currently being made which would alter the phages to require even fewer TB bacteria to measure drug susceptibility. The first experiments required approximately 10,000 bacteria, which would require culturing for several days from a typical sputum sample. The new genetically engineered phage may only require 1,000 bacteria to conduct the test, thereby allowing the use of the patient's sputum with no culturing. In this manner, the traditional month long technique to culture TB and identify drug resistance may be reduced to days or even hours.

Several advantages of this new technique are obvious. Drug resistance can now be determined much sooner, which would decrease the length of communicability of the patient as time would not be wasted on ineffective treatment. The most effective combination of medications may be given to reduce the emergence of additional resistant strains. Pharmaceutical companies also see this technique as a potential time saver in the development of new antibiotics to combat TB. Where four to six weeks were previously required to identify potential new tuberculocidal antibiotics, this time would also be reduced. The research group envisions a simplified test packaged in a manner that would also allow its use in third world countries in order to end the

epidemic overseas.

Other research conducted by the Albert Einstein College of Medicine in conjunction with the Wallaceville Animal research Center in New Zealand (35) have identified the gene which may be responsible for INH resistance. This suspect gene manufactures the protein which INH targets causing its effectiveness. When the gene is mutated, the effectiveness of INH was found to decrease and the strain is resistant to INH.

This new understanding of the action mechanism for INH enables development of other antibiotics for use against TB. The researchers suggest that INH blocks the synthesis of mycolic acid, a fatty acid that is part of the cell wall of all mycobacterium. When the gene which is responsible for the production of proteins which synthesis mycolic acid is mutated, that strain of TB is found to be resistant to INH. Although the exact mechanism of INH is still unknown, these findings represent the beginning of an understanding by developing new techniques to sidestep the cell's resistance, or new antibiotics with similar actions.

8.3 Occupational Safety and Health Research

Published material regarding the transmission of TB in occupational settings prior to 1990 is limited, prompting the CDC's call for more research in this area. Recent studies have been published regarding outbreaks of MRTB in HIV hospital ward settings; however, more information must be gathered in

other clinical settings with regard to the risk of exposure and the benefits of current control methods as well as development of new control measures.

8.3.1 Administrative Controls

The best method available to prevent occupational exposure to TB is the early identification of latent TB, and providing appropriate treatments before the illness becomes communicable via the airborne route. The once mandatory testing of all school children conducted in the 1960's and 70's has been discontinued as a matter of policy, budget cuts and the false sense of security that the illness has been eliminated. Policy makers should consider the advantages of reinstating or more strictly enforcing the screening of school children in geographic regions where TB is prevalent. Local boards of health must again investigate all family contacts of children who test positive to TB. Prophylactic or preventative treatment should be given to all those in need.

Several papers have been published regarding the outbreaks of TB in special health care settings. With the greatest number of outbreaks occurring in HIV wards or clinics, these areas drew the greatest attention. The CDC studied more than 200 cases in an attempt to identify the causative factors. Occurring frequently between patients who shared semiprivate rooms and between healthcare workers before TB is diagnosed, these exposures may be preventable if AFB testing of sputum is accomplished soon after admission. PPD conversions were also found to be high among those health care workers who

cared for known TB patients as compared to workers employed in areas without TB patients. In several cases, the appropriate exposure control systems were either not implemented or found to be inadequate. In one clinic, rooms where aerosolized medication was administered were found to be positively pressurized, thereby blowing the aerosolized TB bacilli throughout the clinic exposing other patients and employees alike.

Typically, only areas where TB patients received inpatient care or outpatient clinics were subject to studies. Control groups utilized in these studies often consisted of staff from the surgical wards or operating rooms where no anticipated contact with TB patients is expected. A more encompassing study that would include all those employees who have contact with infectious TB patients would be more beneficial towards completing the CDC request of: "better quantitating the risk of tuberculosis transmission in a *variety* of health care settings". Members of the emergency medical service, emergency department, home health care, X-ray technicians, laboratory service and housekeeping staff should be included in such a study. PPD conversions and possible patient contacts identified should ascertain the possible cause of the unprotected exposure.

8.3.2 Engineering Controls

The placement of a TB patient in an AFB isolation room may give a false sense of security to the staff. The concepts of flow direction and air changes per hour

are based on sound scientific data. Reducing of the concentrations of airborne aerosols by dilution and providing negative pressurization clearly help to control the path of the contaminant and reduce individual exposure risks. However, proper maintenance of such systems is essential, as a false sense of security may exist if the system fails. The cost of these ventilation systems is high and must be justified. The CDC has recommended the assessment "of the acceptability, efficacy, adverse impact and cost effectiveness" of such systems. Could these expensive systems be replaced safely by some other method or combination of methods? Will the use of HEPA filtration and UV light reduce the operating costs of hospitals and provide the same level of protection to the employee? Definitive answers to these questions are yet to be determined.

The often cited publication regarding the use of UV irradiation dates back 30 years to a experiment conducted at Johns Hopkins University School of Hygiene and Public Health (31). Originally designed to quantify the infectiousness of air from a TB ward, the effectiveness of UV light against the bacilli was documented. The results indicated that no infections occurred in the control group of guinea pigs whose air supply passed through UV light; whereas the untreated ward air group had a statistically significant number which acquired TB. The tuberculocidal effects of UV light has been shown by other researchers in other laboratory settings; however, information regarding the equipment's use in actual clinical situations is limited. Hazards do exist when using these lights in patient rooms as previously discussed. Clinical

experimentation to determine the most effective method of using UV in patients rooms should be conducted. In this manner, health care workers may receive the maximum benefit of such technology while caring for patients.

The use of HEPA filtration in TB settings is based on theoretical data, not clinical testing with TB. These filters have been typically installed in ventilation systems where exhausted room air is filtered before being returned to the hospital reservoir air supply. A study which indicated that entire wall HEPA filtration units with horizontal laminar flow were effective in reducing outbreaks of nosocomial aspergillus infections in bone marrow transplant patients, justified the use of HEPA for TB by the CDC (30). Aspergillus is a systemic fungal disease which infects the lung. The aspergillus is two to seven microns in diameter and is found in grains, leaves, grasses, soil, construction and building materials. Following the installation of these elaborate filtration systems the aspergillus infections in bone marrow transplants were eliminated. The CDC believes that because of the similar physical size of the two microbes, and the effectiveness of HEPA for combatting aspergillus, a direct correlation may be assumed for TB.

