with all the necessary equipment installed and functioning properly to determine the food service establishment's compliance with applicable Law and this Chapter.

Interpretation of this Chapter.

This Manual entitled, "Interpretation Manual for the Georgia Rules and Regulations for Food Service" and its companion manual entitled; "Food Service Establishment Manual for Design, Installation and Construction" are programmatic manuals. Their purpose is to augment the Chapter by providing detail and specificity of its Rules and Regulations. As the need for further clarification arises, updates to these manuals will periodically occur.

511-6-1-.03 MANAGEMENT AND PERSONNEL

Responsibility **PIC Present.**

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Chapter's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Chapter requirements is needed to respond to questions and concerns and to resolve problems.

Knowledge **Demonstration.**

The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Chapter requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Chapter requirements, and to take appropriate preventive and corrective actions.

There are 3 ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. The 3 ways are as follows (only one is needed to demonstrate knowledge at the time of inspection):

Option 1. Demonstrating that his or her food service establishment is in compliance with the Chapter. The person in charge or PIC can demonstrate the required compliance status receiving a food service routine or follow-up inspection without any risk factors and public health interventions being found in violation of the Chapter.

Option 2. Demonstrate knowledge of food safety by receiving and maintaining a food safety certification, as a Certified Food Safety Manager (or CFSM), by passing an

examination that is part of an accredited program. Currently, Georgia only recognizes those exams that are accredited by ANSI as meeting Conference for Food Protection (CFP) criteria.

Option 3. If the food service establishment does not have a CFSM working during the time of the inspection (example CFSM has gone to the bank) and the establishment has one or more risk factors/public health interventions violated during the inspection, the PIC must demonstrate his/her knowledge of foodborne illness, HACCP, and the requirements of the Chapter through assessment by the Health Authority. This assessment will occur through dialogue between the EHS and the PIC determine whether or not the PIC has a clear understanding of the Chapter and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented. During this dialogue, the EHS will assess the PIC's knowledge through a series of questions pertinent to their establishment. If the PIC can answer questions concerning his operation in regards to the Rules and Regulations for food service,then he/she has demonstrated knowledge of food safety as it relates to his/her food service operation.

Demonstration of Knowledge using Option 3 may be assessed by:

1. Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee; (How can each employee's personal hygiene prevent foodborne disease? Example: The dishwasher/server/busboy needs to wash his hands after his hands have touched soiled dishes and before touching clean dishes. The person cooking needs to wash his hands after touching potentially hazardous foods and before handling ready to eat foods. All employees need to wash hands after using the restroom, touching face, carrying out garbage, etc.)

2. Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease; (Does the person in charge know that he has the responsibility to ensure a food employee with a disease or medical condition that may cause a foodborne disease is excluded or restricted? Can he explain the difference between exclude and restrict, and does he know when to exclude or restrict? Can the person in charge name the illnesses that require exclusion from the food service establishment? Does the person in charge know what action to take when a food service worker or health authority notifies him that a food service worker has a reportable disease that can be transmissible through food?)

3. Describing the symptoms associated with the diseases that are transmissible through food; (Can the person in charge describe symptoms that are associated

with diseases that are transmissible through foods, and does he know what to do when the symptoms are present in a food service worker?)

4. Explaining the significance of the relationship between maintaining the time and temperature of potentially hazardous food (PHFs) and the prevention of food-borne illness; (Does the person in charge know what record keeping is required when using time in lieu of temperature when handling PHFs, and can he provide documentation of this information if used? Can the person in charge tell the EHS the maximum amount of time or the temperature limits of PHFs being held? Can the person in charge tell the EHS the corrective action to take when PHFs are found to exceed holding time limits or not at correct temperatures?)

5. Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish; (Can the person in charge explain why a consumer advisory is needed if serving raw or undercooked meat, poultry, eggs, and/or fish? Can the person in charge show where the consumer advisory is required to be printed and displayed?)

6. Stating the required food temperatures and times for safe cooking of potentially hazardous food including meat, poultry, eggs, and fish; (Can the person in charge give the minimum cook temperatures and times of PHFs or produce documentation of this information for the employees who are cooking PHFs?)

7. Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food; (Can the person in charge state the times and temperatures for holding, cooling, and reheating PHFs that are served in the establishment?)

8. Describing the relationship between the prevention of food-borne illness and the management and control of the following (Can the person in charge explain how these can contribute to food-borne illness, and the proper procedures to ensure that incorrect practices do not contribute to food-borne illness?):
    a. Cross contamination,
    b. Hand contact with ready-to-eat foods,
    c. Handwashing, and
    d. Maintaining the food establishment in a clean condition and in good repair.

9. Explaining the relationship between food safety and providing equipment that is (Can the person in charge explain why the right equipment is needed and must be kept in good repair to ensure food safety?):
    a. Sufficient in number and capacity, and
    b. Properly designed, constructed, located, installed, operated, maintained, and cleaned.

10. Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment; (Can the person in charge explain the correct cleaning and sanitizing procedures and frequency needed for the equipment and utensils used in the establishment?)

11. Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections; (Can the person in charge identify the water source and the protective measures to prevent contamination from backflow?)

12. Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safety stored, dispensed, used, and disposed of according to law; (Can the person in charge show the EHS proper storage, labeling, and use of chemicals in the establishment?)

13. Identifying critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of food-borne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of the Rules and Regulations for Food Service; (Can the person in charge identify proper thermometers and/or other monitoring equipment and calibration techniques?)

14. Explaining the details of how the person in charge and food employees comply with an approved HACCP plan for a process that varies from the Rules; (Can the person in charge identify the critical control points, mode of monitoring, location of records, and corrective actions when out of compliance situations are identified?)

15. Explaining the responsibilities, rights, and authorities assigned by the Rules and Regulations for Food Service to the Food employee; (Has the food employee been made aware of diseases that he must report to person in charge?); Conditional employee(Has the person who has been made a job offer been made aware of diseases and symptoms that he must report to the person in charge?); Person in charge, (Does the person in charge know his responsibilities to prevent food-borne illnesses, promote food safety, and provide information to the EHS during inspection?); and Regulatory authority (Does the person in charge know that the regulatory authority should introduce himself or herself to the person in charge, present identification if requested, and follow all policies and procedures to prevent food-borne illnesses that are required of industry?

16. Explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and exclusion or restriction of food employees.

NOTE: The above questions must be pertinent to the food service operation. The PIC is not responsible for demonstrating knowledge regarding processes or operational steps that are not performed in the facility. For instance, if cooling of PHF/TCS (Potentially Hazardous Foods/Temperature Control for Safety Foods) is not part of the food processing of the food service establishment, then the PIC would not be expected to answer questions regarding cooling. Another example would be in the case where a food service establishment did not process PHF/TCS foods that required an approved HACCP plan. However, all PICS are expected to understand the general Hazard Analysis Critical Control Point principles and when the Chapter would require a HACCP plan.

Key Drop Deliveries.

When food and other purchased goods are delivered and placed into designated locations within the food establishment during non-operating hours, the Person in Charge must make sure food employees inspect such product and verify that it is from the appropriate supplier, is in the desired condition, and was delivered to a proper storage location. Distributors deliver and place food and other goods in refrigeration units, freezers, and dry storage areas for confirmation of receipt and inspection by employees immediately upon arrival to the food establishment. Distributors contracted by the food establishment are often given a key to allow access into the establishment outside of normal working hours. Upon delivery, all food must be appropriately stored in a safe and secure manner within the food establishment. For example, time/temperature control for safety foods must be stored within refrigeration units and held at temperatures of 41°F or below. Likewise, if the food product is frozen, it must be placed into the freezer. For purposes of enforcing the Chapter, an entity performing delivery work under contract for the establishment shall be considered to be an employee of the establishment.

Certified Food Protection Manager.

The increasing complexity of the food industry, the improved ability to identify/trace foodborne outbreaks and other economic, staffing, cultural and behavioral challenges make it imperative that food protection managers know and control the risk factors that impact the safety of the food they sell or serve. Food protection managers have an important role in formulating policies, verifying food employees carry out these policies, and communicating with these same employees to give information about recommended practices to reduce the risk of foodborne illness. A Centers for Disease Control and Prevention Environmental Health Specialist-Network (EHS-Net) study suggests that the presence of a certified food protection manager reduces the risk for a foodborne outbreak

for an establishment and was a distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had not. FDA's Retail Food Risk Factor Studies suggest that the presence of a certified manager has a positive correlation with more effective control of certain risk factors, such as poor personal hygiene, in different facility types. The phrase “who is responsible for managing food safety of the operation” at the time of inspection was added to the term Person in charge within the Chapter to denote that the person in charge should have managerial authority to take control of out of control risk factors. Of course, if no individual has been designated as the person in charge at the time of inspection, then any employee present may be considered the person in charge by the Health Authority. At least one employee that has supervisory and management responsibility and the authority to direct and control food preparation and service shall be a certified food safety manager who has shown proficiency of required information through passing a test that is part of an accredited program that conforms to the national standards for organizations that certify individuals. Certified Food Safety Managers must be designated to one food service establishment only and maintain and renew certification in accordance with the requirements of the examination taken. An establishment must employ a CFSM within 60 days of initial permit issuance, change of ownership permit issuance, or termination of employment of its CFSM. The CFSM is responsible for providing active managerial control for the risk factors within an establishment so it is very important to have a CFSM for each establishment within a reasonable amount of time.

Certification Requirements and Exemptions.

