



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-08-28

DATE: June 20, 2008

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes** - Issuance of Revised Nutrition and Sanitary Conditions (Tags F325 and F371) as Part of Appendix PP, State Operations Manual, and Training Materials

Memorandum Summary

- **Effective Date:** Revised guidance for long-term care surveyors regarding Nutrition and Sanitary Conditions (Tags F325 and F371) will be effective September 1, 2008.
- **Memo Includes:** An advance copy of this guidance and training slides are attached.
- **Action:** A comprehensive training guide has been sent to State and regional office training coordinators under separate cover to assure that all surveyors who survey nursing homes are trained in the revised guidance by the implementation date.

Revised surveyor guidance for surveying Nutrition and Sanitary Conditions requirements in long-term care facilities will become effective on September 1, 2008. At that time, a final copy of this new guidance will be available at <http://www.cms.hhs.gov/Transmittals/> and ultimately incorporated into Appendix PP of the State Operations Manual. Corresponding Automated Survey Process Environment (ASPEN) changes are expected to be in place by the end of August.

Here, we are providing an advance copy of the revised Nutrition and Sanitary Conditions guidance, which addresses the interpretive guidelines, the investigative protocol, and determination of compliance. The interpretive guidelines clarify areas such as assessment, care planning, and interventions related to nutrition and sanitary conditions for nursing home residents. The investigative protocol explains objectives and procedures surveyors will need for their investigations. Deficiency categorization provides severity guidance for the determination of the correct level of severity of outcome to residents from deficiencies found at Tags F325 and/or Tag F371.

Also attached to this memo are training slides for the revised Tags F325 and F371. A comprehensive training guide has been sent to State and regional office training coordinators under separate cover to assure that all surveyors who survey nursing homes are trained in the revised guidance by the implementation date. We encourage training to be conducted in person with group discussion to optimize learning. However, if this is not feasible to meet the needs of your surveyors, it is acceptable to use other methods. This guide may also be used to communicate with provider groups and other stakeholders.

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RO training coordinators will document the completion of training on this new guidance for all RO and State nursing home surveyors within their region.

Enclosed with this memorandum is the advance copy of the surveyor guidance on Tags F325 & F371 Guidance and Training slides.

For questions on this memorandum, please contact Debra Swinton-Spears at 410-786-7506 or via email at debra.swinton-spears@cms.hhs.gov).

Effective Date: September 1, 2008. The State Agency should disseminate this information within 30 days of the date of this memorandum.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Enclosures: Advance copy of Tags F325 and F371 Interpretive Guidelines
Training slides

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human
Services (DHHS)
Centers for Medicare & Medicaid
Services (CMS)

Transmittal

Date: Advance Copy

SUBJECT: Revisions to Appendix PP – “Interpretive Guidelines for Long-Term Care Facilities,” Tags F325 and F371

I. SUMMARY OF CHANGES: This instruction deletes Tag F326 and incorporates the guidance into Tag F325. It also deletes Tag F370 and incorporates that guidance into F371.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance

IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/§483.25(i)/Nutrition/Tag F325
D	Appendix PP/§483.25(i)(2)/Therapeutic Diets/Tag F326
D	Appendix PP/§483.35(i)(1)/Approved Food Source/Tag F370
R	Appendix PP/§483.35(i)(2)/Food Sanitation/Tag F371

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
x	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

F325

(Rev.)

§483.25(i) Nutrition

Based on a resident's comprehensive assessment, the facility must ensure that a resident--

§483.25(i)(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

§483.25(i)(2) Receives a therapeutic diet when there is a nutritional problem.

INTENT: §483.25(i) Nutritional Status

The intent of this requirement is that the resident maintains, to the extent possible, acceptable parameters of nutritional status and that the facility:

- Provides nutritional care and services to each resident, consistent with the resident's comprehensive assessment;*
- Recognizes, evaluates, and addresses the needs of every resident, including but not limited to, the resident at risk or already experiencing impaired nutrition; and*
- Provides a therapeutic diet that takes into account the resident's clinical condition, and preferences, when there is a nutritional indication.*

DEFINITIONS

Definitions are provided to clarify clinical terms related to nutritional status.