But several questions remain unanswered as to its effectiveness in filtering TB. The research was unclear if the laminar flow reduced the infectiousness of the aspergillus. The CDC did not determine if any differences might exist between HEPA's effectiveness at trapping a fungus as opposed to a bacteria. A definitive answer to the use of HEPA filtration in ventilation systems will only

be known after clinical testing with actual *Mycobacteria tuberculosis*.

8.3.3 Personal Protection Equipment

Another area which needs particular clarification is the selection of the personal respirator. Several agencies have different opinions as to the type of PR should be utilized. NIOSH recommends the use of air purifying respirators as the minimum level of protection against TB as the bacteria is a biological hazard and any exposure is considered hazardous. The CDC is vague as to the specific type of PR to be utilized, stating only that it should be capable of filtering particles 1 to 5 microns in diameter. OSHA, which is responsible for the enforcement of the workplace hazards, has selected HEPA PR's as the acceptable standard. As with HEPA filtration, no clinical evidence regarding the use of HEPA personal respirators has been shown. With the HEPA PR sometimes serving as the only protection between the health care worker and the *Mycobacteria tuberculosis*, the importance of determining its effectiveness is essential.

CHAPTER 9

CONCLUSIONS AND RECOMMENDATIONS

9.1 Conclusions and Recommendations

In 1989 the CDC published their *Strategic Plan for the Elimination of Tuberculosis in the United States* after recognizing the resurgence of the illness in the general population. The CDC's publication set as a goal the elimination of TB by the year 2010 in the United States based on the following three point plan:

1. More effective use of existing prevention and control methods, especially in high risk populations.
2. The development and evaluation of new technologies for treatment, diagnosis and prevention.
3. The rapid assessment and transfer of newly developed technologies into clinical and public health practice. (7)

Once this plan is completed successfully, occupational exposure to TB would no longer be an issue. However, in the interim, occupational exposures will continue to occur and efforts must be made to analyze the risk and reduce its occurrence.

An increasing number of outbreaks of TB is occurring within the general population; similarly, the number of nosocomial TB infections among health care workers is also increasing. Health care facilities and regulatory agencies reanalyzed the adequacy of current regulations and existing infrastructures. At

many sites, the analysis indicated that prevention measures were often non-existent or minimal at best. In some circumstances, infections may have actually occurred as a result of faulty ventilation which distributed infectious aerosols throughout the facility.

In December 1990, the CDC published the *Guidelines for Preventing the Transmission of Tuberculosis in Health Care Settings, With a Special Focus on HIV Related Issues* as a response to these outbreaks. The recommendations of this document have been frequently cited within this thesis as they serve as the groundwork for preventing occupational exposure to TB. These guidelines were based on the best technology available at the time of publication, and called for additional research to be conducted. Three years have passed since the introduction of this document and only studies which investigated outbreaks among health care workers who care for TB patients continuously have been published. Details regarding the effectiveness and cost efficiency of these existing engineering methods and PPE measures have not been examined nor have new techniques been extensively researched.

The following items are suggested by the author as recommendations concerning specific research needs and administrative measures which may enhance our understanding and control of TB exposure in the work place:

- 1. Epidemiological studies which concentrate on all health care employees who have contact with patients before and after placement on AFB isolation should be conducted.*

A cohort study which identifies patients with a diagnosis of TB during a stay at

a health care facility would provide the basis for the study. Employees with prolonged and casual contact with TB patients would be identified, when possible, and monitored for TB infection. Information gathered may include the initial admitting diagnosis of the patient, time when AFB isolation began if at all, length of stay, clinical signs of communicability, types of infection control measures employed, areas where unrecognized unprotected exposures occurred, lab and autopsy results. Information regarding those employees who were subjected to unprotected exposures should be closely scrutinized as to length of exposure and potential communicability of the illness. Information of this nature may be obtained from patients' charts in most cases. Statistical analyses should be employed to determine if any correlation exists between these criteria for a variety of employee locations.

2. Testing the effectiveness of HEPA filtration and UV irradiation in ventilation systems for the use in Mycobacteria tuberculosis should be conducted.

A test may be utilized similar in design to Riley's in 1960, where TB ward air was drawn off into test chambers occupied by guinea pigs. A TB ward where the exhaust from several rooms is discharged through a single ventilation duct would be the most ideal. A system of louvers and baffles may be employed to allow the exhaust air to be segregated into test chambers with variable combinations of rooms to the entire ward to first enable the determination the baseline infectiousness of TB room exhaust air. Ward air may be vectored into three individual test chambers one with HEPA, UV light and untreated. Factors

which may be analyzed include the variable intensities of UV light required to efficiently destroy airborne bacilli in the duct work and the ultimate effectiveness of HEPA and life of the filter. Varying degrees of human exposure may be extrapolated by removing guinea pigs at predetermined intervals for pathological examination.

3. A study which determines the effectiveness of UV lamps placed in the patients room should be explored. Lamp placement, light intensity and exposure limits are all factors which should be considered.

The effectiveness of placing of UV lamps in patient rooms may be determined by utilizing the test chambers as mentioned in the previous recommendation. Once the baseline infectiousness of the exhaust from a TB ward is known, the UV lamps may be placed in patient rooms to determine the effectiveness by comparing the baseline infectiousness among the guinea pigs with the irradiated room air. Care must be utilized as to the placement of the lamp to avoid the irradiation of air in close proximity to the exhaust vent which would tend to skew the data. The ideal placement of the lamps would allow the destruction of bacilli in the rooms breathing zone as to protect those who occupy the same room as the patient. The safest and most effective intensities must also be determined.

4. Standard testing protocols for personal respirators should be developed to determine the optimal type to be utilized for TB protection.

Tests which determine the effectiveness of PR's for use with TB need to be

developed. PR's currently being utilized for TB are based on theoretical data related to filtration effectiveness in industrial settings determined in a loaded condition. This loaded condition will tend to increase the filtration effect possibly giving a false sense of security when new. PR's utilized in the hospital environment are often new or clean and the need to determine the filtration effect at this level is necessary. Once this testing criteria is established the effectiveness of various PR's may be determined including the HEPA for use with TB. Perhaps this standard testing protocol will end the confusion which currently exists among the health care community as to the proper PR to utilize.

5. Development of stand alone filtration technologies for use in patient rooms may provide a temporary alternative to permanent exhaust systems.

