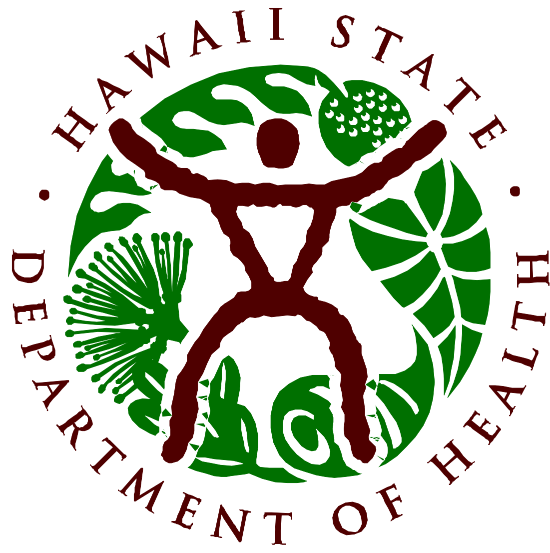

Communicable Disease and Public Health Nursing Division

Tuberculosis Control Branch

DOH TB Clearance Manual

To accompany
Chapter 11-164.2 of the Hawaii Administrative Rules

July 18, 2017

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1.0 Welcome

Aloha to the Hawaii Health Care Provider Community,

Hawaii has long carried a heavy burden of tuberculosis, and our location as a regional crossroads requires a state TB program that is robust and responsive. The updated TB rules (Chapter 11-164.2 of the Hawaii Administrative Rules) are carefully tailored to our State's specific TB epidemiologic profile. Successful implementation of the updated TB rules is essential for us to take the next step towards TB elimination in Hawaii.

The TB Control Branch of the Communicable Disease and Public Health Nursing Division created this "DOH TB Clearance Manual" to assist you with complying with the current requirements for TB screening and reporting. This new edition, dated July 18, 2017, enhances our ability to provide up-to-date reporting requirements, targeted TB screening and testing to:

- quickly find and treat TB cases,
- efficiently identify high-risk residents for TB prevention, and
- minimize over-screening among Hawaii residents who are at the lowest risk for tuberculosis.

Additionally, Hawaii's health care providers should be comfortable with TB diagnosis and referral, as well as providing TB prevention in their clinics. We strongly encourage health care providers who identify residents with inactive TB to offer/provide the life-long benefits of TB prevention in accordance with Centers for Disease Control and Prevention (CDC) and American Thoracic Society (ATS) standards.

Health care providers may, at their discretion, consult with the TB Control Branch or refer a possible TB case for further workup or curative treatment. Toward that end, the TB Control Branch remains a strong partner as we accomplish our shared goals of TB prevention and reducing the unnecessary spread of TB in our community.

Mahalo for your valuable service to tuberculosis control in our State,

Richard Brostrom, MD-MSPH
Hawaii TB Control Branch
CDC Pacific Regional TB Field Medical Officer

Elizabeth MacNeill, MD, MPH
Chief, TB Control Branch
Hawaii State Department of Health

2.0 Key Changes for our updated TB Clearance Procedures

The following list summarizes four major changes from prior Hawaii TB clearance requirements:

1. With the implementation of a TB Risk Assessment, some low-risk individuals who required screening by the State of Hawaii in the past will no longer require a tuberculin skin test (TST) or other test for TB infection. For example, individuals born in the US, who have no TB symptoms and no additional TB risk factors, will no longer require an actual test. For these individuals, a TB Clearance can be completed without performing a blood test or skin test for latent TB infection. TB clearance requirements for individuals living or working in healthcare facilities or residential care centers licensed or otherwise regulated by the department will still require a TB test.

2. For schools, workplaces, employers, and others who require TB screening by the State of Hawaii, a new TB Clearance form is provided. The Hawaii Department of Health strongly urges you to use the form provided. If community clinicians are required to use a different form due to proprietary electronic medical records requirements, then the local form must contain the same wording as the TB Clearance form included in this manual.

3. Correctly interpreting a TST requires an understanding of each person's individual risk factors and the reason for testing. In accordance with CDC and ATS guidelines, the test should be read as positive at 5mm, 10mm, or 15mm depending upon individual risk factors. Rules for interpreting a TST test are described in TB Document J included in this manual.

4. Other types of tests for TB infection are now accepted in addition to the TST.
   Note: At this time, an IGRA-based blood test is not considered valid for persons under 5 years of age.

3.0 TB Clearance Procedures

There are several different TB testing strategies under the new rules, depending on the reason for testing. Table 1 provides specific screening instructions for each category of state-mandated screening. These documents are designed to provide straightforward instructions for each category of TB screening.

To complete the proper screening procedures required for each resident, first determine the reason for screening. If the reason for TB screening is included in the list below, then this manual will provide updated screening instructions. If the reason for screening is not included on this list, and you have questions about the appropriate TB screening methodology, please call the State TB Nurse Consultant at the State of Hawaii Department of Health TB Control Branch at phone number (808) 832-5731.

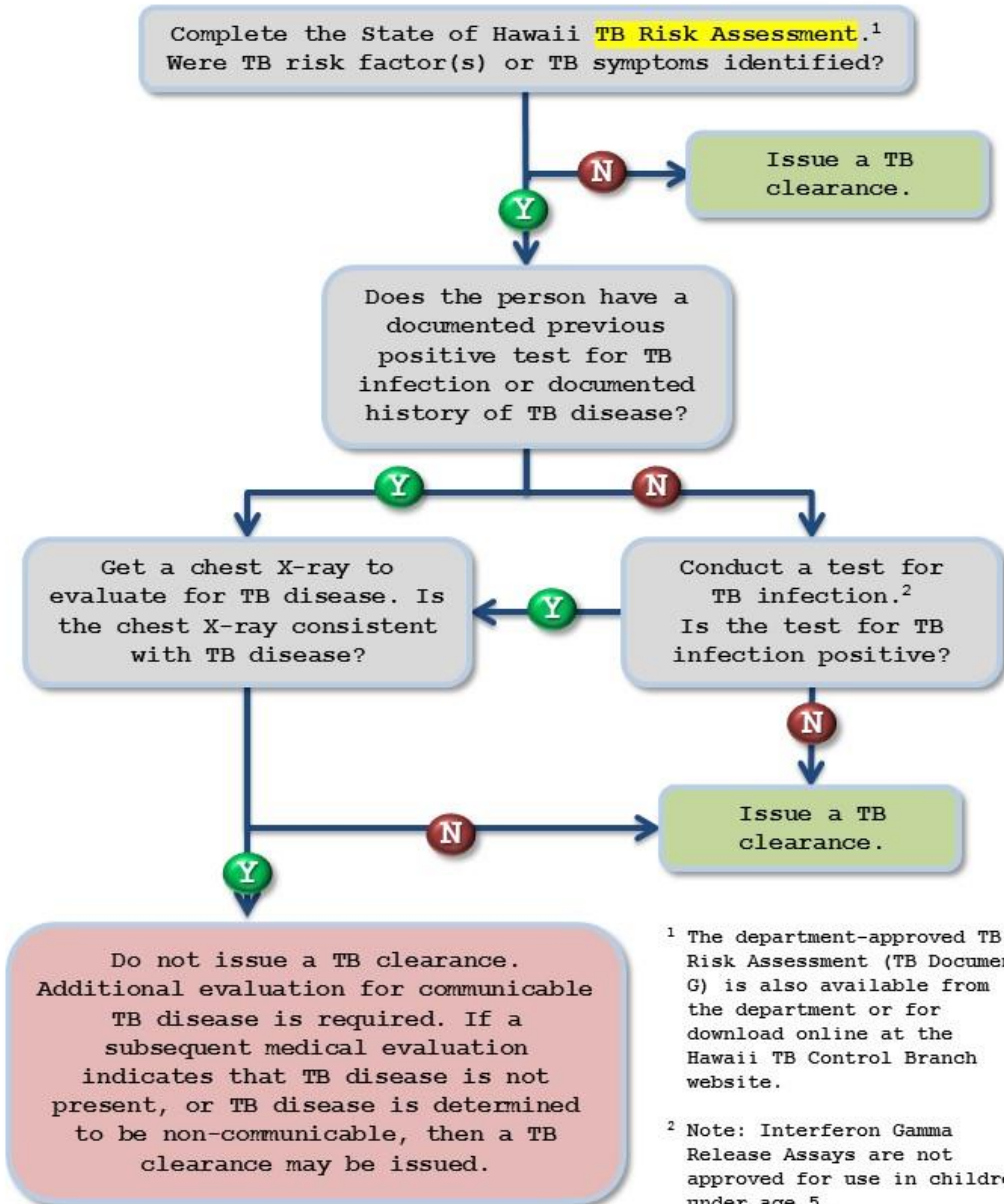
Table 1. List of TB Clearance Procedures

Reason for Screening	Refer to HAR Section	Procedure Document Name	Page
Primary and Secondary Schools: Personnel	§11-164.2-20	TB Document A	6
Primary and Secondary Schools: Attendance (Students)	§11-164.2-21	TB Document A	6
Post-secondary Schools: Personnel	§11-164.2-22	TB Document A	6
Post-secondary Schools: Attendance (Students)	§11-164.2-23	TB Document A	6
Child Care Facilities: Personnel	§11-164.2-24	TB Document A	6
Child Care Facilities: Attendance (Children)	§11-164.2-25	TB Document A	6
Persons living or working in health care facilities or residential care settings licensed or otherwise regulated by the department: (3 categories listed below) I. Initial Evaluation Procedure for Persons with No Documented Previous Positive Test for TB Infection and No Documented History of TB Disease.	§11-164.2-26	TB Document B	7

II. Initial Evaluation Procedure for Persons with a Documented Previous Positive Test for TB Infection or a Documented History of TB Disease. III. Follow-up Annual TB Evaluation Procedure	§11-164.2-26 §11-164.2-26	TB Document C TB Document D	8 9
Food handlers	§11-164.2-27	TB Document E	10

Procedure documents are provided to the community for implementing Chapter 11-164.2, Hawaii Administrative Rules. The Department of Health maintains an updated hard-copy library of this TB Clearance Manual that is available to the community. These documents are available on the Department of Health TB Control Branch website. Hard copies of these documents can be obtained from the Lanakila Health Center TB Clinic at 1700 Lanakila Avenue, Ground Floor, Honolulu, HI 96817. Questions should be directed to the State TB Nurse Consultant at the State of Hawaii Department of Health TB Control Branch at phone number (808) 832-5731.

TB Document A: TB Clearance Evaluation Procedures for First-time Entry to a Child Care Facility, Child Care Facility Personnel, First-time School Entry, School Personnel, Post-Secondary School Entry, and Post-Secondary School Personnel

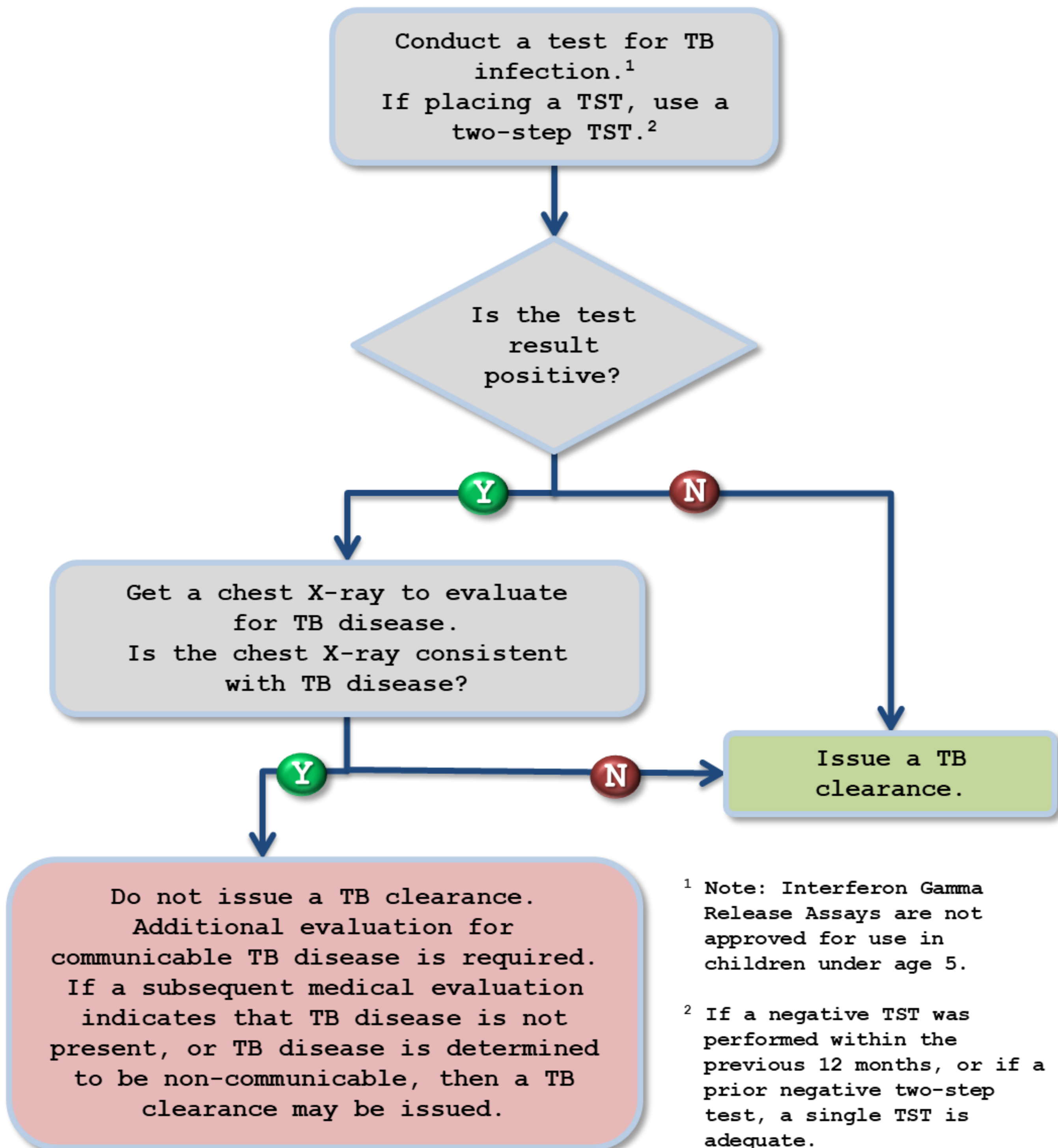


[1] The department-approved TB Risk Assessment (TB Document G) is also available from the department or for download online at the Hawaii TB Control Branch website.

