State of Wisconsin / Department of Health Services

Wisconsin Division of Quality Assurance

F325 and F371 Q & A DOCUMENT

1. **Q: I was at a conference recently. The speaker from Florida showed us a change in the ADA Standards of Practice. The October 2008 publication of the ADA journal has a chart showing that the Registered Dietetic Technician will be supervised by the Registered Dietitian and will work under his/her license or in Wisconsin under the RD'd Certification. The new F-Tags discuss the ADA Standards of Practice. In Florida the surveyors are already citing facilities for not having the RD review the DTR's notes and sign or confirm the note. Apparently, there are other States doing the same as Florida. The speaker also stated that the role of the CDM was to collect data and to not do resident assessment. This all has to do with the new ADA Resident Assessment Standards.**

   A: CMS states there are no federal regulations that specifically require dietitians to co-sign dietetic technicians' documentation. The federal regulations do not require that nutritional assessments be completed by a qualified dietitian. The comprehensive assessment may be completed by any member of or a combination of members from the interdisciplinary team. This would meet the federal regulations, which are minimum requirements.

   The newly revised interpretive guidance for F325 states that facility identifies key competent individuals who participate in the assessment of nutritional status. It states that qualified dietitians help identify nutritional risk factors and recommend nutritional interventions, based on each resident's medical conditions, needs, desires, and goals.

2. **Q: How often should you chart on refusal of a therapeutic diet?**

   A: There is no magical number or detailed timeline for charting on this topic. According to F325, a facility is responsible to provide acceptable parameters of nutrition for all residents in-house. When a resident's right issue surfaces, or any other issue surfaces that has an impact on a particular resident's nutritional status, the facility is responsible to respond to that challenge. The interdisciplinary team is to determine any causative factors that may affect the resident's nutritional status and plan individualized care. F325 states that "a resident's designation as 'high risk'" does not necessarily indicate that failure to maintain acceptable parameters of nutritional status is unavoidable and does not release the facility from the responsibilities outlined under the Intent."

   Remember to keep current individual resident assessments and documented evidence of planned interventions for any potential causal reasons (physical or psychosocial) for nutritional status decline, potential for dehydration, or decline of lack of improvement in any resident's functional eating abilities. No facility should ever wait for resident weight loss before they act.

3. **Q: I am evaluating a resident with significant weight loss due to poor appetite. If I identify a medication that has the potential to cause anorexia, document my findings in the chart, and the MD does not make a medication change---then---what further interventions would you recommend? Let's assume that a nutritional supplement is being provided, food preferences have been obtained, he/she is receiving the appropriate texture, and the resident is receiving feeding assistance as needed. Any other suggestions? Would a State surveyor be expecting further interventions?**

   A: The surveyor would expect to see that the facility followed the care process of assessment, care planning, implementation of the care plan, and evaluation according to current standards of practice. The surveyors would look to see if the consultant had contacted the MD again. Surveyors expect that, if a consultant

makes a recommendation to a doctor, the MD documents his/her comments on that recommendation. If there is a concern when the primary physician is not responding to a consultant's recommendation, the consultant should get the Medical Director involved.

4. **Q: Do we need to have a nutritional problem on each resident?**

   A: No, you do not need a nutritional problem on every resident. According to the RAI Manual, the facility is responsible for evaluating triggered items further and determining triggered items and the need to care plan. In many cases, triggered items do not lead to the facility proceeding to a care plan.

5. **Q: How does that work when a resident does not want to change their diet consistency and waivers are not any good? If they refuse a diet consistency, then, do you just leave them on their diet with education and documentation? You say educate, but what if they choke and die? Also, how often is enough to educate resident and/or family? Quarterly?**

   A: F155 states that a resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment, either directly or through an advance directive, may not be treated against his/her wishes. They have the right to make that decision. However, in F155, it also states that, if the resident's refusal of treatment brings about a significant change, the facility should reassess the resident and institute care planning changes. You ask how often you should review the resident's refusal; there is no defined time frame. The resident has the right to make an informed choice based on discussions that include the risk/benefits of the decision. The interdisciplinary team should be involved, including the resident physician, and staff should be educated about the resident's right to make a decision which they might not agree with. The facility would need to determine what is necessary for that particular resident.

6. **Q: Should we be doing IBW on residents? Or, should it be BMI? Is one better than the other for the elderly?**

   A: You can document the Ideal Body Weight(IBW); however, F325 recommends using the usual body weight in calculating weight losses/gains. You can use the (Basal Metabolic Indicator)BMI in your dietary assessments; however, there is no standard of practice for the elderly population in specific ideal weight ranges. The current standards of practice state to use the usual body weight. The current CMS recommendation is to use the usual weight, versus the ideal weight, for calculating weight changes. Please see the 2.0 version of the RAI Manual

7. **Q: How are liberalized diets viewed in the survey process? How does one do buffet dining and still follow strict diets? I do not mean mechanically altered diets, but 2 gm sodium, calorie diets, etc.**

   A: F371 states, "Research suggests that a liberalized diet can enhance the quality of life and nutritional status of older adults in long-term care facilities. Thus, it is often beneficial to minimize restrictions, consistent with a resident's condition, prognosis, and choices before using supplementation. It may also be helpful to provide the residents their food preferences, before using supplementation. This pertains to newly developed meal plans as well as to the review of existing diets. Dietary restrictions, therapeutic (e.g., low fat or sodium restricted) diets, and mechanically altered diets may help in select situations. At other times, they may impair adequate nutrition and lead to further decline in nutritional status, especially in already undernourished or at-risk individuals. When a resident is not eating well or is losing weight, the interdisciplinary team may temporarily abate dietary restrictions and liberalize the diet to improve the resident's food intake to try to stabilize their weight. Sometimes, a resident or resident's representative decides to decline medically relevant dietary restrictions. In such circumstances, the resident, facility and practitioner collaborate to identify pertinent alternatives."

   Additional information can be found in the published article, from the American Dietetic Association, *Liberal Diets for Older Adults in Long-Term Care*, 2005.

8. **Q: 'Listened to the conference today and had a question on slide #32. On this slide you indicated to remember that "therapeutic" includes altered textures. Would this mean a resident with arthritis whose food we cut? Would this be considered therapeutic?**

   A: F325 states that a therapeutic diet refers to a diet ordered by a health care practitioner as part of the treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium, potassium), or to provide mechanically altered food when indicated. The mechanically altered diet accommodates the resident's difficulty with cutting the food rather than swallowing or chewing concerns. Therefore, the cutting of food for a person without teeth or whose arthritis prevents them from cutting food, is not considered a therapeutic diet.

9. **Q: We have long ago liberalized our diets. We offer therapeutic diets if the resident requests OR if the MD feels that certain restrictions are absolutely necessary. We do not encourage the use of therapeutic diets, as they are often restrictive and ineffective in our elderly population. Do you feel that this will have to be changed OR through facility policy and procedures, care planning; will we be able to continue with our current practice?**

   A: F325 states that liberalized diets are encouraged and appropriate for person directed care. Your facility should have a policy and procedure in place to define your practice. F325 has now included mechanically altered diets as therapeutic diets. Liberalized diets were recommended prior to the person directed care movement. Additional information can be found in the published article from the American Dietetic Association, *Liberal Diets for Older Adults in Long-Term Care*, 2005.

10. **Q: MDS question: How do we code the modified consistency diets on the MDS 2.0?**

    A: Currently, the RAI Manual states to code mechanically altered diets as a mechanically altered diet, not a therapeutic diet, unless the diet consistency is managing a problematic health condition. The newly revised F325 states that a mechanically altered diet is considered a therapeutic diet. The new definition of a therapeutic diet "refers to a diet order by a health care practitioner as part of the treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (i.e., sodium, potassium) **OR** to provide a mechanically altered food when indicated." Until MDS 3.0 comes out, continue to code the MDS based on the MDS 2.0 instructions.

11. **Q. After reviewing the advanced copy of the revised F325 and Guidance to surveyors, it appears that, according to the definition of "therapeutic diet," all mechanically altered diets should now also be coded as a "therapeutic diet" on the MDS. Am I interpreting that correctly? If so, will the RAI manual be revised to reflect that?**

    A: Please review the answer to Question #10. F325 definitions are stated above in answer #10. However, in the definition, it does not direct you to code the MDS. Therefore, for purposes of using the F325 tag, it has changed the definition, but has not told you to code the MDS differently. Continue to code the current MDS following the current 2.0 MDS Version.