Technology of this nature may reduce the concentration of airborne contaminants in patient rooms by circulating air through HEPA filters or across high intensity UV lamps by means of a fan. The device may be utilized where temporary air filtering measures may be required in the emergency department, X-ray department or also where appropriate ventilation systems are not available in patient rooms. Smaller portable filtering units may be developed for use in ambulances which transport infectious persons. Portable filtering units are currently available for laboratory use where harmful fumes are vented across the appropriate filter. Advantages to this device would include a decrease of the concentration in the patient rooms, limited expense and portability. Only after clinical testing would devices of this nature be utilized

as a substitute or interim measure when utilized for TB areas.

6. OSHA should develop regulations to enforce tuberculosis control measures similar to those developed for bloodborne pathogens.

The current enforcement policies in the area of TB exposure are tenuous at best. Utilizing regulations and standards which are primarily related to industrial settings, the correlation to healthcare use is at times distant. Although several outbreaks of TB have occurred among health care workers and been investigated, OSHA has yet to levy any fines. With regulations specifically designed to protect the health care worker, enforcement may be more readily executed. Many questions still remain unanswered as to the effectiveness of the current technology and only after examination of the actual data resulting from clinical research may the regulations be developed. Areas which should be regulated by code include the administrative policies, PPE and engineering controls as previously discussed in this thesis.

7. The financial means to establish funding of these research projects and the execution of the exposure control plans including the capital improvements required must be developed.

The difficulty in providing the funding and implementing occupational safety programs in health care is as difficult in the health care industry as in general industry. The required isolation areas equipped with special ventilation systems are expensive to design, construct and maintain. Although most hospitals currently possess isolation areas, an increased volume of patients will require the construction of additional units. The provision of respiratory protection

equipment, PPD testing and medical surveillance are all expenses which must be recouped. Such costs will typically be passed onto the patients occupying these rooms through normal billing procedures. However, the great majority of these patients often will not have health insurance as they belong to lower socio-economic status, the expense then remains uncollected and is borne by the hospital or other patients. Will the health care industry find alternative funding for these programs and capital improvements? Should special centers be established which receive federal funding to provide the proper facilities for TB patients? The Federal government must once again show resolve in the elimination of TB and provide the necessary financial backing within the proposed health care reform act to adequately treat the afflicted patients and protect the health care worker.

The cooperation of all those involved with the exposure control plan is necessary to allow the desired effect to be achieved. The belief that some may have nothing to fear from acquiring TB is a false assumption. MRTB is particularly stubborn to cure and especially lethal for those who have a depressed immunosuppressant system. If TB were as lethal as HIV, would this complacency exist? Would questions still remain unanswered as to the actual risk and effectiveness of current exposure control measures? A hard lesson was learned when HIV infections began to spread among the general population. We cannot permit the same complacency to allow TB again to spread as a result of similar misunderstandings and lack of concern.

APPENDIX A

UNITED STATES DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Part Number 1910

Standard Number 1910.134

Title Respiratory protection.

(a) Permissible practice.

(1) In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to the following requirements.

(2) Respirators shall be provided by the employer when such equipment is necessary to protect the health of the employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protective program which shall include the requirements outlined in paragraph (b) of this section.

(3) The employee shall use the provided respiratory protection in accordance with instructions and training received.

(b) Requirements for a minimal acceptable program.

(1) Written standard operating procedures governing the selection and use of respirators shall be established.

(2) Respirators shall be selected on the basis of hazards to which the worker is exposed.

(3) The user shall be instructed and trained in the proper use of respirators and their limitations.

(4) [Reserved]

(5) Respirators shall be regularly cleaned and disinfected. Those used by more

than one worker shall be thoroughly cleaned and disinfected after each use.

(6) Respirators shall be stored in a convenient, clean, and sanitary location.

(7) Respirators used routinely shall be inspected during cleaning. Worn or deteriorated parts shall be replaced. Respirators for emergency use such as self-contained devices shall be thoroughly inspected at least once a month and after each use.

(8) Appropriate surveillance of work area conditions and degree of employee exposure or stress shall be maintained.

(9) There shall be regular inspection and evaluation to determine the continued effectiveness of the program.

(10) Persons should not be assigned to tasks requiring use of respirators unless it has been determined that they are physically able to perform the work and use the equipment. The local physician shall determine what health and physical conditions are pertinent. The respirator user's medical status should be reviewed periodically (for instance, annually).

(11) Approved or accepted respirators shall be used when they are available. The respirator furnished shall provide adequate respiratory protection against the particular hazard for which it is designed in accordance with standards established by competent authorities. The U.S. Department of Interior, Bureau of Mines, and the U.S. Department of Agriculture are recognized as such authorities. Although respirators listed by the U.S. Department of Agriculture continue to be acceptable for protection against specified pesticides, the U.S. Department of the Interior, Bureau of Mines, is the agency now responsible for testing and approving pesticide respirators.

(c) Selection of respirators. Proper selection of respirators shall be made according to the guidance of American National Standard Practices for Respiratory Protection Z88.2-1969.

(d) Air quality.

(1) Compressed air, compressed oxygen, liquid air, and liquid oxygen used for respiration shall be of high purity. Oxygen shall meet the requirements of the United States Pharmacopoeia for medical or breathing oxygen. Breathing air shall meet at least the requirements of the specification for Grade D breathing air as described in Compressed Gas

Association Commodity Specification G-7.1-1966. Compressed oxygen shall not be used in supplied-air respirators or in open circuit self-contained breathing apparatus that have previously used compressed air. Oxygen must never be used with air line respirators.

(2) Breathing air may be supplied to respirators from cylinders or air compressors.

(i) Cylinders shall be tested and maintained as prescribed in the Shipping Container Specification Regulations of the Department of Transportation (49 CFR Part 178).

(ii) The compressor for supplying air shall be equipped with necessary safety and standby devices. A breathing air-type compressor shall be used. Compressors shall be constructed and situated so as to avoid entry of contaminated air into the system and suitable in-line air purifying sorbent beds and filters installed to further assure breathing air quality. A receiver of sufficient capacity to enable the respirator wearer to escape from a contaminated atmosphere in event of compressor failure, and alarms to indicate compressor failure and overheating shall be installed in the system. If an oil-lubricated compressor is used, it shall have a high-temperature or carbon monoxide alarm, or both. If only a high-temperature alarm is used, the air from the compressor shall be frequently tested for carbon monoxide to insure that it meets the specifications in paragraph (d)(1) of this section.

(3) Air line couplings shall be incompatible with outlets for other gas systems to prevent inadvertent servicing of air line respirators with nonrespirable gases or oxygen.

