- A. 21 CFR Part 110 Statement
- B. FDA Food Code 2009
- C. FDA Food Code -2013
- D. HIPPA Laws
- E. Americans with Disabilities law

21 CFR Part 110

Sec. 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a)Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

#### §117.10 Personnel.

The management of the establishment must take reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (*e.g.*, by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

#### FOOD CODE 2009

#### 2-2 Employee Health

#### **Overall goals**

The purpose of this section of the Food Code is to reduce the likelihood that certain viral and bacterial agents will be transmitted from infected food workers into food. The agents of concern are known to be readily transmissible via food that has been contaminated by ill food workers, and so for that reason, are the primary focus of the Employee Health section of the Food Code. However, there are different levels of risk associated with different levels of clinical illness. The structure of the restrictions and exclusions has, therefore, been designed in a tiered fashion depending on the clinical situation to offer the maximum protection to public health with the minimal disruption to employees and employers.

Four levels of illness or potential illness have been identified with the first level being the highest potential risk to public health and the fourth level being the lowest. The first level relates to employees who have specific symptoms (e.g., vomiting, diarrhea, jaundice) while in the workplace. These symptoms are known to be associated commonly with the agents most likely to be transmitted from infected food workers through contamination of food. The first level also relates to employees who have been diagnosed with typhoid fever or an infection with hepatitis A virus (within 14 days of symptoms). The second level relates to employees who have been diagnosed with the specific agents that are of concern, but who are not exhibiting symptoms of disease because their symptoms have resolved. The third level relates to employees who are diagnosed with the specific agents, but never develop any gastrointestinal symptoms. The fourth level relates to those individuals who are clinically well but who may have been exposed to a listed pathogen and are within the normal incubation period of disease.

The most significant degree of restriction and exclusion applies to the first level of food employee illness. Infected food employees in the first level are likely to be excreting high levels of their infectious pathogen, increasing the chance of transmission to food products, and thus on to those consuming the food. The first level includes food employees who are:

- Experiencing active symptoms of diarrhea or vomiting with no diagnosis,
- Experiencing jaundice within the last 7 days-- with no diagnosis,
- Diagnosed with typhoid fever,
- Diagnosed with hepatitis A within 7 days of jaundice or 14 days of any symptoms, or
- Experiencing active symptoms of diarrhea or vomiting, and diagnosed with Norovirus, *E. coli* O157:H7 or other Enterohemorrhagic *Escherichia coli* (EHEC) or Shiga toxin-producing *Escherichia coli* (STEC), or *Shigella* spp. infection.

Diagnosis with typhoid fever or hepatitis A virus is included in level 1 because employees diagnosed with these pathogens are likely to be shedding high levels of the pathogen in their stool without exhibiting gastrointestinal symptoms. Peak levels of hepatitis A viral shedding in

the feces typically occurs before symptoms appear. Diarrhea and vomiting are reliable indicators of infection with Norovirus, *E. coli* O157:H7 or other EHEC, and *Shigella* spp., but are not typical symptoms of typhoid fever or hepatitis A. For example, employees diagnosed with typhoid fever are more likely to experience constipation, rather than diarrhea. Jaundice is also not always reliable as an indicator of a hepatitis A infection because employees can be infected with hepatitis A virus without experiencing jaundice (anicteric employees).

Maximum protection to public health requires excluding food employees suffering from typhoid fever, hepatitis A virus, or specific gastrointestinal symptoms associated with diseases identified as likely to be transmitted through contamination of food (See section 2-201.12, Tables 2-201.12 #1a and #1b in this Annex). This situation describes the highest level of risk in transmitting pathogens to food, or what we would find in the first level.

Food employees who have been diagnosed with one of the agents of concern, but are not symptomatic because their symptoms have resolved, are still likely to be carrying the infected agent in their intestinal tract. This makes such employees less likely to spread the agent into food than others who are actually symptomatic, but employees diagnosed with one of the agents of concern still pose an elevated threat to public health. For this reason, there are a series of exclusions (if the employees work in facilities serving highly susceptible populations (HSP)) and restrictions (for non-HSP facilities) depending on the agent involved (See section 2-201.12, Table #2). This situation describes the second level of risk in transmitting pathogens to food.

Diagnosed, asymptomatic food employees who never develop symptoms are typically identified during a foodborne illness outbreak investigation through microbiological testing. If infected and asymptomatic employees are not microbiologically tested, they will remain undetected and could therefore extend the duration of a foodborne illness outbreak through continued contamination of food. The Food Code provides restriction or exclusion guidelines for employees that are identified through microbiological testing with an infection from a listed foodborne pathogen, but are otherwise asymptomatic and clinically well (See section 2-201.12, Table #3). The exclusion or restriction guidelines are applied until the identified food employees no longer present a risk for foodborne pathogen transmission. This situation describes the third level of risk in transmitting pathogens to food.

Some food employees or conditional employees may report a possible exposure to an agent. For example, a food employee may have attended a function at which the food employee ate food that was associated with an outbreak of shigellosis, but the employee remains well. Such individuals fall into the category of having had a potential exposure and present a lower risk to public health than someone who is either symptomatic or who has a definitive diagnosis. They present a level of risk to public health that is greater than if they had not had the exposure. The approach taken in the Food Code to food employees who have had a potential exposure is based on the incubation times (time between exposure and the onset of symptoms) of the various agents. The times chosen for restriction are the upper end of the average incubation periods for the specific agents. The reasoning is that this will restrict food employees only up to the time when it is unlikely they will develop symptoms. As a further protection to public health, it is recommended that such exposed food employees pay particular attention to personal hygiene and

report the onset of any symptoms (See section 2-201.12, Table #4). This situation describes the fourth level of risk in transmitting pathogens to food.

This structured approach has linked the degree of exclusion and restriction to the degree of risk that an infected food worker will transmit an agent of concern into food. The approach strikes a balance between protecting public health and the needs of the food employee and employer.

The Food Code provisions related to employee health are aimed at removing highly infectious food employees from the work place. They were developed with recognition of the characteristics of the five important pathogens, and of the risk of disease transmission associated with symptomatic and asymptomatic shedders. The provisions also account for the increased risk associated with serving food to HSP's and the need to provide extra protection to those populations.

The Employee Health section was developed and revised with assistance and input from the Centers for Disease Control and Prevention (CDC) and the U.S. Equal Employment Opportunity Commission (EEOC). The exclusion and restriction criteria are based on communicable disease information, as required by the Americans with Disabilities Act of 1990, in the list of infectious and communicable "Diseases Which are Transmitted through the Food Supply" (also available in PDF, 48 kB), published in the Federal Register on November 17, 2008, (Volume 73, Number 222) by the CDC, and from the Control of Communicable Diseases Manual, 18th Ed., David L. Heymann, MD, Editor, by the American Public Health Association, Washington D.C., 2004.

#### 2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201

The information provided in Subpart 2-201 is designed to assist food establishment managers and regulatory officials in removing infected food employees when they are at greatest risk of transmitting foodborne pathogens to food. Practical applications of the information in Subpart 2-201 by a food establishment manager may involve using Subpart 2-201 as a basis for obtaining information on the health status of food employees and can also be used as a basis in developing and implementing an effective Employee Health Policy. Regulatory officials can benefit by using the information provided below as a basis for determining compliance with Subpart 2-201 during a facility food safety inspection.

The development and effective implementation of an employee health policy based on the provisions in Subpart 2-201 may help to prevent foodborne illness associated with contamination of food by ill or infected food employees. The person in charge and food employees should be familiar with and able to provide the following information through direct dialogue or other means when interviewed by facility managers or regulatory officials. Compliance must be based, however, on first hand observations or information and cannot be based solely on responses from the person in charge to questions regarding hypothetical situations or knowledge of the Food Code. Also, when designing and implementing an employee health policy, the following information should be considered and addressed:

- 1. Does the establishment have an Employee Health Policy? If so, are the food employees aware of the employee health policy, and is it available in written format and readily available for food employees? (Note: A written Employee Health Policy is not a Food Code requirement unless the facility is operating under a pre-approved alternative procedure specified under ¶ 3-301.11(D)).
- 2. Does the establishment require conditional employees and food employees to report certain illnesses, conditions, symptoms, and exposures?
- 3. Are the reporting requirements explained to all employees?
- 4. What are the reporting requirements for conditional employees, food employees, and the food establishment manager?
- 5. Are conditional employees asked if they are experiencing certain symptoms or illnesses upon offer of employment? If so, which symptoms or illnesses?
- 6. If a food employee reports a diagnosis with one of the 5 listed pathogens in the Food Code, what questions are asked of the food employee? (The first question every food manager should ask a food employee who reports diagnosis with a listed pathogen is if the employee is currently having any symptoms.)
- 7. Who does the establishment notify when a food employee reports a diagnosis with one of the listed pathogens?
- 8. What gastrointestinal symptoms would require exclusion of a food employee from the food establishment?
- 9. What history of exposure is a conditional employee or food employee required to report?
- 10. If a food employee reports a gastrointestinal symptom, what criteria are used to allow the employee to return to work?

