

INSPECTIONS AND APPEALS DEPARTMENT[481]

Adopted and Filed

Rule making related to tuberculosis (TB) screening

The Inspections and Appeals Department hereby rescinds Chapter 59, “Tuberculosis (TB) Screening,” Iowa Administrative Code, and adopts a new Chapter 59 with the same title.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 10A.104(5), 135B.7 and 135C.14.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 135B.7 and 135C.14.

Purpose and Summary

Following the adoption of the Department’s original tuberculosis screening rules in 2013, health care facilities, hospitals, and employees sought clarification regarding the applicability of the rules under a variety of circumstances, such as transfer of health care workers between facilities, testing time frames for “two-step TST” and whether health care students, such as nursing students, are included in the definition of “health care worker.” This adopted rule making rescinds Chapter 59 and adopts a new Chapter 59 that incorporates several suggestions from the Department’s stakeholders, clarifies the baseline TB screening process and what the TB risk assessment shall include, and clarifies and expands the definitions of “two-step tuberculin skin test,” “health care worker,” and “transfer” as the term relates to health care workers changing employment between health care facilities or hospitals.

The Hospital Licensing Board reviewed this rule making at its April 6, 2018, meeting.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on June 6, 2018, as **ARC 3818C**. No public comments were received. Three changes from the Notice have been made. In the definition of “Tuberculosis,” “M.” has been added to the term “canetti” to more clearly identify the species of the disease. Also, “that” has been changed to “who” in the second sentence of the definition of “TB patient” to more clearly identify that the relevant clause is referencing the person and not the type of TB. This same change has been made in 59.3(3) to clearly identify that the clause is referencing a person and not the type of TB.

Adoption of Rule Making

The rule making was initially reviewed by the State Board of Health at its May 8, 2018, meeting, and subsequently approved by the Board at its July 11, 2018, meeting. This rule making was adopted by the Department on July 11, 2018.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to 481—Chapter 6.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on September 5, 2018.

The following rule-making action is adopted:

Rescind 481—Chapter 59 and adopt the following **new** chapter in lieu thereof:

CHAPTER 59
TUBERCULOSIS (TB) SCREENING

481—59.1(135B,135C) Purpose. The intent of this chapter is to outline requirements and procedures to conduct tuberculosis screening for health care workers in health care facilities and hospitals and for residents of health care facilities regulated by the department.

481—59.2(135B,135C) Definitions. For purposes of this chapter, the following definitions apply:

“Bacille Calmette-Guérin vaccination” or *“BCG vaccination”* means a vaccine for TB. BCG vaccination is used in many countries with a high prevalence of TB to prevent childhood tuberculosis meningitis and miliary disease. BCG vaccination is not generally recommended for use in the United States because of the low risk of infection with *Mycobacterium tuberculosis*, the variable effectiveness of the vaccine against adult pulmonary TB, and the vaccine's potential interference with tuberculin skin test reactivity.

“Baseline TB screening” means the screening of health care workers (HCWs) of health care facilities or hospitals at the beginning of employment in a facility or hospital and of residents of health care facilities upon admission to a facility for latent tuberculosis infection (LTBI) and TB disease. Baseline TB screening includes a symptom screen for all HCWs and residents, and two-step tuberculin skin test (two-step TST) or single interferon-gamma release assay (IGRA) for *M. tuberculosis* for those persons with previous negative test results for *M. tuberculosis* infection.

“Baseline TST” or *“baseline IGRA”* means the two-step TST or IGRA, respectively, which is administered at the beginning of employment to newly hired HCWs or upon admission of residents to health care facilities.

“Boosting” means a phenomenon in which a person has a negative TST (i.e., false-negative) result years after infection with *M. tuberculosis* and then a positive subsequent TST result. The positive TST result is caused by a boosted immune response of previous sensitivity rather than by a new infection (false-positive TST conversion). Two-step testing reduces the likelihood of mistaking a boosted reaction for a new infection.

“Department” means the department of inspections and appeals.