BARE HAND CONTACT

12. **Q: The new F371 states bare hand contact with ready-to-eat foods is prohibited. The US FDA Food Code states it can not be used for ready-to-eat foods. My understanding is that there is absolutely no bare hand contact in the kitchen. However, what about in the dining room with the CNAs? If a CNA has washed his hands, is assisting with feeding residents, and is serving bananas or toast, can the CNA touch the banana, peel it, and slice it up for the resident without using gloves because the banana has a peeling that the resident doesn't eat? What would you expect?**

    A: The WI Food Code and the US Food Codes have jurisdiction in the food preparation areas. In support of the current standards of practice, the updated Guidance to Surveyors for F371 also states that bare hand

contact with food is prohibited. The Guidance to Surveyors for F371 applies to both traditional and non-traditional food preparation areas.

The CDC Guideline for Hand Hygiene in Health Care Settings, Oct. 25, 2002 /Vol. 51/No. RR-16, is the standard that the Division of Quality Assurance (DQA) recommends that providers follow in resident care areas to include the dining room. CMS has stated that it would be pretty difficult to peel an orange or a banana, without touching the actual fruit portion. They do not recommend touching the peelings with bare hands. CNAs cannot touch toast without using something to prevent bare hand contact.

13. Q: Can you talk about the glove issue a little further? At one point, bare hands were allowed if good hand washing occurred in the kitchen... Is that not ever acceptable at this point?

A: No, it is not acceptable to have bare hand contact with food. F371, states, "bare hand contact with food is prohibited." WI Food Code 3-801.11 and the US FDA Food Code state that there is no bare hand contact with ready-to-eat foods in food preparation areas. These are the current standards of practice, for serving a highly susceptible population. This would also include household satellite kitchens, activity department kitchens, etc., wherever food is prepared for resident consumption.

14. Q: Presently, gloves must be worn in the kitchen when there is contact with foods that will not be reheated to appropriate temperatures. As an example, if eggs are to be peeled for egg salad, gloves need to be worn. But, if eggs are peeled for hot, hard boiled eggs and are to be re-heated to appropriate temp, do gloves need to be worn?

A: This is not a glove rule. As stated in question #12, F371 states that bare hand contact with food is prohibited. You are able to use any of the following to prepare or serve foods without bare hand contact: tongs, forks and spoons, deli paper, disposable gloves, wax paper, napkins, spatulas, etc. Therefore, in either situation, you would need to use something to prevent food borne illness. There is no requirement to use gloves in food preparation areas.

15. Q: Should CNAs or anyone else be able to have bare hand contact in the dining room?

A: No one can use bare hand contact in the dining room. All CNAs are advised to wash their hands with soap and water prior to entering a dining room. CMS recommends no bare hand contact with food items in the dining room, for anyone.

16. Q: Is no bare hand contact just for the kitchen or does it apply in the dining room too?

A: It applies to both the kitchen and the dining room areas.

GEL SANITIZER

17. Q: Under what circumstance can hand sanitizer be used in the kitchen?

A: F371 states, "Since the skin carries microorganisms, it is critical that staff involved in food preparation consistently utilize good hygienic practices and techniques. Staff should have access to proper hand washing facilities with available soap (regular or anti-microbial), hot water, and disposable towels and/or heat/air drying methods. Antimicrobial gel (hand hygiene agent that does not require water) cannot be used in place of proper hand washing techniques in a food service setting." The US FDA Food Code, 2-301.16 states: Hand Sanitizers.

"(A) a hand Sanitizer and a chemical hand sanitizing solution used as a hand dip shall: (1) Comply with one of the following: (a) Be an approved drug that is listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations as an approved drug based on safety and effectiveness…" According to the F371 webcast, Public Health, the enforcers of the Food Code stated that there are no approved hand sanitizers on the FDA approved list. The US Dept. of Health and Human Services, published Food Service Safety Facts, May 2003, *Hand Hygiene in Retail and Food Service Establishments*. It states: "Proper hand washing, as described in the Food Code continues to serve as a

vital and necessary public health practice in retail and food service. Using alcohol gel in place of hand washing in retail and food service does not adequately reduce important food borne pathogens on food workers' hands. Concern about the practice of using alcohol-based hand gels in place of hand washing with soap and water in a retail or food service setting can be summarized into the following points:

- Alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain nonenveloped (nonlipophilic) viruses; and
- Ingredients used in alcohol-based hand gels for retail or food service must be approved food additives, and approved under the FDA monograph or as a New Drug Application (NDA); and
- Retail food and food service work involves high potential for wet hands and hands contaminated with proteinaceous material. Scientific research questions the efficacy of alcohol on moist hands and hands contaminated with proteinaceous material."

Subject: **Update from FDA** On Use of Hand Antiseptic In Food Service Operations.

January 2009: This is a ***preliminary*** explanation from FDA regarding the use of hand antiseptic gels in foodservice operations. While this particular inquiry was directed toward ECOLAB, Kay Chemicals, and YUMS! Brands Inc., the information is relevant to all food service operations contemplating the use of hand antiseptic with or without the use of gloves.

As you know, we have a no bare hand contact rule in Wisconsin and the food code is rather explicit regarding any deviations to this rule. The WFC provides for methods in the use of hand antiseptics and should be followed without hesitation. However, the following information should be helpful if and when a situation arises whereas confusion follows.

FDA is currently working with FDA's Center for Drug Evaluation and Research (CDER), which has responsibility for Over-The-Counter (OTC) Drug Review. There are two aspects to consider when assessing the use of hand sanitizers in a food service setting: (1) Drug status of the product and (2) Indirect Food Additive potential.

(1) *Drug Status of the Product.* Under the OTC Drug Review, FDA is currently in the process of evaluating the safety and effectiveness of active ingredients in OTC antiseptic hand and body cleansers that were marketed in the United States before the Review began in 1994. To be covered by the OTC Drug Review, a product's formulation **and** labeling, as well as the dosage form and the method of application, must have existed in the U.S. marketplace prior to December 4, 1975. Any hand antiseptic does not have to be marketed before December 4, 1975 to be covered by FDA's OTC Drug Review, if a product with the same formulation, labeling, dosage form, and method of application existed in the U.S. marketplace before that date; then that hand antiseptic would also be covered. If any one of these elements is lacking, the hand antiseptic would not be covered by the OTC Drug review and would, instead, be a "new drug" requiring New Drug Approval (NDA) to be legally marketed in the U.S.

(2) *Indirect Food Additive Potential.* Regarding the status of an ingredient in a topical antimicrobial as a GRAS food additive, it is irrelevant in determining the regulatory status of a drug product. It may, however, be relevant in determining the suitability of the product for use in and around food where the ingredient may become an indirect food additive. For this reason, you may need to further consider the use of the antiseptic in bare hand contact situations with non-RTE food, should such situations exist.

    FDA stated that the self-reported procedure for hand washing and hand antiseptic use described by ECOLAB and Yum Brands for use in their restaurants is acceptable per the Food Code. The procedure outlined is: wash hands with antimicrobial soap; rinse with water; dry hands with a disposable towel; use of ACTIGEL hand antiseptic; follow by putting on gloves (in states requiring no bare hand contact such as WI).

    http://www.fda.gov/cder/ob/default.htm

    http://www.fda.gov/cder/orange/obannual.pdf

http://www.fda.gov/ohrms/dockets/98fr/75n-183H-nec00001.pdf

18. Q: Please explain the position on use of soap and water versus handgels. The CDC has stated that use of handgels is sometimes more effective than hand washing. Why is this different in the kitchen setting?

A: Hand gels do not replace hand washing. The CDC has jurisdiction over resident care delivery. The US FDA Food Code has jurisdiction over the food preparation areas in long term care settings.

19. Q: I sat in on the teleconference yesterday and I do have one question. I believe I understood you to say that the use of hand sanitizers in food prep will now be prohibited. Is this correct? What about in the dish room? We have some smaller facilities that have only one operator for the dish machine, so frequently using the gel to sanitize their hands before moving from dirty to clean. Will this still be allowed?

A: No. As we have learned, gels do not take the place of hand washing. The FDA is currently reviewing the use of gels in a food preparation area. The ware washing area is considered part of the kitchen; therefore, gels would not be allowed. Please see answer #27 under dish machine questions, for further information.