[2] Note: Interferon Gamma Release Assays are not approved for use in children under age 5.

TB Document B: TB Clearance Evaluation Procedures for Persons Living or Working in Health Care Facilities or Residential Care Settings Licensed or Otherwise Regulated by the Department.

I. Initial Evaluation Procedure for Persons with No Documented Previous Positive Test for TB Infection and No Documented History of TB Disease.

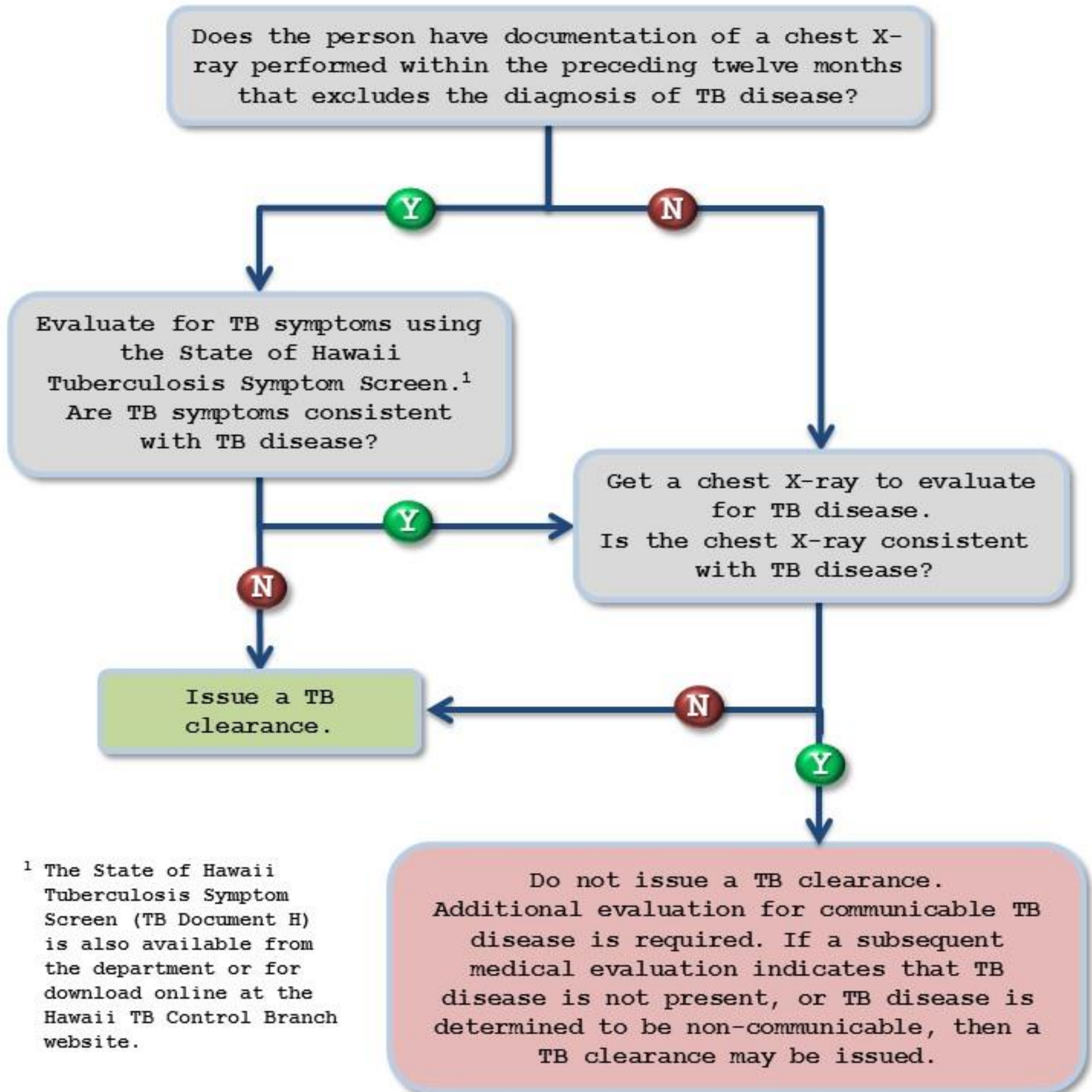


[1] Note: Interferon Gamma Release Assays are not approved for use in children under age 5.

[2] If a negative TST was performed within the previous 12 months, or if a prior negative two-step test, a single TST is adequate.

TB Document C: TB Clearance Evaluation Procedures for Persons Living or Working in Health Care Facilities or Residential Care Settings Licensed or Otherwise Regulated by the Department.

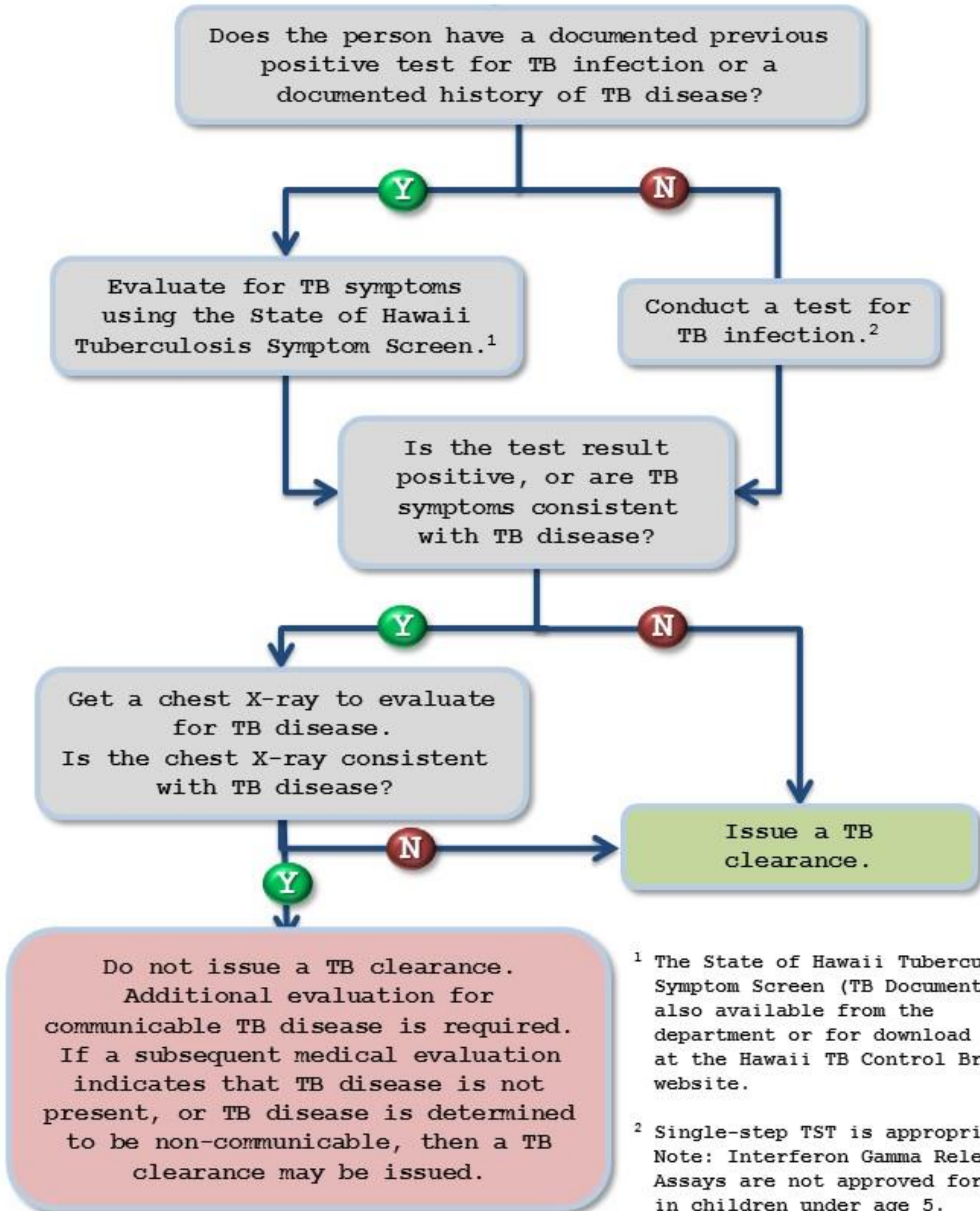
II. Initial Evaluation Procedure for Persons with a Documented Previous Positive Test for TB Infection or a Documented History of TB Disease.



[1] The State of Hawaii Tuberculosis Symptom Screen (TB Document H) is also available from the department or for download online at the Hawaii TB Control Branch website.

TB Document D: TB Clearance Evaluation Procedures for Persons Living or Working in Health Care Facilities or Residential Care Settings Licensed or Otherwise Regulated by the Department.

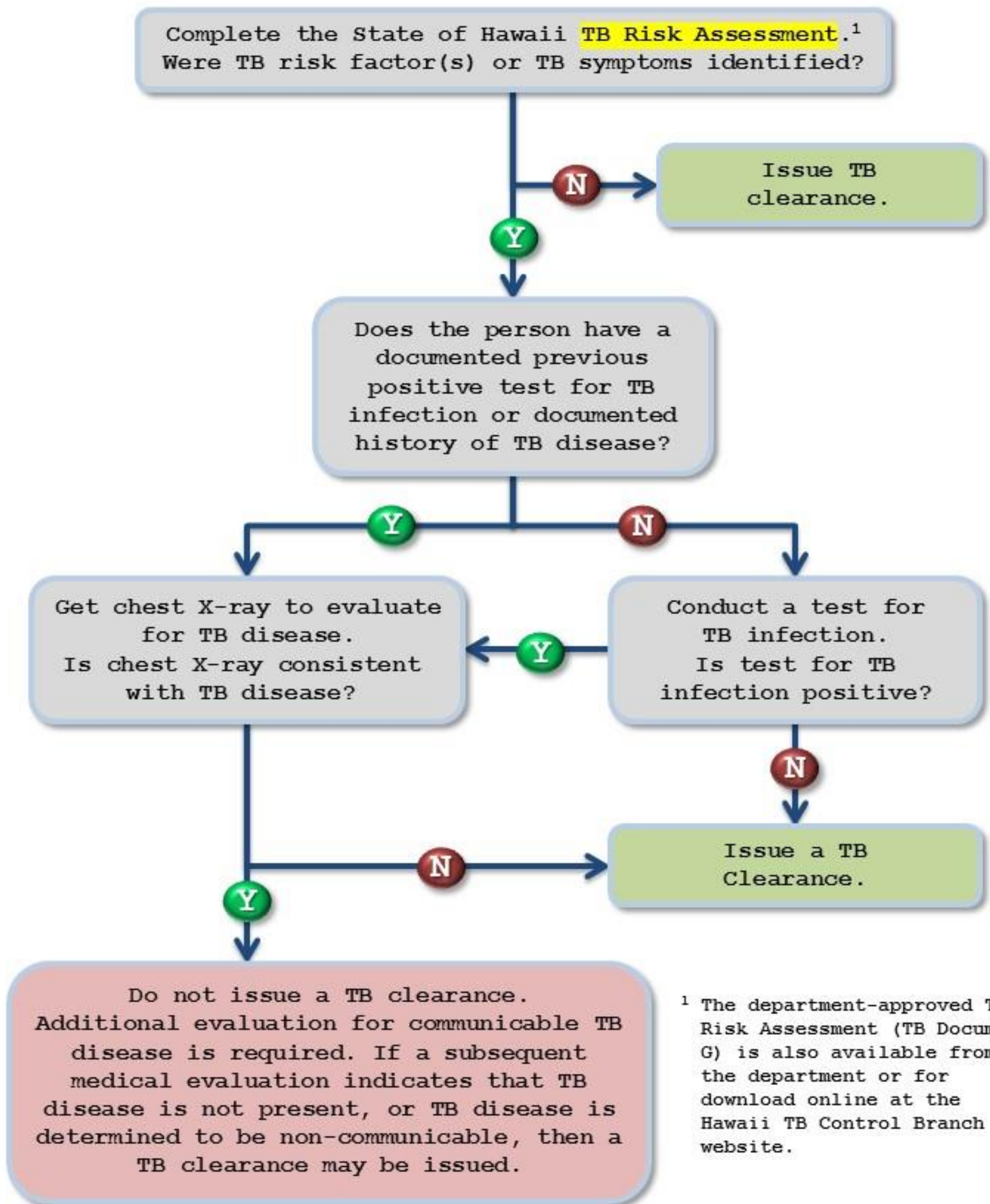
III. Follow-up Annual TB Evaluation Procedure



[1] The State of Hawaii Tuberculosis Symptom Screen (TB Document H) is also available from the department or for download online at the Hawaii TB Control Branch website.

