Appendix B

Recommendations for Counting Reported Tuberculosis Cases
(Revised July 1997)

Since publication of the "Recommendations for Counting Reported Tuberculosis Cases"[1] in January 1977, numerous changes have occurred and many issues have been raised within the field of tuberculosis (TB) surveillance. This current version updates and supersedes the previous version; it clarifies the parameters for counting TB cases among (a) immigrants, resident aliens, and border crossers, (b) military personnel stationed in the United States and abroad, and (c) persons diagnosed within the Indian Health Service and correctional facilities.

A distinction should be made between ***reporting*** TB cases to a health department and ***counting*** TB cases for determining incidence of disease. Throughout each year, TB cases and suspected cases are reported to public health authorities by sources such as clinics, hospitals, laboratories, and health care providers. From these reports, the state or local TB control officer must determine which cases meet the current surveillance definition for TB disease. These verified TB cases are then counted and reported to the Centers for Disease Control and Prevention (CDC).

I. Reporting TB Cases. CDC recommends that health care providers and laboratories be required to report all TB cases or suspected cases to state and local health departments based on the current "Case Definition for Public Health Surveillance."[2] This notification is essential in order for TB programs to

- Ensure case supervision,
- Ensure completion of appropriate therapy,
- Ensure completion of timely contact investigations,
- Evaluate program effectiveness, and
- Assess trends and characteristics of TB morbidity.

II. TB Surveillance. For purposes of surveillance, a case of TB is defined on the basis of laboratory and/or clinical evidence of active disease due to *M. tuberculosis* complex.*

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* Because most laboratories use tests that do not routinely distinguish *Mycobacterium tuberculosis* from very closely related species, these laboratories report culture results as being positive or negative for "*Mycobacterium tuberculosis* complex." Although in almost all cases of human disease, isolates in the *M. tuberculosis* complex are, in fact, *M. tuberculosis*, other species are possible. For example, one study in San Diego found that 6% of human tuberculosis was caused by *Mycobacterium bovis*; cultures from these cases would be reported by most laboratories as being positive for *M. tuberculosis* complex. Other species in the *Mycobacterium tuberculosis* complex include *M. africanum, M. microti, M. canetii, M. caprae, and M. pinnipedii*. Although *M. microti , M. canetii , M. caprae, and M. pinnipedii* are newly described species, their inclusion in *M. tuberculosis* complex should not impact public health laboratories or programs because only a few laboratories identify to the species level. These seven species are almost identical in DNA homology studies. In terms of their ability to cause clinical disease and be transmissible from person to person, *M. bovis*, *M. africanum, M. microti,* and *M. canetti* behave like *M. tuberculosis*; therefore, disease caused by any of the organisms should be reported as TB, using the Report of Verified Case of Tuberculosis (RVCT). The only exception is the BCG strain of *M. bovis*, which may be isolated from persons who have received the vaccine for protection against TB or as cancer immunotherapy; disease caused by the BCG strain of *M. bovis* should not be reported as TB because the transmission is iatrogenic (treatment-induced), rather than person-to-person or communicable.

a. Laboratory Case Definition

- Isolation of *M. tuberculosis* complex from a clinical specimen. The use of rapid identification techniques for *M. tuberculosis* performed on a culture from a clinical specimen, such as DNA probes and high-pressure liquid chromatography (HPLC), is acceptable under this criterion.

OR

- Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification (NAA) test. NAA tests must be accompanied by cultures of mycobacterial species. However, for surveillance purposes, CDC will accept results obtained from NAA tests that are approved by the Food and Drug Administration (FDA).