20. Q: We use Purell hand sanitizer. The packaging says Food Code Compliant meets food code hand sanitizer requirements. Rinsing with water not required after using product. Why did you say we can't use it?

A: During the taping of the F371 DQA Webcast, Purell was not considered an acceptable hand sanitizer to be used in food preparation areas. Please see Question #17 for the January FDA Update. The procedure outlined is: wash hands with antimicrobial soap; rinse with water; dry hands with a disposable towel; use of ACTIGEL hand antiseptic; follow by putting on gloves (in states requiring no bare hand contact such as WI).

21. Q: Do the regulations require a special or specified "Food Grade" hand soap?

A: According to F371, Prevention of Food borne Illness, Hand Washing, Gloves and Antimicrobial Gel, it states, "Staff should have access to proper hand washing facilities with available soap (regular or anti-microbial), hot water and disposable towels…"The US FDA FC 2-301.12 (B) Food employees' states, "(2) Apply an amount of cleaning compound recommended by the cleaning compound manufacturer." Therefore, you can use regular or an anti-microbial soap.

22. Q: When in the dining room, can CNAs use hand sanitizer when going from resident to resident to assist with feeding if they do not touch the ready-to-eat foods or do they need to wash every time?

A: If the CNA does not contaminate their hands, they do not need to wash/sanitize their hands between residents. If they have touched items---the food, the resident, the wheelchair, door knobs, phones, etc.---which have contaminated their hands, they need to use an antiseptic sanitizer or soap and water between residents.

DISH MACHINE QUESTIONS

23. Q: On a double basin sink on a nursing unit, do you need to identify which side of the sink is for hand washing and which side is for doing dishes or does the rule for having specific dishwashing and hand washing sides only pertain to "kitchen prep areas"?

A: Only in food preparation areas does there have to be a hand washing sink available. Therefore, if the food preparation area is using a two-compartment sink, the facility has to identify which side will be used for hand washing and only hand washing can be done on that side. Signage is required above the hand washing side.

In a kitchen preparation area, you need one hand washing sink. So, if you only have one sink with two bowls, then you need to designate one of the sides(bowls) as a hand washing sink. Food Code(FC) 6-301.14 Hand washing Signage states, “A sign or poster is required to remind food employees to wash their hands.” FC 6-301.11 talks about a hand cleanser being present and FC 6-301.12 says that provisions for drying employees hands has to be present. FC 5-203.11 Hand washing facilities: “Because hand washing is such an important factor in the prevention of food borne illness, sufficient facilities must be available to make hand washing not only possible, but likely.”

Public Health said that water can be poured from the faucet at anytime, to give someone a glass of water. The dirty side of a two sided sink, does not need to be sanitized to pour water or rinse fruits. He did say that NO food preparation can be completed in the dirty side, even after the sink has been sanitized because there is no air gap. No slicing, dicing, or cutting can be done in household food preparation areas that do not have a food preparation sink. Those tasks need to be completed in the main kitchen.

24. Q: The US FDA Food Code at 4-501.112 talks about how a stationary rack, single temp dishwasher needs to reach 165 degrees. If test strips verify that this temperature has been reached, do non-commercial dishwashers in households meet the regulations and thus eliminate the additional step of sanitizing outside of the dishwasher?

A: A non-commercial dish machine must be an approved equipment item that meets American National Standards Institute (ANSI)/National Sanitation Foundation (NSF) standards for dishwashing. The machine must be capable of reaching the appropriate temperature as envisioned by the WFC --- "the temperature of the fresh hot water SANITIZING rinse as it enters the manifold may not be more than 90 degrees C (194 degrees F), or less than: (1) For a stationary rack, single temperature machine, 74 degrees C (165 degrees F); or (2) For all other machines, 82 degrees C (180 degrees F).”

25. Q: The question of using a residential style dishwasher in an area like an Occupation Therapy Kitchen or Activity area where residents might do some occasional baking came up during planning of a new Therapy Addition. I know the standards require sanitizing by heat or chemical and that the standard for achieving the heat method is with an 180• F rinse cycle. I have found that the NSF (National Sanitation Foundation) certifies a residential style dishwasher that achieves the same level of sanitation as the 180• commercial units which, according to the NSF, is a 3-log reduction of bacteria with the difference being a longer cycle with a lower temperature (150•- 155•). The cost associated with a commercial type 180• F unit is about $3500. The standard residential units are around $350 and the NSF/ANSI Standard 184 units are around $650. This is a substantial difference. If the units achieve the same level of bacteria reduction and are only used for cleaning and sanitizing baking ware, would they meet the regulatory requirements? They typically do not come standard with temperature gauges like the commercial units. I would be concerned with the potential exposure of residents to high temperature steam associated with the commercial units.

A: We accept ANSI/NSF approved equipment. The important factor to keep in mind is whether or not the level of activity will impact the durability of the equipment to maintain certain standards. NSF meets that requirement. For operations like this, where no other food preparation is ongoing on a routine basis, it is acceptable to use. However, to supplant such a system across the spectrum of the entire facility is problematic. Therefore, these types of dish machines would only be considered acceptable for minimal usage areas, like therapy or activity departments.

26. Q: The surveyors were observing a low temp dishwasher, rinsing dishes at 140 degrees. The sanitizer was running and a question arose about the high temperature and what effect it might have on the sanitizer. Is this an issue?

A: There are a couple of things to consider. Check the sanitizer directions and see if there is a temperature requirement. Some sanitizers are temperature sensitive. If temperature is not a factor effecting the sanitizer, again, refer to the machine specifications. The sanitizer must be able to work within the machine specifications and, if the current sanitizer does not, a replacement sanitizer is needed. The F371 and the Food Codes do not discuss whether or not the higher temperature destroys the sanitizer. Therefore, at this point in time, there is not an issue with the 140 degree, rinse cycle on a low temp machine. The manufacturer's instructions determine whether or not there is a compliance concern. The data plate on the dish machine provides the manufacturer's recommendations. The data plate is what the surveyors will be using to determine compliance.

27. Q: We have a pass-through corner unit. Since it is 20 years old, I have received approval to purchase a new one. The way our system is currently set up, we have two staff members on the dirty side of the dish machine. One staff member places dirty dishes in racks and the rack is passed through to another staff member. This staff member sprays the dishes and puts the dirty dishes in the dish machine. I have allowed this staff member to remove the clean rack as long as only the outside of the rack is touched. After we have several clean racks of dishes and they are dry, this staff member washes his or her hands and removes the clean dishes. We think that this is not the best practice and that there is potential for cross contamination.

A: F371 states, under the Investigative Protocol: Observation, that "the surveyor will be observing whether proper hand washing is occurring between handling soiled and clean dishes to prevent cross-contamination of the clean dishes. Employees working on the dirty side of the dish machine need to wash their hands before going over to the clean side of the dish machine and putting away clean dishes. Consider whether or not, the employee is wearing a dirty, soiled apron as well. An employee should not be wearing a soiled apron while putting away clean dishes, even if they did wash their hands." The US FDA Food Code, 2-301.14 When to Wash states, "Food employees shall clean their hands and exposed portions of their arms (E) After handling soiled equipment or utensils." (Notice that it does not state "sanitize").

28. Q: What is the temperature of the sanitation water with the use of bleach and for how long should items be immersed --- 70 degrees for 10 seconds?

A: A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at exposure times specified under US FDA FC: 4−703.11(C) shall be APPROVED as specified in US FDA FC: 7−204.11; shall be used in accordance with approved manufacturer's label use instructions; and shall be used as follows: (A) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart; US FDA FC: 4−703.11 Hot Water and Chemical.

Except as specified otherwise in this section, an exposure time of at least 10 seconds for a chlorine solution specified under ¶ 4−501.114(A), (2) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38 degrees C (100 degrees F) or a pH of 8 or less and a temperature of at least 24 degrees C (75 degrees F).

29. Q: Can you review the three-step process of manual pot and pan washing again please?

A: F371 states, under Manual Washing and Sanitizing, "A 3-step process is used to manually wash, rinse, and sanitize dishware correctly. The first step is thorough washing using hot water (US FDA FC 4-501.19 states not less than 110 degrees F) and detergent after food particles have been scraped. The second is rinsing with hot water to remove all soap residues. The third step is sanitizing with either hot water (US FDA FC & F371 state not less then 171 degrees F) or a chemical solution maintained at the correct concentration, based on periodic testing, and for the effective contact time according to manufacturer's guidelines."