[2] Single-step TST is appropriate. Note: Interferon Gamma Release Assays are not approved for use in children under age 5.

TB Document E: TB Clearance Evaluation Procedures for Food Handlers



[1] The department-approved TB Risk Assessment (TB Document G) is also available from the department or for download online at the Hawaii TB Control Branch website.

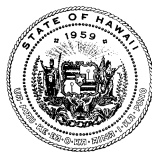
4.0 TB Clearance Resource Documents

In addition to the clearance procedures, there are several essential resource documents to assist clinicians who are screening individuals in Hawaii. Table 2 lists these resource documents.

Table 2. List of TB Clearance Resource Documents

Resource Document Name	Resource Document Name	Page
State of Hawaii TB Clearance Form	TB Document F	12
State of Hawaii TB Risk Assessment for Adults and Children	TB Document G	13
State of Hawaii TB Symptom Screen	TB Document H	14
State of Hawaii List of Approved Tests for TB Infection	TB Document I	15
State of Hawaii List of High Risk Countries	TB Document J	17
State of Hawaii Notifiable Disease Report for Tuberculosis	TB Document K	19
State of Hawaii Notifiable Disease Report for Tuberculosis: Definitions and Instructions	TB Document L	21
State of Hawaii Tuberculosis Case / Suspect Follow-Up Report	TB Document M	43

Resource documents in this manual are provided to the community for implementing Chapter 11-164.2, Hawaii Administrative Rules. The Department of Health maintains an updated hard-copy library of this TB Clearance Manual that is available to the community. These documents are also available on the Department of Health TB Control Branch website. Hard copies of these documents can be obtained from the Lanakila Health Center TB Clinic at 1700 Lanakila Avenue, Ground Floor, Honolulu, HI 96817. Questions should be directed to the State TB Nurse Consultant at the State of Hawaii Department of Health TB Control Branch at phone number (808) 832-5731.



TB Document F: State of Hawaii TB Clearance Form

Hawaii State Department of Health
Tuberculosis Control Program

Patient Name	DOB	TB Screening Date

I have evaluated the individual named above using the process set out in the DOH TB Clearance Manual dated 2/10/17 and determined that the individual does not have TB disease as defined in section 11-164.2-2, Hawaii Administrative Rules.

Screening for schools, child care facilities or food handlers *(TB Document A or E)*
☐ Negative TB risk assessment
☐ Negative test for TB infection
☐ Positive test for TB infection, and negative chest X-ray

Initial Screening for health care facilities or residential care settings (*TB Document B or C)*
☐ Negative test for TB infection (2-step)
☐ New positive test for TB infection, and negative chest X-ray
☐ Previous positive test for TB infection, negative CXR within previous 12 months, and negative symptom screen
☐ Previous positive test for TB infection, and negative CXR

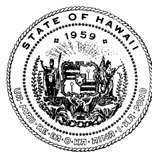
Annual Screening for Health care facilities or residential care settings (*TB Document D)*
☐ Negative test for TB infection
☐ New positive test for TB infection, and negative chest X-ray
☐ Previous positive test for TB infection, and negative symptoms screen
☐ Previous positive test for TB infection, and negative CXR

Signature or Unique Stamp of Practitioner: ______________________________________

Printed Name of Practitioner: ______________________________________

Healthcare Facility: ______________________________________

This TB clearance provides a reasonable assurance that the individual listed on this form was free from tuberculosis disease at the time of the exam. This form does not imply any guarantee or protection from future tuberculosis risk for the individual listed.



TB Document G: State of Hawaii TB Risk Assessment for Adults and Children

Hawaii State Department of Health
Tuberculosis Control Program

1. Check for TB symptoms

- If there are significant TB symptoms, then further testing (including a chest x-ray) is required for TB clearance.
- If significant symptoms are absent, proceed to TB Risk Factor questions.

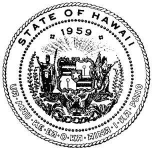
☐ Yes ☐ No	**Does this person have significant TB symptoms?** Significant symptoms include <u>cough for 3 weeks or more</u>, plus at least one of the following: ☐ Coughing up blood ☐ Fever ☐ Night sweats ☐ Unexplained weight loss ☐ Unusual weakness ☐ Fatigue

2. Check for TB Risk Factors

- If any "Yes" box below is checked, then TB testing is required for TB clearance
- If all boxes below are checked "No", then TB clearance can be issued without testing

☐ Yes ☐ No	**Was this person born in a country with an elevated TB rate?** Includes countries other than the United States, Canada, Australia, New Zealand, or Western and North European countries.
☐ Yes ☐ No	**Has this person traveled to (or lived in) a country with an elevated TB rate for four weeks or longer?**
☐ Yes ☐ No	**At any time has this person been in contact with someone with *infectious TB disease*? (Do not check "Yes" if exposed only to someone with latent TB)**
☐ Yes ☐ No	**Does the individual have a health problem that affects the immune system, or is medical treatment planned that may affect the immune system?** *(Includes HIV/AIDS, organ transplant recipient, treatment with TNF-alpha antagonist, or steroid medication for a month or longer)*
☐ Yes ☐ No	**For persons under age 16 only: Is someone in the child's household from a country with an elevated TB rate?**

Provider Name with Licensure/Degree:	**Person's Name and DOB:**
Assessment Date:	**Name and Relationship of Person Providing Information (if not the above-named person):**

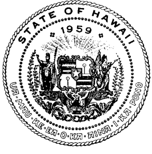


TB Document H: State of Hawaii TB Symptom Screen

Hawaii State Department of Health
Tuberculosis Control Program

TB Symptom			Onset and Duration of Symptoms
1. Cough for ≥3 weeks duration	❑ No	❑ Yes	
2. Coughing up blood	❑ No	❑ Yes	
3. Fever	❑ No	❑ Yes	
4. Night sweats	❑ No	❑ Yes	
5. Unexplained weight loss	❑ No	❑ Yes	Amount:
6. Unusual weakness or fatigue	❑ No	❑ Yes	Duration:

Interpreting the TB Symptom Screen
If the client responds “Yes” to having a cough for ≥3 weeks duration AND “Yes” to at least one of the other symptoms (#2-#6), perform a test for TB infection and refer the client for a chest X-ray to rule out TB disease.



TB Document I: State of Hawaii List of Approved Tests for TB Infection

Hawaii State Department of Health
Tuberculosis Control Program

DOH-Approved Tests for TB Infection

The following is a DOH-approved list of tests for TB infection for the purposes of TB screening as required by the state. These tests are approved by the U.S. Food and Drug Administration (FDA) for the diagnosis of TB infection. Additionally, CDC has provided guidance on test application and interpretation of results.

1. Tuberculin Skin Test (TST)*

The TST is used to determine if a person is infected with *Mycobacterium tuberculosis*. If a person is infected, a delayed-type hypersensitivity reaction is detectable 2 to 8 weeks after infection. The skin test is administered intradermally using the Mantoux technique by injecting 0.1ml of 5 TU purified protein derivative (PPD) solution. The reading and interpretation of TST reactions should be conducted within 48 to 72 hours of administration.

- Training is essential for health care providers to gain proficiency in the administration and interpretation of the TST.
- The TST should not be performed on a person who has written documentation of either a previous positive TST result or treatment for TB disease.
- Patients or family members should never measure TST results; this should only be done by a trained health care professional.
- Interpretation of the TST result is the same for persons who have had Bacille de Calmette et Guerin (BCG) vaccination and those who have not received BCG, because a majority of BCG cross-reactivity wanes with time.
- A positive tuberculin skin test is determined as follows:

A TST reaction of ≥ 5 mm of induration is considered positive in the following individuals:

- **HIV-infected persons**
- **Recent contacts of a person with infectious TB disease**
- **Persons with fibrotic changes on chest radiograph consistent with prior TB**
- **Patients with organ transplant(s) and other immunosuppressed patients (including patients taking the equivalent of ≥15 mg/day of prednisone for 1 month or more, or those taking TNF-α antagonists)**

A TST reaction of ≥10 mm of induration is considered positive in the following individuals:

- **Arrivals to the United States from high-prevalence areas*****
- **Residents, volunteers, or employees of high-risk congregate settings (e.g., correctional facilities, long-term care facilities, hospitals and other health care facilities, residential facilities for patients with HIV infection/AIDS, and homeless shelters)**
- **Persons with clinical conditions that increase the risk for progression to TB disease**
- **Injection drug users**
- **Children under 16 living in a household who are exposed to adults from a country with an elevated TB rate.**

A TST reaction of ≥15 mm of induration is considered positive in the following individuals:

- **Persons with no known risk factors for TB**

2. Interferon–Gamma Release Assays (IGRAs)*

IGRAs are used to determine if a person is infected with *Mycobacterium tuberculosis* by measuring the immune response to TB proteins in whole blood. Because of inadequate data at the present time, these tests are not approved for children under age 5 and will not be accepted by the Department of Health when administered to children under 5 years of age.

At present, there are two U.S. Food and Drug Administration (FDA)-approved IGRA tests commercially available in the United States:

- QuantiFERON®-TB Gold-in-Tube test (QFT-GIT)
- T-SPOT® TB test

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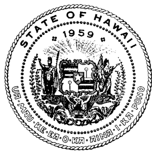
*Source: CDC Tests for TB Infection, accessed on 4/19/2013 at: http://www.cdc.gov/tb/publications/LTBI/diagnosis.htm

** Source: CDC Targeted Tuberculosis Testing and Interpreting Tuberculin Skin Test Results, accessed on 10/08/2013 at: http://www.cdc.gov/tb/publications/factsheets/testing/skintestresults.pdf

*** See Document J: State of Hawaii List of High Risk Countries



TB Document J: State of Hawaii List of High Risk Countries

Hawaii State Department of Health
Tuberculosis Control Program

Africa		
Algeria	Ethiopia	Niger
Angola	Gabon	Nigeria
Benin	Gambia	Rwanda
Botswana	Ghana	Sao Tome and Principe
Burkina Faso	Guinea	Senegal
Burundi	Guinea-Bissau	Seychelles
Cameroon	Kenya	Sierra Leone
Cape Verde	Lesotho	South Africa
Central African Rep.	Liberia	Swaziland
Chad	Madagascar	Togo
Comoros	Malawi	Uganda
Congo	Mali	United Rep. of Tanzania
Côte d'Ivoire	Mauritania	Zambia
Dem. Rep. of the Congo	Mauritius	Zimbabwe
Equatorial Guinea	Mozambique	
Eritrea	Namibia	
Eastern Mediterranean		
Afghanistan	Libyan	South Sudan
Djibouti	Morocco	Sudan
Iran	Pakistan	Tunisia
Iraq	Qatar	Yemen
Kuwait	Somalia	
Europe		
Armenia	Kazakhstan	Russian Federation
Azerbaijan	Kyrgyzstan	Tajikistan
Belarus	Latvia	The Former Yugoslav
Bosnia - Herzegovina	Lithuania	Turkey
Bulgaria	Poland	Turkmenistan
Estonia	Portugal	Ukraine
Georgia	Republic of Moldova	Uzbekistan
Greenland	Romania	
South-East Asia		
Bangladesh	Indonesia	Sri Lanka
Bhutan	Maldives	Thailand
Dem. People's Rep. of Korea	Myanmar	Timor-Leste
India	Nepal	

The Americas		
Anguilla	El Salvador	Paraguay
Argentina	Guatemala	Peru
Belize	Guyana	Saint Vincent - Grenadines
Bolivia	Haiti	Suriname
Brazil	Honduras	Trinidad and Tobago
Colombia	Mexico	Turks and Caicos Islands
Dominican Republic	Nicaragua	Uruguay
Ecuador	Panama	Venezuela
Western Pacific		
Brunei Darussalam	Lao People's Dem. Rep.	Papua New Guinea
Cambodia	Malaysia	Philippines
China	Marshall Islands	Republic of Korea
China, Hong Kong SAR	Micronesia (Fed. States of)	Singapore
China, Macao SAR	Mongolia	Solomon Islands
Fiji	Nauru	Tuvalu
French Polynesia	New Caledonia	Vanuatu
Guam	Niue	Viet Nam
Japan	Northern Mariana Islands	Wallis and Futuna Islands
Kiribati	Palau	

High-incidence countries include any country with an annual TB rate over 20/100,000.
Source: http://www.who.int/tb/country/data/download/en/
Revised Oct 2016.

