Overview of CPL 2.106, Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis (TB)
TB Occurrence

- Since 1985, the incidence of TB in the general population has increased 14% reversing a 30 year downward trend
- In 1993, over 25,000 new cases of TB were reported in the U.S.
- During 1994 and 1995, however, there was a decrease in TB cases in the U.S. likely due to increased awareness and efforts in prevention and control of TB
TB Occurrence (Continued)

- Cases of multi-drug resistant (MDR) TB have recently been reported in 40 states.
- Worldwide, 8 million new TB cases and 3 million deaths occur annually.
Why Is TB Increasing?

Multiple contributing factors:
- Homelessness
- Intravenous drug use
- Overcrowding in institutional settings
- HIV infection
- Reduced TB control and treatment resources
- Immigration from high TB prevalence areas
TB Transmission

• Infectious disease caused by the bacterium, *Mycobacterium tuberculosis*
• Spread by airborne droplets, “droplet nuclei,” 1 to 5 microns in size
• Droplet nuclei generated when a person with TB disease coughs, sneezes, speaks, or sings
• TB infection occurs when a susceptible person inhales droplet nuclei containing the bacteria becomes established in the body
General Signs and Symptoms of TB

- Lethargy/weakness/fatigue
- Fever
- Weight loss
- Persistent productive cough
- Coughing up blood
- Loss of appetite
- Night sweats
TB Screening

• Mantoux tuberculin skin test detects TB infection
• Positive result indicate TB infection;
• other tests are needed to confirm TB disease
Summary of OSHA
TB Enforcement Activities

• 5/92: OSHA Region 2 issued enforcement guidelines for occupational exposure to TB
• Guidelines based on CDC 1990 “Guidelines for Preventing the Transmission of Tuberculosis in Health Care Settings with Special Focus on HIV-Related Issues”
• OSHA inspections revealed that employers have not fully implemented the CDC guidelines
Summary (Continued)

• 10/93: OSHA issued agency-wide TB enforcement policy guidelines based on the CDC 1990 guidelines. Guidelines were effective immediately except for respirator requirements which became effective 1/94.

• 2/96: OSHA issued agency-wide CPL 2.106, “Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis” which cancels the enforcement policy guidelines.
Summary (Continued)

• CPL 2.106 is based on CDC 1994 “Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health- Care Facilities” issued 10/94

• OSHA believes the guidelines reflect an industry recognition of the hazard as well as appropriate widely accepted standards of practice to be followed by employers in carrying out their responsibilities the OSH Act
Inspection
Scheduling and Scope

• The evaluation of occupational exposure to TB is conducted in response to:
  – Employee complaints;
  – Related fatality/catastrophes; or
  – As part of all industrial hygiene inspections conducted in workplaces identified by the CDC as having a greater incidence of TB infection than in the general population.
Inspection Scheduling and Scope (Continued)

• CDC has identified the following workplaces as having high incidences of TB:
  – Healthcare Facilities
  – Correctional Institutions
  – Homeless Shelters
  – Long-term Care Facilities for the Elderly
  – Drug Treatment Centers
Inspection Scheduling and Scope (Continued)

- Health care facilities include hospitals where patients with confirmed or suspect TB are treated or to which they are transported.
- Coverage of non-health care setting includes only personnel present during performance of high hazard procedures on suspect or active TB patients.
- Dental health care personnel are covered only if they treat suspect or active patients in a hospital, correctional facility, or as part of their practice.
All inspections in affected workplaces shall include a review of employer's plans for employee TB protection, if any. Such plans may include the infection control program, respiratory protection, and skin testing. Employee interviews and site observations are an integral part of the process evaluation.

Complaints received from state and local government employees outside federal jurisdiction in federal enforcement states are referred to the appropriate agency by the Area Office.
Inspection Procedures

• Procedures in the FIRM, Chapter II, are followed except as modified in the following:
  – Upon entry, CSHO shall request the presence of infection control director and employee occupational health professional responsible for occupational hazard control
  – CSHO shall establish whether or not the facility had a suspect or confirmed TB case within last 6 months to determine coverage under the OSH Act
Inspection Procedures (Continued)

- If the facility has had a suspect or confirmed TB case within the previous 6 months, the CSHO shall proceed with the TB portion of the inspection.
- CSHO shall verify the implementation of the employer’s plans for TB protection through employee interviews and direct observation where feasible.
Inspection Procedures (Continued)

• After review of the facility plans for worker protection, employee interviews combined with an inspection of the facility shall be used to determine compliance

• CSHO who perform smoke-trail visualization tests should review protocol and be prepared to present employer with MSD for the smoke that is released on a smoke-trail visualization
Compliance Officer Protection