30. Q: Where can you purchase test strips?

A: Food Vendors, such as Reinhart Foods, Sysco, US Foods, etc.

DINING ROOM QUESTIONS

The CDC Hand Hygiene for Health-Care Settings, Oct. 25, 2002/Vol. 51/No. RR-16, is the current standard of practice in the dining room.

31. Q: What about CNAs helping to serve trays (not directly touching food, but taking lids off, etc.); are they allowed to use hand gels?

A: Yes

32. Q: Would resident's families be able to make food for residents in the facility's kitchen if they followed F371?

A: No. The US FDA Food Code 2-103.11(B) states, "Persons unnecessary to the food establishment operation are not allowed in the food preparation, food storage or ware washing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination …"

33. Q: Can resident's hands be washed with sanitary wipes?

A: Resident's hands may be sanitized with the antiseptic wipes. Recommendation would be to watch for skin outbreaks, due to compromised skin conditions.

34. Q: If a CNA passes a tray, takes the food off the tray, places the food onto the table in front of a resident, then goes back and collects another tray, and repeats these steps, do they have to wash their hands between trays?

A: No, staff is not required to wash their hands each time they pass a tray, as long as they follow proper technique for handling dishware. All staff is encouraged to wash their hands prior to beginning dining room tasks. They can pass multiple plates and cups if they are handling them following proper food handling techniques. However, when they contaminate their hands by touching food, a resident, door knobs, or by picking up dirty dishware or trays, they need to sanitize or wash their hands before getting more clean trays. When they don't touch anything except the tray and the non-lip contact of the dishware, they do not have to wash or sanitize their hands in between passing the trays.

35. Q: If a C.N.A. is assisting two residents and touches only utensils, do they need to wash between residents?

A: No. CMS has stated that, as long as the CNA has not contaminated their hands, it is not expected that they have to wash their hands between residents. The issue is --- if the CNA soils their hands, if there is visible debris on the utensil, if the utensil is touched by the resident, etc. --- do they then need to wash/sanitize their hands prior to assisting the other resident. There needs to be evidence that the facility has a system in place to prevent food borne illness.

36. Q: After watching the webinar 8-28-08, my understanding of the rules regarding bare hand contact and how this pertains to nursing assistants is as follows. Please correct me if I'm incorrect. If nursing assistants are passing trays and going from one resident to another, cutting meat, buttering or jellying bread or toast, etc., they must use deli tissue, gloves, or a utensil so they do not touch the actual food. However, if they are feeding a resident finger foods, this does not pertain (so long as they use good hand washing). Am I correct or is this a misunderstanding?

A: Originally, we had thought that was correct. In the F371 Guidance to Surveyors, it has been determined that there is no bare hand contact with food. If the CNA is going to sit down and assist a resident with a

meal, they need to wash their hands with soap and water or an antiseptic gel, and use no bare hand contact with food. It is advised that all CNAs wash their hands with soap and water, prior to entering a dining room.

37. Q: Do you have to use separate serving utensils on each item on the salad bar?

A: Yes. US FDA Food Code 3-302.11 Packaged, and Unpackaged, Food – Separation, Packaging, and Segregation states, "(A) Food shall be protected from cross contamination by:

(1) Separating raw animal FOODS during storage, preparation, holding, and display from:
   (a) Raw Ready-to-eat food including other raw animal food such as fish, for sushi or molluscan shellfish, or other raw ready-to-eat food such as fruits and vegetables, and
   (b) Cooked ready-to-eat food;
(2) Except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:
   (a) Using separate equipment for each type……………"

38. Q: Does a CNA serving from a buffet line in the dining room need to wear gloves when serving directly from the steam table?

A: No**,** this is not a glove rule, but the employee would need to use an alternative to prevent bare hand contact with food. Dietary employees working on a buffet line could use tongs, deli papers, gloves, or whatever other item they can use, to not touch the food.

39. Q: What if residents are served family style and reach inside the bread basket on the table and touch other bread?

A: If a facility serves a community bread bowl on the table, or any food item that is not individually wrapped, they need to put a system in place to prevent the food from being contaminated from the other residents. The expectation is, once food is contaminated, it must be discarded and not shared with another resident.

40. Q: If residents are making food in the pantry kitchens do they need to wear gloves?

A: If residents or resident's families are making food in the pantry kitchens, for themselves, they do not have to follow the F371 guidelines. CMS S & C memo 09-39 says, "The facility does have a responsibility under the food safety regulatory language at F371 to help visitors to understand safe food handling practices and to ensure that, if they are assisting visitors with reheating or other preparation activities, that facility staff use safe food handling practices and encourage visitors and residents who are contributing to food preparation in the facility to use these safe practices as well."

If residents or residents' families are preparing any food items for the general resident population, then they need to follow the current standard of practice, wash hands with soap and water, and have no bare hand contact with the food.

41. Q: Can resident families prepare food for residents in the facility?

A: Yes, they can if your individual nursing home allows it. CMS S & C Memo 09-39 states, "Foods accepted by residents from visitors, family, friends, or other guests are not subject to the regulatory requirement at F371." See Question #40 for more information. Nursing homes may want to develop an individual nursing home policy and procedure on this issue. They should seek their corporate counsel on this.

42. Q: What is the proper way to take food temps?

A: US FDA Food Code, 4-901.11 Equipment and Utensils, Air-Drying Required states, "After cleaning and sanitizing, equipment and utensils: (A) shall be air-dried or used after adequate draining, before contact with food, and may not be cloth dried."

Bimetallice Stemmed Thermometers: The proper way to take food temps with a thermometer is to use an alcohol wipe, swab the stem of the thermometer, air dry and then stick the sensing area in the tip, into the middle of the food item. F371 Investigative Protocols states: "If the facility is cooking a PHF/TCS food, evaluate if the food reached the acceptable final cooking temperatures, by inserting the stem of a calibrated thermometer into the middle or thickest part of the food;"

Infrared (Laser) Thermometers: When using Infrared(Laser) Thermometers, hold the thermometer as close to the product without touching it. Remove any barriers between the thermometer and the product being checked. Do not take temperature measurements through glass, or shiny or polished-metal surfaces, such as stainless steel or aluminum. Always follow the manufacturer's guidelines.

43. Q: What would be an acceptable procedure for a CNA who is serving or feeding a piece of toast or a sandwich (RTE-food) to a dependent resident, i.e., the use of gloves, hand washing or hand sanitizer?

A: Wash hands prior to assisting the resident. Utilize tools so as not to touch the ready-to-eat foods. Toast and sandwiches are ready-to-eat foods. There are several methods that could be used, which include cutting the food with a fork and knife and feeding it to the resident using the fork, holding the food item with a piece of deli paper, or using gloves. Consider asking the resident what they might prefer.

44. Q: CNA that assist residents with their meals: Should they be wearing gloves to feed ready to eat items, such as potato chips, cookies, sandwiches, toast, and finger foods?

A: The goal is to minimize food borne illness. CNAs do not have to wear gloves. There are many other alternatives, as stated in question #45.

45. **Q: Does a CNA need to wear gloves when peeling a banana or putting jelly on toast?**

A: A banana or preparing toast with jelly would be considered a food item that requires minimal preparation for consumption, or a ready-to-eat food. According to the US FDA Food Code and F371, there is no bare hand contact with ready to eat food. CMS recommends not to touch banana and orange peels. CNAs may utilize napkins, deli tissues, forks, or gloves when they butter or put jelly on a piece of toast, to avoid bare hand contact with the toast.

LINKS

46. Q: I have given them info from the 2005 codes, but wondering if there is anything more current. Where can I find the Food Code?

A: US FDA Food Code: edition 2005 is the most current edition. If you go on the link that the Food Code has, there was an edition in 2007, some updates; but the most current is 2005. The government only updates the full food code every 4 years, but does notify the public with updated inserts every two years. http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2005/default.htm

F325 & F371 webcast and handouts: http://dhs.wisconsin.gov/rl_dsl/Training/dqaWebcasts.htm

APPROVED FOOD SOURCES

Historically, under F370, institutionalized residents could not receive food from an unapproved food source. With the new CMS Memo 09-39, dated May 29, 2009, CMS has reconsidered its position and now allows residents to choose to accept food from visitors, family, friends, or other guests according to their rights to make choices.