State of Hawaii TB Document K: NOTIFIABLE DISEASE REPORT FOR TUBERCULOSIS

Hawaii State Department of Health
Tuberculosis Control Program

FAX TO:
Hawaii Tuberculosis Control Program
ATTN: TB REGISTRY SECTION
1700 Lanakila Avenue, Honolulu, HI 96817
FAX: (808) 832-5624 PHONE: (808) 832-3534

1. Name: ______________________ (LAST / FIRST / MIDDLE INITIAL)

2. Address: ______________________ (STREET NUMBER and STREET NAME)
______________________ (CITY, STATE, and ZIP CODE)

3. Homeless Within Past Year: ☐ No ☐ Yes ☐ Unknown

4. Home Phone: __________ Cellular: __________ Work: __________

5. Next of Kin: __________ Relationship: __________ Phone: __________

6. Date of Birth: ____/____/______ (MM DD YYYY)

7. Sex at Birth : ☐ Male ☐ Female

8. U.S. Citizen: ☐ No ☐ Yes ☐ Unknown

9. Place of Birth: ______________

10. Foreign Born:
Date Arrived in U.S.: ____/____/______

11. Primary Occupation Within the Past Year (SELECT ONE): ☐ Unknown ☐ Other (SPECIFY): __________
☐ Unemployed ☐ Health Care Worker ☐ Correctional Facility Employee
☐ Retired ☐ Migrant/Seasonal Worker ☐ Not Seeking Employment (E.G., INFANT, CHILD, STUDENT, HOMEMAKER, DISABLED PERSON)

12. Race / Ethnicity (CHECK ALL THAT APPLY):
☐ African American ☐ Carolinian ☐ Chinese ☐ Guamanian ☐ Japanese ☐ Marshallese ☐ Palauan ☐ Tongan
☐ Alaskan Native ☐ Caucasian ☐ Chuukese ☐ Hawaiian ☐ Korean ☐ Micronesian ☐ Pohnpeian ☐ Vietnamese
☐ American Indian ☐ Chamorro ☐ Filipino ☐ Hispanic ☐ Kosraean ☐ Okinawan ☐ Samoan ☐ Yapese
☐ Other (SPECIFY): __________

13. Reason Evaluated for TB (SELECT ONE): ☐ TB Symptoms ☐ Abnormal Chest Radiograph (Incidental Finding)
☐ TB Contact Investigation ☐ Health Care Worker Screening ☐ DOH Mandated TB Screening (CATEGORY): __________
☐ Immigration Medical Exam ☐ Lab Result (Incidental Finding) ☐ Other (SPECIFY): __________

14. Date of Diagnosis: ____/____/______
☐ Suspect ☐ Confirmed

15. Status at Diagnosis of TB:
☐ Alive ☐ Dead
Date of Death: ____/____/______

16. Previous TB Disease
☐ No ☐ Yes
IF YES, Enter Year of Previous TB Disease: ☐☐☐☐

17. Site(s) of TB Disease (CHECK ALL THAT APPLY):
☐ Pulmonary ☐ Lymphatic: Intrathoracic ☐ Lymphatic: Unknown
☐ Pleural ☐ Lymphatic: Cervical ☐ Bone AND/OR Joint
☐ Laryngeal ☐ Lymphatic: Axillary ☐ Genitourinary
☐ Meningeal ☐ Lymphatic: Other ☐ Peritoneal
☐ Other: __________

18. Bacteriology

DATE COLLECTED	SPECIMEN TYPE & SITE (E.G., SPUTUM, TISSUE, PLEURAL FLUID, ETC.)	SMEAR RESULT (IF POSITIVE, ENTER SMEAR COUNT (E.G., 1+, 2+, 3+, 4+))	NUCLEIC ACID AMPLIFICATION (E.G., MTD DIRECT)	CULTURE	DRUG SUSCEPTIBILITY RESULTS (IF CULTURE POSITIVE FOR MTB, INDICATE DRUG RESISTANCE)
/ /	Type: Site:	☐ NEG ☐ POS ____ ☐ PENDING	☐ NEG ☐ POS ☐ PEND ☐ INDET	☐ PEND ☐ NEG ☐ MTB COMPLEX ☐ NOT TB (SPECIFY ID): ______	☐ PEND ☐ PAN SUSCEPTIBLE ☐ RESISTANT TO: ______
/ /	Type: Site:	☐ NEG ☐ POS ____ ☐ PENDING	☐ NEG ☐ POS ☐ PEND ☐ INDET	☐ PEND ☐ NEG ☐ MTB COMPLEX ☐ NOT TB (SPECIFY ID): ______	☐ PEND ☐ PAN SUSCEPTIBLE ☐ RESISTANT TO: ______
/ /	Type: Site:	☐ NEG ☐ POS ____ ☐ PENDING	☐ NEG ☐ POS ☐ PEND ☐ INDET	☐ PEND ☐ NEG ☐ MTB COMPLEX ☐ NOT TB (SPECIFY ID): ______	☐ PEND ☐ PAN SUSCEPTIBLE ☐ RESISTANT TO: ______
/ /	Type: Site:	☐ NEG ☐ POS ____ ☐ PENDING	☐ NEG ☐ POS ☐ PEND ☐ INDET	☐ PEND ☐ NEG ☐ MTB COMPLEX ☐ NOT TB (SPECIFY ID): ______	☐ PEND ☐ PAN SUSCEPTIBLE ☐ RESISTANT TO: ______

19. Tuberculin Skin Test (TST) at Diagnosis: ☐ Not Done
☐ Negative -- Date TST Placed: ___/___/_____ Induration: ____ mm
☐ Positive -- Date TST Placed: ___/___/_____ Induration: ____ mm

20. Interferon Gamma Release Assay (IGRA) (E.G., QUANTIFERON AND T-SPOT.TB):
☐ Not Done ☐ Negative ☐ Positive ☐ Indeterminate
Date Collected: ___/___/_____ Type of IGRA (SPECIFY): __________

TB NDR (Rev. 1/2016) PAGE 1 OF 2

Patient Name: ______________________________ (LAST, FIRST, MIDDLE INITIAL) **Date of Birth:** ____/____/______ (MM DD YYYY)

21. Date of 1st Chest Radiograph: ____/____/________
Check One: ☐ Abnormal ☐ Normal ☐ Not Done
IF Abnormal: Evidence of Cavity: ☐ No ☐ Yes ☐ Unknown
Evidence of Miliary TB: ☐ No ☐ Yes ☐ Unknown

22. Date of 2nd Chest Radiograph: ____/____/________
Check One: ☐ Stable ☐ Worsening ☐ Improving

23. Date of 1st Chest CT Scan or Other Chest Imaging: ____/____/________
Check One: ☐ Abnormal ☐ Normal ☐ Not Done
IF Abnormal: Evidence of Cavity: ☐ No ☐ Yes ☐ Unknown
Evidence of Miliary TB: ☐ No ☐ Yes ☐ Unknown

24. Date of 2nd Chest CT Scan or Other Chest Imaging: ____/____/________
Check One: ☐ Stable ☐ Worsening ☐ Improving

25. Date Therapy Started: ____/____/________
☐ Therapy Not Started

26. Patient on Directly Observed Therapy (DOT):
☐ No ☐ Yes ☐ Unknown

27. Patient's Weight at Diagnosis: ________(kg)

28. Initial Drug Regimen and Frequency:

Drug	mg	times/week
Isoniazid	______mg	______times/week
Rifampin	______mg	______times/week
Pyrazinamide	______mg	______times/week
Ethambutol	______mg	______times/week
Levofloxacin	______mg	______times/week
Moxifloxacin	______mg	______times/week
Ofloxacin	______mg	______times/week
________ (OTHER DRUG USED)	______mg	______times/week
________ (OTHER DRUG USED)	______mg	______times/week

29. HIV Status at Time of Diagnosis (SELECT ONE): ☐ Negative ☐ Positive ☐ Refused
☐ Indeterminate ☐ Not Offered ☐ Test Done, Results Unknown ☐ Unknown

30. HIV Antibody Test Date: ____/____/________

31. Excess Alcohol Use Within Past Year:
☐ No ☐ Yes ☐ Unknown

32. Injecting Drug Use Within Past Year:
☐ No ☐ Yes ☐ Unknown

33. Non-Injecting Drug Use Within Past Year:
☐ No ☐ Yes ☐ Unknown

34. Resident of Correctional Facility at Time of Diagnosis: ☐ No ☐ Yes ☐ Unknown
IF YES, (SELECT ONE): ☐ Federal Prison ☐ State Prison ☐ Local Jail ☐ Juvenile Correctional Facility ☐ Unknown
☐ Other Correctional Facility (SPECIFY): ______________________________

35. Resident of Long-Term Care Facility at Time of Diagnosis: ☐ No ☐ Yes ☐ Unknown
IF YES, (SELECT ONE): ☐ Nursing Home ☐ Alcohol or Drug Treatment Facility ☐ Residential Facility ☐ Unknown
☐ Hospital-Based Facility ☐ Mental Health Residential Facility ☐ Other (SPECIFY): ______________

36. Additional TB Risk Factors (SELECT ALL THAT APPLY): ☐ None ☐ Other (SPECIFY): ______________
☐ Diabetes Mellitus ☐ Contact of Infectious TB Patient (2 YEARS OR LESS) ☐ Post-Organ Transplantation
☐ End-Stage Renal Disease ☐ Contact of MDR TB Patient (2 YEARS OR LESS) ☐ Immunosuppression (NOT HIV/AIDS)
☐ Incomplete LTBI Treatment ☐ Missed Contact (2 YEARS OR LESS) ☐ TNF-α Antagonist Therapy (E.G., HUMIRA, REMICADE, AND ENBREL)

37. Date Reported: ____/____/________
Reported By: ______________________
Name of Institution: ______________________
Address: ______________________ (STREET NUMBER and STREET NAME)
______________________ (CITY, STATE, and ZIP CODE)
Work: ______________ Cell: ______________
Pager: ______________ Fax: ______________
Email Address:

38. Hospital Admission Date: ____/____/________

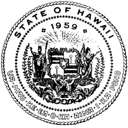
39. Hospital Discharge Date: _____ / _____ / ________

40. Name of Primary Care Physician:
Phone Number:

41. Will the Patient Be Referred to the Hawaii Department of Health for TB Care?
☐ Yes - For TB treatment and DOT (call DOH to initiate referral)
☐ Yes - For DOT only (call DOH to initiate referral)
☐ No - If patient is not referred to DOH, the physician treating TB must complete a TB follow-up report every 2 months to DOH.
- Name of Physician Treating TB:
- Phone Number:

42. Additional Notes/Remarks:

43. DOH USE ONLY
CC# / MR#:
TB Class:
TBCMD:
Nurse Case Manager:



State of Hawaii TB Document L:
Notifiable Disease Report for Tuberculosis: Definitions and Instructions
Hawaii State Department of Health, Tuberculosis Control Program

This document provides reporting requirements for suspected or confirmed tuberculosis (TB) as well as definitions and instructions for completing the Notifiable Disease Report (NDR) for Tuberculosis (TB).

NDR QUESTION LIST

1. Name
2. Address
3. Homeless Within Past Year
4. Home Phone, Cellular, and Work
5. Next of Kin, Relationship, and Phone
6. Date of Birth
7. Sex at Birth
8. U.S. Citizen
9. Place of Birth
10. Foreign Born: Date Arrived in U.S.
11. Primary Occupation Within the Past Year
12. Race / Ethnicity
13. Reason Evaluated for TB
14. Date of Diagnosis
15. Status at Diagnosis of TB
16. Previous TB Disease
17. Site(s) of TB Disease
18. Bacteriology
19. Tuberculin Skin Test (TST) at Diagnosis
20. Interferon Gamma Release Assay (IGRA)
21. Date of 1st Chest Radiograph
22. Date of 2nd Chest Radiograph
23. Date of 1st Chest CT Scan or Other Chest Imaging
24. Date of 2nd Chest CT Scan or Other Chest Imaging
25. Date Therapy Started
26. Patient on Directly Observed Therapy (DOT)
27. Patient's Weight at Diagnosis
28. Initial Drug Regimen and Frequency
29. HIV Status at Time of Diagnosis
30. HIV Antibody Test Date
31. Excess Alcohol Use Within Past Year
32. Injecting Drug Use Within Past Year
33. Non-Injecting Drug Use Within Past Year
34. Resident of Correctional Facility at Time of Diagnosis
35. Resident of Long-Term Care Facility at Time of Diagnosis
36. Additional TB Risk Factors
37. Date Reported (Reporting Section)
38. Hospital Admission Date
39. Hospital Discharge Date
40. Name of Primary Care Physician
41. Will the Patient be Referred to the Hawaii Department of Health for TB care?
42. Additional Notes/Remarks
43. DOH USE ONLY

Reporting Requirements for Suspected or Confirmed Tuberculosis

Health care providers, laboratories, and infection control practitioners are required by section 325-71, Hawaii Revised Statues to report any patient suspected of or confirmed with active TB disease to the Hawaii State Department of Health, TB Control Program. The reports must be submitted to the TB Control Program by facsimile or mail within 72 hours of a diagnosis of confirmed or suspected TB.