Background: The FDA in a Memorandum of Understanding recognizes the Conference for Food Protection (CFP) as a voluntary national organization qualified to develop standards to promote food protection. The FDA encourages agencies of government to accept certificates issued by listed certifiers as meeting their jurisdiction’s food safety knowledge and certification requirements. The American National Standards Institute (ANSI) hasindependently evaluated these certification programs under an agreement with the Conference for Food Protection.

Certification Program Recognition:

The State of Georgia Department of Public Health (DPH)’s Environmental Health office recognizes the American National Standards Institute (ANSI) as an accrediting organization. ANSI, as a recognized accrediting organization for personnel certification in food safety, is a source to meet Certified Food Safety Manager (CFSM) certification requirements. Generally, Georgia recognizes a food safety course that consists of at least an 8-hour minimum curriculum (including test time). In addition, Georgia will only accept food safety exams that are currently certified through ANSI as meeting the Conference for Food Protection requirements. A link to the ANSI website can be found at the Environmental Health website at www.georgiaeh.us for more information.

The following food service operations are not required to have a food safety certified owner or manager (i.e., CFSM):

1. A mobile food service unit that does not do any processing of food onboard other than holding and serving does not require a CFSM on board the unit. Food is loaded onto the unit prepackaged in single servings ready to be served to the consumer or limited to commercially processed PHF/TCS, ready-to-eat foods that only require warming prior to service. These also could be units where all food is processed at their base of operation and their unit is just a holding and service (or vending) unit. Examples of these types of units are the vehicle vender as referenced in Rule -.08 subsections (1) (b) 1. & 2. and the hotdog/food cart as referenced in Rule -.08 subsection (1) (b) 3. or could be a fully enclosed-type units where no food processing is taking place on board the units.

2. Food service establishments that serve non-PHF/non-TCS foods (or non-potentially hazardous foods) requiring limited preparation, such as popcorn or snow cones. In addition, foods that prove to be non-PHF/non-TCS foods as defined within Rule -.01 of the Chapter would be considered as well. Further, these establishments could be food service establishments that do serve PHF/TCS foods (or potentially hazardous foods) that are prepared within a central kitchen and transported to food service establishments owned by the permit holder of the central kitchen.

3. All temporary food service establishments that are in compliance with Rule -.08 subsection (2) (a) of the Chapter.

Food Protection Manager Certification.

Many food protection manager certification programs have shared a desire to have the food manager certificates they issue universally recognized and accepted by others – especially by the increasing number of regulatory authorities that require food manager certification.

Needed has been a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and administration.

After a multi-year effort involving a diversity of stakeholder groups, the Conference for Food Protection (CFP) completed work on its ***Standards for Accreditation of Food Protection Manager Certification Programs*** found at: http://www.ansi.org/Accreditation/documents/cfpstandard.pdf. In 2002 the Conference entered into a cooperative agreement with the American National Standards Institute (ANSI) to provide independent third-party evaluation and accreditation of certification

bodies determined to be in conformance with these Conference standards. ANSI published its first listing of accredited certifiers in 2003.

The Acting Commissioner of the Food and Drug Administration, in his address before the 2004 biennial meeting of the Conference for Food Protection, commended this Conference achievement and encouraged universal acceptance based on the CFP/ANSI accreditation program.

Distributed at this meeting was the following letter addressed to the Conference Chair and signed by the Director of FDA's Center for Food Safety and Applied Nutrition. The letter puts forth the Agency's basis for its support of universal acceptance of food protection manager certifications.

> "The 2004 biennial meeting of the **Conference for Food Protection** is a fitting occasion for FDA's Center for Food Safety and Applied Nutrition to commend the Conference for its significant achievements in support of State and local food safety programs.
>
> The FDA in a Memorandum of Understanding recognizes the Conference for Food Protection as a voluntary national organization qualified to develop standards to promote food protection. Conference recommendations contribute to improvements in the model FDA Food Code and help jurisdictions justify, adopt and implement its provisions.
>
> Conference mechanisms involving active participation by representatives of diverse stakeholder groups produce consensus standards of the highest quality. An excellent example is the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***, and its announcement of the new on-line listing of accredited certifiers of industry food protection managers. Many years in their development, these Conference standards identify the essential components necessary for a credible certification program. Components cover a wide range of requirements such as detailed criteria for exam development and administration, and responsibilities of the certification organization to candidates and the public.
>
> FDA applauds the Conference for this significant achievement, and encourages agencies at all levels of government to accept certificates issued by listed certifiers as meeting their jurisdictions' food safety knowledge and certification requirements. The American National Standards Institute (ANSI) has independently evaluated these certification programs under an agreement with the Conference for Food Protection. Governments and industry widely recognize and respect ANSI as an accrediting organization. ANSI has found certifiers it lists as accredited

(http://www.ansi.org/) under "conformity assessment" – "personnel certification accreditation" to conform to the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***.*

FDA encourages food regulatory authorities and others evaluating credentials for food protection managers to recognize the Conference for Food Protection/ANSI means of accrediting certification programs. This procedure provides a means for universal acceptance of individuals who successfully demonstrate knowledge of food safety. The procedure provides officials assurance that food safety certification is based on valid, reliable, and legally defensible criteria. In addition, universal acceptance eliminates the inconvenience and unnecessary expense of repeating training and testing when managers work across jurisdictional boundaries.

FDA, along with State, local, tribal, and other Federal agencies and the food industry, share the responsibility for ensuring that our food supply is safe. It is anticipated that this new Conference for Food Protection/ANSI program will lead to enhanced consumer protection, improve the overall level of food safety, and be an important component of a seamless national food safety system."

Duties **Person in Charge.**

A primary responsibility of the person in charge is to ensure compliance with the Chapter requirements. The PIC is in charge during all hours of operation and ensures the continuous presence of someone who is responsible for monitoring employee activity, training of employees and who is authorized to take corrective actions to ensure food is safe. When the Certified Food Safety Manager (CFSM) is on the premises of the food service establishment, he or she is the person in charge (PIC). If the CFSM is not on the premises of the food service establishment, the CFSM must designate an employee to be the PIC. If no employee of the establishment has been designated as the PIC at the time of a food service inspection, then any employee of the establishment will be considered as the establishment's PIC.Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Chapter requirements, the person in charge establishes an important

*The ANSI-CFP Accreditation Program list of accredited organizations utilizing the Conference for Food Protection (CFP) Standards may be viewed on-line by going to: https://www.ansica.org/wwwversion2/outside/ALLdirectoryListing.asp?menuID=8&prgID=8&status=4

** Accredited program does not refer to training functions or educational programs.

barrier to food contamination.

Authorized Personnel Access.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

When food and other purchased goods are delivered and placed into designated locations within the food establishment during non-operating hours, the Person in Charge must make sure food employees inspect such product and verify that it is from the appropriate supplier, is in the desired condition, and was delivered to a proper storage location. Distributors deliver and place food and other goods in refrigeration units, freezers, and dry storage areas for confirmation of receipt and inspection by employees immediately upon arrival to the food establishment. Distributors contracted by the food establishment are often given a key to allow access into the establishment outside of normal working hours. Upon delivery, all food must be appropriately stored in a safe and secure manner within the food establishment. For example, time/temperature control for safety foods must be stored within refrigeration units and held at temperatures of 41°F or below. Likewise, if the food product is frozen, it must be placed into the freezer.

To minimize the potential for access to the food establishment and the food by an unauthorized person, precautions should be applied overall to the food establishment and especially when access to the facility is made under key access deliveries. Additional information on food defense can be viewed at:
http://www.fda.gov/Food/FoodDefense/default.htm

Food Safety Training and Allergy Awareness.

Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S. population, or twelve million Americans. Restaurant and retail food service managers need to be aware of the serious nature of food allergies, including allergic reactions, anaphylaxis, and death; to know the eight major food allergens; to understand food allergen ingredient identities and labeling; and to avoid cross-contact during food preparation and service. The 2008 Conference of Food Protection (CFP) passed Issue 2008-III-006 which provided that food allergy awareness should be a food safety training duty of the Person in Charge. Accordingly, the Person in Charge's Duties under paragraph (M) were amended to assure the food safety training of employees includes food allergy awareness in order for them to safely perform duties related to food allergies.
As per DPH Rule 511-6-1-.03(2)(l), employees must be properly trained in food safety, including food allergy awareness, as it relates to their assigned duties to allow industry

to develop and implement operational-specific training programs for food employees. It is not intended to require that all food employees pass a test that is part of an accredited program.

Role of CFSM and PIC: The Chapter does not require that a CFSM be in the food service establishment at all hours of operation. It does require that each food service establishment that is required to have a CFSM employs at least one CFSM that is designated for that establishment only as specified in Rule -.03(3)(b) and that the CFSM has the responsibility for ensuring that all employees who handle or have responsibility for handling, unpackaged foods of any kind have sufficient knowledge of safe preparation and service of the food as specified in Rule -.03(3)(d) and be the person-in-charge or PIC when he or she is on the premises or designate someone else as the PIC that has adequate food safety knowledge when he or she is not on the premises to ensure proper management of food safety during all hours of operation.

Employee Health.

The purpose of this section is to reduce the likelihood that certain viral and bacterial agents will be transmitted from infected food employees into food. Food-borne illness outbreaks have been linked to food employees preparing foods while they are sick. Outbreaks of illness have also been linked to employees experiencing symptoms of illness. These illnesses are then transferred to the food that the ill employees are preparing.

Management must be aware that an Employee Health Policy is required, and they must have such a policy in place. While a written policy is not required at this time, it is highly recommended so that record keeping and training is easier to manage.