47. Q: What is an approved food source?

A: According to federal regulation 483.35(i) (1) or F371, an approved food source is defined as food procured from sources approved or considered satisfactory by Federal, State, or local authorities. The US FDA Food Code 3-201.11 (A) states, "Food shall be obtained from sources that comply with Law." Food must be obtained from licensed sources and raw agricultural foods are considered approved sources. Raw agricultural food items, such as fruits, vegetables, and potatoes, etc., are not regulated in Wisconsin and, therefore, may come from any garden and be served to residents. It does not include home canned food stuff, any food prepared at home, or food prepared from an unlicensed source. Grocery Stores, restaurants, bakeries, and healthcare facilities, where the entity is regulated by government, are establishments that are an approved food source.

48. Q: How does the approved food source requirement apply to a special meal in which a volunteer prepares spaghetti in his home and brings it to the nursing home for a special activity meal? The residents sign up for this special meal and it is served in the activity room. Would this be considered an approved food source? The volunteer's home is not a regulated entity; therefore, homemade food from the volunteer's home would not be an approved food source.

A: The CMS S & C Memo 09-39, dated May 29, 2009 states, "Residents have the right to choose to accept food from visitors, family, friends, or other guests according to their rights to make choices." This memo clarifies that residents (that are able to make choices) may now choose to eat at a 'special' meal prepared by a volunteer, in their home. The memo clarifies that the facility must still procure food from sources approved or considered satisfactory by Federal, State, or local authorities.

49. Q: A similar question arises regarding picnics. Once a year, a volunteer hosts a picnic for our residents at a park. She prepares the food from her home. The residents sign up for the meal in the park and it is considered an activity function.

A: The picnic idea is the same situation as the question in #48. Residents (according to their rights to make choices) may make the choice to participate in a picnic, regardless if the food comes from an approved food source or not. (CMS S & C Memo 09-39)

50. Q: Scenario: A group of friends who got to know each other while in a SNF facility meet weekly for a gathering. This group meets independently of any organized facility function. They share a meal which is sometimes prepared by the group at the facility or is sometimes ordered in. On occasion, a member of the group who is <u>not</u> a resident prepares something at home to share with the group. (This woman also happens to be a beautician at the nursing home, but is not an employee of the home.)

(a) In this situation, is it acceptable for her to share the food she prepared, assuming this is a group of consenting adults who are able to make decisions for themselves?

A: Yes, it is acceptable. This scenario is similar to questions #48 & #49; please see those responses.

(b) Could this be the same thing as a visitor sharing something homemade with a <u>single</u> friend or family member?

A: Yes; please see question responses to #48 and #51.

(c) This appears to be a resident driven activity made to fit the definition of culture change and quality of life efforts. Wouldn't denying them this be a violation of resident rights?

A: The CMS S & C Memo, dated May 29, 2009, states that residents have the right to choose to accept food from friends, family, visitors, or other guests, according to their rights to make choices at F242. The new memo and CMS revising their interpretation of these issues, your previously mentioned activities are all acceptable for culture change.

51. Q: What if roommates/friends choose to share a homemade treat made by one of their family members?

A: The resident may share his homemade treats with any resident (that is able to make choices) based on CMS S & C Memo 09-39.

52. Q: Can you please give us more ideas of what ready-to-eat foods are?

A: The US FDA FC at 1-201.10 (1) & (2) states at Applicability and Terms Defined, for ready-to-eat foods, means food that "(a) is in a form that is edible without additional preparation to achieve food safety, (b) is a raw or partially cooked animal, (c) food that has been cooked and is ready to eat, (2) (b) raw fruits & vegetables that are washed, salads, (c) cooked fruits and vegetables that are cooked for hot holding, (e) plant foods for which further washing, cooking or other processing is not required, (f) spices, seasonings, sugar, (g) bread, cakes, pies, fillings, or icing, (h) dry salami or pepperoni, salt-cured meat and poultry products, deli meats, ham, jerky, beef sticks, thermally processed low-acid foods packaged in hermetically sealed containers and leftovers." F371, Guidance to Surveyors states, "…refers to food that is edible with little or no preparation to achieve food safety. It includes foods requiring minimal preparation for palatability or culinary purposes, such as mixing with other ingredients (e.g., meat type salads, such as tuna, chicken or egg salad)." Other ideas include toast, sandwiches, salty snacks, etc.

53. Q: Do herbs and spices need to be from a licensed source or can they be grown within the facility gardens?

A: These are not regulated so, yes, they can be grown within the facility gardens.

54. Q: Why is produce, such as watermelon, okay to be purchased by an unapproved food source?

A: Watermelon is an agricultural item and agricultural items are not regulated in Wisconsin. Raw agricultural products are considered approved food sources. Therefore, watermelon is an approved food source. Once a melon is cut, it requires refrigeration because it then becomes a potentially hazardous food due to the water and PH content.

55. Q: Many residents eat vegetables grown from the facility's garden, a staff's garden, a family's garden, or purchased from a farmers market --- things like fresh raspberries, fresh strawberries (in season), fresh corn on the cob, etc. Can they continue to do that?

A: Yes; however, the nursing home must follow the manufacturer's guidelines on fertilizers and pesticides; i.e., does the food need to be washed prior to use? The Department of Agriculture does not regulate fruits and vegetables. Therefore, these fruits and vegetables are an approved food source that can be served in nursing homes. Also, see the response for question #48.

56. Q: Can nursing home residents eat homemade jams and jellies that they themselves prepared in the nursing home?

A: Public Health states, "Yes, because these are not regulated in Wisconsin and the actual product has a decreased PH and increased sugar content." The staff and residents need to follow safe food handling practices when making the jams and jellies.

57. Q: Can we serve fresh caught fish in the nursing home?

A: Yes. CMS S & C Memo 09-39, dated May 29, 2009, states, "Residents have the right to choose to accept food from visitors, family, friends, or other guests according to their rights to make choices."

If the facility is purchasing fresh fish, then the US FDA Food Code at 3-201.14 Fish states, "(A) Fish that are received for sale or service shall be: a. Commercially and legally caught or harvested; or b. approved for sale or service.

58. Q: Residents catch many fish at our local lake; staff cleans the fish from the ice pail and fries the fish fillets in our kitchen with the help of our cooks for Friday night fish fry. Is this OK under the "found in nature" provision?

A. Please see the answer for question #48.

59. Q: Can donated deer be served to residents in a nursing home?

A: Yes. A family member can bring in deer sausage or a wild deer food item for their family member or other residents (according to their ability to make decisions) to enjoy.

If the facility is purchasing deer for its menu, then the US FDA FC at 3-201.17 Game Animals states, "(A) if game animals are received for sale or service they shall be: (1) Commercially raised for food and: (2) Under a voluntary inspection program… (3) As allowed by law, for wild game animals that are live-caught:." Since our deer in Wisconsin are usually wild, they would not meet these criteria for an approved food source.

60. Q: Our facility has adopted restaurant style dining and resident centered care within the last two years. The staff want to have "potlucks" in which staff bring in food for the residents. My concern is the food safety aspect. Some staff feel that, since the food is not going into dietary, it does not need to be a concern. Another aspect discussed was that food service would provide the potentially hazardous foods and the staff can bring in the rest.

A: CMS S & C Memo 09-39 states, "Foods accepted by residents from visitors, family, friends, or other guests are not subject to the regulatory requirement at F 371." Therefore, you can plan your potlucks, including the resident's participation. The memo also states "that facility staff use safe food handling practices and encourage visitors and residents who are contributing to food preparation in the facility to use these safe practices as well." Your facility may want to have a policy and procedure on what food items they are willing to accept from staff and other visitors.

61. Q: I am just clarifying. When a family member brings in a cake for a resident at the nursing home, can the cake come directly into the food service department to be cut, dished up, and served?

A: Yes.

62. Q: For an activity, on occasion, they will purchase food from a restaurant and bring it into the residents. When we need to alter the food product to change possible texture of the food item, can this product be brought into the kitchen or do we need to take the equipment to the service area to process?

A: Yes, you can modify the texture in the kitchen.

63. Q: Can a resident choose to eat at a facility potluck? What if the resident was given the risks & benefits, then can they eat foods from unapproved food sources?