OR

- Demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained; historically this criterion has been most commonly used to diagnose TB in the postmortem setting.

b. Clinical Case Definition. In the absence of laboratory confirmation of *M. tuberculosis* complex after a diagnostic process has been completed, persons must have **all** of the following criteria for clinical TB:

- Evidence of TB infection based on a positive tuberculin skin test result

AND

- One of the following:
  (1) Signs and symptoms compatible with current TB disease, such as an abnormal, unstable (worsening or improving) chest radiograph, or
  (2) Clinical evidence of current disease (e.g., fever, night sweats, cough, weight loss, hemoptysis)

AND

- Current treatment with two or more anti-TB medications

NOTE: *The case definition described herein was developed for use in this document and is not intended to replace the case definition for TB as stated in the current "Case Definitions for Infectious Conditions Under Public Health Surveillance."*

In addition, the software for TB surveillance developed by CDC includes a calculated variable called "Vercrit," for which one of the values is "Provider Diagnosis." "Provider Diagnosis" is selected when the user chooses to override a "Suspect" default value in the case verification screen as "Verified by Provider Diagnosis." Thus, "Provider Diagnosis" is not a component of the case definition for TB in the current "Case Definitions for Infectious Conditions Under Public Health Surveillance" publication. CDC's national morbidity reports have traditionally included all cases that are considered verified by the reporting areas, without a requirement that cases meet the published case definition.

III. Counting TB Cases. Cases that meet the current CDC surveillance case definition for verified TB are counted by 52 reporting areas with count authority (50 states, District of Columbia, and New York City) to determine annual incidence for the United States. The remaining 7 reporting areas (American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Puerto Rico, Republic of Palau, and U.S. Virgin Islands) report cases to CDC, but are not included in the annual incidence for the United States. The laboratory and clinical case definitions are the two diagnostic categories used by the CDC "Case Definitions for Infectious Conditions Under Public Health Surveillance."

Most verified TB cases are accepted for counting based on laboratory confirmation of *M. tuberculosis* complex from a clinical specimen.

A person may have more than one discrete (separate and distinct) episode of TB. If disease recurs in a person within any 12-consecutive-month period, count only one episode as a case for that year. However, if TB disease recurs in a person, and if more than 12 months have elapsed since the person was discharged from or lost to supervision, the TB is considered a separate episode and should be counted as a new case. *Note*: Discharged from supervision implies completion of therapy.

Mycobacterial diseases other than those caused by *M. tuberculosis* complex should not be counted in TB morbidity statistics unless there is concurrent TB.

a. Verified TB Cases

COUNT
Count only verified TB cases that meet the laboratory or clinical case definitions (see Section II). The diagnosis of TB must be verified by the TB control officer or designee. The current CDC surveillance case definition for TB describes and defines the criteria to be used in the case definition for TB disease.

DO NOT COUNT
If diagnostic procedures have not been completed, do not count; wait for confirmation of disease. Do not count a case for which two or more anti-TB medications have been prescribed for preventive therapy for exposure to multidrug- resistant (MDR) TB, or while the diagnosis is still pending.

b. Nontuberculous Mycobacterial Diseases (NTM)

COUNT
An episode of TB disease diagnosed concurrently with another nontuberculous mycobacterial disease should be counted as a TB case.

DO NOT COUNT
Disease attributed to or caused by nontuberculous mycobacteria alone should not be counted as a TB case.

c. TB Cases Reported at Death

COUNT
TB cases first reported to the health department at the time of a person's death are counted as incident cases, provided the person had current disease at the time of death. The TB control officer should verify the diagnosis of TB.

DO NOT COUNT
Do not count as a case of TB if there is no evidence of current disease at the time of death or at autopsy.

d. Immigrants, Refugees, Permanent Resident Aliens, Border Crossers,* and Foreign Visitors[3]

COUNT
Immigrants and refugees who have been screened overseas for TB and

- have been classified as Class B (B1, B2, or B3)[4] or resident aliens,
- are not already on anti-TB medications for treatment of TB disease, and
- are examined after arriving in the United States and diagnosed with clinically active TB requiring anti-TB medications,
- should be counted by the locality of their current residence at the time of diagnosis regardless of citizenship status.