Reporting Symptoms.

The person in charge is responsible for ensuring all food employees are knowledgeable and understand their responsibility to report whenever they are ill with vomiting, diarrhea, jaundice, sore throat with fever or a lesion containing pus or have been diagnosed with one of the following “Big 6” food-borne illnesses: typhoid fever (Salmonella Typhi), nontyphoidal Salmonella, Hepatitis A virus, Norovirus, Shigella spp. or Enterohemorrhagic or Shiga-toxin producing Escherichia coli. Management must ensure newly hired employees are interviewed so that it is clear whether or not the employee has experienced any of the symptoms of foodborne illness listed above or has been diagnosed with any of the “Big 6” foodborne illnesses. The person in charge also must be cognizant of when an employee might be experiencing symptoms or illness. When an employee does report symptoms of foodborne illness or that they have been diagnosed with one of the “Big 6”, the PIC is responsible for knowing whether to restrict or exclude the employee, and to know when it is safe for the employee to be removed from a restriction or exclusion as per the Chapter.

Responsibility of the PIC and Food Employees.

In Rule -.03, the Chapter emphasizes the important role the Person in Charge (PIC) has in making sure employees properly report certain information about their health status as it relates to diseases that are transmitted by food. In an effort to reinforce dialogue between food employees and the PIC, there must be a way to verify that food employees and conditional employees are informed of their responsibility to report such information. Examples of ways to verify that employees have been appropriately informed include:

- The ability to provide documentation that all food employees and conditional employees are informed of their responsibility to report to management, such as completion of “Conditional Employees or Food Employees Reporting Agreement”;

- Presenting evidence such as curriculum and attendance rosters documenting that each employee has completed a training program which includes all the information required for reporting in the “Conditional Employees or Food Employees Reporting Agreement”;

- Implementation of an employee health policy that includes a system of employee notification using a combination of training, signs, pocket cards or other means to convey all the required information;

- Other methods that satisfactorily demonstrate that all food employees and conditional employees are informed of their responsibility to report to the PIC information about their health and activities as it relates to diseases that are transmissible through food, as specified by the Chapter.

Exclusion and Restriction of Ill Employees.

Except when the symptoms are from a noninfectious condition, employees who have specific symptoms (e.g., vomiting, diarrhea, jaundice) must be excluded from the food facility.

Written Plans and Procedures

In various places throughout the Chapter, it is specified that either written operating procedures or operational plans be developed. The link between management responsibility for developing and implementing the procedures or plans is now established as a new duty for the Person in Charge (PIC). This new provision does not establish new requirements in the development of plans or procedures; rather it emphasizes the importance of the role the PIC plays in ensuring active managerial control of the food establishment with the development and implementation of plans

and/or procedures as specified in the Chapter. Some examples of Chapter provisions that call for written plans or procedures are clean-up of vomiting and diarrheal events, pets in outside dining areas (only when accessed through the outside only), non-continuous cooking of raw animal foods, Time as a Public Health Control (TPHC), variance/HACCP plans, emergency operations plans (as needed), etc. In addition, records for cleaning playground equipment (when applicable) must be maintained. Ultimately, responsibility for food safety at the retail level lies with retail and food service operators and their ability to develop and maintain effective food safety management systems. There are many tools that industry can use to develop an effective system to achieve active managerial control of foodborne illness risk factors. An important tool in controlling risk factors inherent in a food establishment is the development and implementation of written procedures or plans such as those mentioned above and others that are used to control for risk factors.

Employee Health.

The purpose of this section of the Chapter is to reduce the likelihood that certain viral and bacterial agents will be transmitted from infected food employees into food. The agents of concern are known to be readily transmissible via food that has been contaminated by ill food employees, and so for that reason, are the primary focus of the Employee Health section of the Chapter. 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 employees 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 Shiga toxin-producing ***Escherichia coli*** (STEC), ***Shigella*** spp. infection, or nontyphoidal *Salmonella*.

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 STEC, 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). Dark urine and light colored stool may be an indicator of a hepatitis A infection but may go unreported.

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.

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. 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. 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 Chapter provides restriction guidelines for food employees working in facilities serving a HSP. 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 working in facilities not serving a HSP pay particular attention to personal hygiene and report the onset of any symptoms. 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 employee 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 Chapter 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 six 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 with the Food Code (by which the Chapter is based upon) 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 Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens posted on CDC's website, and from the Control of Communicable Diseases Manual, 19th Ed., David L. Heymann, MD, Editor, by the American Public Health Association, Washington D.C., 2008.

Infected Food Employees and Conditional Employees Practical Applications of Using DPH 511-6-1-.03

The information provided in Rule -.03 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 Rule -.03 by a food establishment manager may involve using Rule -.03 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 Rule -.03 during a facility food safety inspection.

The development and effective implementation of an employee health policy based on the provisions in Rule -.03 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 Chapter. 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 Chapter requirement unless the facility is operating under a pre-approved required HACCP plan.
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 6 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 Reporting Symptoms and Diagnosis

Responsibility of the Person in Charge, Food and 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 Chapter 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 Chapter 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. The questions or examinations are designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990. 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. When a symptomatic or diagnosed conditional employee has met the same criteria for reinstatement that apply to an excluded

symptomatic or diagnosed food employee, 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 Chapter 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.

The symptoms of vomiting, diarrhea, or jaundice 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 employees 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).

For a comprehensive understanding of the ADA and its implications, contact the U. S. Equal Employment Opportunity Commission. 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*, found at http://www.eeoc.gov/facts/restaurant_guide.html or http://www.eeoc.gov/facts/restaurant_guide_summary.html for detailed information about the interaction between the FDA Food Code and the ADA.

Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens

Some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle food may indicate infection by a pathogen that could be transmitted to others through handling the food supply: diarrhea, vomiting, open skin sores, boils, fever, dark urine or jaundice. The failure of food-handlers to wash hands in certain situations (such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage), wear clean gloves, or use clean utensils is responsible for the foodborne transmission of these pathogens. Non-foodborne routes of transmission, such as from one person to another, are also major contributors in the spread of these pathogens.

Some pathogens usually cause disease when food is intrinsically contaminated or cross-contaminated during production, processing or transportation, but may also be contaminated when prepared by infected persons. Bacterial pathogens in this category often cause disease after bacteria have multiplied in food after it has been kept at improper temperatures permitting their multiplication to an infectious dose. Preventing food contact by persons who have an acute diarrheal illness will decrease the risk of transmitting these pathogens.

The following represent both types of pathogens that may be transmitted by an infected food handler:

Astroviruses	*Bacillus cereus*	*Campylobacter jejuni*
Clostridium perfringens	*Cryptosporidium species*	*Entamoeba histolytica*
Enterohemorrhagic *E. coli*	Enterotoxigenic *E. coli*	*Giardia intestinalis*
Hepatitis A virus	Nontyphoidal *Salmonella*	Noroviruses
Rotaviruses	*Salmonella* Typhi*	Sapoviruses
Shigella species	*Staphylococcus aureus*	*Streptococcus pyogenes*

Taenia solium - cysticercosis *Vibrio cholera* *Yersinia enterocolitica*

* 1. Kauffmann-White scheme for designation of Salmonella serotypes

The 6 Listed Pathogens:

The CDC has designated the 6 organisms listed in the Chapter 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 19th Edition of Control of Communicable Diseases Manual, the CDC website, and the FDA Bad Bug Book, 2nd Edition, and is provided as background information on pathogen virulence, infectivity, and common symptoms exhibited with infection of each of the 6 listed pathogens.

NOROVIRUS

Noroviruses (genus Norovirus, family Caliciviridae) are small (27-40 nm), round structured, single-stranded RNA, nonenveloped viruses. They are a genetically diverse group classified into at least five genogroups, designated GI-GV, which are further sub-divided into at least 35 genotypes. Noroviruses are recognized as the most common cause of epidemic and sporadic gastroenteritis across all age groups worldwide.

Transmission of norovirus occurs primarily through the fecal-oral route, including direct person-to-person contact and indirect transmission through contaminated food, water, or environmental surfaces. Vomitus-oral transmission can also occur through aerosolization followed by direct ingestion or environmental contamination.

Noroviruses are the leading cause of foodborne illness in the United States. Food handler contact with raw or other ready-to-eat foods is the most common scenario resulting in foodborne norovirus outbreaks. Norovirus contamination of produce and shellfish can also occur during production. Secondary household transmission is common.

Noroviruses are environmentally stable, able to survive both freezing and heating (although not thorough cooking), are resistant to many common chemical disinfectants, and can persist on surfaces for up to 2 weeks. Proper hand hygiene and exclusion of food employees exhibiting symptoms of norovirus disease (i.e., diarrhea or vomiting) are critical for norovirus control.

Incubation Period: In volunteer studies, the range is 10-50 hours. In foodborne

norovirus outbreaks, the median incubation period is 33 hours.

Symptoms and Complications: Acute-onset of vomiting, watery non-bloody diarrhea, abdominal cramps, and nausea, or a combination of these symptoms. Low grade fever and body aches may also be associated. Symptoms typically last 24 to 72 hours. Norovirus disease is usually self-limited without any serious long-term sequelae. Among the young and the elderly, dehydration is a common complication. Volunteer studies have found that as many as 30% of individuals infected with norovirus are asymptomatic. There is no specific treatment for norovirus disease. Supportive therapy consists of oral or intravenous rehydration solutions to replace fluid loss and electrolytes. Previous exposure does not provide long-term immunity; thus, individuals may be repeatedly infected throughout their lifetimes.