• Area Directors or Assistant Area Directors shall ensure that CSHOs performing TB related inspections are familiar with the CDC guidelines, terminology, and are adequately trained in health care settings.
• CSHO shall not enter occupied respiratory isolation (acid fast bacilli) rooms unless, in their determination, entry is required to document a violation.
Compliance Officer Protection - Continued

• CSHOs shall exercise professional judgment and extreme caution when engaging in activities that may involve exposure to TB
• On rare occasions when entry into potentially hazardous areas is judged necessary, CSHOs shall wear negative pressure elastomeric face piece respirators equipped with a HEPA filter
• CSHOs who conduct TB inspections shall have been offered the TB skin test
Compliance Officer
Protection - Continued

• CSHOs exposed to an individual(s) with active infectious TB shall receive a follow-up examination
• If an isolation room is occupied by a patient with confirmed or suspect TB or has not been adequately purged when a smoke-trail is performed, then the CSHO should assume that the isolation room is not under negative pressure
• Under such circumstances, CSHOs shall wear negative pressure HEPA respirators when performing test or entry into room is necessary
Citation Policy

• The following requirements apply when citing hazards found in target workplaces. Employers must comply with the provisions of these requirements whenever an employee may be occupationally exposed to TB:
  – Section 5 (a)(1) - General Duty Clause and Executive Order 12196, Section 1-201(a) for federal facilities
Citation Policy (Continued)

- 29 CFR 1910.145 - Accident Prevention Signs and Tags
- 29 CFR 1910.20 - Access to Employee Exposure and Medical Records
- 29 CFR 1904 - Recording and Reporting Occupational Injuries and Illnesses
Violations

All elements listed in the citation policy section must be addressed to ensure adequate protection of employees from TB hazards. Violations of these OSHA requirements will normally be classified as serious.
General Duty Clause

Section 5 (a)(1) of the OSH Act states:

“Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees”
General Duty Clause (Continued)

• Section 5 (a)(1) citations must meet the requirements outlined in the FIRM, and shall be issued only when there is no standard that applies to the particular hazard.
• The hazard, not the absence of a particular means of abatement, is the basis for a general duty clause citation.
• All applicable abatement methods identified as correcting the same hazard shall be issued under a single 5 (a)(1) citation.
General Duty Clause (Continued)

Four required elements necessary for issuing general duty clause violations include:

– The employer failed to keep the workplace free of a hazard to which employees of that employer were exposed
– The hazard was recognized
– The hazard was causing or was likely to cause death or serious physical harm
– There was a feasible and useful method to correct the hazard
General Duty Clause (Continued)

Citations shall be issued to employers with employees working in one of the workplaces where the CDC has identified workers as having a higher incidence of TB infection than the general population, when the employees are not provided appropriate protection and who have exposure as defined as:

Exposure to the exhaled air of an individual with suspected or confirmed pulmonary TB disease, or
General Duty Clause (Continued)

Employee exposure without appropriate protection to a high hazard procedure performed on an individual with suspected or confirmed infectious TB disease and which has the potential to generate infectious airborne droplet nuclei.
High Hazard Procedures

- Characterized by potential to generate airborne secretions
- Aerosolized medication treatment
- Bronchoscopy
- Sputum induction
- Endotracheal intubation and suctioning
- Autopsies conducted in hospitals
Feasible and Useful Abatement Methods

- Protocol for the early identification of individuals with active tuberculosis
- Medical surveillance
- Case management of infected employees
- Worker training and education
- Engineering controls
Feasible and Useful Abatement Methods (Continued)

The protocol for the early identification of individuals with active TB shall include the following elements:

- Assignment of responsibility for the TB infection control program;
- Conduct risk assessment;
- Develop TB infection control plan;
- Periodically reassess risk;
- Identification, evaluation, and treatment for patients who may have active TB.
Feasible and Useful Abatement Methods (Continued)

• Management of patients who may have TB in ambulatory-care settings and emergency departments
• Management of hospitalized patients who may have TB;
• Engineering controls;
• Respiratory protection
Feasible and Useful Abatement Methods (Continued)

- Cough-inducing and aerosol-generating procedures;
- Educating and training health care workers;
- Evaluating health care workers PPD test conversions and possible nosocomial transmission of *M. tuberculosis*; and
- Coordination of efforts with the public health department
Feasible and Useful Abatement Methods (Continued)

• Medical surveillance includes:
  – Initial examinations for new and current employees exposed to TB
  – Periodic TB skin test evaluations; and
  – Reassessment of employees following exposure or change in health
Feasible and Useful Abatement Methods (Continued)