### **Responsibilities Symptoms and Diagnosis**

# 2-201.11 Responsibility of the Person in Charge, Food Employees, and Conditional Employees.

Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. The person in charge is responsible for ensuring all food employees and conditional employees are knowledgeable and understand their responsibility to report listed symptoms, diagnosis with an illness from a listed pathogen, or exposure to a listed pathogen to the person in charge. The person in charge is also responsible for reporting to the regulatory official if a food employee reports a diagnosis with a listed pathogen.

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or has a history of exposure to a listed pathogen in this Code may transmit disease through the food being prepared. The person in charge must first be aware that a food employee or conditional employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

The person in charge may observe some of the symptoms that must be reported. However, food employees and conditional employees share a responsibility for preventing foodborne illness and

are obligated to inform the person in charge if they are suffering from any of the listed symptoms, have a history of exposure to one of the listed pathogens, or have been diagnosed with an illness caused by a listed pathogen. Food employees must comply with restrictions or exclusions imposed upon them.

A conditional employee is a potential food employee to whom a job offer has been made, conditional on responses to subsequent medical questions or examinations. A conditional employee becomes a food employee as soon as the employee begins working, even if only on a restricted basis. When a conditional employee reports a listed diagnosis or symptom, the person in charge is responsible for ensuring that the conditional employee is prohibited from becoming a food employee until the criteria for reinstatement of an exclusion are met (as specified under section 2-201.13 of the Food Code). When a symptomatic or diagnosed conditional employee has met the same criteria for reinstatement that apply to an excluded symptomatic or diagnosed food employee (as specified under section 2-201.13 of the Food Code), the conditional employee may then begin working as a food employee.

#### **Reporting Symptoms:**

In order to protect the health of consumers and employees, information concerning the health status of conditional employees and food employees must be disclosed to the person in charge. The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. A food employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness.

<u>The symptoms of vomiting, diarrhea, or jaundice</u> serve as an indication that an individual may be infected with a fecal-oral route pathogen, and is likely to be excreting high levels of the infectious agent. When a food employee is shedding extremely high numbers of a pathogen through the stool or vomitus, there is greater chance of transmitting the pathogen to food products.

Sore throat with fever serves as an indication that the individual may be infected with *Streptococcus pyogenes. Streptococcus pyogenes* causes a common infection otherwise known as "streptococcal sore throat" or "strep throat." Streptococcal sore throat can spread from contaminated hands to food, which has been the source of explosive streptococcal sore throat outbreaks. Previous foodborne episodes with streptococcus sore throat have occurred in contaminated milk and egg products. Food products can be contaminated by infected food workers hands or from nasal discharges. Untreated individuals in uncomplicated cases can be communicable for 10-21 days, and untreated individuals with purulent discharges may be communicable for weeks or months.

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing *Staphylococcus aureus* into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but an impermeable bandage is not considered necessary for food safety purposes. Food employees should be aware that hands and fingers that contact pustular lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for introducing *Staphylococcus aureus* into food.

If a food employee has an infected cut and bandages it and puts on a glove, the employee does not have to report the infected cut to the person in charge. However, if the employee does not bandage it, reporting is required.

### Title I of the Americans with Disabilities Act of 1990 (ADA)

Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the permit holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant's health status.

The ADA also requires that employers provide reasonable accommodation to qualified applicants and employees with disabilities. A reasonable accommodation is a change in the application process, in the way a job is done, or to other parts of the job that enables a person with a disability to have equal employment opportunities. ADA disabilities are serious, long-term conditions. Most people with diseases resulting from the pathogens listed in the Food Code do not have ADA disabilities because these diseases are usually short-term in duration. In addition, the gastrointestinal symptoms listed in the Food Code usually are not long-term and severe enough, in themselves, to be ADA disabilities. Of course, these symptoms may be linked to other conditions that may be serious enough to be ADA disabilities, like Crohn's disease or cancer.

A food employer may exclude any employee under the Food Code upon initially learning that the employee has *Salmonella* Typhi, or has a gastrointestinal symptom listed in the Food Code. The excluded employee may then ask for an ADA reasonable accommodation instead of the exclusion. In response, the employer's first step should be to ask the employee to establish that the employee is disabled by the disease or symptom (or that the symptom is caused by another ADA disability). If the employee successfully proves that the employee has an ADA disability, then the employer may continue to exclude the employee under the Food Code if:

- there is no reasonable accommodation at work that would eliminate the risk of transmitting the disease while also allowing the employee to work in a food handling position, or
- all reasonable accommodations would pose an undue hardship on the employer's business; and
- there is no vacant position **not involving food handling** for which the employee is qualified and to which the employee can be reassigned.

Example 1: A food employee working in the café of a department store informs the employer that the employee has been diagnosed with a disease caused by *Salmonella* Typhi. The employee immediately excludes the employee under the requirements of the Food Code. The employee then establishes that the disease is an ADA disability because it is severe and long-term and the employee requests reasonable accommodation instead of an exclusion. The employer determines that no reasonable accommodation would eliminate the risk of transmitting *Salmonella* Typhi through food and refuses to remove the exclusion. However, there is a vacant clerical position in another part of the store for which the employee is qualified. Unless the employer can establish that reassigning the employee to this position would be an undue hardship, the employer's failure to make the reassignment instead of continuing the exclusion would be a violation of the ADA.<sup>[1]</sup>

<sup>[1]</sup> Whether or not the employee in question is an individual with an ADA disability, in those jurisdictions where the Code is adopted, Food Code exclusions or restrictions must be removed when requirements for removal under § 2-201.13 of the Code are met.

<u>Example 2</u>: A food employee has diarrhea and is excluded. The employee establishes that the diarrhea is caused by Crohn's disease. This employee also establishes a serious longstanding history of Crohn's disease and is an individual with an ADA disability. Crohn's disease is not a communicable disease and cannot be transmitted through food. No reasonable accommodation is needed to eliminate the risk of transmitting the disease through the food supply, so the Food Code exclusion should be removed. Of course, the Food Code's provisions on personal cleanliness for hands and arms apply as usual, requiring employees to clean hands and exposed portions of arms after using the toilet room and in other specified circumstances (Subpart 2-301).

Somewhat different rules apply to conditional employees. If a conditional employee reports a disease or symptom listed in the Food Code and shows that the disease or symptom makes the conditional employee an individual with an ADA disability, the employer may withdraw the job offer only if:

- The job involves food handling; and
- The employer determines that either there is no reasonable accommodation that would eliminate the risk of transmitting the disease through food, or any such accommodation would be an undue hardship to the business.
- There is no need to offer the conditional employee a vacant position not involving food handling as a reasonable accommodation.

It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in Annex 2 that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission. For detailed information about the interaction between the FDA Food Code and the ADA, see the Equal Employment Opportunity Commission's *How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers*, or Summary How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other <u>Food Service Employers</u> for detailed information about the interaction between the FDA Food Code and the ADA.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease that can be transmitted through food. It is the responsibility of the permit holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness. Applicants, to whom a conditional offer of employment is extended, and food employees are required to report their specific history of exposure, medical symptoms, and previous illnesses. The symptoms listed may be indicative of a disease that is transmitted through the food supply by infected food employees.

As required by the ADA, the CDC published in the Federal Register November 17, 2008, (Volume 73, Number 222) a list of infectious and communicable diseases that are transmitted through food. The CDC updates the list annually. See "List of Infectious and Communicable Diseases which are Transmitted through the Food Supply". The list is divided into two parts: pathogens often transmitted and pathogens occasionally transmitted by infected persons who handle food.

The following Lists summarize the CDC list by comparing the common symptoms of each pathogen. Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. The CDC has no evidence that the HIV virus is transmissible via food. Therefore, a food employee positive for the HIV virus is not of concern unless suffering secondary illness listed below. The following Lists include all enterohemorrhagic or Shiga toxin-producing *E. coli* likely to occur in foods in the United States.

#### LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens.

	D	F	$\mathbf{V}$	J	S
1. Noroviruses	D	F	V		
2. Hepatitis A virus	-	F	-	J	-
3. SalmonellaTyphi	-	F	-	-	-
4. Shigella species	D	F	V	-	-
5. Staphylococcus aureus	D	-	V	-	-
6. Streptococcus pyogenes	-	F	-	-	S

#### LIST II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons Who Handle Food, But Usually Transmitted by Contamination at the Source or in Food Processing or by Non-foodborne Routes.

	D	F	$\mathbf{V}$	J	S
1. Campylobacter jejuni	D	F	V	-	-
2. Cryptosporidium parvum	D	-	-	-	-
3. Entamoeba histolytica	D	F	-	-	-
4. Enterohemorrhagic <i>Escherichia coli</i>	D	-	-	-	-
5. Enterotoxigenic Escherichia coli	D	-	V	-	-
6. Giardia lamblia	D	-	-	-	-
7. Non-typhoidal <i>Salmonella</i>	D	F	V	-	-
8. Taenia solium	-	-	-	-	-
9. Vibrio cholerae 01	D	-	V	-	-
10. Yersinia enterocolitica	D	F	V	-	-
KEY: D = Diarrhea					
V = Vomiting					
S = Sore throat with fever					

F = Fever

J = Jaundice

#### The 5 Listed Pathogens:

The CDC has designated the 5 organisms listed in the Food Code as having high infectivity via contamination of food by infected food employees. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and/ or the severity of the medical consequences to those who become ill.