A: Yes, they can per CMS S & C Memo 09-39. Please refer to the answer for question #48. A risk and benefit discussion is not necessary.

64. Q: Can a resident choose to buy food prepared in homes at a facility sponsored bake sale?

A: Yes, they can, per CMS S & C Memo 09-39.

POTENTIALLY HAZARDOUS FOODS (PHF)

65. Q: Are leftovers only allowed if they are not a Potentially Hazardous Food and are not held below 135 degrees?

A: Leftovers apply to all foods and may be re-served if the food items have been stored following proper food handling techniques outlined in F371 or the food codes.

66. Q: Would food items typically held in a steam table for serving be a PHF?

A: No, because sometimes kitchens will put cold food items in a steam table with ice underneath the pan. You need to determine the water content versus and the PH content to determine your PHF foods. Determining the water activity and the PH content of the food item is the route to go unless there is prior knowledge regarding the PHF status of the food item(s). The purpose of the steam table is not to be used for maintaining cold temperatures. It is important that hot foods placed in a steam table be at 135 or above before being placed in the steam table. Additionally, the steam table must not be utilized for bringing food up to temperature.

67. Q: Is there a tool to measure the moisture level of food?

A: Yes, it is called a water activity meter. You can Google "water activity meters" for a listing. The Aqua Lab LITE is an intermediate bench-top unit that incorporates technology from both the Aqua Lab Series 3 (the world's fastest and most accurate water activity meter) and the portable, ultra-compact Pawkit. The LITE is ideal for lab-based applications where ± 0.015 aw accuracy is adequate.

Reasons for using the Aqua Lab LITE:

Easy menu-based 3-button interface
Fixed 5-minute read time
Very low maintenance; one-step cleaning procedure
Higher accuracy than most standard dielectric water activity meters

DQA is not endorsing this product; this is just an example of one resource.

68. Q: If a food temperature goes below 135 degrees F for more than the 15 min., it must be thrown out; but if it's less than 15 min., can it be reheated to 165 degrees?

A: US FDA Food Code (US FDA FC) 3-501.19(B)(1) states, "PHF hot foods that have time only (not temperature control so it is NOT held safely above 135 degrees F or below 41 degrees F) are allowed up to a maximum of 4 hours."

US FDA FC 3-403.11(A) states, "Reheating of PHG that are cooked, cooled, and then reheated to 165 degrees F for 15 seconds before being held for hot holding."

US FDA FC 3-403.11(D) states, "Reheating to 165 degrees F for hot holding may not exceed 2 hours." An example would be the steam table or buffet where hot foods may drop in temperature and may be reheated, but this process is not to exceed 2 hours. The revised F371 states that foods may be reheated only once (at the 2 hrs, point) and kept no longer than 4 hours on the steam table.

US FDA FC 3-501.14 Cooling of Hot PHF states, "If they do not reach 70 degrees F (from a safe 135 degrees F) in two hours, they are to be reheated to 165 degrees F and the process started over."

69. Q: How long can non-PHF foods (such as the sliced, processed cheese) be kept?

A: Most sliced, processed cheese is assumed to be non-Potentially Hazardous Food; however, not all. You should check your label before deciding. However, if it is not PHF, temperature requirements do not apply.

70. Q: Are there required time frames that food temps and equipment temps need to be recorded? For example, food in a steam table is every ? minutes and refrigeration every ? hours?

A: Part 1, Food Temps: F371 states under Food Service and Distribution, "The maximum length of time that foods can be held on a steam table is a total of 4 hours." Monitoring of the temperature by food service workers while food is on the steam table is essential. A facility will need to determine how they ensure

that hot foods being served and maintained in holding units are at 135 F degrees or more and cold foods being at 41 F degrees or less. In the US FDA FC, there are no required recording of temperatures. However, if recording temperatures, most operators will utilize a system of recording that is of their liking, usually anywhere from 3X per day to 4X per day. If you are choosing to use the Temperature Control System method, review the information at US FDA FC, 3-501.19 Time as a Public Health Control.

Part 2, Equipment Temps: F371, under refrigerated storage states, "Monitor food temperatures and functioning of the refrigeration equipment daily and at routine intervals during all hours of operation."

71. Q: Is it true that there aren't any required freezer temps for walk-in freezers anymore?

A: Yes, F371 doesn't specify a temperature, but tells you that you need to ensure that the food being delivered, if ordered frozen, comes in frozen. The surveyors are instructed to interview your staff and see how you ensure a frozen product is delivered frozen. F371 states that the following are methods to determine the proper working order of the refrigerators and freezers: "Document the temperature of external and internal refrigerator gauges as well as the temperature inside the refrigerator …"check the firmness of frozen food and inspect the wrapper to determine if it is intact enough to protect the food;" Therefore, even though a specific temperature is not stated, you still need to have a system in place to monitor frozen food products. The US FDA FC, 3-501.11 Frozen Food: "Stored frozen foods shall be maintained frozen." 3-501.12 "Frozen potentially hazardous food that is slacked to moderate the temperature shall be held: (B) At any temperature if the food remains frozen."

72. Q: So, would you need to date mark chicken base? A 6 lb container?

A: You need to determine if the product you are purchasing is a PHF. F371 under Food Receiving and Storage states, "Keeping track of when to discard perishable foods and covering, labeling and dating all foods stored in the refrigerator or freezer is indicated." If your product is not PHF/TCS (time/temperature control system), then F371 states the focus of protection for dry storage is to keep non-refrigerated foods, etc. free from contaminants.

73. Q: So, I can explain to our staff why they need to sanitize the thermometer between each pan of food? Do they need to do that if it's the same food item?

A: Yes, each pan needs to be tested for temperature. The expectation is that the thermometer is to be sanitized between each pan of food. What is in the pan is of no interest. The concern is cross-contamination. F371 Investigative Protocols states, "Observe the staff measuring the temperature of **all** hot and cold menu items." Therefore, the interpretation is that every pan must have a temperature taken.

74. Q: I did want to ask you about the 7 day issue. The supervisor of the kitchen believes that food can be kept in the walk-in for up to 7 days. This does not mean after it has been frozen, but when it has been on the tray line and then cooled. Can you clarify this so I can give her this information?

A: 7 days for keeping PHFs is correct. You need to have a system in place to prevent leftovers from going past the 7 day cut-off. The US FDA FC 3-501.17(A) states, "Date marking PHC prepared on the premises can be safely held up to 7 days (with day 1 as the preparation day) and if held at 41 degrees F or below."

75. Q: Is it Aw below 8.5 and pH below 4.6 or is it only one value that is important to determine if the food is potentially hazardous?

A: Pathogens need food, acidity, temperature, time, oxygen, and moisture to grow; also known as FATTOM. Pathogens typically do not grow in alkaline food; therefore, a pH of 4.6 or below is needed. The amount of moisture available in food for this growth is called its water activity or Aw. An Aw needed to prevent the spread of food borne illness would be below .85. You need both values to determine if the food item is a potentially hazardous food. Sources: F371, Public Health and ServSafe.

76. Q: Milk is only good for 7 days, after opening regardless of the stamped date, is this correct?

A: The US FDA FC 3-501.17(B) states, "Commercially produced PHF with high acid or special treatments may be opened and used until the 'use by dates' (such as cultured dairy Yogurt, sour cream, buttermilk), deli salads, hard cheeses, and cured meats. PHF such as milk and cottage cheese do not fall into these categories and once opened (day 1) have until the 7th day which must be within the 'use by date'."

TIME AND TEMP

Time/Temperature Information found in the 2005 US FDA FC at 3-501.11

77. Q: At the point of service, we used to use 120 degrees +/- 2 degrees for hot and 50 degrees +/-2 for cold foods --- what happened to these standards?

A: CMS has defined 'point of service' as the temperatures on tray line or alternate serving areas when the food is 'plated'. In the past, 'point of service' has often been referred to as the time residents received their food; that is not the case in the revised F371. In the past, there have been general guidelines for palatability temperatures, but not anymore. The Surveyor Investigative Protocol for the Sanitary Conditions guides surveyors to observe the staff measuring the temperatures of all hot and cold menu items. Cold foods should be at or below 41 degrees F when served (plated) and hot foods should be at 135 degrees F or above when served.

As far as the +/- 2 degrees part of the question, please see the US FDA FC, 4-203.11 "(A) food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to +/- 1 degree C in the intended range of use. (B) Food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to +/-2 F in the intended range of use."