It is **mandatory** to report patients who have ***any*** of the following criteria:

- Any laboratory specimen with smear positive results for acid fast bacilli (AFB) *with* suspicion of active TB disease.
- Any laboratory specimen with a positive result from a rapid diagnostic test, such as nucleic acid amplification (NAA) test [e.g., Gen-Probe's Amplified MTD® (Mycobacterium Tuberculosis Direct)].
- Any laboratory specimen with a positive culture for *M. tuberculosis* complex.
- Any other clinical specimen or pathology or autopsy findings consistent with active TB disease. For example, this may include, but is not limited to, caseating granulomas in a biopsy of the lung, lymph node, or other anatomic area.
- Treatment with two or more anti-TB medications (e.g., isoniazid, rifampin, pyrazinamide, ethambutol) for suspected or confirmed active TB disease.
- Clinical suspicion of pulmonary or extrapulmonary TB such that the health care provider has initiated or intends to initiate airborne isolation, or treatment for TB.
- *FOR HAWAII DEPARTMENT OF HEALTH TB CLINICS ONLY:* TB classification of 3, 4 or 5.

For infection control purposes, practitioners are required to report whenever TB is suspected, even if bacteriologic evidence of disease is lacking, or is preliminary, or treatment has not yet been initiated. When a patient has an AFB-positive smear or has been started on clinical treatment for TB, reporting should not be delayed pending laboratory identification of *M. tuberculosis* with rapid diagnostic tests (e.g., NAA tests) or culture results.

Definitions and Instructions for Completing the NDR for TB

1. Name
   Indicate the last name, first name, and middle initial for the TB patient. Also, indicate any aliases or maiden names.

2. Address
   Indicate the street number, street names, city, state, and zip code of the TB patient's residence at the time of diagnosis. To the extent possible, the address should represent the home address (whether permanent or temporary) of the TB patient.

   Follow these guidelines for special circumstances:
   a. Patients who are residents of correctional facilities (e.g., local, state, federal, military) – the address of the correctional facility should be entered in this field.
   b. Patients who are residents of long term care facilities – the address of the long-term care facility should be entered in this field.
   c. Homeless persons or others without any fixed residence – the address at which they are living at the time of diagnosis (e.g., the locality of the shelter in which the patient was living) should be entered in this field.

3. Homeless Within Past Year
   - Check "**No**" if the patient was not homeless during the 12 months prior to the time when the TB diagnostic evaluation was performed.

   - Check "**Yes**" if the patient was homeless at any time during the 12 months prior to the time when the TB diagnostic evaluation was performed.

   - Check "**Unknown**" if it is not known whether the patient was homeless during the 12 months prior to the time when the TB diagnostic evaluation was performed.

   A homeless person may be defined as:

   1. An individual who lacks a fixed, regular, and adequate nighttime residence and who has a primary nighttime residence that is:
      a. A supervised publicly or privately operated shelter designed to provide temporary living accommodations, including welfare hotels, congregate shelters, and transitional housing for the mentally ill; or
      b. A public or private place not designated for, or ordinarily used as, a regular sleeping accommodation for human beings; or
      c. An institution that provides a temporary residence for individuals intended to be institutionalized

   2. An individual who has no home (e.g., is not paying rent, does not own a home, and is not steadily living with relatives or friends).

   3. An individual who lacks customary and regular access to a conventional dwelling or residence. Included as homeless are persons who live on streets or in non-residential buildings.

4. Also included are residents of homeless shelters, shelters for battered women, welfare hotels, and single room occupancy (SRO) hotels. In the rural setting, where there are usually few shelters, a homeless person often will live on the street or with relatives in substandard housing.

5. Being homeless does not refer to a person who is imprisoned or in a correctional facility.

4. Home Phone, Cellular, and Work
Indicate the home, cellular, and work phone numbers that can be used to contact the TB patient.

5. Next of Kin, Relationship, and Phone
Indicate the next of kin of the TB patient, the relationship to the TB patient, and the phone number that can be used to contact this person.

6. Date of Birth
Indicate the month, day, and year of birth for the TB patient. For example: 04/26/1968. A complete date of birth is required. Partial dates are acceptable ONLY for patients where date of birth is truly unknown. For example, certain societies or cultures throughout the world do not document the day, month, or sometimes, even the year of birth. In such cases, enter “99” for either the day and/or month, and enter the year of birth. If the month, day, and year of birth are all unknown, enter "99/99/9999" on the form.

7. Sex at Birth
Check the appropriate box for the biological sex of the TB patient at birth: “**Male**” or “**Female**”.

8. U.S. Citizen
Check the appropriate box for the U.S. citizenship of the TB patient: “**No**”, “**Yes**”, or “**Unknown**”. Persons born abroad to a U.S. citizen parent are considered U.S. citizens. NOTE: People born in the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and U.S. Virgin Islands are U.S. citizens. Those born in the Federated States of Micronesia, Republic of Marshall Islands, and Palau are not considered U.S. citizens.

9. Place of Birth
Enter the country in which the patient was born. If the patient was born in one of the 50 United States, include the specific state.

10. Foreign Born
“**Date Arrived in U.S.**” – For patients who were NOT born in one of the 50 United States, indicate the month, day, and year that the TB patient arrived in the U.S., for example: 04/26/1968. A complete date of arrival in the U.S. is required. Partial dates are acceptable ONLY for patients where date arrived in U.S. are truly unknown. In such cases, enter “99” for either the day and/or month, and enter the year of arrival. If the month, day, and year of arrival are not all known, enter "99/99/9999" on the form.

11. Primary Occupation Within the Past Year
Within the past 12 months from the diagnostic TB evaluation, select the primary occupation of the patient (*select one*). If more than one occupation is applicable to the patient, choose the occupation which the patient performed for the longest period of time within the past 12 months (i.e. the patient’s

primary occupation). For example, if the patient was a health care worker and a student (e.g. taking night classes), then the patient's primary occupation would be classified as "**Health Care Worker**".

- Check "**Unemployed**" if the patient was not employed during the past 12 months prior to the diagnostic TB evaluation. This should not include persons who are not seeking employment such as infants, children, students, homemakers, retirees, and persons receiving permanent disability benefits or persons who were institutionalized. Such individuals should be included in the appropriate occupation option such as "Retired" or "Not Seeking Employment". "**Unemployed**" should be checked if the person was unemployed for the majority of the prior 12 month period; shorter time frames, such as 1 week of unemployment in the past 12 months should not be marked as "**Unemployed**".

- Check "**Retired**" if the patient was retired within the 12 months before the TB diagnostic evaluation was performed.

- Check "**Health Care Worker**" if the patient was a paid or unpaid person working in healthcare settings with potential for exposure to *M. tuberculosis*. These may include but are not limited to physicians, nurses, aides, dental workers, technicians, staff in laboratories and morgues, emergency medical personnel, students, part-time staff, temporary and contract staff, and persons not involved directly in patient care but potentially at risk for occupational exposure (e.g., volunteers, outreach workers, dietary, housekeeping, maintenance, clerical, and janitorial staff). Also included are persons who deliver health care in the community (e.g., public health nurse, visiting nurse, outreach worker).

- Check "**Migrant/Seasonal Worker**" if the patient was required to be absent from a permanent place of residence for the purpose of seeking employment or who may vary their employment for the purpose of remaining employed while maintaining a permanent place of residence [e.g., migratory agricultural worker, seasonal agricultural worker, migrant factory worker, migrant construction worker, migrant service industry worker, migrant sporting worker (e.g., horse racing, dog racing)].

- Check "**Unknown**" if the employment status during the 12 months prior to the diagnostic TB evaluation of the patient was unknown.

- Check "**Correctional Facility Employee**" if the patient works in a correctional facility. The facility may be a federal or state prison, local jail, juvenile correctional facility, Immigration and Customs Enforcement (ICE) Detention Center, or other correctional facility (see Question 35).

- Check "**Not Seeking Employment**" if the patient was not employed for reasons other than unemployment within the 12 months before the TB diagnostic evaluation, such as infants, children, students, homemakers (e.g., housewife, househusband), persons receiving permanent disability benefits, or persons who were institutionalized.

- Check "**Other**" if the patient was a person who has been regularly employed for pay or income at any occupation that is not included in the above choices within the 12 months before the TB diagnostic evaluation and specify the primary occupation within the past year.

12. Race/Ethnicity
    The answer to this question should be based on the individual's self-identity or self-reporting (if possible). Indicate the race/ethnicity that the patient considers themselves to be and check all that apply.

    Check "**Other**" if the race/ethnicity of the TB patient is not included in the above choices and specify the race/ethnicity.

    Note: If the patient is Micronesian (i.e., from the Federated States of Micronesia), check one of the following if known: Chuukese, Kosraean, Pohnpeian, or Yapese. If this information is not known, check "**Micronesian**".

13. Reason Evaluated for TB
    Indicate the single primary or initial reason why the TB patient was evaluated for TB disease (*select one choice only*). The definition of "single primary or initial" for the purpose of this question is the situation or reason that led to the initial suspicion that the patient may have TB disease. If a TB patient was referred, but the reason is unknown, an attempt should be made to identify that initial reason.

    - Check "**TB Contact Investigation**" if the patient was diagnosed with TB disease as a result of a contact investigation or source case finding.

    - Check "**Immigration Medical Exam**" if the patient underwent a medical examination as part of the immigration application process and was found to have TB disease. A medical examination is mandatory for specific persons seeking admission to the U.S. (e.g., immigrants, refugees, asylees). These medical examinations may occur overseas or in the U.S. depending on the situation. This includes patients found to have TB disease as a result of being evaluated for a Class A or B (i.e., Class A, Class B1, Class B2, or Class B3) TB condition. In addition, some persons applying for non-immigrant visas or special status (e.g., parolees) for temporary admission to the U.S. may be required to have a medical examination.

    - Check "**TB Symptoms**" if the patient was evaluated for TB disease due to signs and symptoms consistent with TB (e.g., prolonged or persistent cough, fever, lymphadenopathy, night sweats, weight loss). For example, if a TB patient seeks medical care due to TB symptoms, then "**TB Symptoms**" should be the primary reason the TB patient was evaluated for TB disease. If however, a TB patient was initially encountered via a contact investigation, and during the contact investigation the TB patient was also noted to have TB symptoms, "TB Contact Investigation" should be chosen as the primary reason the TB patient was evaluated for TB disease.

    - Check "**Health Care Worker Screening**" if the patient was evaluated for TB disease due to a positive tuberculin skin test administered because the patient was a health care worker. "Health care worker" refers to all paid and unpaid persons working in healthcare settings who have the potential for exposure to *M. tuberculosis*. These may include but are not limited to physicians, nurses, aides, dental workers, technicians, staff in laboratories and morgues, emergency medical personnel, students, part-time staff, temporary and contract staff, and persons not involved directly in patient care but potentially at risk for occupational exposure (e.g., volunteers, outreach workers, dietary, housekeeping, maintenance, clerical, and janitorial staff). Also included are persons who deliver health care in the community (e.g., public health nurse, visiting nurse, outreach worker).

- Check "**Lab Result (Incidental Finding)**" if an incidental specimen is positive for acid fast bacilli (AFB) or an incidental culture is positive for *M. tuberculosis* (e.g., when the specimen was tested for AFB or cultured for TB without suspicion of TB disease or when TB disease was not considered a possible diagnosis, such as during a bronchoscopy, autopsy, organ donation, hospitalization, or evaluation for other disease).

- Check "**Abnormal Chest Radiograph (Incidental Finding)**" if the patient had an incidental chest radiograph consistent with TB disease. The reason for taking the chest radiograph should be independent of the other choices listed in the question and should not have been done to rule out TB disease. For example, if a chest radiograph was taken as part of preoperative testing, where there was no suspicion of TB disease, then select "**Abnormal Chest Radiograph (Incidental Finding)**".

- Check "**DOH Mandated TB Screening**" if the patient was diagnosed with TB disease due to a positive tuberculin skin test administered because the patient was fulfilling the requirements of the mandated TB screening per the Hawaii Administrative Rules (HAR) for TB.

  Enter one of the following categories of "**DOH Mandated TB Screening**" that led to the TB diagnosis:
  - Primary and Secondary Schools: Personnel
  - Primary and Secondary Schools: Student
  - Post-Secondary Schools: Personnel
  - Post-Secondary Schools: Student
  - Child Care Facilities: Personnel
  - Child Care Facilities: Children
  - Persons living or working in health care facilities or residential care settings licensed or otherwise regulated by the department
  - Foodhandler

  Note: The following mandated screening categories are listed as separate options: Health Care Worker, Contact/Source Investigation, and Immigrant.

- Check "**Other**" if the reason why the TB patient was evaluated for TB disease is not included in the above choices and specify the reason the patient was evaluated for TB.

14. Date of Diagnosis
    Indicate the month, day, and year of the diagnosis of TB.
    - Check "**Suspect**" if laboratory or clinical confirmation of TB is not available.
    - Check "**Confirmed**" if there is laboratory or clinical confirmation of TB.