The following is taken from information provided in the 18<sup>th</sup> Edition of Control of Communicable Diseases Manual, the CDC website, and the FDA Bad Bug Book, and is provided as background information on pathogen virulence, infectivity, and common symptoms exhibited with infection of each of the 5 listed pathogens.

#### NOROVIRUS

Noroviruses (genus Norovirus, family Caliciviridae) are a group of small (27-40nm), round structured, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in

humans. Norovirus has also been commonly known as "Norwalk-like virus," "Small Roundstructured Virus," and "Winter Vomiting Disease."

The CDC estimates that Norovirus is the leading cause of foodborne illness in the United States. Transmission of Norovirus has been shown to occur most commonly through the fecal oral route, with contaminated food identified as a common vehicle of transmission. Exclusion of food employees exhibiting or reporting diarrhea symptoms is an essential intervention in controlling the transmission of Norovirus from infected food employees' hands to RTE food items. Norovirus also has a high secondary attack rate (> 50%) via person-to-person contact.

Norovirus has also been reported to cause infection by airborne transmission when individuals are in close physical proximity to an infected individual vomiting in the facility. Therefore an infected individual vomiting in a food facility increases the risk of infecting employees and consumers. Foodborne illness outbreaks have occurred from consumers vomiting in the dining room, or employees vomiting on the premises. Removing food employees exhibiting or reporting vomiting symptoms from the food facility protects consumers and fellow workers from infection with Norovirus.

**Incubation Period:** Generally between 24 and 48 hours (median in outbreaks 33 to 36 hours), but cases can occur within 12 hours of exposure.

**Symptoms and Complications**: Acute-onset explosive (or projectile) vomiting, watery nonbloody diarrhea with abdominal cramps, nausea, and occasionally, a low grade fever. Symptoms usually last 24 to 60 hours. Vomiting is more common in children. Recovery is usually complete and there is no evidence of any serious long-term sequelae. Among the young and the elderly, dehydration is a common complication. There is no long-term immunity to Norovirus and individuals may be repeatedly infected throughout their lifetimes. There is no specific therapy for viral gastroenteritis. Symptomatic therapy consists of replacement of fluid loss by the administration of liquids orally, and in rare instances, through parenteral intravenous fluid therapy. Earlier feeding studies conducted on Norovirus have found that as many as 30% of individuals infected with Norovirus are asymptomatic.

**Infectivity:** Noroviruses are highly contagious, and it is thought that an inoculum of as few as 10 viral particles may be sufficient to infect an individual. Although pre-symptomatic shedding may occur, shedding usually begins with onset of symptoms and may continue for 2 weeks after recovery. However the degree of infectivity of prolonged shedding has not been determined. Norovirus is shed at high levels in the stool:  $10^5 - 10^7/g$  or more.

### SALMONELLA Typhi

*Salmonella enterica* subspecies *enterica* serovar Typhi (commonly *S*. Typhi) causes a systemic bacterial disease, with humans as the only host. This disease is relatively rare in the United States, with fewer than 500 sporadic cases occurring annually in the U.S. Worldwide, the annual estimated incidence of Typhoid fever is about 17 million cases with approximately 600,000 deaths. Currently, most cases of *S*. **Typhi** in industrialized nations are imported into the country

from developing countries. Antibiotic-resistant strains have become prevalent in several areas of the world.

**Incubation period:** Depends on inoculum size and on host factors: from 3 days to over 60 days, with a usual range of 8-14 days.

**Symptoms:** Insidious onset of sustained fever, marked headache, malaise, anorexia, relative bradycardia, splenomegaly, and nonproductive cough in the early stage of the illness, rose spots on the trunk in 25% of white skinned patients and constipation more often than diarrhea in adults. The illness varies from mild illness with low-grade fever to severe clinical disease with abdominal discomfort and multiple complications.

**Infectivity:** The minimal infectious dose is estimated to be less than 1000 bacterial cells. An individual infected with *S*. **Typhi** is infectious as long as the bacilli appear in the excreta, usually from the first week throughout the convalescence; variable thereafter. About 10% of untreated typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%-5% become permanent carriers; fewer persons affected with paratyphoid organisms may become permanent gallbladder carriers.

### Enterohemorrhagic or Shiga Toxin-Producing Escherichia Coli

*E. coli* O157:H7 is the most commonly identified strain of Enterohemorrhagic *Escherichia coli* (EHEC) or Shiga toxin-producing *Escherichia coli* (STEC) as a cause of foodborne illness in the United States. *E. coli* O157:H7 is a zoonotic disease derived from cattle and other ruminants. However, *E. coli* O157:H7 also readily transmits from person-to-person, so contaminated raw ingredients and ill food employees both can be sources of foodborne disease. Other EHEC or STEC serotypes have been identified as a source of foodborne illness in the United States, however not as frequently as *E. coli* O157:H7. The other serogroups most commonly implicated as a cause of foodborne illness in the United States are 026, 0111, 0103, 045, and 0121.

The Food Code definition of STEC covers all *E. coli* identified in clinical laboratories that produce Shiga toxins. Nearly 200 O:H combinations of *E. coli* have been shown to produce Shiga toxins. The Food Code definition includes all STEC, including those that have not been specifically implicated in human disease such as hemorrhagic colitis (i.e., bloody diarrhea) or hemolytic uremic syndrome (HUS). A subset of STEC that has the capacity to both produce Shiga toxin and cause "attaching and effacing" lesions in the intestine is classified as "enterohemorrhagic" (EHEC). EHEC *E. coli* cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. Infections with EHEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Virtually all human isolates of *E. coli* O157:H7 seotypes are EHEC.

**Incubation period:** From 2-10 days, with a median of 3-4 days.

**Symptoms:** The illness is characterized by severe cramping (abdominal pain) and diarrhea with a range from mild and nonbloody to stools that are virtually all blood. Occasionally vomiting

occurs. Some individuals exhibit watery diarrhea only. Lack of fever in most patients can help to differentiate this infection from other enteric pathogens. About 8% of individuals with *E. coli* O157:H7 diarrhea progress to HUS. This rate varies for other serotypes of Enterohemorrhagic *E. coli*.

**Infectivity:** The infectious dose is for example *E. coli* O157:H7 can be as low as 10 bacterial cells. Children under 5 years old are most frequently diagnosed with infection and are at greatest risk of developing HUS. The elderly also experience a greater risk of complications. The duration of excretion of Enterohemorrhagic *E. coli* in the stool is typically 1 week or less in adults, but can be up to 3 weeks in one-third of infected children.

### SHIGELLA SPP.

Causes an acute bacterial disease, known as shigellosis, and primarily occurs in humans, but also occurs in other primates such as monkeys and chimpanzees. An estimated 300,000 cases of shigellosis occur annually in the U.S. *Shigella* spp. consist of 4 species or serogroups, including *S. flexneri*, *S. boydii*, *S. sonnei*, and *S. dysenteriae*; which all differ in geographical distribution and pathogenicity. *Shigella* spp. are highly infectious and highly virulent. Outbreaks occur in overcrowding conditions, where personal hygiene is poor, including in institutions, such as prisons, mental hospitals, day care centers, and refugee camps, and also among men who have sex with men. Water and RTE foods contaminated by feces, frequently from food workers' hands, are common causes of disease transmission. Multidrug-resistant *Shigella* (including *S. dysenteriae* 1) have appeared worldwide. Concern over increasing antimicrobial resistance has led to reduced use of antimicrobial therapy in treating shigellosis.

**Incubation period:** Usually 1-3 days, but ranges from 12 to 96 hours, and up to 1 week for *S. dysenteriae* 1.

**Symptoms and Complications**: Abdominal pain, diarrhea, fever, nausea, and sometimes vomiting, tenesmus, toxaemia, and cramps. The stools typically contain blood, pus, or mucus resulting from mucosal ulcerations. The illness is usually self-limited, with an average duration of 4-7 days. Infections are also associated with rectal bleeding, drastic dehydration, and convulsions in young children. The fatality rate for *Shigella dysenteriae* 1 may be as high as 20% among hospitalized cases. Other complications can also occur, such as Reiter's disease, reactive arthritis, intestinal perforation, and hemolytic uremic syndrome.

**Infectivity:** The infectious dose for humans is low, with as few as 10 bacterial cells depending on age and condition of the host. Infectivity occurs during acute infection and until the infectious agent is no longer present in feces, usually within 4 weeks after illness. Asymptomatic carriers may transmit infection; rarely, the carrier state may persist for months or longer.

#### **HEPATITIS A VIRUS**

Hepatitis A virus (HAV) is a 27-nanometer picornavirus (positive strand RNA, non-enveloped virus). The hepatitis A virus has been classified as a member of the family *Picornaviridae*. The exact pathogenesis of HAV infection is not understood, but the virus appears to invade from the

intestinal tract and is subsequently transported to the liver. The hepatocytes are the site of viral replication and the virus is thought to be shed via the bile.