78. Q: Do you need to record/log all temperatures; e.g., when they are taken out to ensure they reached the proper cooking temperature, then again on tray line to make sure they are above 135?

A: Please see the answer for #70.

79. Q: You made comment about ensuring the hot puree items are at least 135 degrees after pureeing. Do we need to log this temperature?

A: You need to determine your facility's system that determines how you are going to ensure that proper food temperatures are being served and maintained. There is no requirement that says you have to **document** your temperatures. However, if temperature concerns come up, for example with a family or on a survey, what evidence would you have that showed you monitor food temperatures, if you don't document? F371 Guidance to Surveyors directs surveyors to "Observe the staff measuring the temperature of **all** hot and cold menu items."

80. Q: Is it standard protocol to take temperatures at the end of tray line to ensure the food has been maintained above 135 to save?

A: Your facility needs to define how you want to ensure food temperatures, considering time/temperature control systems. Taking temperatures at the end of the tray line could be one part of monitoring food temperatures. Please see the answer for #70.

81. Q: When and how often do the new regulations require temps to be taken? If they are required to be taken often, are there alternatives to this procedure other than the expensive computer control program that some facilities are able to afford and others are not?

A: A computer control program is not required. Please see the answer for #70.

82. Q. Under the investigative protocol: Sanitary Conditions, under the Service of food during meal times, it is stated, "Cold Foods should be at or below 41 degrees F when served. Hot foods should be

at 135 degrees F or above when served. Please define "when served"--- is it when it is served to the resident or when it is plated up from the steam table?

A: CMS is referring to when plated. This is in the "kitchen" guidance, per F371.

83. Q: Time and Temperature Control System (TCS) is not included in our Wisconsin Rule ATCP 75 and DHS 196. (These rule's appendices are identical.) We currently use it as guide for policy at this point. We have had discussions with Public Health about opening our rules. But, you may know that is, at least, a two year process. Did DHS 132 change at all in the Dietary Services?

A: DHS 132.63 regulations for dietary have had significant changes. Many sections of the regulation have been eliminated. In the State Operations Manual, CMS has combined F370 with F371. The actual rule for both federal tags has not changed. They were combined under the one federal tag. The F371 Guidance to Surveyors has changed, giving more specificity information to the rule.

84. Q: We have a "happy hour" fridge that only holds beer and wine. Since neither of these will "spoil" if the temperature is off, does the temp of the refrigerator need to be taken daily? If the refrigerator does not have any perishable food, does a temp need to be taken?

A: If your refrigerator does not hold any PHF foods, temperature monitoring is not required. However, you would be responsible for maintaining the cleanliness and functioning of the refrigerated unit.

85. Q: What would an acceptable Point of Service temperature be? My rationale for a temperature outside of the danger zone is based on the following reasoning. If foods and beverages are held out of the Danger Zone in the kitchen, are plated and distributed to a unit dining room within a 20 minute period of time, would it be acceptable if the temperature of the food or beverage were several degrees into the danger zone? The food or beverage in question would still be within the acceptable holding time based on the PHF/TCS recommendation of holding in the danger zone for no more than 4 hours. I pose this question because it is often very difficult to hold temperature on a thin slice of ham, a fried egg, or pancake. Furthermore, on hot humid days, cartons of milk held and transported in ice tubs to unit dining rooms have been temped and will occasionally be @ 44 degrees. Will this pass the surveyors scrutiny?

A: If a facility is not using a time/temperature control system for the monitoring of food temperatures, the US FDA Food Code will be used by the surveyors as the standard of practice for that particular facility. This means that the hot foods will be not less then 135 degrees F and cold foods not more then 41 degrees F, at the point of service. CMS contributed this: "Under F371 also, one of the criteria listed under Determination of Compliance in the revised guidance to surveyors at F371 indicates, 'Cooks food to the appropriate temperature and HOLDS (emphasis added) PHF/TCS food at or below 41 degrees F or at or above 135 degrees F." So, it stands to reason that, if the facility failed to hold food at safe temperatures, this would warrant a citation."

86. Q: Could you please discuss acceptable point of service temperatures or let us know where we can find information about point of service temps? We need this info for both hot and cold food items.

A: CMS contributed this: **"**The revised guidance given for F371 speaks to holding temps and when food is 'plated.'" This is mentioned again in other areas within the guidance under Determination of Compliance, Criteria for Compliance, which states, "Cooks food to the appropriate temperature and holds PHF/TCS food…above 135 degrees F." It is mentioned again under Noncompliance for F371, which states, "Noncompliance…may include…failure to do one or more of the following…Maintain PHF/TCS foods at safe temperatures…at or above 135 degrees F (for hot foods) except during preparation, cooking, or cooling, and ensure that PHF/TCS food plated for transport was not out of temperature control for more than four hours from the time it is plated."

There is no CMS regulation that requires a particular temperature when the resident receives their food. However, as you already know, the Investigative Protocol for Dining and Food Service, instructs

surveyors to "Observe the food service for…whether meals are attractive, palatable, served at appropriate temperatures and are delivered to residents in a timely fashion." This investigative protocol directs surveyors to evaluate whether foods are at the proper temperature in terms of palatability. The guidance at F364 has not changed. The Federal regulation 483.35(d) (2), F364, requires that "Each resident receives and the facility provides food that is palatable, attractive, and the proper temperature." The intent of this regulation, as mentioned in the interpretive guidelines, is that "Food should be palatable, attractive, and at the proper temperature as determined by the type of food to ensure resident's satisfaction." The Guidance to Surveyors includes a probe that states, "Food temperature: Is food served at preferable temperature (hot foods are served hot and cold foods are served cold) AS DISCERNED BY THE RESIDENT AND CUSTOMARY PRACTICE (emphasis added). Not to be confused with the proper holding temperature." So, although there's no specific temperature required when food is served to the resident, surveyors should determine compliance to F364. Palatable food temperatures are based on interviews and complaints received from residents and family members, supported by additional information gathered by the survey team.

87. Q: If we serve juices or jello salads (with no dairy products) on the trayline and they are out of refrigeration for 30 min., can the holding temp be above 41 degrees since they are not potentially hazardous foods?

A: See the answer for #86.

RAW AND PASTEURIZED EGG QUESTIONS

88. Q: What is the standard of practice for refrigeration of eggs? Can eggs be stored in a refrigerator on a solid shelf, over fruits and vegetables?

A: F371 Guidance to Surveyors states, "…stored off the floor, covered, labeled and dated, in refrigeration of at or below 41 degrees F, good circulation, daily monitored refrigeration temperatures, and separated from other food products on shelves below fruits, vegetables, or other ready-to-eat foods." The US FDA Food Code, for the standard of practice, 3-305.11 states. "…food shall be protected from contamination by storing the food in a clean, dry location, where it is not exposed to splash, dust or other contamination and at least 6 in. off the floor." It also requires that a potentially hazardous food be in refrigeration of at or below 41 degrees F, plus the same expectations as F371.

Since eggs are a PHF, they require good circulation, as stated above. The storage racks in a refrigerator, the US FDA FC 4-101.19 states, "Nonfood-contact surfaces of equipment that are exposed to splash, spillage, or other food soiling or that require frequent cleaning shall be constructed of a corrosion-resistant, nonabsorbent, and smooth material."

89. Q: Is it still necessary to care plan and review risk and benefits of consuming undercooked pasteurized eggs with the residents even though they are pasteurized?

A: No; if the eggs are pasteurized, you do not need to care plan or discuss risks and benefits.

90. Q: The revised code states that an egg should be cooked with the white set and the yolk congealed. Do resident's rights override that when a resident demands that it be a runny yolk?

A: The regulation has not changed. The Guidance to Surveyors was updated to reflect current standards of practice. The US FDA FC 3-801.11(C) (2) does not recommend that undercooked shell eggs be served to a susceptible population. This does not mean that residents who prefer a "runny yolk" cannot have them. It means that facilities will have to use only pasteurized eggs when serving undercooked eggs.

F371 states, "Pasteurized shell eggs are available and allow for safe consumption of undercooked eggs." And, "Waivers to allow undercooked unpasteurized eggs for resident preference are not acceptable." Therefore, only pasteurized undercooked eggs can be served to a susceptible population. This practice

allows a facility to follow the current standard of practice and meet the needs of resident rights, at the same time.