- "Acceptable parameters of nutritional status" refers to factors that reflect that an individual's nutritional status is adequate, relative to his/her overall condition and prognosis.*
- "Albumin" is the body's major plasma protein, essential for maintaining osmotic pressure and also serving as a transport protein.*
- "Anemia" refers to a condition of low hemoglobin concentration caused by decreased production, increased loss, or destruction of red blood cells.*
- "Anorexia" refers to loss of appetite, including loss of interest in seeking and consuming food.*

- *“Artificial nutrition” refers to nutrition that is provided through routes other than the usual oral route, typically by placing a tube directly into the stomach, the intestine or a vein.*
- *“Avoidable/Unavoidable” failure to maintain acceptable parameters of nutritional status:*
 - *“Avoidable” means that the resident did not maintain acceptable parameters of nutritional status and that the facility did not do one or more of the following: evaluate the resident’s clinical condition and nutritional risk factors; define and implement interventions that are consistent with resident needs, resident goals and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.*
 - *“Unavoidable” means that the resident did not maintain acceptable parameters of nutritional status even though the facility had evaluated the resident’s clinical condition and nutritional risk factors; defined and implemented interventions that are consistent with resident needs, goals and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.*
- *“Clinically significant” refers to effects, results, or consequences that materially affect or are likely to affect an individual’s physical, mental, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.*
- *“Current standards of practice” refers to approaches to care, procedures, techniques, treatments, etc., that are based on research or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.*
- *“Dietary supplements” refers to nutrients (e.g., vitamins, minerals, amino acids, and herbs) that are added to a person’s diet when they are missing or not consumed in enough quantity.*
- *“Insidious weight loss” refers to a gradual, unintended, progressive weight loss over time.*
- *“Nutritional Supplements” refers to products that are used to complement a resident’s dietary needs (e.g., total parenteral products, enteral products, and meal replacement products).*
- *“Parameters of nutritional status” refers to factors (e.g., weight, food/fluid intake, and pertinent laboratory values) that reflect the resident’s nutritional status.*
- *“Qualified dietitian” refers to one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association or as permitted by State law, on the basis of education, training, or*

experience in identification of dietary needs, planning, and implementation of dietary programs.

- *“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 or potassium), or to provide mechanically altered food when indicated.*
- *“Usual body weight” refers to the resident’s usual weight through adult life or a stable weight over time.*

OVERVIEW

Nutrients are essential for many critical metabolic processes, the maintenance and repair of cells and organs, and energy to support daily functioning. Therefore, it is important to maintain adequate nutritional status, to the extent possible.

Other key factors in addition to intake can influence weight and nutritional status. For example, the body may not absorb or use nutrients effectively. Low weight may also pertain to: age-related loss of muscle mass, strength, and function (sarcopenia),¹ wasting (cachexia) that occurs as a consequence of illness and inflammatory processes, or disease causing changes in mental status.² Changes in the ability to taste food may accompany later life.³

Impaired nutritional status is not an expected part of normal aging. It may be associated with an increased risk of mortality and other negative outcomes such as impairment of anticipated wound healing, decline in function, fluid and electrolyte imbalance/dehydration, and unplanned weight change.⁴ The early identification of residents with, or at risk for, impaired nutrition, may allow the interdisciplinary team to develop and implement interventions to stabilize or improve nutritional status before additional complications arise. However, since intake is not the only factor that affects nutritional status, nutrition-related interventions only sometimes improve markers of nutritional status such as body weight and laboratory results.⁵ While they can often be stabilized or improved, nutritional deficits and imbalances may take time to improve or they may not be fully correctable in some individuals.

A systematic approach can help staff’s efforts to optimize a resident’s nutritional status. This process includes identifying and assessing each resident’s nutritional status and risk factors, evaluating/analyzing the assessment information, developing and consistently implementing pertinent approaches, and monitoring the effectiveness of interventions and revising them as necessary.

ASSESSMENT

According to the American Dietetic Association, “Nutritional assessment is a systematic process of obtaining, verifying and interpreting data in order to make decisions about the nature and cause of nutrition-related problems.”^{6,7} The assessment also provides

information that helps to define meaningful interventions to address any nutrition-related problems.