Infectivity: Noroviruses are highly contagious, and it is thought that an inoculum of as few as 18 viral particles may be sufficient to infect an individual. Although pre-symptomatic shedding may occur, shedding usually begins with onset of symptoms, peaks 4 days after exposure, and may persist for 3 weeks after recovery. However the degree of infectivity of prolonged shedding has not been determined and peak contagiousness is during the acute stage of disease. Peak viral loads in both symptomatic and asymptomatic infections (may be as high as 100 billion viral particles/g feces).

NONTYPHOIDAL *SALMONELLA*

Caused by serotypes ***other than*** *S.* Typhi and *S.* Paratyphi A.

Unlike previous editions of the FDA Food Code, the 2013 edition requires food employees to report a diagnosis of nontyphoidal *Salmonella* (NTS), prompts the person in charge to exclude food employees with diagnosis of NTS, and provides conditions for reinstatement of a food employee who provides to the person in charge written medical documentation from a health practitioner that states the food employee is free from NTS, and where appropriate, approval from the regulatory authority

Nontyphoidal *Salmonella* (NTS) *enterica* serotypes are among the most common bacterial cause of foodborne illness. NTS are estimated to cause more than one million domestically acquired foodborne illnesses in the United States each year (Scallan et. al. 2011), and are the leading cause of hospitalizations and deaths due to foodborne illness in the United States (Barton-Behravesh et al. 2011, CDC 2011). Whereas reductions in incidence have been achieved for many other foodborne pathogens in recent years, no significant change in incidence of NTS infections has occurred since the start of FoodNet surveillance during 1996–1998 (CDC 2011). Therefore, further interventions are needed to reduce the incidence of NTS infections.

Commercial food establishments are an important setting for the transmission of NTS, both in the form of recognized foodborne disease outbreaks as well as sporadic

infections. During 1998 to 2002, the 585 *Salmonella enterica* outbreaks reported to the Centers for Disease Control and Prevention accounted for 49% of all bacterial outbreaks (Lynch et al. 2006). Forty-six percent of *Salmonella* outbreaks occurred in restaurant/deli establishments, the most common setting for *Salmonella* outbreaks (Lynch et al. 2006). For the period of 2009-2010, the 243 *Salmonella* outbreaks reported to the CDC accounted for 51% of bacterial foodborne disease outbreaks. Outbreaks of salmonellosis at commercial food establishments frequently involve direct transmission to patrons from fresh produce or undercooked foods of animal origin, or cross contamination from these foods. However, numerous NTS outbreak investigations have implicated food workers as the source of the outbreak or strongly suggested transmission from food workers (Ethelberg et al. 2004; Greig et al. 2007; Hedberg et. al. 1991; Hedican et al. 2009; Hundy and Cameron 2002; Khuri-Bulos et al. 1994; Maguire et al. 2000; Medus et al. 2006; Todd et al 2007a, 2007b).

In a study of restaurant-associated salmonellosis outbreaks in Minnesota published by Medus et al. (2006), the importance of infected food workers as a source of contamination in the outbreaks was supported by several observations. First, a specific food vehicle was statistically implicated or suspected in a low proportion of the restaurant outbreaks (39%), which suggests that the specific food items or food handling errors were not the primary causes for these outbreaks. Second, food workers infected with NTS were identified in the majority (83%) of the outbreak investigations. Infected food workers who reported a history of illness shed NTS in the stool for a median of 1 month. The authors concluded that regardless of the original source of a *Salmonella* outbreak in a restaurant (e.g., raw meat or eggs), the initial source of a salmonellosis outbreak, food workers frequently serve as reservoirs for NTS and contribute to transmission to patrons. Thus, assessment of food worker history, i.e., symptoms and exposures, testing of stool samples and exclusion or restriction of infected food workers from the food establishment are essential for controlling restaurant-associated outbreaks of salmonellosis.

In a study of food workers with salmonellosis who were detected through routine surveillance (Medus et al. 2010), 2.2% of identified culture-confirmed *Salmonella* cases were food workers, and identification of these cases were critical to the identification of numerous outbreaks. The authors concluded that the rapid identification and follow-up of food workers among reported cases of salmonellosis is important to the early detection and control of outbreaks in restaurant settings. Importantly, even hostesses, servers, bartenders, and others who theoretically have limited food preparation duties can serve as sentinels of transmission within the restaurant. The authors also stated that food workers should be considered an important source of *Salmonella* transmission, and those identified through surveillance should raise a high index of suspicion of a possible outbreak at their place of work. Food service managers need to be alert to *Salmonella*-like illnesses among food workers to facilitate prevention and control efforts, including exclusion of infected food workers or restriction of their duties.

The biology of NTS and the epidemiology of salmonellosis are complex; food workers may be an underappreciated part of that complexity. In order to decrease the incidence of NTS infections in the United States, commercial food establishments should also be targets for more focused prevention measures, and prevention and control efforts should consider food workers as an important source of NTS transmission.

General Description:
Nontyphoidal *Salmonella* (NTS) *enterica* are bacteria that cause a diarrheal illness called salmonellosis. NTS are among the most common and important causes of enteric disease. An estimated 1.2 million cases occur annually in the United States; of these, approximately 42,000 are culture-confirmed cases reported to the Centers for Disease Control and Prevention.

Salmonella lives in the intestines of animals or humans. It can be found in water, food, soil, or surfaces that have been contaminated with the feces of infected animals or humans. People can become infected with *Salmonella* by:

- Eating foods contaminated with the bacteria. Contaminated foods are often of animal origin, such as beef, poultry, unpasteurized milk, or eggs. Fruits and vegetables may also be contaminated. Any food can be contaminated by an infected food handler.
- Contacting farm animals or pets (including reptiles, amphibians, chicks, and ducklings), animal feces, or animal environments.
- Touching contaminated surfaces or objects and then touching ones mouth or putting a contaminated object into ones mouth.
- Drinking contaminated water.

Most infections are thought to be acquired through consumption of contaminated food.

Incubation Period: Symptoms often begin 12 to 72 hours after being exposed to the bacteria, although it can take up to a week or more for symptoms to develop in some people.

Symptoms and Complications:
Symptoms of salmonellosis include diarrhea, abdominal cramps, and fever. The illness usually lasts 4 to 7 days. Persons with NTS infections usually recover without treatment. However, in approximately 20% of persons, the illness is so severe that hospitalization is required. In these patients the NTS infection may spread from the intestine to the blood stream, and then to other body sites and can cause death unless the person is treated promptly with antibiotics. An estimated 400 fatal cases of salmonellosis occur each year. A small number of persons experience long-term consequences from NTS infections, such as arthritis that can last for months or years.

Antibiotic treatment for salmonellosis is generally not indicated for typical intestinal

illness. Antibiotics typically do not shorten the duration of illness or eliminate the carrier state. However, antibiotic treatment is recommended for persons who develop invasive (extraintestinal) infections, infants under 2 months of age, the elderly, or those who have certain underlying medical conditions that predispose them to invasive infection.

Infectivity:
The minimum infectious dose of NTS for humans is generally described as 100 to 1,000 organisms. However, doses of fewer than 10 organisms have caused illness in multiple outbreaks. Persistence of NTS in the stool after the acute phase of illness is a well described consequence of NTS infections. This persistence is often referred to as a temporary carrier state, and the term “shedding” is used to describe the excretion of *Salmonella* in the stool.

Studies have consistently shown that the median duration of shedding in the stool to be 4 to 5 weeks after onset of acute gastroenteritis. Persons who have been exposed to NTS but who never develop symptoms can also be temporary carriers of NTS; these persons shed NTS for a shorter period of time than persons who experienced illness. Carriers of NTS are known to shed the bacteria in the stool intermittently. Treatment with antimicrobials does not eradicate NTS from stool and may actually prolong the duration of shedding.

TYPHOID FEVER (CAUSED BY SALMONELLA TYPHI)

Salmonella enterica subspecies *enterica* serovar Typhi which is referred to in the Chapter as typhoid fever (caused by Salmonella 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 ***typhoid fever*** 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: Generally 1 to 3 weeks, but may be as long as 2 months after exposure.

Symptoms and Complications: High fever, from 103° to 104°F; lethargy; gastrointestinal symptoms, including abdominal pains and diarrhea or constipation; headache; achiness; loss of appetite. A rash of flat, rose-colored spots sometimes occurs. Septicemia, with colonization of other tissues and organs; e.g., may lead to endocarditis. Septic arthritis may occur, in which the infection directly affects the joints and may be difficult to treat. Chronic infection of the gallbladder may occur, which may cause the infected person to become a carrier.

Infectivity: The minimal infectious dose is estimated to be less than 1000 bacterial

cells. An individual infected with ***typhoid fever*** 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.

SHIGA TOXIN-PRODUCING ESCHERICHIA *COLI*

E. coli O157:H7 is the most commonly identified serotype of 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 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 O26, O111, O103, O45, and O121.

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). Infections with STEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). [Note: "enterohemorrhagic" (EHEC) is a subset of STEC that has the capacity to both produce Shiga toxin and cause "attaching and effacing" lesions in the intestine.]

Incubation period: Symptoms usually begin 3 to 4 days after exposure, but the time may range from 1 to 9 days.