“Employment” or *“employed”* means to be hired or retained for paid or unpaid work in a facility or hospital.

“Extrapulmonary TB” means TB disease in any part of the body other than the lungs (e.g., kidney, spine, or lymph nodes).

“*Health care facility*” or “*facility*” means a health care facility as defined in Iowa Code section 135C.1 or a long-term care service of a hospital as defined in rule 481—51.38(135B).

“*Health care worker*” or “*HCW*” means any paid or unpaid person (including health care students) working in a health care facility or hospital, including any person who is paid either by the health care facility or hospital or paid by any other entity (i.e., temporary agency, private duty, Medicaid/Medicare or independent contractors), or any volunteer who volunteers in a health care facility or hospital on a consistent and regularly scheduled basis for five or more hours per week. Specifically excluded from the definition of “health care worker” are individuals such as visitors, building contractors, repair workers or others who are in the facility or hospital for a very limited purpose and are not in the facility or hospital on a regular basis.

“*Hospital*” means a hospital as defined in Iowa Code section 135B.1.

“*Interferon-gamma release assay*” or “*IGRA*” means a whole-blood test that can aid in diagnosing *M. tuberculosis* infection.

“*Laryngeal TB*” means a form of TB disease that involves the larynx and may be highly infectious.

“*Latent TB infection*” or “*LTBI*” means infection with *M. tuberculosis* without symptoms or signs of disease having manifested.

“*Mantoux method*” means a skin test performed by intradermally injecting 0.1 mL of purified protein derivative (PPD) tuberculin solution into the volar or dorsal surface of the forearm.

“*Patient*” means a person admitted to a hospital.

“*Pulmonary TB*” means TB disease that occurs in the lung parenchyma, usually producing a cough that lasts greater than three weeks. Pulmonary TB is usually infectious.

“*Purified protein derivative tuberculin*” or “*PPD tuberculin*” means a material used in diagnostic tests for detecting infection with *M. tuberculosis*.

“*Resident*” means a person admitted to a health care facility or a long-term care service of a hospital as defined in rule 481—51.38(135B). For purposes of this chapter, “resident” does not include a patient admitted to a hospital.

“*Risk classification*” means the category that the infection control team, or designated other staff, determines is appropriate for the facility or hospital as a result of the TB risk assessment.

“*Serial TB screening*” means TB screening performed at regular intervals following baseline TB screening. Serial TB screening, also called annual or ongoing TB testing, consists of two components: (1) assessing for current symptoms of active TB disease, and (2) testing for the presence of infection with *M. tuberculosis* by administering either a TST or single IGRA.

“*Symptom screen*” means a procedure used during a clinical evaluation in which persons are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g., cough).

“*TB patient*” means a person who had undiagnosed infectious pulmonary or laryngeal TB while in a health care facility or hospital during the preceding year. “TB patient” does not include persons with LTBI (treated or untreated), extrapulmonary TB disease, pulmonary TB, or laryngeal TB who have met criteria for noninfectiousness.

“*TB risk assessment*” means an initial and ongoing annual evaluation of the risk for transmission of *M. tuberculosis* in a particular health care setting.

“*TB screening*” means an administrative control measure in which evaluation for LTBI and TB disease is performed through baseline and serial screening of HCWs in hospitals and health care facilities and residents of health care facilities.

“*Transfer*” means an HCW changes employment from one health care facility or hospital to another health care facility or hospital where the time frame between employment does not exceed 90 days.

“*Treatment for LTBI*” means treatment that prevents the progression of *M. tuberculosis* infection into TB disease.

“*Tuberculin skin test*” or “*TST*” means a diagnostic aid for finding *M. tuberculosis* infection. The Mantoux method is the recommended method to be used for TST.

“*Tuberculosis*” or “*TB*” means the namesake member organism of *M. tuberculosis* complex and the most common causative infectious agent of TB disease in humans. In certain instances, the species name

refers to the entire *M. tuberculosis* complex, which includes *M. bovis*, *M. african*, *M. microti*, *M. canetti*, *M. caprae*, and *M. pinnipedii*.