HAV is most commonly spread by the fecal-oral route through person-to-person contact. Risk factors for reported cases of hepatitis A include personal or sexual contact with another case, illegal drug use, homosexual male sex contact, and travel to an endemic country. Common source outbreaks also can occur through ingestion of water or food that has fecal contamination. However, the source of infection is not identified for approximately 50% of reported cases.

HAV infection is endemic in developing countries, and less common in industrialized countries with good environmental sanitation and hygienic practices. In the developing world, nearly all HAV infections occur in childhood and are asymptomatic or cause a mild illness. As a result, hepatitis A (symptomatic infection with jaundice) is rarely seen in the developing world. More than 90% of adults born in many developing countries are seropositive.

Children play an important role in the transmission of HAV and serve as a source of infection for others, because most children have asymptomatic infections or mild, unrecognized HAV infections. In the United States, the disease is most common among school-aged children and young adults. After correction for under-reporting and undiagnosed infections, an estimated 61,000 HAV infections (includes cases of hepatitis A as well as asymptomatic infections) occurred in 2003.

**HAV Immunization:** Immune globulin can be used to provide passive pre-exposure immunoprophylaxis against hepatitis A. Protection is immediately conferred to an exposed individual following administration of IG, and immunity is provided for 3-5 months following inoculation. IG is effective in preventing HAV infection when given as post-exposure immunoprophylaxis, if given within 14 days of exposure. When a food service worker with hepatitis A is identified, IG is often given to co-workers. Active immunoprophylaxis using hepatitis A vaccine (a formalin-inactivated, attenuated strain of HAV) has been shown to provide immunity in > 95% of those immunized, with minimal adverse reactions. Hepatitis A vaccination of food workers has been advocated, but has not been shown to be cost-effective and generally is not recommended in the United States, although it may be appropriate in some communities.

Incubation period: Average 28-30 days (range 15-50 days).

**Symptoms and Complications**: Illness usually begins with symptoms such as nausea/ vomiting, diarrhea, abdominal pain, fever, headache, and/or fatigue. Jaundice, dark urine or light colored stools might be present at onset, or follow illness symptoms within a few days. HAV infection of older children and adults is more likely to cause clinical illness with jaundice (i.e., hepatitis A); onset of illness is usually abrupt. In young adults, 76-97% have symptoms and 40-70% are jaundiced. Jaundice generally occurs 5-7 days after the onset of gastrointestinal symptoms. For asymptomatic infections, evidence of hepatitis may be detectable only through laboratory tests of liver infections such as alanine aminotransferase (ALT) tests. The disease varies in severity from a mild illness to a fulminant hepatitis, ranging from 1-2 weeks to several months in duration. In up to 10-15% of the reported cases, prolonged, relapsing hepatitis for up to 6 months occurs. The degree of severity often increases with age; however, most cases result in complete recovery,

without sequelae or recurrence. The reported case fatality rate is 0.1% - 0.3% and can reach 1.8% for adults over 50 years old.

**Diagnosis:** Diagnosis of HAV infection requires specific serological testing for IgM anti-HAV. IgM anti-HAV becomes undetectectable within 6 months of illness onset for most persons; however, some persons can remain IgM anti-HAV positive for years after acute infection. Total anti-HAV (the only other licensed serologic test) can be detected during acute infection but remains positive after recovery and for the remainder of the person's life.

**Infectivity:** Evidence indicates maximum infectivity during the latter half of the incubation period, continuing for a few days after onset of jaundice. Most cases are probably noninfectious after the first week of jaundice. Chronic shedding of HAV in feces has not been reported. HAV is shed at peak levels in the feces, one to two weeks before onset of symptoms, and shedding diminishes rapidly after liver dysfunction or symptoms appear. Liver dysfunction or symptoms occur at the same time circulating antibodies to HAV first appear. Immunity after infection probably lasts for life; immunity after vaccination is estimated to last for at least 20 years.

### **Reporting History of Exposure:**

The reporting requirements for history of exposure are designed to identify employees who may be incubating an infection due to Norovirus, *Shigella* spp., *E. coli* O157:H7 or other EHEC/STEC, typhoid fever, or HAV.

Which employees who report exposure are restricted?

• Employees who work in a food establishment serving a highly susceptible population (HSP) facility.

What constitutes exposure?

- Consuming a food that caused illness in another consumer due to infection with Norovirus, *Shigella* spp., *E. coli* O157:H7 or other EHEC/STEC, typhoid fever, or HAV.
- Attending an event or working in a setting where there is a known disease outbreak.
- Close contact with a household member who is ill and is diagnosed with a listed pathogen.

Why are other guidelines provided, in addition to restriction for employees serving an HSP who report exposure to hepatitis A virus?

- Employees who have had a hepatitis A illness in the past are most likely protected from infection by life-time immunity to hepatitis A infection.
- Immunity developed through immunization or IgG inoculation prevents hepatitis A infection in exposed employees.
- Our standard definition of HSP doesn't apply very well to HAV. Children under 6 years old who become infected with HAV are generally asymptomatic, and while a higher

proportion of susceptible elderly who become infected have serious illness, most institutionalized elderly are protected from HAV by prior infection.

What is the period of restriction?

- The period of restriction begins with the most recent time of foodborne or household member exposure and lasts for the usual incubation period of the pathogen as defined in the Control of Communicable Diseases Manual. This is the time that the employee is most likely to begin shedding the pathogen.
  - For Norovirus, 48 hours after the most recent exposure
  - For *Shigella* spp., 3 days after the most recent exposure
  - For *E. coli* O157:H7 or other EHEC/STEC, 3 days after the most recent exposure
  - For typhoid fever (S. Typhi), 14 days after the most recent exposure
  - For HAV, 30 days after the most recent exposure

What is the period of restriction when exposed to a diagnosed, ill household member?

- While the household member is symptomatic with an infection due to Norovirus, *Shigella* spp., *E coli* O157:H7 or other EHEC/STEC, typhoid fever (*S.* Typhi) or HAV;
- Plus during the usual incubation period of the pathogen of concern:
  - For Norovirus, symptomatic period plus 48 hours
  - For Shigella spp., symptomatic period plus 3 days
  - For *E. coli* O157:H7 or other EHEC/STEC, symptomatic period plus 3 days
  - For typhoid fever (S. Typhi), symptomatic period plus 14 days
  - For HAV, onset of jaundice plus 30 days

What is the appropriate response to a report of exposure to other food employees?

• Employees who report a history of exposure but who do not work in a HSP facility should be reminded of the requirements for reporting illness, avoidance of bare hand contact with RTE foods, and proper hand washing and personal hygiene.

#### 2-201.12 Exclusions and Restrictions.<sup>[2]</sup>

Refer to public health reasons for § 2-201.11 for actions to take with conditional employees.

It is necessary to exclude food employees symptomatic with diarrhea, vomiting, or jaundice, or suffering from a disease likely to be transmitted through contamination of food, because of the increased risk that the food being prepared will be contaminated such as with a pathogenic microorganism. However, if the food employee is suffering from vomiting or diarrhea symptoms, and the condition is from a non-infectious condition, Crohn's disease or an illness during early stages of a pregnancy, the risk of transmitting a pathogenic microorganism is minimal. In this case, the food employee may remain working in a full capacity if they can substantiate that the symptom is from a non-infectious condition. The food employee can substantiate this through providing to the person in charge medical documentation or other documentation proving that the symptom is from a noninfectious condition.

Because of the high infectivity (ability to invade and multiply) and/ or virulence (ability to produce severe disease), of typhoid fever (*Salmonella* Typhi) and hepatitis A virus, a food employee diagnosed with an active case of illness caused by either of these two pathogens, whether asymptomatic or symptomatic, must be excluded from food establishments. The exclusion is based on the high infectivity, and/or the severe medical consequences to individuals infected with these organisms. A food employee diagnosed with an active case of illness caused by Norovirus, *Shigella* spp., or *E. coli* O157:H7 or other EHEC/STEC, is excluded if exhibiting symptoms of vomiting and diarrhea, and then allowed to work as the level of risk of pathogen transmission decreases (See section 2-201.12, Tables #1b, #2 and #3).

The degree of risk for a food employee or conditional employee who is diagnosed with an infection but asymptomatic with regard to symptoms, to transmit a foodborne pathogen decreases with the resolution of symptoms. This risk decreases even further for those employees that are diagnosed with a listed pathogen, but never developed symptoms. The decrease in risk is taken under consideration when excluding and restricting diagnosed food employees and results in a slight difference in the way food employees diagnosed with Norovirus, but asymptomatic with respect to gastrointestinal symptoms are handled (See section 2-201.12, Table #2).