15. Status at TB Diagnosis
    - Check "**Alive**" if the patient was alive at the time of TB diagnosis. Patients whose TB was suspected and who were started on at least two anti-tuberculosis drugs prior to the day of death should be classified as alive at the time of TB diagnosis even though the TB case may not be verified and counted until after death.

- Check "**Dead**" if the patient was deceased at the time the evaluation for possible TB disease was initiated. This applies to patients who were only on one anti-tuberculosis drug prior to the day of death because TB disease was not suspected, and who were then diagnosed with TB disease after death. For example, if a person was taking isoniazid as preventive therapy for latent TB infection dies, and was found after death to have had TB disease, this person should be classified as "**Dead**" at TB diagnosis.

  If "**Dead**" (e.g., those patients that were classified as "dead" at the time of TB diagnosis), enter the date (month, day, year) that the patient died. For example: 01/17/2005. If the day is unknown, enter '99' on the form (e.g., 01/99/2005).

16. Previous TB Disease
- Check "**No**" if the patient has not had a previous diagnosis of TB disease.

- Check "**Yes**" if the patient has had a previous diagnosis of TB disease. A previous diagnosis of suspected TB or latent TB infection (i.e., LTBI) should not be entered. A patient is considered to have had a previous diagnosis of TB disease if he/she had verified TB disease in the past, had completed therapy, or was lost to supervision for more than 12 consecutive months, and now has verified TB disease again. Often, TB disease is confused with latent TB infection (LTBI) and LTBI should not be considered as previous TB disease. Therefore, documentation of the previous episode of TB disease is important. Written documentation of the previous episode of TB diseases is ideal. However, if the TB disease episode occurred years ago, or in another location (e.g., country), then obtaining written documentation can be difficult. Therefore, when written documentation is not available, reliable verbal documentation of a previous episode of TB disease is acceptable (e.g., medications taken, length of medication, sputum smear examination results).

  If "**Yes**", provide the year in which the patient's previous episode of TB disease was diagnosed. For example, if the patient was diagnosed with TB disease in 1985, was reported to have completed therapy, or was lost to supervision in 1986, and is found to have verified disease again in 2005, enter "1985" in the boxes provided. If the patient had more than one previous episode of TB disease, enter the year of the most recent previous episode.

17. Site(s) of TB Disease

NOTE: If there is evidence that more than one organ or disease site involved, then check all appropriate sites of disease in Question 18 "**Site of Disease**". If the initial chest radiograph is reported "miliary TB" or as showing a "miliary" or "bilateral micronodular" pattern, indicate this finding on Question 22, "**Date of 1st Chest Radiograph**" and/or Question 24, "**Date of 1st Chest CT Scan or Other Chest Imaging**".

- Check the boxes corresponding to the site(s) of TB disease (select all that apply). "**Lymphatic: Intrathoracic**" includes hilar, bronchial, mediastinal, peritracheal, and other lymph nodes within the thorax.

- If the site of TB disease is "**Other**", specify the other organ or disease site.

18. <u>Bacteriology</u>
    - <u>Date Collected:</u> Indicate the month, day, and year the specimen was collected.

    - <u>Specimen Type & Site:</u>
        1. Enter the type of specimen used to make TB diagnosis. Examples of specimens include: sputum, tracheal aspirate, bronchial washing or lavage, urine, bone marrow, lymph node, cerebral spinal fluid, lung, or pleura which are collected from various procedures (e.g., bronchoscopy, biopsy, gastric aspiration, pleural fluid aspiration).
        2. Enter the site if the specimen type is tissue or body fluid. This field does not need to be completed if the specimen type is sputum.

    - <u>Smear Result:</u>
        - Check "**NEG**" if the smear result was negative for AFB.
        - Check "**POS**" if the smear result was positive for AFB and indicate the smear count (e.g., 1+, 2+, 3+, or 4+).
        - Check "**PENDING**" if the smear result has not been finalized.

    - <u>Nucleic Acid Amplification (NAA):</u>
        - Check "**NEG**" if the NAA test does not detect *M. tuberculosis*.
        - Check "**POS**" if the NAA test detects *M. tuberculosis*.
        - Check "**PEND**" if the NAA test has not been finalized.
        - Check **"INDET**" if the NAA test results were indeterminate and could not be determined to be positive or negative.

    - <u>Culture:</u>
        - Check "**PEND**" if the culture result has not been finalized.
        - Check "**NEG**" if the culture result was negative for *M. tuberculosis* complex.
        - Check "**MTB COMPLEX**" if the culture result was positive for *M. tuberculosis* complex.
        - Check "**NOT TB**" if the culture growth was not *M. tuberculosis.* Specify the identification of the organism that grew, if available.

    - <u>Drug Susceptibility Results:</u>
        - Check "**PEND**" if drug susceptibility testing results have not been finalized.
        - Check "**PAN SUSCEPTIBLE**" only if the isolate is completely susceptible to all of the first-line anti-tuberculosis medications tested.
        - Check "**RESISTANT TO**" if there was any degree of resistance, even partial resistance or resistance at a low concentration of the drug or other than completely susceptible result. Enter the drugs that the isolate is resistant to.

19. <u>Tuberculin Skin Test (TST) at Diagnosis</u>

NOTE:	If skin testing was not performed during the current diagnostic evaluation because the patient has a history of a past ***positive*** tuberculin skin test, **AND** the previous positive test is documented in the medical record, the previous positive test result may be reported in this field. <u>Patient self-report of a previous positive TST is not acceptable</u>. A history of a previous ***negative*** tuberculin skin test, whether documented or not, and a patient self-report of a negative previous or current skin test are also not acceptable.

- Check "**Not Done**" if the TST was not performed or if a patient states he/she had a positive TST in the past and it cannot be documented, and now the patient refuses to have a new TST placed.

- Check "**Positive**" if the TST met criteria for a positive tuberculin skin test as defined by current guidelines.

- Check "**Negative**" if the TST did not meet current criteria for a positive test and was negative as defined by current guidelines.

- **IMPORTANT:**
  For "**Positive**" or "**Negative**" tuberculin skin tests (TST), indicate:
  1. The "**Date TST Placed".** The complete date (month, day, year) should be entered. However, if the "day" or "month" portion of the date is unknown, "99" may be entered in the "day" or "month" field.
  2. The "**Induration in Millimeters (mm)**". If the available skin test result indicates only that the result was "positive" or "negative," but does not give the millimeters of induration, indicate whether the test is recorded as "positive" or "negative" and code the millimeters of induration as "99."

20. Interferon Gamma Release Assay (IGRA)
Interferon gamma release assays (IGRA) are blood tests for detecting *Mycobacterium tuberculosis* infection. For this variable, indicate the result of an IGRA test performed during the diagnostic TB disease evaluation.

- Check "**Not done**" if an interferon gamma release assay for *M. tuberculosis* was not performed.
- Check "**Negative**" if all IGRA test results were interpreted as *M. tuberculosis* infection is unlikely.
- Check "**Positive**" if any IGRA test result was interpreted as *M. tuberculosis* infection is likely.
- Check "**Indeterminate**" if the IGRA test results could not be determined to be positive or negative.
- Write in "**Borderline**" if result was interpreted as borderline.
- If any interferon gamma release assay for *M. tuberculosis* was conducted, indicate:
  1. The date the blood sample was collected ("**Date Collected**"). The complete date (month, day, year) should be entered. However, if the "day" portion of the date is unknown, "99" may be entered in the "day" field. If more than one test was conducted, and one or more test results were "Positive," enter the date the first positive IGRA blood sample was collected. If one or more IGRA tests were done and all the results were negative, enter the date the first negative IGRA blood sample was collected. If all test results were indeterminate, enter the date the first indeterminate result was reported.
  2. Specify the type of blood test performed ("**Type of IGRA (specify):** ________________"). If more than one test was conducted, list the test type corresponding to the blood sample result entered.

21. Date of 1st Chest Radiograph
    Indicate the date that the 1st chest radiograph was taken during the diagnostic evaluation for tuberculosis and whether the chest radiograph was "**Abnormal**", "**Normal**", or "**Not Done**".

    - Check "**Abnormal**" if the 1st chest radiograph showed any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB and:
        1. Indicate if the 1st chest radiograph obtained showed evidence of one or more cavities by checking "**No**", "**Yes**", or "**Unknown**".
        2. Indicate if the 1st chest radiograph obtained showed evidence of "miliary" disease (e.g., "miliary" TB or "miliary or "bilateral micronodular" pattern) by checking "**No**", "**Yes**", or "**Unknown**".

    - Check "**Normal**" if the 1st chest radiograph showed no abnormalities consistent with TB and was normal.

    - Check "**Not done**" if the 1st chest radiograph is known not to have been done.

22. Date of 2nd Chest Radiograph
    Indicate the date that the 2nd chest radiograph was taken during the diagnostic evaluation for tuberculosis and whether the chest radiograph was "**Stable**", "**Worsening**", or "**Improving**".

    - Check "**Stable**" if the 2nd chest radiograph showed no change in any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB.

    - Check "**Worsening**" if the 2nd chest radiograph showed worsening abnormalities consistent with TB.

    - Check "**Improving**" if the 2nd chest radiograph shows improvement of abnormalities consistent with TB.

23. Date of 1st Chest CT Scan or Other Chest Imaging
    Indicate the date that the 1st chest CT scan or other chest imaging study was taken during the diagnostic evaluation for tuberculosis and whether the chest CT scan or other chest imaging was "**Abnormal**", "**Normal**", or "**Not Done**".

    - Check "**Abnormal**" if the 1st chest CT scan or other chest imaging study showed any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB and:
        1. Indicate if the 1st chest CT scan or other chest imaging study obtained showed evidence of one or more cavities by checking "**No**", "**Yes**", or "**Unknown**".
        2. Indicate if the 1st chest CT scan or other chest imaging study obtained showed evidence of "miliary" disease (e.g., "miliary" TB or "miliary or "bilateral micronodular" pattern) by checking "**No**", "**Yes**", or "**Unknown**".

    - Check "**Normal**" if the 1st chest CT scan or other chest imaging study showed no abnormalities consistent with TB and was normal.

    - Check "**Not Done**" if the 1st chest CT scan or other chest imaging study is known not to have been done.

24. Date of 2nd Chest CT Scan or Other Chest Imaging
    Indicate the date that the 2nd chest CT scan or other chest imaging study was taken during the diagnostic evaluation for tuberculosis and whether the chest CT scan or other chest imaging was "**Stable**", "**Worsening**", or "**Improving**".

    - Check "**Stable**" if the 2nd chest CT scan or other chest imaging study showed no change in any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB.
    - Check "**Worsening**" if the 2nd chest CT scan or other chest imaging study showed worsening abnormalities consistent with TB.
    - Check "**Improving**" if the 2nd chest CT scan or other chest imaging study shows improvement of abnormalities consistent with TB.

25. Date Therapy Started
    Enter the date (month, day, year) the patient began multidrug therapy for TB disease or suspected TB disease.

    This may be one of several dates:
    a. Date patient first ingested medication, if documented from a medical record, such as hospital or clinic or directly observed therapy (DOT) record; or
    b. Date medication was first dispensed to the patient, as documented by medical or pharmacy record; or
    c. Date medication was first prescribed to the patient by health care provider, as documented by medical record or by prescription given to patient.

    Date of ingestion is the preferred date for this field. If date of ingestion is not known, enter date of dispensation. If neither of those dates is known, enter date of prescription. Patient history without medical documentation is not acceptable.

    If an exact date cannot be determined based on the above guidelines, a partial date may be entered in this field. If the month and year are known, but the exact day therapy was started is not known, "99" may be entered for the 2-digit "day" of the date. For example, if after following the above guidelines, an exact Date Therapy Started cannot be determined for a patient known to have started therapy in August of 2007, enter "08/99/2007" on the form. If the month, day, and year therapy started are all unknown, enter "99/99/9999" on the form.

    Check "**Therapy Not Started**" if the patient did not begin multidrug therapy for TB disease.

26. Patient on Directly Observed Therapy
    Directly observed therapy (DOT) or supervised therapy involves the direct visual observation by a health care provider (e.g., public health nurse, outreach worker, nurse, nurse's aide) or other reliable person (e.g., designated family member or homeless shelter worker) of a patient's ingestion of medication. Delivering medication to a patient without visual confirmation of ingestion does not constitute DOT. Confirmation that the medication has been swallowed may sometimes be necessary. Using such techniques as having the patient swallow a glass of water or talk following ingestion, inspecting the oral cavity with the tongue raised by the patient, or using a tongue blade to inspect between the cheek and the gums are helpful in determining if the medication has been swallowed.

DOT regimens may be administered daily, three times a week, twice weekly, or weekly. DOT is not limited by the location in which it is given. DOT can be administered in the health department, correctional facility, long-term care facility, in the patient's home, or in the field, as long as the person administering the DOT is qualified.

- Check "**No**" if no doses of medication were given under direct supervision and visual observation of ingestion by a health care provider or other reliable person.

- Check "**Yes**" if the medications were given under direct supervision and visual observation of ingestion by a health care provider or other reliable person.