Symptoms and Complications: Hemorrhagic colitis is characterized by severe cramping (abdominal pain), nausea or vomiting, and diarrhea that initially is watery, but becomes grossly bloody. In some cases, the diarrhea may be extreme, appearing to consist entirely of blood and occurring every 15 to 30 minutes. Fever typically is low-grade or absent. Infections from EHEC may range from asymptomatic to mild diarrhea to severe, life threatening complications (e.g., hemorrhagic colitis, hemolytic uremic syndrome)). About 3% to 7% STEC infections progress to HUS .

Infectivity: The infective dose of E. coli O157:H7 is estimated to be very low, in the range of 10 to 100 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 STEC in the stool is typically 1 week or less in adults, but can be up to 3 weeks or longer 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 employees' hands, are common causes of disease transmission. Multidrug-resistant ***Shigella*** (including ***S. dysenteriae* type** 1) have appeared worldwide. Concern over increasing antimicrobial resistance has led to reduced use of antimicrobial therapy in treating shigellosis.

Incubation period: Eight to 50 hours.

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 5-7 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 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 (IG) 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 employee 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 employee 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 undetectable 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: The infective dose of HAV is presumed to be low (10 to 100 viral particles), although the exact dose is unknown. The viral particles are excreted in the feces of ill people (symptomatic and asymptomatic) at high densities (10^6 to 10^8/gm) and have been demonstrated to be excreted at these levels for up to 36 days post-infection. 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 STEC, typhoid fever, HAV.

Which employees who report exposure are restricted?

Answer: Employees who work in a food establishment serving a highly susceptible population (HSP) facility, except those employees who are exposed to nontyphoidal Salmonella (NTS).

Why don't employees who are exposed to nontyphoidal *Salmonella* (NTS) need to be restricted?

Answer: For those employees who are exposed to nontyphoidal Salmonella, exposure alone does not necessitate restriction of the employee based on epidemiologic evidence of no increased risk of employees with only a history of exposure versus employees who were infected and diagnosed.

What constitutes exposure?

1. *Consuming a food that caused illness in another consumer due to infection with Norovirus, **Shigella** spp., **E. coli** O157:H7 or other STEC, typhoid fever, or HAV.*
2. *Attending an event or working in a setting where there is a known disease outbreak.*
3. *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?

Answer: 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?

Answer: 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 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?

*Answer: While the household member is symptomatic with an infection due to Norovirus, **Shigella** spp., **E coli** O157:H7 or other 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 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?

Answer: 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.

Exclusions and Restrictions.[1]

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 noninfectious 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 (caused by ***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., STEC, or nontyphoidal *Salmonella* (NTS), is excluded if exhibiting symptoms of vomiting and diarrhea, and then allowed to work as the level of risk of pathogen transmission decreases.

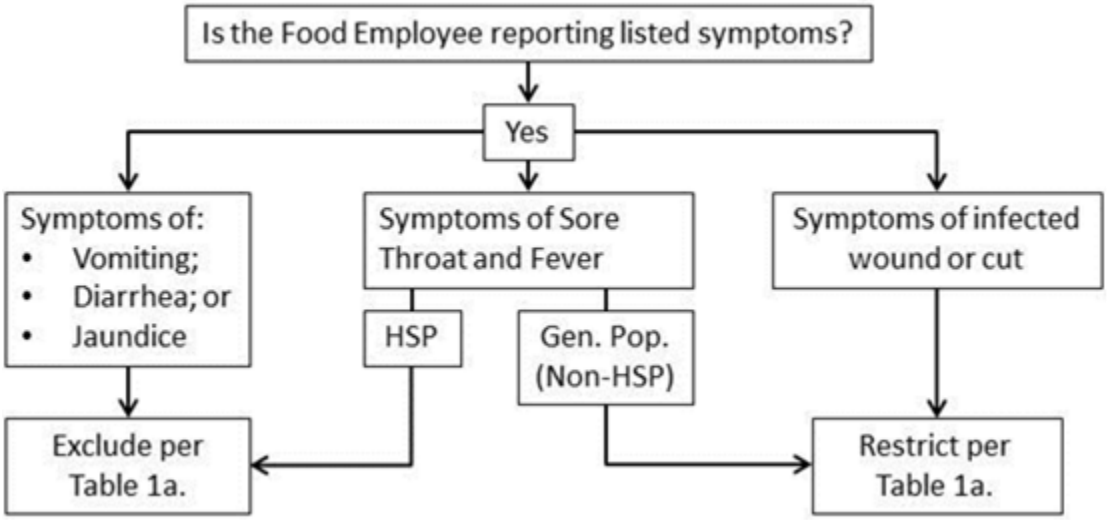
[1]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11 of the FDA Food Code. However, it is not possible to explain all relevant aspects of the ADA within the Annex. When faced with an apparent conflict between ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

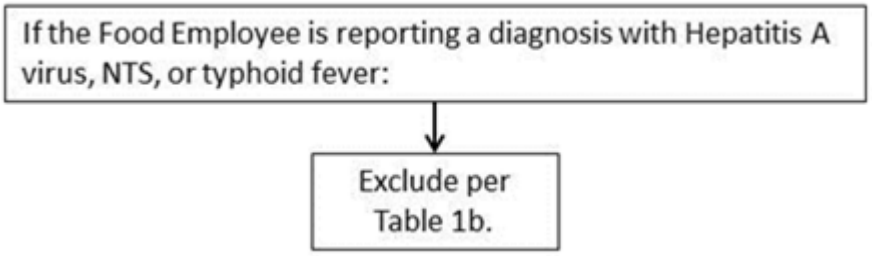
The degree of risk for a food employee or conditional employee who is diagnosed with an infection but asymptomatic with regard to symptoms, to transmit a foodborne pathogen decreases with the resolution of symptoms. This risk decreases even further for those employees that are diagnosed with a listed 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.

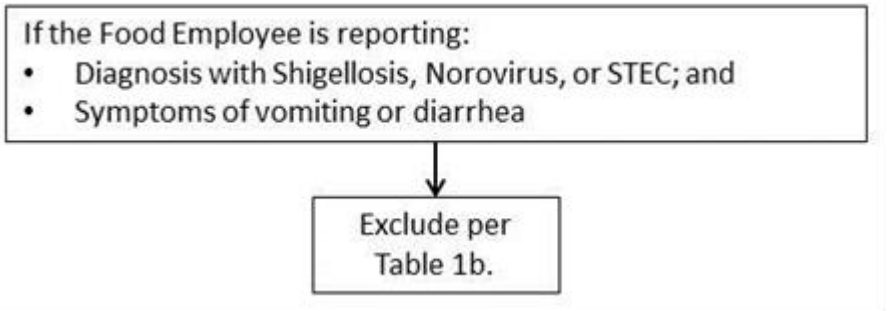
Restriction of food employees infected with NTS after resolution of symptoms has not been a national standard. However, because of the prolonged duration of shedding of NTS, evidence that food workers have been the source of foodborne outbreaks, evidence that food workers work while ill (Green et al. 2005), and evidence of inadequate hand hygiene practices (Green et al. 2006; US FDA 2004), exclusion or restriction of infected food worker duties is a reasonable public health measure. At a minimum, potential for transmission and how to prevent it should be discussed with the food employee and their manager.

There is no epidemiological evidence of an increased risk of NTS transmission from food employees in highly susceptible populations over the general population. Current evidence suggests that restriction is sufficient in food establishments that serve either highly susceptible populations or the non-highly susceptible populations to control transmission on NTS. Further, events where an infected food handler is involved in nontyphoidal salmonellosis outbreaks in establishments serving highly susceptible populations are much less frequent than those in establishments not serving highly susceptible populations. For example, from 1998-2011, only 41 nontyphoidal salmonellosis outbreaks were reported to CDC that occurred in nursing home facilities and 16 outbreaks in hospitals, compared with 731 outbreaks in restaurants or delis. There are many highly susceptible persons in the general population who eat in regular, non-institutionalized settings. A more restrictive exclusion criteria for establishments serving highly susceptible populations is not warranted at this time.