2-201.11 / 2-201.12 Decision Tree 1. When to Exclude or Restrict a Food Employee Who Reports a Symptom and When to Exclude a Food Employee Who Reports a Diagnosis with Symptoms Under the Food Code



#### Key:

Listed Symptoms for Reporting: (V) Vomiting; (J) Jaundice; (D) Diarrhea; (ST with F) Sore Throat with Fever; (HSP) Highly Susceptible Population; (Gen. Pop.) General Population

#### 2-201.11 / 2-201.12 Decision Tree 2.

When to Exclude or Restrict a Food Employee Who is Asymptomatic and Reports a Listed Diagnosis and When to Restrict a Food Employee Who Reports a Listed Exposure Under the Food Code





Symptom		SION/ OR ICTION	Removing Symptomatic Food Employees from	RA Approval
	Facilities Serving an HSP	Facilities Not serving an HSP	Exclusion or Restriction	Needed to Return to Work?
Vomiting	EXCLUDE 2-201.12(A)(1)	EXCLUDE 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2- 201.13(A)(1). <i>Exceptions:</i> If diagnosed with Norovirus, <i>Shigella</i> spp., <i>E. coli</i> O157:H7 or other EHEC/STEC, HAV, or typhoid fever ( <i>S. Typhi</i> ) (see Tables 1b & 2).	No if not diagnosed
Diarrhea	EXCLUDE 2-201.12(A)(1)	EXCLUDE 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2- 201.13(A). <i>Exceptions:</i> If Diagnosed with Norovirus, <i>E. coli</i> O157:H7 or other EHEC/STEC, HAV, or <i>S. Typhi</i> (see Tables 1b & 2).	No if not diagnosed
Jaundice	EXCLUDE2- 201.12(B)(1) if the onset occurred within the last 7 days	EXCLUDE2- 201.12(B)(1) if the onset occurred within the last 7 days	<ul> <li>When approval is obtained from the RA 2-201.13 (B), and:</li> <li>Food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or</li> </ul>	Yes

# 2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees

RESSymptomFacilities		SION/ OR ICTION	Removing Symptomatic Food Employees from	RA Approval Needed to Return to Work?
	Facilities Serving an HSP	Facilities Not serving an HSP	Exclusion or Restriction	
			• Food employee provides medical documentation 2- 201.13(B)(3).	
Sore Throat with Fever	<b>EXCLUDE</b> 2-201.12(G)(1)	<b>RESTRICT</b> 2-201.12(G)(2)	When food employee provides written medical documentation 201.13(G) (1)-(3).	No
Infected wound or pustular boil	<b>RESTRICT</b> 2-201.12(H)	<b>RESTRICT</b> 2-201.12(H)	When the infected wound or boil is properly covered 2- 201.13(H)(1)-(3).	No

#### 2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees

Notes:

- Food employees and conditional employees shall report symptoms immediately to the person in charge.
- The person in charge shall prohibit a conditional employee who reports a listed symptom from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a symptomatic food employee.

Key for Tables 1, 2, 3, and 4: RA = Regulatory Authority EHEC/STEC = Enterohemorrhagic, or Shiga toxin-producing *Escherichia coli* HAV = Hepatitis A virus HSP = Highly Susceptible Population

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees					
Diagnosis	EXCLUSION Facilities Serving an HSP or Not Serving an HSP	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?		
Hepatitis A virus	EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2- 201.12(B)(2)	<ul> <li>When approval is obtained from the RA 2-201.13(B), and:</li> <li>The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or</li> <li>The anicteric food employee has had symptoms or more than 14 days 2-201.13(B)(2), or</li> <li>The food employee provides medical documentation 2-201.13(B)(3) (also see Table 2).</li> </ul>	Yes		
Typhoid Fever ( <b>S.</b> <b>Typhi</b> )	<b>EXCLUDE</b> 2-201.12(C)	<ul> <li>When approval is obtained from the RA 2-201.13(C)(1), and:</li> <li>Food employee provides medical documentation, that states the food employee is free of a <i>S</i>. Typhi infection 2-201.13(C)(2) (also see Table 2).</li> </ul>	Yes		
<i>E. coli</i> O157:H7 or other EHEC/ STEC	EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	<ol> <li>Serving a non-HSP facility: 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3.</li> <li>Serving an HSP facility: 2- 201.13(A)(4)(b): Remains</li> </ol>	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non- HSP facility		

Diagnosis	EXCLUSION Facilities Serving an HSP or Not Serving an HSP	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
		<ul> <li>excluded until meeting the requirements listed in No. 3.</li> <li>3. <u>Restriction or Exclusion remains until:</u> <ul> <li>Approval is obtained from RA 2-201.13(F), and</li> <li>Medically cleared 2-201.13(F)(1), or</li> <li>More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2) (also see Table 2).</li> </ul> </li> </ul>	
Norovirus	EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	<ol> <li>Serving a non-HSP facility: 2-201.13 (A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3.</li> <li>Serving an HSP facility: 2- 201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3.</li> <li><u>Restriction or Exclusion remains until:</u> <ul> <li>Approval is obtained from the RA 2- 201.13(D), and</li> <li>Medically cleared 2- 201.13(D)(1), or</li> </ul> </li> </ol>	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non- HSP facility

# 2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees

Diagnosis	EXCLUSION Facilities Serving an HSP or Not Serving an HSP	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
		<ul> <li>More than 48 hours have passed since the food employee became asymptomatic 2- 201.13(D)(2) (also see Table 2).</li> </ul>	
Shigella spp.	EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	<ol> <li>Serving a non-HSP facility: 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3.</li> <li>Serving an HSP facility: 2- 201.13(A)(3)(b): Remains excluded until meeting the requirements in No. 3.</li> <li><u>Restriction or Exclusion remains until:</u> <ul> <li>Approval is obtained from the RA 2- 201.13(E), and</li> <li>Medically cleared 2- 201.13(E)(1), or</li> <li>More than 7 calendar days have passed since the food employee became asymptomatic 2- 201.13(E)(2) (also see Table 2).</li> </ul> </li> </ol>	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non- HSP facility

# 2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees

- Food employees and conditional employees shall report a listed Diagnosis with symptoms immediately to the person in charge.
- The person in charge shall notify the RA when a food employee is jaundiced or reports a listed diagnosis.
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis with symptoms from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed, symptomatic food employee.

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Typhoid fever ( <b>S. Typhi</b> ) including previous illness with <b>S. Typhi</b> (see 2- 201.11(A)(3))	<b>EXCLUDE</b> 2-201.12(C)	<b>EXCLUDE</b> 2-201.12(C)	<ul> <li>When approval is obtained from the RA 2-201.13(C)(1), and:</li> <li>Food employee provides medical documentation, that states the food employee is free of an <i>S. Typhi</i> infection 2-201.13)(C)(2) (also see Table 1b).</li> </ul>	Yes
<i>Shigella</i> spp.	EXCLUDE 2- 201.12(E)(1)	<b>RESTRICT</b> 2- 201.12(E)(2)	<ol> <li>Serving a non-HSP <u>facility</u>: 2- 201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3.</li> <li>Serving an HSP <u>facility</u>: 2-</li> </ol>	Yes to return to an HSP or to return unrestricted not required to work on a restricted basis in a non-HSP facility

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
			201.13(A)(3)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or</u> <u>Exclusion remains</u> <u>until:</u> • Approval is obtained from the RA 2- 201.13(E), and: • Medically cleared 2- 201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 201.13(E)(3)(a) (also see Table 1b).	
Norovirus	EXCLUDE 2- 201.12(D)(1)	<b>RESTRICT</b> 2- 201.12(D)(2)	<ol> <li>Serving a non-HSP <u>facility</u>: 2- 201.13(A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains</li> </ol>	Yes to return to an HSP or to return unrestricted; not required to work on

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approva Required to Return to Work?
			restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP</u> <u>facility</u> : 2- 201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or Exclusion remains until:</u> • Approval is obtained from the RA 2- 201.13(D), and • Medically cleared 2- 201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 1b).	a restricted basis in a non-HSP facility

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
<i>E. coli</i> O157:H7 or other EHEC/ STEC	EXCLUDE 2- 201.12(F)(1)	<b>RESTRICT</b> 2- 201.12(F)(2)	<ol> <li>Serving a non-HSP <u>facility</u>: 2- 201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3.</li> <li>Serving an HSP <u>facility</u>: 2- 201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 3.</li> <li><u>Restriction or Exclusion remains</u> <u>until:</u> <ul> <li>Approval is obtained from the RA 2- 201.13(F), and</li> <li>Medically cleared 2- 201.13(F)(1), or</li> <li>More than 7 calendar days have passed since the food employee became</li> </ul> </li> </ol>	Yes to return to an HSP or to return unrestricted not required to work on a restricted basis in a non-HSP facility

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
			asymptomatic 2-201.13(F)(2).	
Hepatitis A virus	EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2- 201.12(B)(2)	EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2- 201.12(B)(2)	<ul> <li>When approval is obtained from the RA 2-201.13(B), and:</li> <li>The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or</li> <li>The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or</li> <li>The food employee provides medical documentation 2-201.13(B)(3) (see also Table 1b).</li> </ul>	Yes

Notes:

- Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge.
- The person in charge shall notify the RA when a food employee reports a listed diagnosis.
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee.