- Check "**Unknown**" if it is not known whether any doses of medication were given under supervision.

27. <u>Patient's Weight at Diagnosis</u>
    Indicate the weight of the patient at diagnosis in kilograms.

28. <u>Initial Drug Regimen and Frequency</u>
    Indicate the dosage in milligrams for each drug and the frequency that was prescribed for treatment of active TB disease. For combination drugs (e.g., Rifamate, Rifater), indicate the dosage in milligrams for each individual drug.

29. <u>HIV Status at Time of Diagnosis</u>
    CDC recommends that <u>**ALL**</u> TB cases receive HIV counseling, testing, and referral at the time of TB diagnostic evaluation or TB diagnosis.

- HIV status is "**Negative**" <u>if the patient has had a documented negative HIV test at the time of TB diagnostic evaluation or at TB diagnosis.</u> Undocumented patient history that an HIV test result was negative is not acceptable. Such patients should be offered the opportunity to be tested for HIV. In addition, if a patient has had a negative test in the past, regardless of when the HIV test was performed, the patient should be offered HIV counseling and testing at the time of TB diagnostic evaluation or TB diagnosis. If the patient had received HIV counseling and testing less than 12 months before the TB diagnostic evaluation or TB diagnosis and the documented results were negative for HIV infection, and the patient has absolutely no risk for HIV, then these HIV test results may be used for this question. The length of time prior to TB diagnosis for which a negative HIV test result may be accepted should be based on clinical judgment of patient risk, not to exceed one year.

- HIV status is "**Positive**" if one of the following is applicable:
    1. The patient is tested for HIV and the laboratory result is interpreted as positive; <u>or</u>
    2. The patient has a documented medical history of a previous positive HIV test, or a documented previous diagnosis of HIV infection or AIDS.

- HIV status is "**Refused**" if the patient was offered the test at the time of the TB diagnostic evaluation or TB diagnosis, but declined to be tested.

- HIV status is "**Indeterminate**" if the patient has had a documented indeterminate HIV test result at the time of TB diagnostic evaluation or TB diagnosis. Undocumented patient history is not acceptable.

- HIV status is "**Not Offered**" if the patient was not offered the test at the time of the TB diagnostic evaluation or TB diagnosis.

- HIV status is "**Test Done, Results Unknown**" if the patient had a HIV test at the time of the TB diagnostic evaluation or TB diagnosis and the results are not known.

- HIV status is "**Unknown**" if it is not known if the patient has had an HIV test, was ever offered a test, or was referred for HIV counseling and testing (e.g., anonymous testing center, private testing center) but it is unknown whether the HIV counseling and testing was done.

30. HIV Antibody Test Date
    Indicate the month, day, and year that the HIV antibody test was performed.

31. Excess Alcohol Use Within Past Year
    - Check "**No**" if the patient has not used alcohol to excess within the past 12 months.

    - Check "**Yes**" if the patient has used alcohol to excess within the past 12 months.

    - Check "**Unknown**" if it is not known if the patient used alcohol to excess within the past 12 months.

This information is intended to assess the ability of the patient to adhere to anti-tuberculosis drug therapy and to screen for hepatitis risks. Excessive use of alcohol within the past year should be sought as an indicator of recent activity (e.g., when did the patient last have a drink). Since the patient interview for excess alcohol use is often negative initially, it may be necessary to inquire of the patient at multiple visits. If, during the course of TB treatment, information is obtained concerning this variable, please inform the Hawaii TB Control Program.

There is no standard definition for excess alcohol use. Excess alcohol use can be assessed using different methods. Reliable indicators of excess alcohol use include participation in Alcoholics Anonymous or alcohol treatment programs (e.g., outpatient, residential or inpatient, halfway house, prison or jail treatment, or other self-help). There are also numerous screening instruments that can be helpful in identifying persons who may use alcohol to excess (e.g., CAGE, AUDIT, MAST). Other indicators include hospitalizations for alcohol-related medical conditions [e.g., delirium tremors (DT's), pancreatitis, cirrhosis].

The National Household Survey on Drug Abuse assesses alcohol use by asking quantity and frequency of use within the past month. It does not assess if a person has or had a longer history of alcohol use. "Binge alcohol use was defined as drinking five or more drinks on the same occasion (at the same time or within a couple of hours of each other) on at least 1 day in the past 30 days. A drink was defined as a can or bottle of beer, a glass of wine or a wine cooler, a shot of liquor, or a mixed drink containing alcohol. Heavy alcohol use was defined as drinking five or more drinks on the same occasion on each of 5 or more days in the past 30 days."

32. Injecting Drug Use Within Past Year
    - Check "**No**" if the patient has not injected drugs within the past 12 months.
    - Check "**Yes**" if it is known that the patient injected drugs within the past 12 months.
    - Check "**Unknown**" if it is not known if the patient injected drugs within the past 12 months.

    The purpose for collecting this information is to assess the patient's ability to adhere to anti-tuberculosis drug therapy and to screen for hepatitis risks. The intent of this question is not to require a detailed systematic interview of each patient, but to identify those patients whose drug use might interfere with their ability to complete anti-tuberculosis drug therapy. Use of medically unsupervised injecting drugs within the past year should be sought as an indicator of recent activity (e.g., when did the patient last inject drugs). If, during the course of TB treatment, information is obtained concerning this variable, please inform the Hawaii TB Control Program.

    Medical documentation or other indices of a history of enrollment in a drug treatment program (e.g., methadone detoxification, methadone maintenance, outpatient drug free, residential or inpatient, halfway house, prison or jail treatment, narcotics anonymous, cocaine anonymous, or other self-help), medical or laboratory documentation of injecting drug use (e.g., urine testing, if done), or physical evidence (e.g., needle tracks) may be useful in answering this question. Since the patient interview for injecting drug use is often negative initially, it may be necessary to inquire of the patient at multiple visits.

    Injecting drug use involves the use of hypodermic needles and syringes for injection of drugs not prescribed by a health care provider. Route of administration may be intravenous, subcutaneous (e.g., skin popping), or intramuscular. Drugs injected may include heroin or other opiates (e.g., Demerol, Dilaudid, Morphine, opium), cocaine, heroin and cocaine (e.g., speedball), methamphetamines, amphetamines or other stimulants (e.g., Ritalin), phencyclidine (e.g., PCP, Angel Dust), lysergic acid diethylamide (e.g., LSD) or other hallucinogens, barbiturates, steroids or other hormones, Fentanyl, MDMA (e.g., Ecstasy), other drugs or unknown drugs.

33. Non-Injecting Drug Use Within Past Year
    - Check "**No**" if the patient did not use non-injecting drugs within the past 12 months.
    - Check "**Yes**" if it is known that the patient used non-injecting drugs within the past 12 months.
    - Check "**Unknown**" if it is not known whether the patient used non-injecting drugs within the past 12 months.

    The purpose for collecting this information is to assess the patient's ability to adhere to anti-tuberculosis drug therapy. The intent of this question is not to require a detailed systematic interview of each patient but to identify those patients whose drug use might interfere with their ability to complete anti-tuberculosis drug therapy. Use of non-injecting drugs or illicit drugs within the past year should be sought as an indicator of recent activity (e.g., when did the patient last use non-injecting drugs). If, during the course of TB treatment, information is obtained concerning this variable, please inform the Hawaii TB Control Program.

A history of enrollment in a drug treatment program (e.g., outpatient drug free, residential or inpatient, halfway house, prison or jail treatment, cocaine anonymous, or other self-help), as well as medical or laboratory documentation of drug use (e.g., urine toxicology), may be useful in answering this question. Since the patient interview for non-injecting drug use is often negative initially, it may be necessary to inquire of the patient at multiple visits.

NOTE: Alcohol is *not* included as a drug in this question (see "Excess Alcohol Use within Past Year" - Question 32).

Non-injecting drug use involves the use of licensed or prescription drugs or illegal drugs that were not injected and were not prescribed for the patient by a health care provider. The drugs may be ingested, inhaled, sniffed, or smoked. Non-injected drugs may include: heroin or other opiates (e.g., Demerol, Percocet, Codeine, Dilaudid, MS Contin, non-prescription methadone), cocaine (e.g., snorting), crack (e.g., smoking cocaine), ingested amphetamines (e.g., speed, uppers, bennies), Xanax, Ativan, Valium or other benzodiazepams, phencyclidine (e.g., PCP), ketamine, LSD, or other hallucinogens, barbiturates, marijuana (e.g., pot, weed, grass, reefers), hashish, THC, inhalants (e.g., nitrous oxide [whippets], poppers, rush, huff, gasoline, spray paint, butane), steroids, other drugs, or unknown drugs.

34. Resident of Correctional Facility at Time of Diagnosis

NOTE: Any questions regarding classification of a specific correctional facility as federal, state, local, juvenile, or other should be referred to the Department of Corrections within the state.

- Check "**No**" if the patient was not an inmate when the TB diagnostic evaluation was performed.
- Check "**Yes**" if the patient was an inmate of a correctional facility at the time when the TB diagnostic evaluation was performed. If "**Yes**", indicate the type of facility (*select one*). If the TB patient was a resident of more than one facility when the diagnostic evaluation was performed, select the facility where the majority of the TB diagnostic evaluation was performed.
  - "**Federal Prison**" is a confinement facility administered by a federal agency. For the purpose of this question, privately operated federal correctional facilities are included in "federal prison."
  - A "**State Prison**" is a confinement facility administered by a state agency. For the purpose of this question, privately operated state correctional facilities are included in "state prison."
  - A "**Local Jail**" is a confinement facility usually administered by a local law enforcement agency, intended for adults but sometimes also containing juveniles, which holds persons detained pending adjudication and/or persons committed after adjudication for sentences of usually a year or less. Temporary holding facilities, or lockups, that do not hold persons after being formally charged in court are excluded. Both city and county jails are included in this category. Federal and state prisoners who are boarded at local jails should be reported as residents of the local jail. For the purpose of this question, privately operated local correctional facilities are included in "local jail."
  -

- A “**Juvenile Correctional Facility**” is a public or private residential facility, including juvenile detention centers, reception and diagnostic centers, ranches, camps, farms, boot camp, residential treatment centers, and halfway houses or group homes. The juveniles served by these facilities include those charged or adjudicated as delinquents; non-delinquent/non-criminal offender (e.g., runaways, truants, incorrigibles, curfew violators); and those committed or detained for treatment of abuse, dependency, neglect, or other reasons. Juveniles who are boarded at federal or state prisons or local jails should be reported as residents of the sites at which they are boarded.

- “**Unknown**” if the patient was an inmate when the TB diagnostic evaluation was performed, but the type of correctional facility is not known.

- “**Other Correctional Facility**” includes ICE Detention Centers, Indian reservation facilities (e.g., tribal jails), military stockades and jails, federal Park Police facilities, police lockups (temporary-holding facilities for persons who have not been formally charged in court), or other correctional facilities that are not included in the other choices and is not “Unknown.” Please specify type.

▪ Check “**Unknown**” if it is not known if the patient was an inmate when the TB diagnostic evaluation was performed.

35. Resident of Long-Term Care Facility at Time of Diagnosis

NOTE: The state licensing agency for long-term care facilities can assist in determining under which of these categories a facility is classified.

▪ Check “**No**” if the patient was not a resident of a long-term care facility when the TB diagnostic evaluation was performed.

▪ Check “**Yes**” if the patient was a resident of a long-term care facility at the time the TB diagnostic evaluation was performed. If “**Yes**”, indicate the type of facility (*select one*). If the TB patient was a resident of more than one facility when the diagnostic evaluation was performed, select the facility where the majority of the TB diagnostic evaluation was performed.

- **A** “**Nursing Home**” **is defined as** a freestanding facility having 3 or more beds that provides nursing care services (e.g., nursing or medical care and/or supervision over medications that may be self-administered). Facilities may be certified by Medicare or Medicaid, or not certified but licensed by the State as a nursing home (e.g., skilled nursing facility, intermediate care facility, nursing care unit of a retirement center).

- **A** “**Hospital-based Facility**” is defined as a nursing home that is a distinct unit of hospital, with 3 or more beds, that is either physically attached or, if not attached, managed by a hospital. Facilities may be certified by Medicare or Medicaid, or licensed by the State.

- **An** “**Alcohol or Drug Treatment Facility**” includes only long-term rehabilitation/residential facilities designated for treatment of 30 days or longer. *Excluded* are all ambulatory or outpatient facilities, detoxification units, and facilities designated for less than 30 days of treatment. The state alcohol and drug treatment agency can assist in

determining if a facility is considered residential. The National Survey of Substance Abuse Treatment Services (N-SSATS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) are useful references.

- **A** "**Mental Health Residential Facility**" is defined as a mental health residential facility that provides 24-hour care in a hospital or residential treatment or supportive setting. This includes state and local mental hospitals, private psychiatric hospitals, non-federal general hospitals with separate psychiatric services, Department of Veterans Affairs (VA) medical centers, residential treatment centers (RTC's) for emotionally disturbed children, and multi-service mental health organizations with residential treatment programs. *Excluded* are other federal psychiatric facilities, such as those of the Department of Defense, Bureau of Prisons, Public Health Service, and Indian Health Service. *Also excluded* are Indian reservation facilities that are not federal.