(4) Breathing gas containers shall be marked in accordance with American National Standard Method of Marking Portable Compressed Gas Containers to Identify the Material Contained, Z48.1-1954; Federal Specification BB-A-1034a, June 21, 1968, Air, Compressed for Breathing Purposes; or Interim Federal Specification GG-B-00675b, April 27, 1965, Breathing Apparatus, Self-Contained.

(e) Use of respirators.

(1) Standard procedures shall be developed for respirator use. These should include all information and guidance necessary for their proper selection, use, and care. Possible emergency and routine uses of respirators should be anticipated and planned for.

(2) The correct respirator shall be specified for each job. The respirator type is usually specified in the work procedures by a qualified individual supervising the respiratory protective program. The individual issuing them shall be adequately instructed to insure that the correct respirator is issued.

(3) Written procedures shall be prepared covering safe use of respirators in dangerous atmospheres that might be encountered in normal operations or in emergencies. Personnel shall be familiar with these procedures and the available respirators.

(i) In areas where the wearer, with failure of the respirator, could be overcome by a toxic or oxygen-deficient atmosphere, at least one additional man shall be present. Communications (visual, voice, or signal line) shall be maintained between both or all individuals present. Planning shall be such that one individual will be unaffected by any likely incident and have the proper rescue equipment to be able to assist the other(s) in case of emergency.

(ii) When self-contained breathing apparatus or hose masks with blowers are

used in atmospheres immediately dangerous to life or health, standby men must be present with suitable rescue equipment.

(iii) Persons using air line respirators in atmospheres immediately hazardous to life or health shall be equipped with safety harnesses and safety lines for lifting or removing persons from hazardous atmospheres or other and equivalent provisions for the rescue of persons from hazardous atmospheres shall be used. A standby man or men with suitable self-contained breathing apparatus shall be at the nearest fresh air base for emergency rescue.

(4) Respiratory protection is no better than the respirator in use, even though it is worn conscientiously. Frequent random inspections shall be conducted by a qualified individual to assure that respirators are properly selected, used, cleaned, and maintained.

(5) For safe use of any respirator, it is essential that the user be properly instructed in its selection, use, and maintenance. Both supervisors and workers shall be so instructed by competent persons. Training shall provide the men an opportunity to handle the respirator, have it fitted properly, test its face-piece-to-face seal, wear it in normal air for a long familiarity period, and, finally, to wear it in a test atmosphere.

(i) Every respirator wearer shall receive fitting instructions including demonstrations and practice in how the respirator should be worn, how to adjust it, and how to determine if it fits properly. Respirators shall not be worn when conditions prevent a good face seal. Such conditions may be a growth of beard, sideburns, a skull cap that projects under the facepiece, or temple pieces on glasses. Also, the absence of one or both dentures can seriously affect the fit of a facepiece. The worker's diligence in observing these factors shall be evaluated by periodic check. To assure proper protection, the facepiece fit shall be checked by the wearer each time he puts on the respirator. This may be done by following the manufacturer's facepiece fitting instructions.

(ii) Providing respiratory protection for individuals wearing corrective glasses is a serious problem. A proper seal cannot be established if the temple bars of eye glasses extend through the sealing edge of the full facepiece. As a temporary measure, glasses with short temple bars or without temple bars may be taped to the wearer's head. Wearing of contact lenses in contaminated atmospheres with a respirator shall not be allowed. Systems have been developed for mounting corrective lenses inside full facepieces. When a workman must wear corrective lenses as part of the facepiece, the facepiece and lenses shall be fitted by qualified individuals to provide good vision, comfort, and a gas-tight seal.

(iii) If corrective spectacles or goggles are required, they shall be worn so as not to affect the fit of the facepiece. Proper selection of equipment will minimize or avoid this problem.

(f) Maintenance and care of respirators.

(1) A program for maintenance and care of respirators shall be adjusted to the

type of plant, working conditions, and hazards involved, and shall include the following basic services:

- (i) Inspection for defects (including a leak check),
- (ii) Cleaning and disinfecting,
- (iii) Repair,
- (iv) Storage

Equipment shall be properly maintained to retain its original effectiveness.

(2) (i) All respirators shall be inspected routinely before and after each use. A respirator that is not routinely used but is kept ready for emergency use shall be inspected after each use and at least monthly to assure that it is in satisfactory working condition.

(ii) Self-contained breathing apparatus shall be inspected monthly. Air and oxygen cylinders shall be fully charged according to the manufacturer's instructions. It shall be determined that the regulator and warning devices function properly.

(iii) Respirator inspection shall include a check of the tightness of connections and the condition of the facepiece, headbands, valves, connecting tube, and canisters. Rubber or elastomer parts shall be inspected for pliability and signs of deterioration. Stretching and manipulating rubber or elastomer parts with a massaging action will keep them pliable and flexible and prevent them from taking a set during storage.

(iv) A record shall be kept of inspection dates and findings for respirators maintained for emergency use.

(3) Routinely used respirators shall be collected, cleaned, and disinfected as frequently as necessary to insure that proper protection is provided for the wearer. Respirators maintained for emergency use shall be cleaned and disinfected after each use.

(4) Replacement or repairs shall be done only by experienced persons with parts designed for the respirator. No attempt shall be made to replace components or to make adjustment or repairs beyond the manufacturer's recommendations. Reducing or admission valves or regulators shall be returned to the manufacturer or to a trained technician for adjustment or repair.

(5) (i) After inspection, cleaning, and necessary repair, respirators shall be stored to protect against dust, sunlight, heat, extreme cold, excessive moisture, or damaging chemicals. Respirators placed at stations and work areas for emergency use should be quickly accessible at all times and should be stored in compartments built for the purpose. The compartments should be clearly marked. Routinely used respirators, such as dust respirators, may be placed in plastic bags. Respirators should not be stored in such places as lockers or tool boxes unless they are in carrying cases or cartons.

(ii) Respirators should be packed or stored so that the facepiece and exhalation valve will rest in a normal position and function will not be impaired

by the elastomer setting in an abnormal position.

(iii) Instructions for proper storage of emergency respirators, such as gas masks and self-contained breathing apparatus, are found in "use and care" instructions usually mounted inside the carrying case lid.

(g) Identification of gas mask canisters.

(1) The primary means of identifying a gas mask canister shall be by means of properly worded labels. The secondary means of identifying a gas mask canister shall be by a color code.