“*Tuberculosis disease*” or “*TB disease*” means a condition caused by infection with a member of the *M. tuberculosis* complex that has progressed to causing clinical (manifesting signs or symptoms) or subclinical (early stage of disease in which signs or symptoms are not present, but other indications of disease activity are present) illness.

“*Two-step tuberculin skin test*” or “*two-step TST*” means the procedure used for the baseline skin testing of persons who may receive serial TSTs.

481—59.3(135B,135C) TB risk assessment.

59.3(1) Annually, a health care facility or hospital shall conduct a TB risk assessment to evaluate the risk for transmission of *M. tuberculosis*, regardless of whether a person with suspected or confirmed TB disease is expected to be encountered in the facility or hospital. The TB risk assessment shall be utilized to determine the types of administrative, environmental, and respiratory protection controls needed and serves as an ongoing evaluation tool of the quality of TB infection control and for the identification of needed improvements in infection control measures.

59.3(2) The TB risk assessment shall include the number of persons with infectious TB encountered in the facility or hospital that resulted in the facility’s or hospital’s conducting a contact investigation of exposed HCWs or patients during the previous 12 months.

59.3(3) TB cases include persons who had undiagnosed infectious pulmonary or laryngeal TB while in the facility or hospital during the preceding year. This does not include persons with LTBI (treated or untreated), persons with extrapulmonary TB disease, or persons with pulmonary and laryngeal TB who have met criteria for noninfectiousness.

481—59.4(135B,135C) Health care facility or hospital risk classification. The infection control team or designated staff in a health care facility or hospital is responsible for determining the type of risk classification. The facility’s or hospital’s risk classification is used to determine frequency of serial TB screening. The facility or hospital risk classification may change due to an increase or decrease in the number of TB cases during the preceding year. The following criteria are consistent with those of the Centers for Disease Control and Prevention (CDC), TB Elimination Division, as outlined in the MMWR December 30, 2005/Vol.54/No.RR-17, “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005.”

59.4(1) Types of risk classifications.

a. “Low risk” means that a facility or hospital is one in which persons with active TB disease are not expected to be encountered and in which exposure to TB is unlikely.

b. “Medium risk” means that a facility or hospital is one in which health care workers will or might be exposed to persons with active TB disease or to clinical specimens that might contain *M. tuberculosis*.

c. “Potential ongoing transmission” means that a facility or hospital is one in which there is evidence of person-to-person transmission of *M. tuberculosis*. This classification is a temporary classification. If it is determined that this classification applies to a facility or hospital, the facility or hospital shall consult with the department of public health’s TB control program.

59.4(2) Classification criteria—low risk.

a. Inpatient settings with 200 beds or more. If a facility or hospital has fewer than six TB patients for the preceding year, the facility or hospital shall be classified as low risk.

b. Inpatient settings with fewer than 200 beds. If a facility or hospital has fewer than three TB patients for the preceding year, the facility or hospital shall be classified as low risk.

59.4(3) Classification criteria—medium risk.

a. Inpatient settings with 200 beds or more. If a facility or hospital has six or more TB patients for the preceding year, the facility or hospital shall be classified as medium risk.

b. Inpatient settings with fewer than 200 beds. If a facility or hospital has three or more TB patients for the preceding year, the facility or hospital shall be classified as medium risk.

59.4(4) Classification criteria—potential ongoing transmission. If evidence of ongoing *M. tuberculosis* transmission exists at a facility or hospital, the facility or hospital shall be classified as potential ongoing transmission, regardless of the facility's or hospital's previous classification.

481—59.5(135B,135C) Baseline TB screening procedures for health care facilities and hospitals.

59.5(1) All HCWs shall receive baseline TB screening upon employment. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease and (2) testing using the two-step TST procedure or a single IGRA to screen for infection with *M. tuberculosis*. If the first-step TST result is negative, the second stage of the two-step TST is recommended one to three weeks after the first TST result was read. Administration of the second stage of the two-step TST shall not exceed 12 months after the first TST result was read. If initiation of the second stage of the two-step TST is greater than 12 months from when the first TST result was read, the two-step procedure must be restarted. If the first-step TST result is positive, it is not necessary to perform the second stage of the two-step TST.