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Typhoid Fever ( <b>S. Typhi</b> ) including previous illness with <b>S. Typhi</b> (see 2- 201.11 (A)(3))	<b>EXCLUDE</b> 2-201.12(C)	EXCLUDE 2-201.12(C)	When approval is obtained from the RA 2- 201.13(C)(1), and: Food employee provides medical documentation, specifying that the food employee is free of a <i>S</i> . <b>Typhi</b> infection 2- 201.13(C)(2).	Yes
<i>Shigella</i> spp.	EXCLUDE 2- 201.12(E)(1)	<b>RESTRICT</b> 2- 201.12(E)(2)	<ul> <li>Remains excluded or restricted until approval is obtained from the RA, and:</li> <li>Medically cleared 2-201.13(E)(1), or</li> <li>More than 7 calendar days have passed since the food employee was last diagnosed 2-201.13(E)(3).</li> </ul>	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Norovirus	EXCLUDE 2- 201.12(D)(1)	<b>RESTRICT</b> 2- 201.12(D)(2)	Remains excluded or restricted until approval is obtained from the RA 2- 201.13(D), and • Medically cleared 2-201.13(D)(1), or	Yes to return to an HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility

# 2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

# 2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
			• More than 48 hours have passed since the food employee was diagnosed 2- 201.13(D)(3).	
<i>E. coli</i> O157:H7 or other EHEC/ STEC	EXCLUDE 2- 201.12(F)(1)	<b>RESTRICT</b> 2- 201.12(F)(2)	<ul> <li>Remains excluded or restricted until approval is obtained from the RA 2-201.13(F), and:</li> <li>Medically cleared 2-201.13(F)(1), or</li> <li>More than 7 calendar days have passed since the food employee was diagnosed 2-201.13(F)(3).</li> </ul>	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	EXCLUDE 2- 201.12(B)(3)	EXCLUDE 2- 201.12(B)(3)	<ul> <li>When approval is obtained from the RA 2-201.13(B), and</li> <li>The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or</li> <li>The food employee provides medical</li> </ul>	Yes

### 2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
			documentation 2- 201.13(B)(3).	

Notes:

- Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge.
- The person in charge shall notify the RA when a food employee reports a listed diagnosis.
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee.

Key for Tables 1, 2, 3, and 4: RA = Regulatory Authority EHEC/STEC = Enterohemorrhagic, or Shiga toxin-producing *Escherichia coli* HAV = Hepatitis A virus HSP = Highly Susceptible Population

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
Typhoid Fever ( <b>S. Typhi</b> )	<b>RESTRICT</b> 2-201.12(I)	Educate food employee on symptoms to	2-201.13(I)(3)When 14 calendar days have passed since the last exposure, or	No

# 2-201.12 Table 4: History of Exposure, and Absent Symptoms or Diagnosis

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
		watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	more than 14 days has passed since the food employee's household contact became asymptomatic.	
<i>Shigella</i> spp.	<b>RESTRICT</b> 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2)When more than 3 calendar days have passed since the last exposure, or more than 3 days have passed since the food employee's household contact became asymptomatic.	No
Norovirus	<b>RESTRICT</b> 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(1)When more than 48 hours have passed since the last exposure, or more than 48 hours has passed since the food employee's household contact became asymptomatic.	No
<i>E. coli</i> O157:H7 or other EHEC/ STEC	<b>RESTRICT</b> 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and	2-201.13(I)(2)When more than 3 calendar days have passed since the last exposure, or more than 3 calendar days has passed since the food employee's household contact became asymptomatic.	No

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
		no BHC with RTE foods.		
Hepatitis A virus	<b>RESTRICT</b> 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	<ul> <li>2-201.13(I)(4)When any of the following conditions is met:</li> <li>The food employee is immune to HAV infection because of a prior illness from HAV, vaccination against HAV, or IgG administration; or</li> <li>More than 30 calendar days have passed since the last exposure, or since the food employee's household contact became jaundiced; or</li> <li>The food employee does not use an alternative procedure that allows BHC with RTE food until at least 30 days after the potential exposure, and the employee receives additional training.</li> </ul>	No

# 2-201.12 Table 4: History of Exposure, and Absent Symptoms or Diagnosis

Notes:

• Food employees and conditional employees shall report a listed exposure to the person in charge.

- The person in charge shall prohibit a conditional employee who reports a listed exposure from becoming a food employee in a facility serving an HSP until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of an exposed food employee.
- The person in charge shall reinforce and ensure compliance with good hygienic practices, symptom reporting requirements, proper handwashing and no BHC with RTE foods for all food employees that report a listed exposure.

**Key for Table 4:** GHP = Good Hygienic Practices; RTE = Ready-to-Eat foods; BHC = Bare Hand Contact

### 2-201.12 Exclusion and Restrictions (continued)<sup>[3]</sup>

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by *Salmonella* Enteritidis. Over 70% of the deaths in outbreaks attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active gastrointestinal symptoms, followed by diagnosis and history of exposure.

The history of exposure that must be reported applies only to the 5 organisms listed.

Upon being notified of the history of exposure, the person in charge should immediately:

- 1. Discuss the traditional modes of transmission of fecal-oral route pathogens.
- 2. Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of proper handwashing, as described in the Code, after going to the bathroom, changing diapers, or handling stool-soiled material.
- 3. Review the symptoms listed in the Code that require immediate exclusion from the food establishment.
- 4. Remind food employees of their responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.
- 5. Ensure that the food employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

A restricted food employee may work in an area of the food establishment that houses packaged food, wrapped single-service or single-use articles, or soiled food equipment or utensils. Examples of activities that a restricted person might do include working at the cash register,

seating patrons, bussing tables, stocking canned or other packaged foods, or working in a nonfood cleaning or maintenance capacity consistent with the criteria in the definition of the term "restricted." A food employee who is restricted from working in one food establishment may not work in an unrestricted capacity in another food establishment, but could work unrestricted in another retail store that is not a food establishment. A restricted food employee may enter a food establishment as a consumer.

An excluded individual may not work as a food employee on the premises of any food establishment.

### 2-201.13 Removal of Exclusions and Restrictions.<sup>[4]</sup>

Food employees diagnosed with Norovirus, hepatitis A virus, *Shigella* spp., *E. coli* O157:H7 or other EHEC, and symptomatic with diarrhea, vomiting, or jaundice, are excluded under subparagraph 2-201.12 (A)(2) or 2-201.12(B)(2). However these symptomatic, diagnosed food employees differ from symptomatic, undiagnosed food employees in the requirements that must be met before returning to work in a full capacity after symptoms resolve.

The person in charge may allow undiagnosed food employees who are initially symptomatic and whose symptoms have resolved to return to work in a full capacity 24 hours after symptoms resolve.

However, diagnosis with a listed pathogen invokes additional requirements before the person in charge may allow diagnosed food employees to return to work in full capacity.

Asymptomatic food employees diagnosed with Norovirus, *Shigella* spp., *E. coli* O157:H7 or other EHEC may not return to work in a full capacity for at least 24 hours after symptoms resolve. The person in charge shall only allow these food employees to work on a restricted basis 24 hours after symptoms resolve and they shall only allow this if not in a food establishment that serves a highly susceptible population. These restricted food employees remain restricted until they are medically cleared or otherwise meet the criteria for removal from restriction as specified under subparagraphs 2-201.13(D) (1)-(2); 2-201.13(E)(1)-(2); or 2-201.13(F)(1)-(2).

In a food establishment that serves a highly susceptible population, food employees who are diagnosed with Norovirus, *Shigella* spp., *E. coli* O157:H7 or other EHEC and initially symptomatic with vomiting or diarrhea, shall not work on a restricted basis after being asymptomatic for at least 24 hours. These food employees must remain excluded until they are medically cleared or otherwise meet the criteria for removal from exclusion from a highly susceptible population under subparagraph 2-201.13(D)(1)-(2), 2-201.13(E)(1)-(2), or 2-201.13(F)(1)-(2).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B)(1)-(4).
Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B)(1)-(3). A food employee with an anicteric infection with the hepatitis A virus has a mild form of hepatitis A without jaundice. Food employees diagnosed with an anicteric infection with the hepatitis A virus has a mild form of methan 14 days of any symptoms. Anicteric, diagnosed food employees shall be removed from exclusion if more than 14 days have passed since they became symptomatic, or if medically cleared. Asymptomatic food employees diagnosed with an active infection with the hepatitis A virus are also excluded until medically cleared.

Food employees diagnosed with typhoid fever (caused by a *Salmonella* Typhi infection) are always excluded, even without expressing gastrointestinal symptoms, since these symptoms are not typically exhibited with typhoid fever. Outbreaks of foodborne illness involving typhoid fever (*Salmonella* Typhi) have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness. The high virulence combined with the extremely high infectivity of *S*. Typhi warrant exclusion from the food establishment until the food employee has been cleared by a physician or has completed antibiotic therapy.

Despite lacking specific epidemiological evidence of transmission through food contaminated by food employees infected with *E. coli* O157:H7 or other EHEC/STEC bacteria are included with the 5 listed pathogens in the Food Code. This is because of the documented ease of transmission from person-to-person in a day care setting and because characteristics of foodborne outbreaks suggest a low infectious dose and the potential for the organism to be transmitted through food contaminated by soiled hands. The severity and consequences of infection, including hemolytic uremic syndrome (HUS), associated with Shiga toxin-producing *E. coli* warrant the institution of disease interventions.