(2) All who issue or use gas masks falling within the scope of this section shall see that all gas mask canisters purchased or used by them are properly labeled and colored in accordance with these requirements before they are placed in service and that the labels and colors are properly maintained at all times thereafter until the canisters have completely served their purpose.

(3) On each canister shall appear in bold letters the following:

(i) -

Canister for _____ (Name for atmospheric contaminant)

or

Type N Gas Mask Canister

(ii) In addition, essentially the following wording shall appear beneath the appropriate phrase on the canister label: "For respiratory protection in atmospheres containing not more than _____ percent by volume of _____." (Name of atmospheric contaminant)

(4) Canisters having a special high-efficiency filter for protection against radio nuclide and other highly toxic particulate shall be labeled with a statement of the type and degree of protection afforded by the filter. The label shall be affixed to the neck end of, or to the gray stripe which is around and near the top of, the canister. The degree of protection shall be marked as the percent of penetration of the canister by a 0.3-micron-diameter dioctyl phthalate (DOP) smoke at a flow rate of 85 liters per minute.

(5) Each canister shall have a label warning that gas masks should be used only in atmospheres containing sufficient oxygen to support life (at least 16 percent by volume), since gas mask canisters are only designed to neutralize or remove contaminants from the air.

(6) Each gas mask canister shall be painted a distinctive color or combination of colors indicated in Table I-1. All colors used shall be such that they are clearly identifiable by the user and clearly distinguishable from one another. The color coating used shall offer a high degree of resistance to chipping, scaling, peeling, blistering, fading, and the

effects of the ordinary atmospheres to which they may be exposed under normal conditions of storage and use. Appropriately colored pressure sensitive tape may be used for the stripes.

TABLE I-1

Atmospheric contaminants to be protected against	Colors assigned(1)
Acid gases	White.
Hydrocyanic acid gas	White with 1/2-inch green stripe completely around the canister near the bottom.
Chlorine gas	White with 1/2-inch yellow stripe completely around the canister near the bottom.
Organic vapors	Black.
Ammonia gas	Green.
Acid gases and ammonia gases	Green with 1/2-inch white stripe completely around the canister near the bottom.
Carbon Monoxide	Blue.
Acid gases and organic vapors	Yellow.
Hydrocyanic acid gas and chloropicrin vapor	Yellow with 1/2-inch blue stripe completely around the canister near the bottom.
Acid gases, organic vapors, and ammonia gases	Brown.
Radioactive materials, excepting tritium and noble gases	Purple (Magenta).
Particulate (dusts, fumes, mists, fogs, or smokes) in combination with any of the above gases or vapors	Canister color for contaminant, as designated above, with 1/2-inch gray stripe completely around the canister near the top.
All of the above atmospheric contaminants	Red with 1/2-inch gray stripe completely around the canister near the top.

Footnote(1) Gray shall not be assigned as a main color for a canister designed to remove acids or vapors.

NOTE: Orange shall be used as a complete body, or stripe color to represent gases not included in this table. The user will need to refer to the canister label to determine the degree of protection the canister will afford.

(Approved by the Office of Management and Budget under control number 1218-0099)

[39 FR 23502, June 27, 1974, as amended at 43 FR 49748, Oct. 24, 1978; 49 FR 5322, Feb. 10, 1984; 49 FR 18295, Apr. 30, 1984]

APPENDIX B

UNITED STATES DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Part Number 1915

Standard Number 1915.152

Title Respiratory protection.

(a) General.

(1) All respiratory equipment required by this Part shall be approved for the use for which it is intended by the Mine Safety and Health Administration and the National Institute of Occupational Safety and Health pursuant to the provisions of 30 CFR Part 11. Respiratory protective equipment shall be used only for the purpose intended and no modifications of the equipment shall be made.

(2) Respiratory protective equipment shall be inspected regularly and maintained in good condition. Gas mask canisters and chemical cartridges shall be replaced as necessary so as to provide complete protection. Mechanical filters shall be cleaned or replaced as necessary so as to avoid undue resistance to breathing.

(3) Respiratory protective equipment which has been previously used shall be cleaned and disinfected before it is issued by the employer to another employee. Emergency rescue equipment shall be cleaned and disinfected immediately after each use.

(4) Employees required to use respiratory protective equipment approved for use in atmospheres immediately dangerous to life shall be thoroughly trained in its use. Employees required to use other types of respiratory protective equipment shall be instructed in the use and limitations of such equipment.

1915.152(a)(5)

(5) When an air line respirator is used, the air line shall be fitted with a pressure regulating valve and a filter which will remove oil water and rust particles. The air intake shall be from a source which is free from all contaminants, such as the exhaust from internal combustion engines.

(6) In all cases when an employee is stationed outside a compartment, tank or space as a tender or safety man for men working inside in an atmosphere

immediately dangerous to life, the tender shall have immediately available for emergency use respiratory protective equipment equivalent to that required for the men in the compartment. When a tender is stationed outside a compartment for men working inside in an atmosphere not immediately dangerous to life, the tender shall wear respiratory protective equipment equivalent to that required for the men in the compartment if he is exposed for prolonged periods to the same concentration of atmospheric contaminants.

(b) Protection in atmospheres immediately dangerous to life.

(1) Atmospheres immediately dangerous to life are those which contain less than 16.5 percent oxygen, or which by reason of the high toxicity of the contaminant, as in fumigation, or high concentration of the contaminant, as with carbon dioxide, would endanger the life of a person breathing them for even a short period of time.

(2) In atmospheres immediately dangerous to life the only approved types of respiratory protective equipment are the following:

(i) Self-contained breathing apparatus, in which the wearer carries with him a supply of oxygen, air, or an oxygen generating material.

(ii) Hose mask with blower, in which a hand or motor operated blower supplies air at high volume and low pressure through a large diameter hose through which the wearer can draw air in case the blower fails.

(iii) If there is known to be more than 16 percent oxygen and less than 2 percent gas by volume, a gas mask equipped with a canister approved for the particular type gas involved.

Note: A gas mask offers absolutely no protection in an atmosphere deficient in oxygen.

(3) Work in atmospheres immediately dangerous to life shall be performed only in an emergency, as when rescuing a man who has been overcome or when shutting off a source of contamination that cannot otherwise be controlled. When an employee enters such an atmosphere he shall be provided with and use an adequate, attended life line.