59.5(2) An HCW may begin working with patients or residents after a negative TB symptom screen (i.e., no symptoms of active TB disease) and a negative TST (i.e., first step) or negative IGRA. The second TST may be performed after the HCW starts working with patients or residents.

59.5(3) An HCW with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not needed unless signs or symptoms of TB disease develop or unless a repeat radiograph is recommended by a clinician. Treatment for LTBI should be considered in accordance with CDC guidelines.

59.5(4) An HCW with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, does not need another chest radiograph at the time of hire.

59.5(5) TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for HCWs with a documented history of TB disease, documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. A TB symptom screen and documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result. All other HCWs should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

59.5(6) Previous BCG vaccination is not a contraindication to having an IGRA, a TST or a two-step skin testing administered. HCWs with previous BCG vaccination should receive baseline and serial testing in the same manner as those without BCG vaccination. Evaluation of TST reactions in persons BCG-vaccinated should be interpreted using the same criteria for those not BCG-vaccinated. An HCW's history of BCG vaccination should be disregarded when administering and interpreting TST results. Prior BCG vaccination does not cause a false-positive IGRA test result.

481—59.6(135B,135C) Serial TB screening procedures for health care facilities and hospitals.

59.6(1) Health care facilities or hospitals classified as low risk. After establishing baseline TB screening of HCWs, serial TB screening of HCWs is not necessary for health care facilities or hospitals classified as low risk.

59.6(2) Health care facilities or hospitals classified as medium risk.

a. After establishing baseline TB screening, HCWs in health care facilities or hospitals classified as medium risk shall receive serial TB screening annually. However, an HCW with a previous positive TB test result shall only receive annual TB symptom screening in accordance with 59.5(5).

b. An HCW with a baseline positive or new positive test result for *M. tuberculosis* infection or documentation of previous treatment for LTBI or TB disease shall receive one chest radiograph result to exclude TB disease. Instead of participating in serial testing, HCWs should receive a symptom screen annually. This screen should be accomplished by educating HCWs about symptoms of TB disease and

instructing HCWs to report any such symptoms immediately to the occupational health unit. Treatment for LTBI should be considered in accordance with CDC guidelines.

59.6(3) *Health care facilities or hospitals classified as potential ongoing transmission.* HCWs in facilities or hospitals classified as potential ongoing transmission shall receive serial TB screening every eight to ten weeks until lapses in infection control have been corrected and no additional evidence of ongoing transmission is apparent. However, an HCW with a previous positive TB test result shall only receive TB symptom screening in accordance with 59.5(5). The potential ongoing transmission classification should be used only as a temporary classification. This classification warrants immediate investigation and corrective steps. After a determination that ongoing transmission has ceased, the setting shall be reclassified as medium risk for a minimum of one year.

481—59.7(135B,135C) Screening of HCWs who transfer to other health care facilities or hospitals.

59.7(1) *HCWs transferring from a low-risk health care facility or hospital to another low-risk health care facility or hospital.* HCWs with documentation of baseline TB screening who are transferring from a low-risk health care facility or hospital to another low-risk health care facility or hospital do not need to repeat baseline TB screening if the time frame between employment from one facility or hospital to another does not exceed 90 days. If the time frame between employment from one facility or hospital to another exceeds 90 days, baseline TB screening shall be restarted for an HCW with a previous negative test result and a TB symptom screen shall be performed for an HCW with a previous positive TB test result in accordance with 59.5(5).