Border crossers* and permanent resident aliens who are diagnosed with TB and plan to receive anti-TB therapy from a locality in the United States for 90 days or more should be counted by the locality where they receive anti-TB therapy.

Foreign visitors (e.g., students, commercial representatives, and diplomatic personnel) who are diagnosed with TB, are receiving anti-TB therapy, **and** plan to remain in the United States for 90 days or more should be counted by the locality of current residence.

**Border crosser — defined, in part, by the U.S. Citizenship and Immigration Services (USCIS)[3] as "a nonresident alien entering the United States across the Mexican border for stays of no more than 72 hours." Border crossers may go back and forth across the border many times in a short period.*

DO NOT COUNT
TB cases in immigrants or refugees who have been classified as Class A with a waiver (TB, Infectious, Noncommunicable for travel purposes)[4] should not be counted as new cases even if the persons receive routine initial work-ups in the United States. TB in persons who are temporarily (<90 days) in the United States, for whom therapy may have been started but who plan to return to their native country to continue therapy, should not be counted in the United States.

e. Out-of-State or Out-of-Area Residents

COUNT
A person's TB case should be counted by the locality in which he or she resides at the time of diagnosis. TB in a person who has no address should be counted by the locality that diagnosed and is treating the TB. The TB control officer should notify the appropriate out-of-state or out-of-area TB control officer of the person's home locality to (1) determine whether the case has already been counted to avoid "double counting," and (2) agree on which TB control office should count the case if it has not yet been counted.

DO NOT COUNT
Do not count a case in a newly diagnosed TB patient who is an out-of-area resident and whose TB has already been counted by the out-of-area TB control office.

f. Migrants and Other Transients

COUNT
Persons without any fixed U.S. residence are considered to be the public health responsibility of their present locality and their TB case should be reported and counted where diagnosed.

DO NOT COUNT
Cases in transient TB patients should not be counted when there is evidence that they have already been counted by another locality.

g. Federal Facilities (e.g., Military and Veterans Administration Facilities)

COUNT
Cases in military personnel, dependents, or veterans should be reported and counted by the locality where the persons are residing in the United States at the time of diagnosis and initiation of treatment.

However, if military personnel or dependents are discovered to have TB at a military base outside the United States but are referred elsewhere for treatment (e.g., a military base located within the United States), the TB case should be reported and counted where treated and not where the diagnosis was made.

DO NOT COUNT
Do not count if the case was already counted by another locality in the United States.

h. Indian Health Service

COUNT
TB should be reported to the local health authority (e.g., state or county) and counted where diagnosed and treatment initiated. However, for a specific group such as the Navajo Nation, which is geographically located in multiple states, health departments should discuss each case and determine which locality should count the case.

DO NOT COUNT
Do not count if the case was already counted by another locality.

i. Correctional Facilities (e.g., Local, State, Federal, and Military)

COUNT
Persons who reside in local, state, federal, or military correctional facilities may frequently be transferred or relocated within and/or between various correctional facilities. TB in these persons should be reported to the local health authority and counted by the locality where the diagnosis was made and treatment plans were initiated.

DO NOT COUNT
Do not count correctional facility residents' TB cases that were counted elsewhere by another locality or correctional facility, even if treatment continues at another locale or correctional facility.

j. Peace Corps, Missionaries, and Other Citizens Residing Outside the United States

DO NOT COUNT
TB in persons diagnosed outside the United States should not be counted. TB in these persons should be counted by the country in which they are residing regardless of their plans to return to the United States for further work-up or treatment.