(4) In the vicinity of each vessel in which there is a danger of employees being exposed to an atmosphere immediately dangerous to life, the employer shall have on hand and ready for use respiratory protective equipment approved for such use. When such equipment is required, one or more persons shall be thoroughly trained in the use of the equipment.

(c) Protection against gaseous contaminants not immediately dangerous to life.

(1) Gaseous contaminants not immediately dangerous to life are gases present in concentrations that could be breathed for a short period without endangering the life of a person breathing them, but which might produce discomfort and possible injury after a prolonged single exposure or repeated short exposures.

(2) When employees are exposed to a gaseous contaminated atmosphere not

immediately dangerous to life, they shall be protected by respiratory protective equipment approved for use in the type and concentration of the gaseous contaminant as follows:

(i) In high or unknown concentrations, a hose mask or an air line respirator. The use of either a hose mask or an air line respirator in lower concentrations is permissible.

(ii) In concentrations of ammonia of less than 3 percent, or of other gases less than 2 percent, by volume, a canister type gas mask equipped with the proper type of canister. Different canisters are approved for specific use against the following gases or groups of gases: Acid gases, hydrocyanic acid gas, chlorine gas, organic vapors, ammonia gas, carbon monoxide, or combination of the above.

(iii) In low concentrations (less than 0.1 percent by volume), a chemical cartridge respirator equipped with the type of cartridge approved for use against the particular gases or groups of gases listed in paragraph (c)(2)(ii) of this section.

(d) Protection against particulate contaminants not immediately dangerous to life.

(1) When employees are exposed to unsafe concentrations of particular contaminants, such as dusts and fumes, mists and fogs or combinations of solids and liquids, they shall be protected by either air line or filter respirators, except as otherwise provided in this part.

(2) Filter respirators shall be equipped with the proper type of filter. Different filters are approved for specific protection against groups of contaminants, as follows:

(i) Pneumoconiosis-producing dust and nuisance dust filters which provide respiratory protection against pneumoconiosis-producing dusts, such as aluminum, cellulose, cement, charcoal, coal, coke, flour, gypsum, iron ore, limestone and wood.

(ii) Toxic dust filters which provide respiratory protection against toxic dusts that are not significantly more toxic than lead, such as arsenic, cadmium, chromium, lead, manganese, selenium, vanadium, and their compounds.

(iii) Mist filters which provide respiratory protection against pneumoconiosis-producing mists, chromic acid mists, and nuisance mists.

(iv) Fume filters which provide respiratory protection against fumes (solid dispersoids or particulate matter formed by the condensation of vapors, such as those from heated metals and other substances).

(v) Filters which provide respiratory protection against combinations of two or more of the contaminants described in paragraphs (d)(2) (i) through (iv) of this section.

(e) Protection against combinations of gaseous and particulate contaminants not immediately dangerous to life.

(1) When employees are exposed to combinations of gaseous and particulate

contaminants not immediately dangerous to life, as in spray painting they shall be protected by respiratory protective equipment approved for use in the type and concentration of the contaminants, as follows:

(i) In high or unknown concentrations, a hose mask or an air line respirator. The use of either a hose mask or an air line respirator is permissible in lower concentrations.

(ii) In concentrations of gaseous contaminants of less than 2 percent by volume, a canister type gas mask with a combination canister approved for the particular type of gaseous contaminant as specified in paragraph (c)(2) of this section and a filter for the particular type of particulate contaminant as specified in paragraph (d)(1) of this section.

(iii) In low concentrations of gaseous contaminants (less than 0.1 percent by volume) a respirator equipped with the type of cartridge and filter as specified in paragraph (e)(ii) of this section.

APPENDIX C

UNITED STATES DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Part Number 1910

Standard Number 1910.1030

Title Bloodborne pathogens.

* [Effective date for this standard, 1910.1030, is Mar. 6, 1992] Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C.655, 657, Secretary of Labor's Orders Nos. 12-71 (36 FR 8754), 8-76 (41FR 25059), or 9-83 (48 FR 35736), as applicable; and 29 CFR Part 1911. Section 1910.1030 also issued under 29 U.S.C. 653.

(a) Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) Definitions. For purposes of this section, the following shall apply:"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

"Blood" means human blood, human blood components, and products made from human blood.

"Bloodborne Pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

"Clinical Laboratory" means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

"Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

"Contaminated Laundry" means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

"Contaminated Sharps" means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

"Engineering Controls" means controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.

"Exposure Incident" means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

"Handwashing Facilities" means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

"Licensed Healthcare Professional" is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

"HBV" means hepatitis B virus.

"HIV" means human immunodeficiency virus.

"Occupational Exposure" means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

"Other Potentially Infectious Materials" means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

"Parenteral" means piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions.

"Personal Protective Equipment" is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

"Production Facility" means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

"Regulated Waste" means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated

sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

"Research Laboratory" means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

"Source Individual" means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

"Sterilize" means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospore.

"Universal Precautions" is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

"Work Practice Controls" means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

(c) Exposure Control.

(1) Exposure Control Plan.

(i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

(ii) The Exposure Control Plan shall contain at least the following elements:

(A) The exposure determination required by paragraph (c)(2),

(B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Record keeping, of this standard, and (C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

(v) The Exposure Control Plan shall be made available to the Assistant

Secretary and the Director upon request for examination and copying.

(2) Exposure Determination.

(i) Each employer who has an employee(s) with occupational exposure as defined by paragraph

(b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

(A) A list of all job classifications in which all employees in those job classifications have occupational exposure;

(B) A list of job classifications in which some employees have occupational exposure, and (C) A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

(ii) This exposure determination shall be made without regard to the use of personal protective equipment.

(d) Methods of Compliance.

(1) General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

(2) Engineering and Work Practice Controls.

(i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

(ii) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(iii) Employers shall provide handwashing facilities which are readily accessible to employees.

(iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

(v) Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

(vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

(vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

(A) Contaminated needles and other contaminated sharps shall not be recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure.

(B) Such recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

(viii) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

(A) puncture resistant;

(B) labeled or color-coded in accordance with this standard;

(C) leak proof on the sides and bottom; and

(D) in accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

(x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on counter tops or bench tops where blood or other potentially infectious materials are present. (xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

(xii) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

(xiii) Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

(A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

(B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

(C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

(xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping

and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

(A) A readily observable label in accordance with paragraph(g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

(B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

(3) Personal Protective Equipment.

(i) Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

(ii) Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

(iii) Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the work site or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

(iv) Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

(v) Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

(vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

(vii) All personal protective equipment shall be removed prior to leaving the work area. (viii) When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(ix) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph(d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

(A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

(B) Disposable (single use) gloves shall not be washed or decontaminated for re-use.