• Case management of infected employees includes:
  – Protocol for new converters
  – Work restrictions for infectious employees
Feasible and Useful Abatement Methods (Continued)

• Training and education include such issues as:
  – The mode of TB transmission;
  – TB signs and symptoms;
  – Medical surveillance and therapy; and
  – Site specific protocol
Feasible and Useful Abatement Methods (Continued)

• Engineering controls include:
  – Placement of individuals with suspected or confirmed infectious TB in a respiratory acid-fast bacilli (AFB) isolation room;
  – Maintaining isolation and treatment rooms under negative pressure;
  – Exhausting air from AFB isolation or treatment rooms outside instead of recirculation into general ventilation system
Feasible and Useful Abatement Methods (Continued)

- Engineering controls (continued):
  - Maintaining under negative pressure all potentially contaminated air which is ducted through the facility until it is discharges; and
  - Decontamination of air from the isolation and treatment rooms before circulation back to the isolation/treatment rooms
Respiratory Protection

• Respirators shall be provided by the employer when such:
  – equipment is necessary to protect the health of the employee
  – equipment is applicable and suitable for the purpose intended

The establishment and maintenance of the respiratory protective program shall be the responsibility of the employer
Respiratory Protection (Continued)

• The 1994 CDC Guidelines specify the following criteria for respirators for exposure to TB:
  – Ability to filter 1 micron in size in the unloaded state with a filter efficiency greater than 95%;
  – ability to be qualitatively or quantitatively fitted tested in a reliable way to obtain face-seal leakage of less than 10%
Respiratory Protection (Continued)

• CDC Guidelines (continued):
  – The ability to fit the different facial sizes and characteristics of health care workers which can usually be met by making the respirators available in at least three sizes
  – The ability to be checked for face piece fit in accordance with OSHA standards and good industrial hygiene practice, by health care workers each time they put on their respirator
Respiratory Protection (Continued)

- Under the new NIOSH criteria, filter materials would be tested at a flow rate of 85 lpm for penetration by particles with a medial aerodynamic diameter of 0.3 um and if certified would be placed in one of the following categories:
  - Type 100 (99.7% efficient)
  - Type 99 (99% efficient)
  - Type 95 (95% efficient)
Respiratory Protection (Continued)

The minimal acceptable level of respirator protection for TB is the Type 95 respirator. Classes of these air purifying, particulate respirators to be certified are described under 42 CFR Part 84 Subpart K

Until these classes of respirators are commercially available, the minimal acceptable respiratory protection that meets the criteria will remain the HEPA filter
Respiratory Protection (Continued)

• Employees must wear HEPA or respirators certified under 42 CFR Part 84 Subpart K in the following circumstances:
  – When workers enter rooms housing individuals suspected or confirmed TB disease
  – When workers perform high hazard procedures on persons who have suspected or confirmed TB disease
  – When emergency response employees or others must transport in a closed vehicle, an individual with suspected or confirmed TB disease
Respiratory Protection (Continued)

When respiratory protection is required, a complete respiratory protection program must be in place in accordance with 29 CFR 1910.14 (b) and include the following elements:

– Written operating procedures
– Proper selection
– Training and fitting
– Cleaning and disinfecting
Respiratory Protection (Continued)

- Respirator program elements (continued):
  - Storage
  - Inspection and maintenance
  - Work surveillance
  - Inspection/evaluation of program
  - Approved respirators
Access to Employee Medical and Exposure Records

• A record concerning employee exposure to TB is an employee exposure within the meaning of 29 CFR 1910.20

• A record of TB skin test results and medical evaluations and treatments are employee medical records within the meaning of 29 CFR 1910.20

• These records shall be handled according to 29 CFR 1913.10 in order for the CSHO to determine compliance with 29 CFR 1910.20
Accident Prevention
Signs and Tags

In accordance with 1910.145 (f)(8), a warning shall be posted outside the respiratory isolation or treatment room or a message referring one to the nursing station for instruction may be posted.

1910.145 (f)(4) requires that a signal word or biological hazard symbol may be presented as well as a major message.
Accident Prevention
Signs and Tags (Continued)

Employers are also required to use biological hazard tags on air transport components which identify TB hazards to employees associated with working on air systems that transport contaminated air.
OSHA 200 Log

- For OSHA 200 recordkeeping purposes, both TB infections (positive TB skin tests) and TB disease are recordable in the high risk settings.
- If the employee’s TB infection which was entered on the OSHA 200 log progresses to TB disease during the 5 year maintenance period, the original entry for the infection must be updated to reflect new information.
- A positive TB skin test provided within two weeks of employment does not have to be recorded on the OSHA 200 form.