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 Chapter

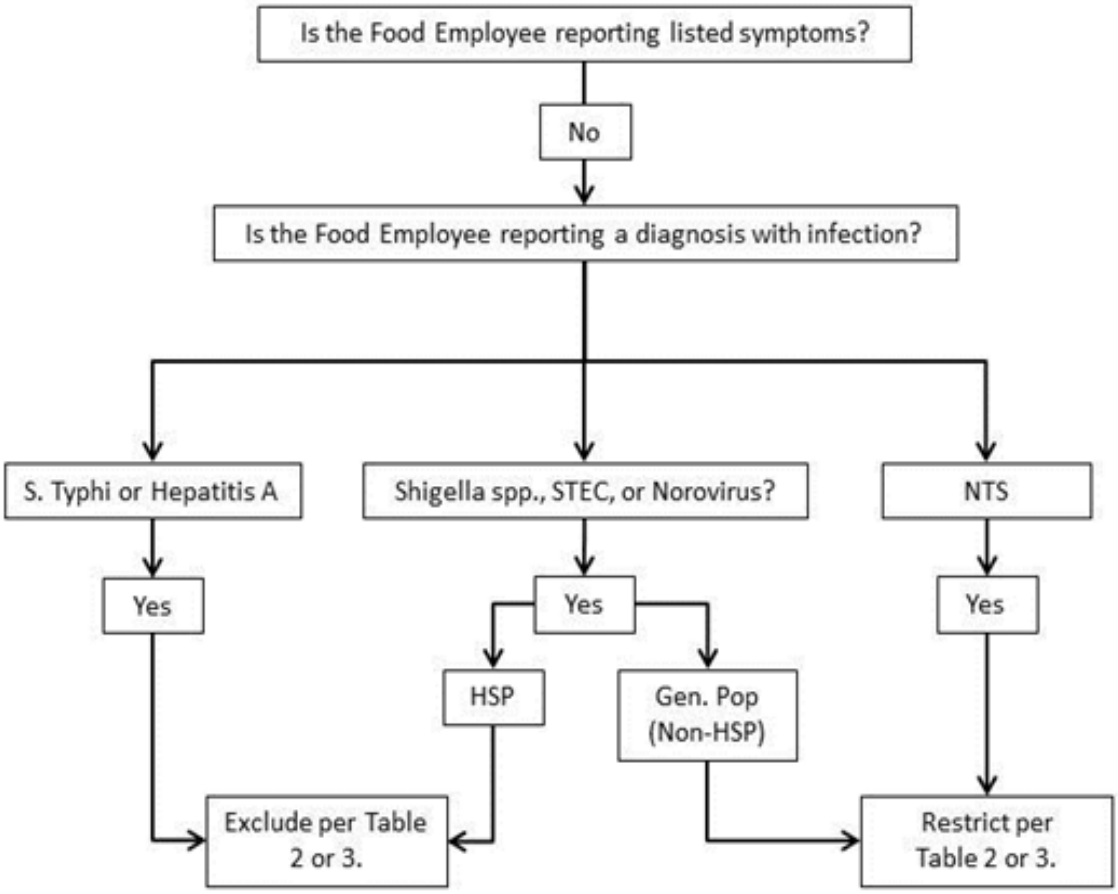






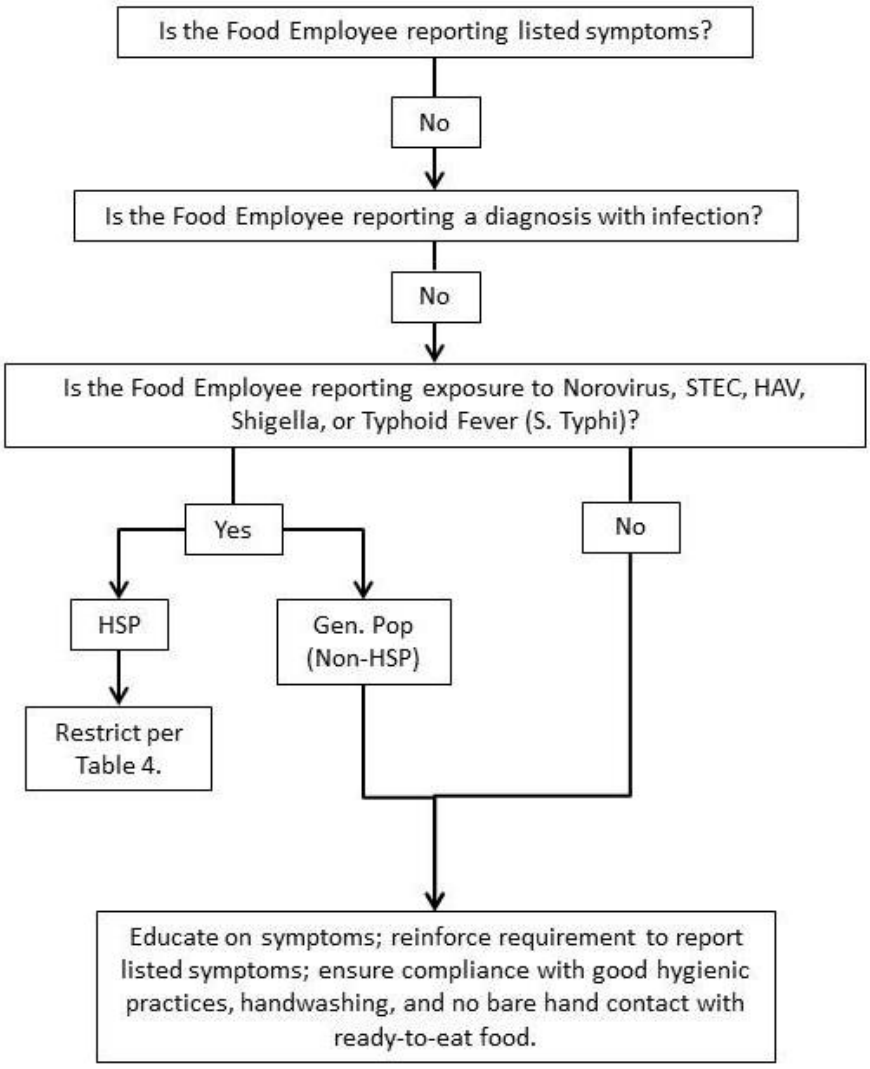
Key: Decision Tree 1
STEC = Shiga toxin-producing *Escherichia coli*
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

Decision Tree 2a. When to Exclude or Restrict a Food Employee Who is Asymptomatic Reports a Listed Diagnosis Under the Chapter



Key: Decision Tree 2a
STEC = Shiga toxin-producing *Escherichia coli*
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

Decision Tree 2b. When to Restrict a Food Employee Who Reports a Listed Exposure Under the Chapter



Key: Decision Tree 2b
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

Table 1a: Summary of Requirements for Symptomatic Food Employees

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 RULE - .03, of the Chapter, for reinstatement of a symptomatic food employee.

Symptom	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not serving an HSP)	Removing Symptomatic Food Employees from Exclusion or Restriction	RA Approval Needed to Return to Work?
Vomiting	**EXCLUDE**	**EXCLUDE**	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation**.** ***Exceptions:*** If diagnosed with Norovirus, ***Shigella*** spp., STEC, HAV, or typhoid fever (***S.*** **Typhi***)* (see Tables 1b & 2).	No if not diagnosed
Diarrhea	**EXCLUDE**	**EXCLUDE**	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation. ***Exceptions:*** If Diagnosed with Norovirus, STEC, HAV, or ***S.*** **Typhi** (see Tables 1b & 2).	No if not diagnosed
Jaundice	**EXCLUDE** if the onset occurred within the last 7 days	**EXCLUDE** if the onset occurred within the last 7 days	When approval is obtained from the RA, and: • Food employee has been jaundiced for more than 7 calendar days, or • Food employee provides medical documentation	Yes
Sore Throat with Fever	**EXCLUDE**	**RESTRICT**	When food employee provides written medical documentation 201.13(G) (1)-(3).	No
Infected wound or pustular boil	**RESTRICT**	**RESTRICT**	When the infected wound or boil is properly covered	No

Key: Table 1a
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

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 RULE-.03 of the Chapter, for reinstatement of a diagnosed, symptomatic food employee.

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	When approval is obtained from the RA and: • The food employee has been jaundiced for more than 7 calendar days, or • The anicteric food employee has had symptoms for more than 14 days**,** or • The food employee provides medical documentation	Yes
Typhoid Fever (***S*. Typhi**)	**EXCLUDE**	When approval is obtained from the RA and: • Food employee provides medical documentation, that states the food employee is free of a ***S*. Typhi** infection	Yes
Nontyphoidal *Salmonella*	**EXCLUDE** **Based on vomiting or diarrhea symptoms**	When approval is obtained from the RA and: • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal *Salmonella* infection or • Food employee symptoms of vomiting or diarrhea resolved and >30 days have passed since the food employee became asymptomatic.	Yes
STEC	**EXCLUDE** **Based on vomiting or diarrhea symptoms**	1. Serving a non-HSP facility: Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from RA, and • Medically cleared, or • More than 7 calendar days have passed since the food employee became asymptomatic.	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

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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?
Norovirus	**EXCLUDE** Based on vomiting or diarrhea symptoms, under	1. Serving a non-HSP facility: Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA, and • Medically cleared**,** or • More than 48 hours have passed since the food employee became asymptomatic	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Shigella spp.	**EXCLUDE** **Based on vomiting or diarrhea symptoms, under**	1. Serving a non-HSP facility: Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: Remains excluded until meeting the requirements in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA, and • Medically cleared, or • More than 7 calendar days have passed since the food employee became asymptomatic	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

Key: Table 1b
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*
Medical clearance/documentation for Shigella spp.; STEC, is based on test results from a health practitioner 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.

Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms

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 **RULE - .02** of the Food Code, for reinstatement of a diagnosed food employee.

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (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 (***S.* Typhi**) including previous illness with ***S.* Typhi**	**EXCLUDE**	**EXCLUDE**	When approval is obtained from the RA and: • Food employee provides medical documentation that states the food employee is free of an ***S*. Typhi** infection	Yes
Nontyphoidal *Salmonella*	**RESTRICT**	**RESTRICT**	When approval is obtained from the RA and: • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal *Salmonella* infection or • Food employee symptoms of vomiting or diarrhea resolved and >30 days have passed since the food employee became asymptomatic.	Yes

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Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Shigella spp.	**EXCLUDE**	**RESTRICT**	1. Serving a non-HSP facility: Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA and: • Medically cleared or • More than 7 calendar days have passed since the food employee became asymptomatic	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**	**RESTRICT**	1. Serving a non-HSP facility: Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA and • Medically cleared or • More than 48 hours have passed since the food employee became asymptomatic	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

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Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
STEC	**EXCLUDE**	**RESTRICT**	1. Serving a non-HSP facility: Shall only work on a restricted basis 24 hours after symptoms resolve and remains Restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA and • Medically cleared or • More than 7 calendar days have passed since the food employee became asymptomatic	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	**EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice**	**EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice**	When approval is obtained from the RA and: • The food employee has been jaundiced for more than 7 calendar days, or • The anicteric food employee has had symptoms for more than 14 days or • The food employee provides medical documentation**.**	Yes

Key: Table 2
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population NTS = Nontyphoidal *Salmonella*
Medical clearance/documentation for Shigella spp.; Enterohemorrhagic (EHEC) or Shiga toxin-producing E coli, is based on test results from a health practitioner 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.

Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

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 RULE - .03 of the Chapter, for reinstatement of a diagnosed food employee

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (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 (***S.* Typhi**) including previous illness with ***S.* Typhi**	**EXCLUDE**	**EXCLUDE**	When approval is obtained from the RA and: Food employee provides medical documentation, specifying that the food employee is free of a ***S.* Typhi** infection.	Yes
Shigella spp.	**EXCLUDE**	**RESTRICT**	Remains excluded or restricted until approval is obtained from the RA, and: • Medically cleared or • More than 7 calendar days have passed since the food employee was last diagnosed.	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Nontyphoidal *Salmonella*	**RESTRICT**	**RESTRICT**	When approval is obtained from the RA and: • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal *Salmonella* infection or • Food employee did not develop symptoms and >30 days have passed since the food employee was diagnosed	

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Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (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?
Norovirus	**EXCLUDE**	**RESTRICT**	Remains excluded or restricted until approval is obtained from the RA and • Medically cleared or • More than 48 hours have passed since the food employee was diagnosed	Yes to return to an HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
STEC	**EXCLUDE**	**RESTRICT**	Remains excluded or restricted until approval is obtained from the RA and: • Medically cleared or • More than 7 calendar days have passed since the food employee was diagnosed	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**	**EXCLUDE**	When approval is obtained from the RA and • The anicteric food employee has had symptoms for more than 14 days or • The food employee provides medical documentation	Yes

Key: Table 3
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*
Medical clearance/documentation for Shigella spp.; Enterohemorrhagic (EHEC) or Shiga toxin-producing E coli, is based on test results from a health practitioner 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.

RULE - .02 Table 4: History of Exposure, and Absent Symptoms or Diagnosis

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 **RULE - .03** of the Chapter, 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.

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
Typhoid Fever (***S.* Typhi**)	**RESTRICT**	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	When 14 calendar days have passed since the last exposure, or more than 14 days has passed since the food employee's household contact became asymptomatic.	No
Shigella spp.	**RESTRICT**	See above	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	**RESTRICT**	See above	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
STEC	**RESTRICT**	See above	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
Hepatitis A virus	**RESTRICT**	See above	When any of the following conditions is met: 1. The food employee is immune to HAC infection because of a prior illness from HAV, vaccination against HAV, or IgG administration; or 2. More than 30 calendar days have passed since the last exposure, or since the food employee's household contact became jaundiced; or 3. 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.	No

Key: Table 4 - HSP = Highly Susceptible Population BHC = Bare Hand Contact RTE = Ready-To-Eat
GHP = Good Manufacturing Practices STEC = Shiga toxin-producing *Escherichia coli*

Exclusion and Restrictions (continued)[2]

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 to Norovirus, Hepatitis A, *Shigella* spp., STEC and *Salmonella* Typhi. It does not include nontyphoidal *Salmonella*.

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.

[2]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

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 non-food 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.

Removal of Exclusions and Restrictions.[3]

Food employees diagnosed with Norovirus, hepatitis A virus**, *Shigella*** spp., ***E. coli*** O157:H7 or other STEC, nontyphoidal *Salmonella* and symptomatic with diarrhea, vomiting, or jaundice, are excluded from a food service establishment. 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 STEC 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

[3]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

restricted food employees remain restricted until they are medically cleared or otherwise meet the criteria for removal from restriction).

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 STEC 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.

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.

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. 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 are excluded if they are within 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.

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 four bacterial pathogens identified in RULE - .03 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 four bacterial pathogens are either restricted or excluded, depending on the population served. Requiring restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases Manual."

Hands and Arms **Clean Condition.**

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Chapter.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

Cleaning Procedure.

Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to RTE food as well as other pathogens that can be transmitted from environmental sources. Many employees fail to wash their hands as often as necessary and even those who do may use flawed techniques.

In the case of a food worker with one hand or a hand-like prosthesis, the Equal Employment Opportunity Commission has agreed that this requirement for thorough handwashing can be met through reasonable accommodation in accordance with the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable the food worker with one hand to adequately generate the necessary friction to achieve the intent of this requirement.

The greatest concentration of microbes exists around and under the fingernails of the hands. The area under the fingernails, known as the “subungal space”, has by far the largest concentration of microbes on the hand and this is also the most difficult area of the hand to decontaminate. Fingernail brushes, if used properly, have been found to be effective tools in decontaminating this area of the hand. Proper use of single-use fingernail brushes, or designated individual fingernail brushes for each employee, during the handwashing procedure can achieve up to a 5-log reduction in microorganisms on the hands.

There are two different types of microbes on the hands, transient and resident microbes. Transient microbes consist of contaminating pathogens which are loosely attached to the skin surface and do not survive or multiply. A moderate number of these organisms can be removed with adequate handwashing. Resident microbes consist of a relatively stable population that survive and multiply on the skin and they are not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential contamination in food service.

All aspects of proper handwashing are important in reducing microbial transients on the hands. However, friction and water have been found to play the most important role. This is why the amount of time spent scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

Research has shown a minimum 10-15 second scrub is necessary to remove transient pathogens from the hands and when an antimicrobial soap is used, a minimum of 15 seconds is required. Soap is important for the surfactant effect in removing soil from the hands and a warm water temperature is important in achieving the maximum surfactant effect of the soap.

Every stage in handwashing is equally important and has an additive effect in transient microbial reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When done properly, each stage of handwashing further decreases the transient microbial load on the hands. It is equally important to avoid recontaminating hands by avoiding direct hand contact with heavily contaminated environmental sources, such as manually operated handwashing sink faucets, paper towel dispensers, and rest room door handles after the handwashing procedure. This can be accomplished by obtaining a paper towel from its dispenser before the handwashing procedure, then, after handwashing, using the paper towel to operate the hand sink faucet handles and restroom door handles.

Handwashing done properly can result in a 2-3 log reduction in transient bacteria and a 2-log reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens, (i.e., > 10^4 microbes, as found on hands contaminated with bodily wastes and infected bodily fluids) handwashing may be ineffective in completely decontaminating the hands. Therefore, a further intervention such as a barrier between hands and ready-to-eat food is necessary.

When to Wash.

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately before, during, or after the activities listed. The specific examples listed in this Code

section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

Where to Wash.

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing facility in order to help ensure that food employees effectively clean their hands. Handwashing sinks are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

Hand Antiseptics.

In the 2005 Food Code, the use of the term “hand sanitizer” was replaced by the term “hand antiseptic” to eliminate confusion with the term “sanitizer,” a defined term in the Food Code, and to more closely reflect the terminology used in the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994.

The term “sanitizer” is typically used to describe control of bacterial contamination of inert objects or articles, or equipment and utensils, and other cleaned food-contact surfaces. The Chapter definition of “sanitizer” requires a minimum microbial reduction of 5 logs, which is equal to a 99.999% reduction. The FDA bases the 5-log reduction on the AOAC International’s “Official Methods of Analysis 2003,” which requires a minimum 5-log reduction in microorganisms to achieve “sanitization.”

Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement. However, removing microorganisms from human skin is a totally different process and sterilization of human skin is nearly impossible to achieve without damaging the skin. Many antimicrobial hand agents typically achieve a much smaller reduction in microorganisms than the 5-log reduction required for “sanitization.” Therefore, the effect achieved from using antimicrobial hand agents is not consistent with the definition of “sanitization” in the Chapter.

The word “antiseptic” is a Greek term, meaning “against putrefaction”, and eventually evolved into a second definition, meaning, “a substance used to destroy pathogenic

microorganisms." The term "antiseptic" is often used to describe agents used on skin to prevent infection of the skin.

"Antiseptic" is defined under section 201 (o) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 (o)), as: "The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation of a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

Section 333.403 of the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994, defines a "health-care antiseptic" as an antiseptic-containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination. An "antiseptic handwash" or "health-care personnel handwash drug product" is defined in Section 333.403 of the Monograph as an antiseptic containing preparation designed for frequent use; it reduces the number of transient microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is a broad spectrum, and persistent antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin. Replacing the term "hand sanitizer" with the term "hand antiseptic" allows the use of a more scientifically appropriate term that is used to describe reduction of microorganisms on the skin and will improve clarification and regulation of these products.

The provisions of Rule -.03(5)(e) are intended to ensure that an antimicrobial product applied to the hands is 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. Because of the need to protect workers and to ensure safe food, hand antiseptics must comply with both the human drug and the food safety provisions of the law. The prohibition against bare hand contact contained in Rule -.04(4)(a)2. applies only to an exposed ready-to-eat food.

<u>As a Drug Product</u>

There are two means by which a hand antiseptic is considered to be safe and effective when applied to human skin:

1. A hand antiseptic may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. This document is maintained by the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs. Also known as the "Orange Book," this document provides "product-specific" listings rather than listings by compound and it is published annually with monthly

supplements. However, as of the end of 1998, no hand antiseptics are listed in this publication since no new drug applications have been submitted and approved for these products.

2. A hand antiseptic active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand antiseptic products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are "drugs" under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand antiseptics and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing, packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP's); and the product must be listed with FDA as a drug product.