Asymptomatic shedders are food employees who do not exhibit the symptoms of foodborne illness but who are identified through diagnosis, or laboratory confirmation of their stools to have Norovirus, or any one of the three bacterial pathogens identified in Chapter 2 in their gastrointestinal system.

The risk that food employees who are asymptomatic shedders will transmit a communicable disease varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism. Exclusion in a food establishment that serves a highly susceptible population affords protection to people who are immune-suppressed. Restriction in a food establishment that does not serve a highly susceptible population affords protection for the general population and the immune-suppressed subset of the general population provided there is adequate attention to personal hygiene and avoidance of bare-hand contact with RTE foods.

To minimize the risk in all food establishments of the transmission of foodborne disease by an asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the three bacterial pathogens are either restricted or excluded, depending on the population served. Requiring restriction for asymptomatic shedders of all three of the <u>bacterial</u> pathogens

results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases Manual."

## 2013 FDA Food CODE

# *Responsibilities and Reporting Symptoms and Diagnosis* 2-201.11 Responsibility of Permit Holder, Person in Charge, and Conditional Employees.

(A) The PERMIT HOLDER shall require FOOD EMPLOYEES and CONDITIONAL EMPLOYEES to report to the PERSON IN CHARGE information about their health and activities as they relate to diseases that are transmissible through FOOD. A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report the information in a manner that allows the PERSON IN CHARGE to reduce the RISK of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE: *reportable symptoms* (1) Has any of the following symptoms:

- (a) Vomiting,
- (b) Diarrhea,
- (c) Jaundice,
- (d) Sore throat with fever, or

(e) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(i) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a SINGLE-USE glove is worn over the impermeable cover,

(ii) On exposed portions of the arms, *unless the lesion is protected by an impermeable cover,* or

(iii) On other parts of the body, *unless the lesion is covered by a dry, durable, tight-fitting bandage; reportable diagnosis* 

(2) Has an illness diagnosed by a HEALTH PRACTITIONER due to:

(a) Norovirus,

(b) Hepatitis A virus,

(c) Shigella spp.,

(d) SHIGA TOXIN-PRODUCING ESCHERICHIA COLI,P

(e) Salmonella Typhi; or

(f) nontyphoidal Salmonella; reportable past illness

(3) Had a previous illness, diagnosed by a HEALTH PRACTITIONER, within the past 3 months due to *Salmonella* Typhi, without having received antibiotic therapy, as determined by a HEALTH PRACTITIONER; *reportable history of exposure* 

(4) Has been exposed to, or is the suspected source of, a CONFIRMED DISEASE OUTBREAK, because the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE consumed or prepared FOOD implicated in the outbreak, or consumed FOOD at an event prepared by a PERSON who is infected or ill with:

(a) Norovirus within the past 48 hours of the last exposure,

(b) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI or Shigella* spp. within the past 3 days of the last exposure,

(c) Salmonella Typhi within the past 14 days of the last exposure, or

(d) Hepatitis A virus within the past 30 days of the last exposure; or *reportable history of exposure* 

(5) Has been exposed by attending or working in a setting where there is a CONFIRMED DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual who works or attends a setting where there is a CONFIRMED DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

(a) Norovirus within the past 48 hours of the last exposure,

(b) SHIGA TOXIN-PRODUCING ESCHERICHIA COLI or Shigella spp. within the past 3 days of the last exposure,

(c) Salmonella Typhi within the past 14 days of the last exposure, or

(d) Hepatitis A virus within the past 30 days of the last exposure. *Responsibility of person in charge to notify the regulatory authority* 

(B) The PERSON IN CHARGE shall notify the REGULATORY AUTHORITY when a FOOD EMPLOYEE is:

(1) Jaundiced, or

(2) Diagnosed with an illness due to a pathogen as specified under Subparagraphs (A)(2)(a) - (f) of this section.

responsibility of the person in charge to prohibit a conditional employee from becoming a food employee

(C) The PERSON IN CHARGE shall ensure that a CONDITIONAL

EMPLOYEE:

(1) Who exhibits or reports a symptom, or who reports a diagnosed illness as specified under Subparagraphs

(A)(1) - (3) of this section, is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria for the specific symptoms or diagnosed illness as specified under § 2-201.13; P and

(2) Who will work as a FOOD EMPLOYEE in a FOOD ESTABLISHMENT that serves as a HIGHLY SUSCEPTIBLE POPULATION and reports a history of exposure as specified under

Subparagraphs (A)(4) – (5), is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria as specified under  $\P$  2-201.13(I). *responsibility* of the person in charge to exclude or restrict

(D) The PERSON IN CHARGE shall ensure that a FOOD EMPLOYEE who exhibits or reports a symptom, or who reports a diagnosed illness or a history of exposure as specified under Subparagraphs

(A)(1) - (5) of this section is:

<u>3</u>5

(1) EXCLUDED as specified under ¶¶ 2-201.12 (A) - (C), and

Subparagraphs (D)(1), (E)(1), (F)(1), (G) or (H)(1) and in compliance with the provisions specified under  $\P\P$  2-201.13(A) - (H); or

(2) RESTRICTED as specified under Subparagraphs 2-201.12

(D)(2), (E)(2), (F)(2), (H)(2), or  $\P\P$  2-201.12(I) or (J) and in compliance with the provisions specified under  $\P\P$  2-201.13(D)

- (J).responsibility of food employees and conditional employees to report

(E) A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report to the

PERSON IN CHARGE the information as specified under  $\P$  (A) of this section.

Responsibility of food employees to comply

(F) A FOOD EMPLOYEE shall:

(1) Comply with an EXCLUSION as specified under

¶¶ 2-201.12(A) - (C) and Subparagraphs 2-201.12(D)(1),

(E)(1), (F)(1), (G), or (H)(1) and with the provisions specified under  $\P\P$  2-201.13(A) - (H); or

(2) Comply with a RESTRICTION as specified under

Subparagraphs 2-201.12(D)(2), (E)(2), (F)(2), (G), (H)(2), or

 $\P\P$  2-201.12 (H), (I), or (J) and comply with the provisions specified under  $\P\P$  2-201.13(D) - (J).

#### *conditions of exclusion and restriction* 2-201.12 Exclusions and Restrictions.

The PERSON IN CHARGE shall EXCLUDE OR RESTRICT A FOOD EMPLOYEE from a FOOD ESTABLISHMENT in accordance with the following:

symptomatic with vomiting or diarrhea

(Å) Except when the symptom is from a noninfectious condition, EXCLUDE a FOOD EMPLOYEE if the FOOD EMPLOYEE is:

(1) Symptomatic with vomiting or diarrhea; or

(2) Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, *Shigella* spp., nontyphoidal *Salmonella*, or SHIGA TOXIN-PRODUCING *E. COLI. jaundiced or diagnosed with hepatitis A infection* 

(B) EXCLUDE a FOOD EMPLOYEE who is:

(1) Jaundiced and the onset of jaundice occurred within the last 7 calendar days, unless the FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER specifying that the jaundice is not caused by hepatitis A virus or other fecal-orally transmitted infection;

(2) Diagnosed with an infection from hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within 7 calendar days of the onset of jaundice; or
(3) Diagnosed with an infection from hepatitis A virus without developing symptoms diagnosed or reported previous infection due to *S. Typhi*

(C) EXCLUDE a FOOD EMPLOYEE who is diagnosed with an infection from *Salmonella* Typhi, or reports a previous infection with *Salmonella* Typhi within the past 3 months as specified under Subparagraph 2-201.11(A)(3). *diagnosed with an asymptomatic infection from* 

### Norovirus

(D) If a FOOD EMPLOYEE is diagnosed with an infection from Norovirus and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD

ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION; or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD

ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.

#### diagnosed with Shigella spp. infection and asymptomatic

(E) If a FOOD EMPLOYEE is diagnosed with an infection from *Shigella* spp. and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD

ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION; or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.

### diagnosed with STEC and asymptomatic

(F) If a FOOD EMPLOYEE is diagnosed with an infection from SHIGA TOXIN-PRODUCING *E. COLI*, and is ASYMPTOMATIC: (1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION; or (2) RESTRICT the FOOD EMPLOYEE who works in a FOOD

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.

### diagnosed with nontyphoidal Salmonella and asymptomatic

(G) If a FOOD EMPLOYEE is diagnosed with an infection from nontyphoidal *Salmonella* and is ASYMPTOMATIC, RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION or in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.

#### symptomatic with sore throat with fever

(H) If a FOOD EMPLOYEE is ill with symptoms of acute onset of sore throat with fever:
(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION; POR
(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.P

symptomatic with **uncovered infected wound or pustular boil** (I) If a FOOD EMPLOYEE is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under Subparagraph 2-201.11(A)(1)(e), RESTRICT the FOOD EMPLOYEE.