- **A** "**Residential Facility**" having 3 or more beds is classified as a residential facility (e.g., congregate residential setting) if it meets both of the following criteria: 1) was not classified as a nursing home or hospital-based facility as described above, and 2) provides personal care or supervision to its residents, not nursing care services, in addition to room and board (e.g., help with bathing, dressing, eating, walking, shopping). Included under residential facilities are assisted living facilities, homes for mentally retarded or developmentally disabled persons, board and care homes (e.g., residential care homes, group homes, homes for the aged, family care homes, adult foster care homes, personal care homes, adult congregate living facilities, residential community care facilities, domiciliary care homes).

- "**Other Long-term Care Facility**" includes facilities not mentioned above that are designated for treatment of 30 days or longer and is not "Unknown." Please specify type.

- "**Unknown**" if the patient was a resident of a long-term care facility, but the type of facility is unknown.

▪ Check "**Unknown**" if it is not known if the patient was a resident of a long-term care facility when the TB diagnostic evaluation was performed.

36. <u>Additional TB Risk Factors</u>
Indicate any additional TB risk factors that the TB patient may have (*select all that apply*). Documentation of additional TB risk factors from the medical records or a reliable source (e.g., health care provider) is preferred. Please note that other specific TB risk factors (e.g., occupation, HIV) are collected elsewhere.

▪ Check "**Diabetes Mellitus**" if the TB patient has diabetes mellitus (Type I or Type II) at the time of TB diagnosis.

▪ Check "**End-Stage Renal Disease**" (i.e., ESRD), if the TB patient has end-stage renal disease or chronic renal failure at the time of TB diagnosis.

- Check "**Incomplete LTBI Treatment**" if patient was previously identified as having latent TB infection (LTBI) and was not treated completely for LTBI. This "risk factor" is trying to capture those TB patients that could be identified as a preventable case of TB.

- Check "**None**" if no TB risk factors could be identified.

- Check "**Contact of Infectious TB Patient**" if the TB patient was a contact of an infectious TB patient. The association between the TB patients may have been found through investigation (e.g., a formal contact investigation) or identified as an incidental finding. For the purpose of this question, the contact should be recent and should <u>not</u> have occurred more than 2 years ago. This question is being asked because clinical management of the TB patient may be affected if the TB patient is a contact of a documented TB patient.

- Check "**Contact of MDR TB Patient**" if the TB patient was a contact of a multidrug resistant (MDR) TB patient, regardless of whether the MDR-TB case was infectious or not. Multi-drug resistant TB is defined as resistance to at least isoniazid and rifampin. The association between the TB patients may have been found through investigation (e.g., a formal contact investigation) or identified as an incidental finding. For the purpose of this question, the contact should be recent and should <u>not</u> have occurred more than 2 years ago. This question is being asked because clinical management of the TB patient may be affected if the TB patient is a contact of a documented MDR-TB patient.

- Check "**Missed Contact**", if <u>after</u> having been diagnosed with TB disease, this TB patient was found to have been a contact of a known TB patient. For the purpose of this question, the contact should be recent and should <u>not</u> have occurred more than 2 years ago. <u>DO NOT</u> include TB patients identified as having TB disease during a contact investigation or as a result of a contact investigation in this choice, because these patients are not "missed contacts" since they were identified during a contact investigation, despite having TB disease. This "risk factor" is trying to capture those TB patients that could be identified as a preventable case of TB.

- Check "**Other**" if the TB patient has a TB risk factor <u>not</u> included in the above choices [e.g., undernutrition (e.g., intestinal bypass surgery for obesity, gastrectomy, jejunoileal bypass, chronic malabsorption syndromes), silicosis, travel to a TB endemic country]. Additional space ("***Specify ____***") is provided to write comments regarding "Other" reasons.

- Check "**Post-Organ transplantation**" if the TB patient has a history of solid organ transplantation (e.g., renal, cardiac).

- Check "**Immunosuppression**" if the TB patient has immunosuppression due to either a medical condition or medication, such as hematological or reticuloendothelial malignancies (e.g., leukemia, Hodgkin's lymphoma, carcinoma of the head or neck), or immunosuppressive therapy, such as prolonged use of high dose adrenocorticosteroids (e.g., prednisone).

  If the TB patient has diabetes mellitus or end-stage renal disease, <u>do not check</u> "immunosuppression" unless the patient has another immunosuppressive condition. Check either "Diabetes Mellitus" and/or "End-Stage Renal Disease" for this question.

If the patient is infected with HIV, do not check "immunosuppression" for this question, unless the patient has another immunosuppressive condition. Instead, complete:

- "HIV Status at Time of Diagnosis" – Question 30
- "HIV Antibody Test Date" – Question 31

- Check "**Tumor Necrosis Factor-Alpha (TNF-α) Antagonist Therapy**" if the TB patient had recently or has been receiving tumor necrosis factor-alpha (TNF-α) antagonist therapy at the time of TB diagnosis. The Food and Drug Administration (FDA) has approved TNF-α antagonist therapy for treatment of rheumatoid arthritis and other selected autoimmune diseases. The FDA has also recently determined that TB disease is a potential adverse reaction from treatment with TNF-α antagonists. Examples of three currently FDA approved TNF-α antagonists are infliximab (Remicade®), etanercept (Enbrel®), and adalimumab (Humira®).

37. Reporting Section
    - "**Date Reported**" – Indicate the month, day, and year that the NDR form was submitted to the Hawaii TB Control Program.
    - "**Reported By**" – Indicate the name of the person who is reporting the TB patient.
    - "**Name of Institution**" – Indicate the name of the institution that the person reporting the TB patient represents.
    - "**Address**" – Indicate the street number, street name, city, state, and zip code of the institution reporting the TB patient.
    - "**Work Phone, Cell Phone, Pager, Fax, and Email Address**" – Indicate the preferred methods of corresponding with the person who reported the TB patient.

38. Hospital Admission Date
    Indicate the month, day, and year that the TB patient was admitted into the hospital, if applicable.

39. Hospital Discharge Date
    Indicate the month, day, and year that the TB patient was discharged from the hospital, if applicable.

40. Name and Phone Number of Primary Care Physician
    Indicate the name of the Primary Care Physician of the TB patient and the preferred phone number of that physician.

41. Will the Patient Be Referred to the Hawaii Department of Health for TB Care? *(This question is only applicable to non-DOH providers)*
    - Check "**Yes – For TB treatment and DOT**" if discharge plans indicate that the TB patient will receive complete follow-up care for TB treatment and DOT at a Hawaii DOH TB Clinic. Please call DOH to initiate referral.
    - Check "**Yes – For DOT only**" if discharge plans indicate that the TB patient will receive TB care from a private physician but will have DOT through the Hawaii Department of Health. Please call DOH to initiate referral.

- Check “**No**” if discharge plans indicate that the TB patient will receive all TB care from a private physician. Indicate the name of physician who will treat the patient for TB and the preferred phone number of that physician.

42. <u>Additional Notes/Remarks</u> - Space for additional notes or remarks.

43. <u>DOH USE ONLY</u>
    - CC#/MR# – Indicate the DOH TB Clinic number or DOH medical record of the TB patient.
    - TB Class – Indicate the TB classification of the TB patient.
    - TBCMD – Indicate the name of the TB Clinic Medical Doctor who is treating the TB patient.
    - Nurse Case Manager – Indicate the name of the Nurse Case Manager for the TB patient.

Hawaii State Department of Health
Tuberculosis Clinic Locations

Call one of the following locations to refer a patient for TB care:

Oahu
TB Clinic at Lanakila Health Center
1700 Lanakila Avenue, Ground Floor
Honolulu, HI 96817
Phone: (808) 832-3539

Maui, Lanai, and Molokai
Maui Public Health Nursing
54 High Street
Wailuku, HI 96793
Phone: (808) 984-2127

Kauai
Kauai Public Health Nursing
Kauai District Health Office
3040 Umi Street
Lihue, HI 96766
Phone: (808) 241-3387

East Hawaii (Big Island)
Hilo Public Health Nursing
Hilo State Office Building
75 Aupuni Street, Room 106
Hilo, HI 96720
Phone: (808) 974-6025

West Hawaii (Big Island)
Kona Public Health Nursing
Kona Health Center
79-1015 Haukapila Road
Kealakekua, HI 96750
Phone: (808) 322-1500

TB Document M:
TUBERCULOSIS CASE / SUSPECT FOLLOW-UP REPORT

Hawaii State Department of Health
Tuberculosis Control Program

FAX TO:
Hawaii Tuberculosis Control Program
ATTN: TB REGISTRY SECTION
1700 Lanakila Avenue, Honolulu, HI 96817
FAX: 808-832-5624 PHONE: 808-832-3534

Name: ______________________ (LAST) ______________________ (FIRST) ______________________ (MIDDLE INITIAL) Date of birth: ____/____/______ (MM DD YYYY)

Date last report received: ____/____/______ (MM DD YYYY) Date current report requested: ____/____/______ (MM DD YYYY)

1. Please record all TB bacteriology results since last report:

DATE COLLECTED	SPECIMEN TYPE & SITE (E.G., SPUTUM, BRONCH WASH, TISSUE, PLEURAL FLUID, ETC.)	SMEAR RESULT IF POSITIVE, ENTER SMEAR COUNT (E.G., 1+, 2+, 3+, 4+)	NUCLEIC ACID AMPLIFICATION (E.G., MTD TEST or MTB-RNA, DIRECT)	CULTURE (CONFIRMED BY DNA PROBE)	DRUG SUSCEPTIBILITY RESULTS IF CULTURE POSITIVE FOR MTB, INDICATE DRUG RESISTANCE	LAB
/ /	Type: Site:	☐ NEG ☐ POS ____ ☐ PENDING	☐ NEG ☐ POS ☐ PEND ☐ INDET	☐ PEND ☐ NEG ☐ MTB COMPLEX ☐ NOT TB (SPECIFY ID): ________	☐ PEND ☐ PAN SUSCEPTIBLE ☐ RESISTANT TO: ________	☐ DLS ☐ Clinical
/ /	Type: Site:	☐ NEG ☐ POS ____ ☐ PENDING	☐ NEG ☐ POS ☐ PEND ☐ INDET	☐ PEND ☐ NEG ☐ MTB COMPLEX ☐ NOT TB (SPECIFY ID): ________	☐ PEND ☐ PAN SUSCEPTIBLE ☐ RESISTANT TO: ________	☐ DLS ☐ Clinical
/ /	Type: Site:	☐ NEG ☐ POS ____ ☐ PENDING	☐ NEG ☐ POS ☐ PEND ☐ INDET	☐ PEND ☐ NEG ☐ MTB COMPLEX ☐ NOT TB (SPECIFY ID): ________	☐ PEND ☐ PAN SUSCEPTIBLE ☐ RESISTANT TO: ________	☐ DLS ☐ Clinical

2. Please record the TB medication regimen:

Drug:	*Dosage:*	*Times/week:*	*Start date:*	*Stop date:*
Isoniazid	_____mg	_____	____/____/______	____/____/______
Rifampin	_____mg	_____	____/____/______	____/____/______
Pyrazinamide	_____mg	_____	____/____/______	____/____/______
Ethambutol	_____mg	_____	____/____/______	____/____/______
________ (OTHER DRUG USED)	_____mg	_____	____/____/______	____/____/______
________ (OTHER DRUG USED)	_____mg	_____	____/____/______	____/____/______

☐ TB medications not started, specify reason: ______________________

3. Patient on Directly Observed Therapy (DOT):

☐ No ☐ Yes ☐ Unknown

4. If TB regimen was stopped, specify reason:

☐ Completed full course of TB treatment
☐ Adverse effects of medicine
☐ Died before completing treatment
☐ Lost to follow-up
☐ Refused to complete treatment
☐ Other reason, please specify:

5. Date of chest x-ray or other chest imaging since last report: ____/____/______

Check one: ☐ Chest x-ray ☐ CT scan ☐ Other: ______________

Check one: ☐ Abnormal ☐ Normal ☐ Not Done

If abnormal: Evidence of cavity: ☐ No ☐ Yes ☐ Unknown
Evidence of miliary TB: ☐ No ☐ Yes ☐ Unknown

If follow-up, check one: ☐ Stable ☐ Worsening ☐ Improving

6. Is the patient still under your supervision for TB?

☐ Yes
☐ No, specify reason:
☐ Completed TB treatment ☐ Delinquent
☐ Died ☐ Lost to follow-up
☐ Referred to different provider:
______________ (NAME) ______________ (PHONE)
☐ Other reason, please specify:

7. Date form completed: ____/____/______

Form completed by: ______________________

Name of physican: ______________________ **Phone:** ______________

8. Additional notes / remarks:

Diabetic: Known Pos [ ] **Known Neg [ ]** Tested, New Pos [ ] **Tested, Neg [ ]** Not tested [ ]

HIV: **Neg [ ]** Pos [ ] **Indeterminate [ ]** Refused [ ] **Not offered [ ]** Test done, results unknown [ ] **Unknown [ ]**

DOH USE ONLY
Diagnosis ____________
Date Changed ________
Reason ____________

TB Follow-up Form (Rev. 1/2016)