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975, for hand antiseptic use by food handlers, are being evaluated under the Over-the-Counter (OTC) Drug Review by FDA's Center for Drug Evaluation and Research. However, as of May 2005, a final OTC drug monograph for these products has not been finalized. Therefore, FDA has not made a final determination that any of these products are generally recognized as safe and effective (GRAS/E).

GRAS/E antimicrobial ingredients for hand sanitizer use by food handlers will be identified in a future final monograph issued under the OTC Drug Review. Information about whether a specific product is covered by the proposed monograph may be obtained from the tentative final monograph (TFM) for "Health Care Antiseptic Drug Products for OTC Human Use; Proposed Rule." This TFM, which was published in the ***Federal Register*** of June 17, 1994 (59 FR 31402), describes the inclusion of hand sanitizers in this Review on page 31440 under Comment 28 of Part II. Information about whether a specific product is included in this proposed monograph may also be available from the manufacturer.

Questions regarding acceptability of a hand antiseptic with respect to OTC compliance may be directed to the Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation & Research Food and Drug Administration 10903 New Hampshire Ave., Building 51, 5th Floor, Silver Spring, MD 20993. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

<u>As a Food Additive</u>

To be subject to regulation under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the substances in a hand antiseptic must *reasonably* be expected to become a component of food based upon the product's intended use.

Where the substances in a hand antiseptic are reasonably expected to become a component of food based upon the product's intended use, circumstances under which those substances may be legally used include the following:

1. The intended use of a substance may be exempted from regulation as a food additive under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. A review by FDA's Center for Food Safety and Applied Nutrition is required in order to determine whether such an exemption can be granted.

2. The intended use of a substance, including substances that contact food such as those in hand antiseptics, may be "generally recognized as safe (GRAS)" within the meaning of the FFDCA. A partial listing of substances with food uses that are generally recognized as safe may be found in CFR Parts 182, 184, and 186. These lists are not exhaustive because the FFDCA allows for independent GRAS determinations.

   For the use of a substance to be GRAS within the meaning of the FFDCA, there must be publicly available data that demonstrate that the substance is safe for its intended use. There also must be a basis to conclude that there is a consensus among qualified experts that these publicly available data establish safety. If the use of a substance in food is GRAS, it is not subject to premarket review by FDA. While there is no legal requirement to notify FDA of an independent GRAS determination, a number of firms have chosen to do so with the expectation of receiving a response letter from FDA (see FDA's Inventory of GRAS Notices at (http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm). Although such a letter does not affirm the independent GRAS determination, it is an opportunity for the firm to receive comment from FDA regarding the materials supporting its determination.

3. The intended use of a substance may be the subject of a prior sanction, which is an explicit approval by the FDA or the United States Department of Agriculture (USDA) prior to September 6, 1958. All known prior sanctions are published under 21 CFR Part 181.

4. A substance may be the subject of a Food Contact Substance Notification that became effective in accordance with the FFDCA Section 409 (h). Substances that are the subject of an effective food-contact substance notification are listed, along with conditions of safe use, in the FDA Inventory of Effective Food Contact Substance (FCS) Notifications. This list is available on-line at: Inventory of Effective Food Contact Substance (FCS) Notifications (http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm). A food-contact substance that is the subject of an effective notification submitted under FFDCA 409(h) does not include similar or identical substances manufactured or prepared by any person other than the manufacturer

identified in that notification.

The Division of Food Contact Substance Notifications does not certify or provide approvals for specific products. However, if the intended use of a substance in contact with food meets the requirements of 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*, FDA may provide a letter to a firm stating that the intended use of this product is exempt from regulation as a food additive. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of substances in hand antiseptics as food additives may be directed to the Division of Food Contact Substance Notifications, HFS-275, 5100 Paint Branch Parkway, College Park, MD 20740. It may be helpful or necessary to provide label/promotional information when inquiring about a specific substance.

Fingernails **Maintenance.**

The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms. Fingernails must be trimmed to be no longer than the edge of the fingertip. Should the fingernails be longer than the food employee's fingertips, a single-use, disposable, food grade glove may be worn as long as there is no danger of the glove being punctured by the fingernails

Jewelry **Prohibition.**

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

The term "jewelry" generally refers to the ornaments worn for personal adornment and medical alert bracelets do not fit this definition. However, the wearing of such bracelets carries the same potential for transmitting disease-causing organisms to food. If a food worker wears a medical alert or medical information bracelet, the conflict between this need and the Chapter's requirements can be resolved through reasonable accommodation in accordance with the Americans with Disabilities Act. The person in charge should discuss the Chapter requirement with the employee and together they can work out an acceptable alternative to a bracelet. For example, the medical alert information could be worn in the form of a necklace or anklet to provide the necessary medical information without posing a risk to food. Alternatives to medical alert bracelets

are available through a number of different companies (*e.g.,* an internet search using the term “medical alert jewelry” leads to numerous suppliers).

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

Outer Clothing **Clean Condition.**

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

Food Contamination Prevention **Eating, Drinking, or Using Tobacco.**

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

Discharges from the Eyes, Nose, and Mouth.

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

Hair Restraints Effectiveness.

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair. The effectiveness of the hair restraint is dependant upon hairstyle of the individual. A "food employee," by definition, is any individual who works with unpackaged food, food equipment or utensils, or food contact surfaces.
The only exception to the hair restraint requirement is for counter staff, wait staff, and hostesses whose activities are limited so as to be a minimal risk of contamination to exposed food, clean utensils and linens and unwrapped single-service and single-use articles. However, these employees would need to wear a hair restraint if they are required to do more involved food preparation such as when wait staff are required to cook food or prepare a salad.

Animals Handling Prohibition.

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

Hygienic Practices

Smoking (tobacco or electronic devices) or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Unsanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Covered single-service drinking cups with single-service straws are approved in food preparation areas.

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food and equipment. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize possibility of contaminating food and surroundings.

Clean-up of Vomiting and Diarrheal Events.

When an employee, customer, or other individual vomits or has a diarrheal event in a food establishment, there is a real potential for the spread of harmful pathogens in the establishment. Putting the proper response into action in a timely manner can help reduce the likelihood that food may become contaminated and that others may become ill as a result of the accident.

According to the CDC, Norovirus is the leading cause of foodborne disease outbreaks

in the United States. More specifically, Noroviruses are the most common cause of sporadic cases and outbreaks of acute gastroenteritis. Norovirus is the most common cause of gastroenteritis in people of all ages and it is responsible for greater than 50% of all foodborne gastroenteritis outbreaks. CDC estimates that 21 million cases of acute gastroenteritis are due to Norovirus infection.

Noroviruses can be highly contagious, and it is thought that an inoculum of as few as 10-18 viral particles may be sufficient to infect an individual. Transmission occurs via foodborne and person-to-person routes, airborne inhalation of vomitus droplets, and also through contact with contaminated environmental surfaces. Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed.

In addition, the potential transmission level of Norovirus shed in the feces at levels up to 1 trillion viral particles per gram of feces and one projectile vomiting incident can contaminate the environment with 300,000 viral particles. One study found that employees who reported having cleaned up vomitus were more likely to contract illness that those who did not.

Norovirus causes acute onset of vomiting (often explosive) and diarrhea (also often explosive) which can contaminate surfaces and become airborne increasing the chances of additional infections. A recent study has also shown that the bathroom environment was identified as a major reservoir of human Norovirus, even in the absence of an ill individual on site. Studies have shown that Norovirus can survive on fomite surfaces for up to at least 5 days at room temperature and that routine cleaning, without a disinfectant specifically to address Norovirus, may be ineffective in eliminating its presence on fomite surfaces and can even serve as a means of spreading the virus to other fomites.

Effective clean up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a more stringent cleaning and disinfecting process. Some compounds that are routinely used for sanitizing food-contact surfaces and disinfecting countertops and floors, such as certain quaternary ammonium compounds, may not be effective against Norovirus. It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration.

Consumers are at risk of contracting Norovirus illness from direct exposure to vomitus or from exposure to airborne Norovirus from vomitus. Additionally, exposed food employees are also at risk of contracting Norovirus illness and can subsequently transfer the virus to ready-to-eat food items served to consumers.

The Chapter specifies that the Person in Charge is to exclude or restrict a food employee who exhibits, or reports a symptom, or who reports a diagnosed illness or a

history of exposure to Norovirus. A clean-up and response plan is intended to address situations where a food employee or other individual becomes physically ill in areas where food may be prepared, stored or served. Once such an episode has occurred, timely effective clean-up is imperative.

When developing a plan that addresses the need for the cleaning and disinfection of a vomitus and/or diarrheal contamination event, a food establishment should consider:

- the procedures for containment and removal of any discharges, including airborne particulates;
- the procedure for cleaning, sanitizing, and, as necessary, the disinfection of any surfaces that may have become contaminated;
- the procedures for the evaluation and disposal of any food that may have been exposed to discharges;
- the availability of effective disinfectants, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and their proper use;
- procedures for the disposal and/or cleaning and disinfection of tools and equipment used to clean up vomitus or fecal matter;
- the circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;
- notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;
- the segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated;
- minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in DPH 511-6-1-.03 of the Chapter;
- minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage; and
- the conditions under which the plan will be implemented.

When a food employee has been diagnosed, has recent history or exposure to, or is the suspect source of a confirmed disease outbreak of Norovirus, it must be reported to the person in charge per the Chapter. If a food employee has been diagnosed with Norovirus it must also be reported to the regulatory authority.