IV. Suggested Administrative Practices

To promote uniformity in TB case counting, the following administrative procedures are recommended:

(a) All TB cases verified by the 52 reporting areas with count authority (50 states, District of Columbia, and New York City) during the calendar year (by December 31) will be included in the annual U.S. incidence count for that year. All tuberculosis cases verified during the calendar year by a reporting area with count authority from one of the remaining 7 reporting areas (American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Puerto Rico, Republic of Palau, and U.S. Virgin Islands) are also counted but are not included in the annual incidence for the United States. Cases for which bacteriologic results are pending or for which confirmation of disease is questionable for any other reason should not be counted until their status is clearly determined; they should be counted at the time they meet the criteria for counting. This means that a case reported in one calendar year could be included in the morbidity count for the following year. The reporting area with count authority should ensure that there is agreement between final local and state TB figures reported to CDC. Currently, some reporting areas may not use this suggested protocol. Some of these areas may wait until the beginning of the following year when they have received and processed all of the TB cases for inclusion in the annual case count for the previous year. If reporting areas decide to revise their protocols, they should be aware that their TB trends may change.

(b) TB is occasionally reported to health departments over the telephone, by letter or fax, or on forms other than the Report of Verified Case of Tuberculosis (RVCT). Such information should be accepted as an official morbidity report if sufficient details are provided; otherwise, the notification should be used as an indicator of a possible TB case (suspect) which should be investigated promptly for confirmation.

V. TB Surveillance Definitions

Case - an episode of TB disease in a person meeting the laboratory or clinical criteria for TB as defined in the document "Case Definitions for Infectious Conditions Under Public Health Surveillance"[2] (see Section II for criteria).

Suspect - a person for whom there is a high index of suspicion for active TB (e.g., a known contact to an active TB case or a person with signs or symptoms consistent with TB) who is currently under evaluation for TB disease.

Verification of a TB case - the process whereby a TB case, after the diagnostic evaluation is complete, is reviewed at the local level (e.g., state or county) by a TB control official who is familiar with TB surveillance definitions; if all the criteria for a TB case are met, the TB case is then verified and eligible for counting.

Counting of a TB case - the process whereby a reporting area with count authority evaluates verified TB cases (e.g., assesses for case duplication). These cases are then counted for morbidity in that locality (e.g., state or county) and reported to CDC for national morbidity counting.

***Mycobacterium tuberculosis* complex** (*M. tuberculosis* complex) - Because most laboratories use tests that do not routinely distinguish *Mycobacterium tuberculosis* from very closely related species, these laboratories report culture results as being positive or negative for "*Mycobacterium tuberculosis* complex." Although in almost all cases of human disease, isolates in the *M. tuberculosis* complex are, in fact, *M. tuberculosis*, other species are possible. For example, one study in San Diego found that 6% of human tuberculosis was caused by *Mycobacterium bovis*; cultures from these cases would be reported by most laboratories as being positive for *M. tuberculosis* complex. Other species in the *Mycobacterium tuberculosis* complex include *M. africanum, M. microti, M. canetii, M. caprae, and M. pinnipedii*. Although *M. microti , M. canetii , M. caprae, and M. pinnipedii* are newly described species, their inclusion in *M. tuberculosis* complex should not impact public health laboratories or programs because only a few laboratories identify to the species level. These seven species are almost identical in DNA homology studies. In terms of their ability to cause clinical disease and be transmissible from person to person, *M. bovis*, *M. africanum, M. microti,* and *M. canetti* behave like *M. tuberculosis*; therefore, disease caused by any of the organisms should be reported as TB, using the Report of Verified Case of Tuberculosis (RVCT). The only exception is the BCG strain of *M. bovis*, which may be isolated from persons who have received the vaccine for protection against TB or as cancer immunotherapy; disease caused by the BCG

strain of *M. bovis* should not be reported as TB because the transmission is iatrogenic (treatment-induced), rather than person-to-person or communicable.

Nontuberculous mycobacteria (NTM) - mycobacteria other than *Mycobacterium tuberculosis* complex that can cause human infection or disease. Common nontuberculous mycobacteria include *M. avium* complex or MAC (*M. avium, M. intracellulare*), *M. kansasii*, *M. marinum, M. scrofulaceum, M. chelonae, M. fortuitum*, and *M. simiae*. Other terms have been used to represent NTM, including MOTT (mycobacteria other than TB) and "atypical" mycobacteria.