**exposed** to foodborne pathogen and works in food establishment serving HSP (J) If a FOOD EMPLOYEE is exposed to a foodborne pathogen as specified under Subparagraphs 2-201.11(A)(4)(a-d) or 2-201.11(A)(5)(a-d), RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION.P

#### Managing Exclusions and Restrictions 2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions.

The PERSON IN CHARGE shall adhere to the following conditions when removing, adjusting, or retaining the EXCLUSION or

RESTRICTION of a FOOD EMPLOYEE:

(A) Except when a FOOD EMPLOYEE is diagnosed with an infection from hepatitis A virus or Salmonella Typhi: removing exclusion for food employee who was symptomatic and not diagnosed

(1) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(1) if the FOOD

EMPLOYEE:

(a) IS ASYMPTOMATIC for at least 24 hours; or

(b) Provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the symptom is from a noninfectious condition.

### Norovirus diagnosis

(2) If a FOOD EMPLOYEE was diagnosed with an infection from Norovirus and EXCLUDED as specified under

Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic (a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE

POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met; or *retaining exclusion for food employee who was asymptomatic and is now asymptomatic and works in food establishment serving HSP* 

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met.

### Shigella spp. diagnosis

(3) If a FOOD EMPLOYEE was diagnosed with an infection from *Shigella* spp. and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic (a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOODESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE

POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2) of this section are met; or *retaining exclusion for food employee who was asymptomatic and is now asymptomatic* 

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who

is ASYMPTOMATIC for at least 24 hours and works in a

FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE

POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2), or (E)(1) and (3)(a) of this section are met.

**STEC diagnosis** (4) If a FOOD EMPLOYEE was diagnosed with an infection from SHIGA TOXIN-PRODUCING ESCHERICHIA COLI and

EXCLUDED as specified under Subparagraph

2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic (a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE

POPULATION, until the conditions for reinstatement as specified under Subparagraphs (F)(1) or (2) of this section are met; or *retaining exclusion for food employee who was symptomatic and is now asymptomatic and works in food establishment serving HSP* 

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (F)(1) or (2) are met.

## Nontyphoidal Salmonella diagnosis

(5) If a FOOD EMPLOYEE was diagnosed with an infection from nontyphoidal *Salmonella* and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

Adjusting exclusion for food employee who was symptomatic and is now asymptomatic (a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 30 days until conditions for reinstatement as specified under Subparagraphs (G)(1) or (2) of this section are met; or *Retaining exclusion for food employee that remains symptomatic* (b) Retain the EXCLUSION for the FOOD EMPLOYEE who is

SYMPTOMATIC, until conditions for reinstatement as specified under Paragraphs (G)(1) or (G)(2) of this section are met.

### hepatitis A virus or jaundice diagnosis - removing exclusions

(B) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ 2-201.12(B) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met;

(1) The FOOD EMPLOYEE has been jaundiced for more than 7 calendar days;

(2) The anicteric FOOD EMPLOYEE has been symptomatic with symptoms other than jaundice for more than 14 calendar days; or

(3) The FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a hepatitis A virus infection.

#### S. Typhi diagnosis - removing exclusions

(C) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under  $\P$  2-201.12(C) if:

(1) The PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY; P and

(2) The FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the FOOD EMPLOYEE is free from *S*. Typhi infection.

### Norovirus diagnosis - removing exclusion or restriction

(D) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2-201.12(A)(2) or (D)(1) who was RESTRICTED under Subparagraph 2-201.12(D)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED OR RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a Norovirus infection;

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;P or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 48 hours have passed since the FOOD EMPLOYEE was diagnosed.

### Shigella spp. diagnosis – removing exclusion or restriction

(E) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2-201.12(A)(2) or (E)(1) or who was RESTRICTED under Subparagraph 2-201.12(E)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED OR RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Shigella* spp. infection based on test results showing 2 consecutive negative stool specimen cultures that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics, and

(b) At least 24 hours apart;

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC; or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 7 calendar days have passed since the FOOD EMPLOYEE was diagnosed.

## STEC diagnosis - removing exclusion or restriction

(F) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(A)(2)

or (F)(1) or who was RESTRICTED under Subparagraph

2-201.12(F)(2) if the PERSON IN CHARGE obtains APPROVAL from

the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED OR RESTRICTED FOOD EMPLOYEE provides

to the PERSON IN CHARGE written medical documentation

from a HEALTH PRACTITIONER stating that the FOOD

EMPLOYEE is free of an infection from SHIGA TOXINPRODUCING

*ESCHERICHIA COLI* based on test results that show 2 consecutive negative stool specimen cultures that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics; and

(b) At least 24 hours apart;

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC; or

(3) The FOOD EMPLOYEE was EXCLUDED OR RESTRICTED and did not develop symptoms and more than 7 days have passed since the FOOD EMPLOYEE was diagnosed.

## Nontyphoidal Salmonella -removing exclusion or restriction

(G) Reinstate a food employee who was EXCLUDED as specified under Subpargraph 2-201.12(A)(2) or who was RESTRICTED as specified under  $\P$  2-201.12(G) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY P and one of the following conditions is met:

(1) The EXCLUDED OR RESTRICTED FOOD EMPLOYEE provides

to the PERSON IN CHARGE written medical documentation

from a HEALTH PRACTITIONER stating that the FOOD

EMPLOYEE is free of a nontyphoidal *Salmonella* infection based on test results showing 2 consecutive negative stool specimen cultures that are taken;

(a) Not earlier than 48 hours after discontinuance of antibiotics. and

(b) At least 24 hours apart;

(2) The FOOD EMPLOYEE was RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 30 days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;

or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 30 days have passed since the FOOD EMPLOYEE was diagnosed.

#### sore throat with fever - removing exclusion or restriction

(H) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(H)(1) or (2) if the FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE meets one of the following conditions:

(1) Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than 24 hours;

(2) Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection; or

(3) Is otherwise determined by a HEALTH PRACTITIONER to be free of a *Streptococcus pyogenes* infection.

#### uncovered infected wound or pustular boil - removing restriction

(I) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(I) if the skin, infected wound, cut, or pustular boil is properly covered with one of the following: (1) An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist;

(2) An impermeable cover on the arm if the infected wound or pustular boil is on the arm; or

(3) A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.

exposure to foodborne pathogen and works in food establishment serving HSP – removing restriction

(J) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under  $\P$  2-201.12(J) and was exposed to one of the following pathogens as specified under Subparagraph 2-201.11(A)(4)(a-d) or 2-201.11(A)(5)(a-d):

**Norovirus** (1) Norovirus and one of the following conditions is met: (a) More than 48 hours have passed since the last day the FOOD EMPLOYEE was potentially exposed; or (b) More than 48 hours have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.

## Shigella spp. Or STEC

(2) Shigella spp. or SHIGA TOXIN-PRODUCING ESCHERICHIA COLI and one of the following conditions is met:
(a) More than 3 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed; or
(b) More than 2 calendar days have passed since the

(b) More than 3 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.

S. Typhi (3) S. Typhi and one of the following conditions is met:

(a) More than 14 calendar days have passed since the

last day the FOOD EMPLOYEE was potentially exposed;

or

(b) More than 14 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.

*hepatitis A* (4) Hepatitis A virus and one of the following conditions is met:

(a) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of a prior illness from hepatitis A;

(b) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of vaccination against hepatitis A;

(c) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of IgG administration;

(d) More than 30 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;

(e) More than 30 calendar days have passed since the FOOD EMPLOYEE'S household contact became jaundiced; or

(f) The FOOD EMPLOYEE does not use an alternative procedure that allows bare hand contact with READY-TOEAT FOOD until at least 30 days after the potential exposure, as specified in Subparagraphs (I)(4)(d) and

(e) of this section, and the FOOD EMPLOYEE receives additional training about:

(i) Hepatitis A symptoms and preventing the transmission of infection,

(ii) Proper handwashing procedures, and

(iii) Protecting READY-TO-EAT FOOD from

contamination introduced by bare hand contact.

#### HIPPA RULE

The Privacy Rule directly regulates three types of "covered entities": health care providers (including individuals and organizations), health plans (including insurers and other payors), and health care clearinghouses (entities, such as billing services, that process health information from nonstandard into standard forms or vice versa).

Business associates are defined as individuals or entities outside of the Partners system that receive, create, or have access to individually identifiable health information and (1) perform a service on behalf of Partners or its affiliates, or (2) fit within the list of specific service providers (i.e., outside legal, actuarial, accounting, consulting, management, administrative, accreditation, data aggregation, and financial services).

*Serious Threat to Health or Safety.* Covered entities may disclose protected health information that they believe is necessary to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat (including the target of the threat). Covered entities may also disclose to law enforcement if the information is needed to identify or apprehend an escapee or violent criminal.

Americans with Disabilities Act (ADA)

"(1) DISABILITY.—The term 'disability' means, with respect to an individual—

"(A) a physical or mental impairment that substantially limits one or more major life activities of such individual;

"(B) a record of such an impairment; or

"(C) being regarded as having such an impairment (as described in paragraph (3)).

"(2) MAJOR LIFE ACTIVITIES.—

"(A) IN GENERAL.—For purposes of paragraph (1), major life activities include, but are not limited to, caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working.

"(B) MAJOR BODILY FUNCTIONS.—For purposes of paragraph (1), a major life activity also includes the operation of a major bodily function, including but not limited to, functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions.

Paragraph (1)(C) shall not apply to impairments that are transitory and minor. A transitory impairment is an impairment with an actual or expected duration of 6 months or less.