(C) Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

{1} Periodically reevaluate this policy;

{2} Make gloves available to all employees who wish to use them for phlebotomy;

{3} Not discourage the use of gloves for phlebotomy; and

{4} Require that gloves be used for phlebotomy in the following circumstances:

{i} When the employee has cuts, scratches, or other breaks in his or her skin;

{ii} When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

{iii} When the employee is receiving training in phlebotomy.

(x) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

(xi) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

(xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

(4) Housekeeping.

(i) General. Employers shall ensure that the work site is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

(ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

(B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they may have become contaminated during the shift.

(C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

(E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

(iii) Regulated Waste.

(A) Contaminated Sharps Discarding and Containment. {1} Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are: [a] Closable; [b] Puncture resistant; [c] Leak proof on sides and bottom; and [d] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

{2} During use, containers for contaminated sharps shall be: [a] Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g.,

laundries); [b] Maintained upright throughout use; and [c] Replaced routinely and not be allowed to overfill. {3} When moving containers of contaminated sharps from the area of use, the containers shall be: [a] Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping; [b] Placed in a secondary container if leakage is possible. The second container shall be: [i] Closable; [ii] Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and [iii] Labeled or color-coded according to paragraph (g)(1)(i) of this standard. {4} Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

(B) Other Regulated Waste Containment. {1} Regulated waste shall be placed in containers which are: [a] Closable; [b] Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; [c] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and [d] Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. {2} If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be: [a] Closable; [b] Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; [c] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and [d] Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

(iv) Laundry.

(A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. {1} Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use. {2} Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions. {3} Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

(B) The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal

protective equipment.

(C) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

(e) HIV and HBV Research Laboratories and Production Facilities.

(1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

(2) Research laboratories and production facilities shall meet the following criteria:

(i) Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as auto claving known to effectively destroy bloodborne pathogens.

(ii) Special Practices

(A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress. (B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leak proof, labeled or color-coded container that is closed before being removed from the work area.

(C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

(E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

(F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

(G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is

unavoidable.

(H) Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

(J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclave or decontaminated before reuse or disposal.

(K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

(L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

(M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(iii) Containment Equipment.

(A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

(B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

(3) HIV and HBV research laboratories shall meet the following criteria:

(i) Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

(ii) An autoclave for decontamination of regulated waste shall be available.

(4) HIV and HBV production facilities shall meet the following criteria:

(i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other

contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

(ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

(iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(iv) Access doors to the work area or containment module shall be self-closing.

(v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

(5) Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

(f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

(1) General.

(i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

(ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

(A) Made available at no cost to the employee;

(B) Made available to the employee at a reasonable time and place;

(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

(D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

(iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

(2) Hepatitis B Vaccination.

(i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working

days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

(ii) The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

(iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

(iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

(v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(3) Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

(i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

(ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(C) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(iii) Collection and testing of blood for HBV and HIV serological status;

(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as

feasible.

(iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(v) Counseling; and

(vi) Evaluation of reported illnesses.

(4) Information Provided to the Healthcare Professional.

(i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

(ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

(A) A copy of this regulation;

(B) A description of the exposed employee's duties as they relate to the exposure incident; (C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(D) Results of the source individual's blood testing, if available; and

(E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

(5) Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating health care professional's written opinion within 15 days of the completion of the evaluation.

(i) The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

(ii) The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

(A) That the employee has been informed of the results of the evaluation; and

(B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(6) Medical Record keeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) Communication of Hazards to Employees.

(1) Labels and Signs.

(i) Labels.

(A) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

(B) Labels required by this section shall include the following legend: Place Symbol here BIOHAZARD

(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color.

(D) Labels required by paragraph (g)(1)(i) shall either be an integral part of the container or shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels.

(F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(I) Regulated waste that has been decontaminated need not be labeled or color-coded. (ii) Signs.

(A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend: biohazard symbol here BIOHAZARD (Name of the Infectious Agent)(Special requirements for entering the area) (Name, telephone number of the laboratory director or other responsible person.)

(B) These signs shall be fluorescent orange-red or predominantly so, with lettering or symbols in a contrasting color.

(2) Information and Training.

(i) Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

(ii) Training shall be provided as follows:

(A) At the time of initial assignment to tasks where occupational exposure may take place; (B) Within 90 days after the effective date of the standard; and

(C) At least annually thereafter.

(iii) For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

(iv) Annual training for all employees shall be provided within one year of their previous training.

(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(vii) The training program shall contain at a minimum the following elements:

(A) An accessible copy of the regulatory text of this standard and an explanation of its contents;

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(C) An explanation of the modes of transmission of bloodborne pathogens;

(D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

(E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

(G) Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

(H) An explanation of the basis for selection of personal protective equipment;

(I) Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

(J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

(M) An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

(N) An opportunity for interactive questions and answers with the person conducting the training session.

(viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

(A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and

operations specific to the facility before being allowed to work with HIV or HBV.

(B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

(C) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) Record keeping.

(1) Medical Records.

(i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

(A) The name and social security number of the employee;

(B) A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

(C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

(D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

(E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

(iii) Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

(A) Kept confidential; and

(B) Are not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

(2) Training Records.

(i) Training records shall include the following information:

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

(D) The names and job titles of all persons attending the training sessions.

(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(3) Availability.

(i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(4) Transfer of Records.

(i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

(i) Dates.

(1) Effective Date. The standard shall become effective on March 6, 1992.

(2) The Exposure Control Plan required by paragraph (c)(2) of this section shall be completed on or before May 5, 1992.

(3) Paragraph (g)(2) Information and Training and (h) Record keeping shall take effect on or before June 4, 1992.