91. Q: Can you please clarify what a runny egg yolk is? Is the white not being solid (opaque) considered runny? We have residents that request poached eggs daily and we serve them with the whites done. Can we continue this practice?

A: Runny egg yolk is when the yolk is not congealed. The egg white not being solid is considered runny. You can continue to serve poached eggs daily, only if you are using pasteurized eggs. If you use non-pasteurized eggs and serve them runny, this would warrant an Immediate Jeopardy severity level F371 tag citation for the facility.

92. Q: We have been getting a lot of questions about eggs lately. Could you please clarify the rule of when you are required to purchase pasteurized eggs and when it is alright to use unpasteurized eggs?

A: F371 under the Guidance to Surveyors states, "Unpasteurized eggs when cooked to order in response to resident request and to be eaten promptly after cooking; - 145 degrees G for 15 seconds; until the white is completely set and the yolk is congealed." If a resident should want an egg cooked with runny yolks or an opaque egg white, the facility should be using pasteurized eggs. For cooking and baking, see F371 under Pooled Eggs.

The US FDA FC 3-801.11(B) states:

(B) Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of:
(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, Eggnog, ice cream, and EGG-fortified BEVERAGES, and (2) Except as specified in ¶ (F) of this section, recipes in which more than one EGG is broken and the EGGS are combined;

(C) The following FOODS may not be served or offered for sale in a READY-TO-EAT form:

(1) Raw animal FOODS such as raw FISH, raw marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare, (2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw EGGS, and meringue; and (3) Raw seed sprouts.

(D) FOOD EMPLOYEES may not contact READY-TO-EAT FOOD as specified under ¶¶ 3-301.11(B) and (D).

(E) Time only, as the public health control as specified under § 3-501.19(D), may not be used for raw EGGS.

(F) Subparagraph (B) (2) of this section does not apply if:
(1) The raw EGGS are combined immediately before cooking for one CONSUMER=S serving at a single meal cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled EGGS; (2) The raw EGGS are combined as an ingredient immediately before baking and the EGGS are thoroughly cooked to a READY-TO-EAT form, such as a cake, muffin, or bread; or (3) The preparation of the food is conducted under a HACCP plan…"

The US FDA FC at 3-202.14, Eggs and Milk Products, Pasteurized, "(A) Liquid, frozen and dry eggs and egg products shall be obtained pasteurized."

The Centers for Disease Control (CSC) state, "Many dishes made in restaurants or commercial or institutional kitchens, however, are made from pooled eggs. If 500 eggs are pooled, one batch in 20 will be contaminated and everyone who eats eggs from that batch is at risk. The CDC recommends that eggs not be pooled."

MISCELLANEOUS

93. Q: If a facility does not select either the US FDA Food Code or the WI Food Code to use as their standard of practice, what standard of practice do we hold them accountable to?

A: The facility is free to select the standard that they want to use as long as it is current. Facilities are also required to meet the regulatory standard at F371. The surveyors will select the US FDA Food Code in making compliance decisions while at the facility, if the facility has not chosen a current standard of practice to follow.

94. Q: One of the buildings I cover is thinking about changing specific meal times to a time range. For example, Breakfast will be served from 7am-9am versus specific time for all the various serving areas. Do you see an issue with this?

A: F371 states, "Meals or snacks may be served at times other than scheduled meal times and convenience foods, RTE foods and pre-packaged foods may be stored and microwave heated on the nursing units." Additionally, facilities are free to determine what works best for their residents. The federal regulation at F368 addresses the frequency of meals. For facilities with open dining and late breakfast times, the facility has met the intent of the 14 hour minimum if a resident could dine within those hours. But, residents have the right of choice to sleep later, have breakfast later, or have dinner earlier.

If breakfast is served from 7-9 am, supper would be served from 5-7 pm to maintain the 14 hr. minimum between meals, unless a substantial evening meal is served.

95. Q: Can hats be worn instead of hair nets?

A: Yes

Q: What constitutes a hair net?

A: See below.

Q: Does a beard need to be covered? (

A: Yes

US FDA Food Code 2-402.11(A) Effectiveness states:

(A) Except as provided in paragraph (B) of this section, food employees shall wear hair restraints such as hats, hair coverings or nets, beard restraints and clothing that covers body hair, that are designed and worn to effectively keep their hair from contacting exposed food; clean equipment, utensils and linens; and unwrapped single-service and single-use articles.

(B) This section does not apply to food employees such as counter staff who only serve beverages and wrapped or packaged foods, hostesses, and wait staff if they present a minimal risk of contaminating exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

F371 Guidance to Surveyors states: Dietary staff must wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent their hair from contacting exposed food.

96. Q: We listened to the webinar on the changes to F371, regarding sharing food among residents. I know that, if a family member wants to bring in a treat for everyone, then it must come from an approved source.

A: The new CMS S & C Memo 09-39, dated May 29, 2009 has clarified that residents can choose to accept food provided by visitors, friends, family members, or resident guests. It did not restrict the food from these people to be from an approved food source. It does state that the facility has the responsibility to help visitors to understand safe food handling practices. Therefore, food from approved food sources is not a requirement for resident consumption, unless it is being purchased from the facility.

97. Q: Are leftovers only allowed if they are not PHF and are not held below 135?

A: Leftovers apply to all foods. They can be re-served if the hot foods are reheated to the 165 degrees F. Foods sent out on trays or plated up may not be re-served.

98. Q: Disposable items. We have always served residents with the flu disposable trays, c-diff residents disposable until resident has full course of antibiotics or has formed stools. We heard we will no longer be able to do this, because of dignity.

A: There is no current standard of practice that directs a facility to use disposable trays for MRSA, C-Diff, pneumonia, etc. If a dignity issue arises (i.e., a resident complains about the disposable tray), the surveyor will ask you what standard of practice you are following. If you don't have a standard of practice that supports that practice, it's possible that you may get a dignity citation.

99. Q: Is it acceptable to re-use containers, such as cottage cheese or sour cream containers, to store different foods? Can you re-use these containers multiple times after sending them through the dish machine?

A: As long as they can be sanitized in the dish machine and stored appropriately, you could reuse the containers. The containers should be correctly labeled and dated as necessary.

100.Q: If an employee has a chronic disease, such as irritation of the bowels, in which the person is continuing to have to go to the restrooms, is the person allowed to work in food service?

A: Yes. An employee with a chronic disease, such as irritation of the bowels, can work in a kitchen. They need to follow the same proper food handling procedures as anyone else and personnel should ensure that the employee does not have a communicable disease. The US FDA Food Code 2-201.11 discusses, in great detail, the responsibilities and reporting symptoms expectations in a food preparation area.

101. Q: Do the cans, etc., need to be dated in the dry food storage area or can we use the First-In-First-Out (FIFO) rule?

A: F371 does not specify dating cans in dry storage. Your facility has to have a system in place and evidence to prove that you are rotating your stock. The FIFO method works as long the surveyor has evidence of it and the staff understand it. It is important to be aware of expiration dates.

102.Q: Is it required to have a Certified Dietary Manager (CDM) in the facility if you have a consultant dietitian?

A: No. F361/483.35(a)(1)states, "If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian." Intent: A director of food services has no required minimum qualifications, but must be able to function collaboratively with a qualified dietitian in meeting the nutritional needs of the residents.

DHS 132.63(2)(b), Wisconsin Administrative Code, states:

1. The nursing home shall designate a person to serve as the director of food services. A qualified director of food services is a person responsible for implementation of dietary service functions in the nursing home and who meets any of the following requirements:

a. Is a dietitian,
b. Has completed at least a course of study in food service management approved by the dietary managers association or an equivalent program,
c. Holds an associate degree as a dietetic technician from a program approved by the American Dietetic Association 2. If the director of food services is not a dietitian, the director of food services shall consult with a qualified dietitian on a frequent and regularly scheduled basis.

103.Q: A question came up about the dating of spices and other rarely used items in the food service. What do you expect there?

A: See #101 for the response.

104.Q: What is the standard of practice for holding condiments such as salad dressings, ketchup, mustard, etc.?

A: In the dry storage area, you would follow the same expectations as described in question #90. Because these food items are not considered potentially hazardous foods, you would store them---once opened---in a monitored refrigeration unit. Follow your current standard of practice for refrigeration storage. They should be monitored and used by the manufacturer's "used by date."

For follow-up questions, please contact:

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