59.7(2) *HCWs transferring from a low-risk health care facility or hospital to a medium-risk health care facility or hospital.* HCWs with documentation of baseline TB screening who are transferring from a low-risk health care facility or hospital to a medium-risk health care facility or hospital do not need to repeat baseline TB screening if the time frame between employment from one facility or hospital to another does not exceed 90 days. If the time frame between employment from one facility or hospital to another exceeds 90 days, baseline TB screening shall be restarted for an HCW with a previous negative test result and a TB symptom screen shall be performed for an HCW with a previous positive TB test result in accordance with 59.5(5).

59.7(3) *HCWs transferring from a low- or medium-risk health care facility or hospital to a health care facility or hospital classified as potential ongoing transmission.* HCWs with documentation of baseline TB screening who are transferring to a potential ongoing risk health care facility or hospital do not need to repeat baseline TB screening if the time frame between employment from one facility to another does not exceed 90 days. If the time frame between employment from one facility or hospital to another exceeds 90 days, baseline TB screening shall be restarted for an HCW with a previous negative test result and a TB symptom screen shall be performed for an HCW with a previous positive TB test result in accordance with 59.5(5).

59.7(4) *HCWs transferring from a medium-risk health care facility or hospital to a low-risk health care facility or hospital.*

a. An HCW who is transferring from a medium-risk health care facility or hospital to a low-risk health care facility or hospital and whose previous TB test result was negative shall receive a symptom screen and a single TST or IGRA upon employment if the time frame between employment from one facility to another does not exceed 90 days. If the time frame between employment from one facility or hospital to another exceeds 90 days, baseline TB screening shall be restarted.

b. An HCW who is transferring from a medium-risk health care facility or hospital to a low-risk health care facility or hospital and whose previous TB test result was positive shall receive a symptom screen upon employment in accordance with 59.5(5).

59.7(5) *HCWs transferring from a health care facility or hospital classified as potential ongoing transmission to a low- or medium-risk health care facility or hospital.*

a. An HCW who is transferring from a health care facility or hospital classified as potential ongoing transmission to a low- or medium-risk health care facility or hospital and whose previous TB test result was negative shall receive a symptom screen and a single TST or IGRA upon employment if the time frame between employment from one facility to another does not exceed 90 days. If the

time frame between employment from one facility or hospital to another exceeds 90 days, baseline TB screening shall be restarted.

b. An HCW who is transferring from a health care facility or hospital classified as potential ongoing transmission to a low- or medium-risk health care facility or hospital and whose previous TB test result was positive shall receive a symptom screen upon employment in accordance with 59.5(5).

481—59.8(135B,135C) Baseline TB screening procedures for residents of health care facilities.

59.8(1) Baseline TB screening is a formal procedure to evaluate residents for LTBI and TB disease. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease, and (2) using the two-step TST procedure or a single IGRA to screen for infection with *M. tuberculosis*. If the first-step TST result is negative, the second stage of the two-step TST is recommended one to three weeks after the first TST result was read. Administration of the second stage of the two-step TST shall not exceed 12 months after the first TST result was read. If the second stage of the two-step TST is greater than 12 months from when the first TST result was read, the two-step procedure must be restarted. If the first-step TST result is positive, it is not necessary to perform the second stage of the two-step TST.

59.8(2) All residents shall be assessed for current symptoms of active TB disease upon admission. Within 72 hours of a resident's admission, baseline TB screening for infection shall be initiated unless baseline TB screening occurred within 90 days prior to the resident's admission.

59.8(3) A resident with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not needed unless signs or symptoms of TB disease develop or unless a repeat radiograph is recommended by a clinician.

59.8(4) Residents with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, do not need another chest radiograph at the time of admission.

59.8(5) TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for residents with a documented history of TB disease, documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result, including the concentration of cytokine measured (e.g., IFN-g). All other residents should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

481—59.9(135B,135C) Serial TB screening procedures for residents of health care facilities. After baseline TB screening is accomplished, serial TB screening of residents is not recommended.

481—59.10(135B,135C) Performance of screening and testing. Any nurse licensed in Iowa and properly trained to screen for TB and perform TB testing may screen for TB and perform TB testing.

These rules are intended to implement Iowa Code sections 135B.7 and 135C.14.

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