Reporting area - areas responsible for counting and reporting verified TB cases to CDC. Currently there are 60 reporting areas: the 50 states, District of Columbia, New York City, American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Marshall Islands, Puerto Rico, Republic of Palau, and U.S. Virgin Islands. The annual incidence of tuberculosis for the United States is based on 52 reporting areas (the 50 states, District of Columbia, and New York City).

Alien - defined by the U.S. Citizenship and Immigration Services (USCIS)[3] as "any person not a citizen or national of the United States."

Border crosser - defined, in part, by the USCIS[3] as "a nonresident alien entering the United States across the Mexican border for stays of no more than 72 hours." Border crossers may go back and forth across the border many times in a short period.

No TB Classification - Applicants with normal tuberculosis screening examinations.

Class A TB with waiver - All applicants who have tuberculosis disease and have been granted a waiver.

Class B1 TB, Pulmonary -

No treatment

- Applicants who have medical history, physical exam, HIV, or CXR findings suggestive of pulmonary tuberculosis but have negative AFB sputum smears and cultures and are not diagnosed with tuberculosis or can wait to have tuberculosis treatment started after immigration.

Completed treatment

- Applicants who were diagnosed with pulmonary tuberculosis and successfully completed directly observed therapy prior to immigration. The cover sheet should indicate if the initial sputum smears and cultures were positive and if drug susceptibility testing results are available.

Class B1 TB, Extrapulmonary - Applicants with evidence of extrapulmonary tuberculosis. Document the anatomic site of infection.

Class B2 TB, LTBI Evaluation - Applicants who have a tuberculin skin test ≥10 mm but otherwise have a negative evaluation for tuberculosis. The size of the TST reaction, the applicant's status with respect to LTBI treatment, and the medication(s) used should be documented. For applicants who had more than one TST, whether the applicant converted the TST should be documented (i.e., initial TST <10 mm but subsequent TST ≥10 mm).

Class B3 TB, Contact Evaluation - Applicants who are a recent contact of a known tuberculosis case. The size of the applicant's TST reaction should be documented. Information about the source case, name, alien number, relationship to contact, and type of tuberculosis should also be documented.

Immigrant - defined by the USCIS[3] as "an alien admitted to the United States as a lawful permanent resident. Immigrants are those persons lawfully accorded the privilege of residing permanently in the United States. They may be issued immigrant visas by the Department of State overseas or adjusted to permanent resident status by the USCIS of the United States."

Permanent Resident Alien - see Immigrant.

Waivers - A provision allows applicants undergoing pulmonary or laryngeal tuberculosis treatment to petition for a Class A waiver. Waivers should be pursued for any immigrant or refugee who has a complicated clinical course and would benefit from receiving treatment of their tuberculosis in the United States. Applicants diagnosed with tuberculosis disease who are both smear- and culture-negative and will be traveling to the United States prior to start of treatment do not need to complete the waiver process.

References

1. *Recommendations for Counting Reported TB Cases.* Atlanta: CDC, January 1977.
2. CDC. Case definitions for infectious conditions under public health surveillance. *MMWR* 1997;46(No. RR 10):40–41.
3. *Statistical Yearbook of the Immigration and Naturalization Service, 1994.* Washington, DC: US Department of Homeland Security, U.S. Citizenship and Immigration Services; http://uscis.gov.
4. *CDC Immigration Requirements: Technical Instructions for Tuberculosis Screening and Treatment, 2007*. Atlanta: CDC, Division of Global Migration and Quarantine, revised September 2007; http://www.cdc.gov/ncidod/dq/pdf/ti_tb_8_9_2007.pdf.

Notes

1. Reference to details of FDA-approved labeling for NAA (IIa) was deleted from this document in September 2002.
2. A note of clarification was added to Section III, Counting TB Cases, in September 2003.