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.* [Effective date for this standard 1910.1030, is March 6, 1992]

Part Number 1910 Standard Number 1910.1030 App A Title Appendix A - Hepatitis B Vaccine Declination (Mandatory) * [Effective date for this standard, 1910.1030, is March 6, 1992] I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis

B vaccine, I can receive the vaccination series at no charge to me.* (Approved by the Office of Management and Budget under control number 1218-0180)* [56 FR 64004, Dec. 06, 1991; 57 FR April 13, 1992]

WORKS CITED

1. Castiglioni, A. *History of Tuberculosis*. New York: Medical Life Press (1936).
2. Webb, G.B. *Tuberculosis*. New York: Paul B. Hoeber (1936).
3. Villemin, J.A. *Et Udes Sur La Tuberculose*. Paris: J.B. Balliere (1868).
4. Waksman, Selman A. *The Conquest of Tuberculosis*. Los Angeles: University of California Press (1964).
5. Koch, R. *The Aetiology of Tuberculosis*. New York: National Tuberculosis Association (1932).
6. Villemin, J.A. "Cause et nature de la tuberculose: Son inoculation de l'homme au lapin." *Compt. Rend. Academy Science*. 61 (1865): 1012-1015.
7. Center for Disease Control. "A Strategic Plan for the Elimination of Tuberculosis in the United States." *Morbidity and Mortality Weekly Report*. 38 No S-3 (1988): 1-25.
8. Center for Disease Control. "Guidelines for Preventing the Transmission of Tuberculosis in Health Care Settings, With Special Focus on HIV Related Issues." *Morbidity and Mortality Weekly Report*. 39 RR-17 (1990): 1-29.
9. Adler, Jack. "Hospital Acquired Tuberculosis: Addressing the Challenge." *Hospital Practice*. 28 (1993): 112-120.
10. Snider, Dixie E. and Samuel W. Dooley. "Nosocomial Tuberculosis in the AIDS Era With a Emphasis on Multidrug Resistant Disease." *Heart and Lung*. 22 (1993): 365-369.
11. Center for Disease Control. "The Use of Preventive Therapy for Tuberculosis Infection in the United States." *Morbidity and Mortality Weekly Report*. 39 RR-8 (1990): 9-12.
12. Center for Disease Control. "Tuberculosis Morbidity in the United States Final Data, 1990." *Morbidity and Mortality Weekly Report*. 40 SS-3 (1990): 24-27.
13. Bouttotte, Janice. "T. B. The Second Time Around and How You Can Control It." *Nursing*. (1993): 42-49.

14. Wyngraaren, James and Lloyd Smith. eds. *The Textbook of Medicine*. Philadelphia: W.B. Saunders Company (1985): 1620-1630.
15. Drabkin, I.E. *Caelius Aurelianus. De morbis chronicis. On Acute Diseases and on Chronic Diseases*. Chicago: University of Chicago Press (1950).
16. Berkow, Robert ed. *The Merck Manual*. Rahway: Merck Sharp and Dohme Research (1987).
17. Kochi, A. "The Global Tuberculosis Situation and the New Control Strategy of the World Health Organization." *Tubercle*. 72 (1991): 1-6.
18. Center for Disease Control. "1993 Revised Classification System for HIV infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults." *Morbidity and Mortality Weekly Report*. 41 RR-17 (1992): 1-11.
19. Center for Disease Control. "Initial Therapy for Tuberculosis in the Era of Multidrug Resistance." *Morbidity and Mortality Weekly Report*. 42 RR-7 (1993): 1-8.
20. Pearson, Michele, et al. "Nosocomial Transmission of Multidrug Resistant Mycobacterium Tuberculosis, A Risk to Patients and Health care Workers." *Annals of Internal Medicine*. 117 (1992): 191-196.
21. Flick, L.F. *Development of Our Knowledge of Tuberculosis*. Philadelphia: Wickersham Printing Company (1925).
22. Cummins, S.L. *Tuberculosis in History*. London: Bailliere, Tindall and Cox (1949).
23. Porterfield, John D. *Community Health its Needs and Resources*. New York: Basic Books Inc. (1966) 34-46.
24. Plog, Barbara A. ed. *Fundamentals of Industrial Hygiene*. Chicago: National Safety Council. (1988) 521-568.
25. Nightingale, F. *Notes on Hospitals*. New York: Appleton (1860).
26. Thompson, John D. and Grace Goldin. *The Hospital: A Social and Architectural History*. New Haven and London: Yale University Press (1975).

27. Stoner, David, et al. *Engineering a Safe Hospital Environment*. New York: John Wiley & Sons (1982): 94-113, 144-161.
28. American Society of Heating, Refrigeration and Air-Conditioning Engineers Inc. *1991 ASHRAE Handbook*. Atlanta (1991): 7.1-7.12.
29. Michealson, G.S., et al. *The Laminar Air Flow Concept for the Care of Low Resistance Hospital Patients*. Paper Presented at the American Public Health Association Meeting: San Francisco, November 1966.
30. Sherertz R.J., et al. "Impact of air Filtration on Nosocomial Aspergillus Infections." *American Journal of Medicine*. 83 (1987): 709-718.
31. Riley, R.L., et al. "Infectiousness of Air From a Tuberculosis Ward." *American Review of Respiratory Diseases*. 85 (1962): 511-525.
32. Adler, Jack. "Hospital Acquired Tuberculosis: Addressing the Challenge." *Hospital Practice*. 28 (1993): 112-120.
33. Jacobs, William, et al. "Rapid Assessment of Drug Susceptibilities of Mycobacterium Tuberculosis By Means Of Luciferase Reporter Phages." *Science*. 260 (1993): 819-822.
34. Barinaja, Marcia. "New Test Catches Drug-Resistant TB in the Spotlight." *Science*. 260 (1993):750.
35. Banerjee, Aresh, et al. "inhA, A Gene Encoding a Target for Isoniazid and Ethionamide in Mycobacterium tuberculosis." *Science*. 263 (1994): 227-230.

GLOSSARY

ACET - Advisory Committee for Elimination of Tuberculosis

AFB - Acid Fast Bacilli

ASHRAE - American Society of Heating, Refrigeration and Air-Conditioning Engineers

ATP - Adenosine Triphosphate

CDC - Center for Disease Control

ED - Emergency Department

EMB - Ethionamide

EMS - Emergency Medical Service

HBV - Hepatitis B Virus

HEPA - High Efficiency Particulate Airfilter

HIV - Human Immunodeficiency Virus

INH - Isoniazid

MRTB - Multidrug Resistant Tuberculosis

NIOSH - National Institute for Occupational Safety and Health

OSHA - Occupational Safety and Health Administration

PAPR - Powered Air-purified Respirator

PAS - Para-Aminosalicylic Acid

PEL - Permissible Exposure Limit

PPD - Purified Protein Derivative

PPE - Personal Protective Equipment

PR - Personal Respirator

PZA - Pyrazinamide

QLFT - Qualitative Fit Testing

QNFT - Quantitative Fit Testing

RIF - Rifampin

SM - Streptomycin

TB - Tuberculosis

TLV - Threshold Limit Value

TU - Tuberculin Units

UV - Ultra Violet