The interdisciplinary team clarifies nutritional issues, needs, and goals in the context of the resident's overall condition, by using observation and gathering and considering information relevant to each resident's eating and nutritional status. Pertinent sources of such information may include interview of the resident or resident representative, and review of information (e.g., past history of eating patterns and weight and a summary of any recent hospitalizations) from other sources.

The facility identifies key individuals who should participate in the assessment of nutritional status and related causes and consequences. For example, nursing staff provide details about the resident's nutritional intake. Health care practitioners (e.g., physicians and nurse practitioners) help define the nature of the problem (e.g., whether the resident has anorexia or sarcopenia), identify causes of anorexia and weight loss, tailor interventions to the resident's specific causes and situation, and monitor the continued relevance of those interventions. Qualified dietitians help identify nutritional risk factors and recommend nutritional interventions, based on each resident's medical condition, needs, desires, and goals. Consultant pharmacists can help the staff and practitioners identify medications that affect nutrition by altering taste or causing dry mouth, lethargy, nausea, or confusion.

Although the Resident Assessment Instrument (RAI) is the only assessment tool specifically required, a more in-depth nutritional assessment may be needed to identify the nature and causes of impaired nutrition and nutrition-related risks. Completion of the RAI does not remove the facility's responsibility to document a more detailed resident assessment, where applicable. The in-depth nutritional assessment may utilize existing information from sources, such as the RAI, assessments from other disciplines, observation, and resident and family interviews. The assessment will identify usual body weight, a history of reduced appetite or progressive weight loss or gain prior to admission, medical conditions such as a cerebrovascular accident, and events such as recent surgery, which may have affected a resident's nutritional status and risks. The in-depth nutritional assessment may also include the following information:

General Appearance - *General appearance includes a description of the resident's overall appearance (e.g., robust, thin, obese, or cachectic) and other findings (e.g., level of consciousness, responsiveness, affect, oral health and dentition, ability to use the hands and arms, and the condition of hair, nails, and skin) that may affect or reflect nutritional status.*

Height - *Measuring a resident's height provides information that is relevant (in conjunction with his or her weight) to his/her nutritional status. There are various ways to estimate height if standing height cannot be readily measured.⁸ A protocol for determining height helps to ensure that it will be measured as consistently as possible.*

Weight - *Weight can be a useful indicator of nutritional status, when evaluated within the context of the individual's personal history and overall condition. When weighing a*

resident, adjustment for amputations or prostheses may be indicated. Significant unintended changes in weight (loss or gain) or insidious weight loss may indicate a nutritional problem.

Current standards of practice recommend weighing the resident on admission or readmission (to establish a baseline weight), weekly for the first 4 weeks after admission and at least monthly thereafter to help identify and document trends such as insidious weight loss. Weighing may also be pertinent if there is a significant change in condition, food intake has declined and persisted (e.g., for more than a week), or there is other evidence of altered nutritional status or fluid and electrolyte imbalance. In some cases, weight monitoring is not indicated (e.g., the individual is terminally ill and requests only comfort care).

Obtaining accurate weights for each resident may be aided by having staff follow a consistent approach to weighing and by using an appropriately calibrated and functioning scale (e.g., wheelchair scale or bed scale). Since weight varies throughout the day, a consistent process and technique (e.g., weighing the resident wearing a similar type of clothing, at approximately the same time of the day, using the same scale, either consistently wearing or not wearing orthotics or prostheses, and verifying scale accuracy) can help make weight comparisons more reliable.

A system to verify weights can help to ensure accuracy. Weights obtained in different settings may differ substantially. For example, the last weight obtained in the hospital may differ markedly from the initial weight upon admission to the facility, and is not to be used in lieu of actually weighing the resident. Approaches to improving the accuracy of weights may include reweighing the resident and recording the current weight, reviewing approaches to obtaining and verifying weight, and modifying those approaches as needed.

Examples of other factors that may impact weight and the significance of apparent weight changes include:

- The resident's usual weight through adult life;*
- Current medical conditions;*
- Calorie restricted diet;*
- Recent changes in dietary intake; and*
- Edema.*

Food and fluid intake - *The nutritional assessment includes an estimate of calorie, nutrient and fluid needs, and whether intake is adequate to meet those needs. It also includes information such as the route (oral, enteral or parenteral) of intake, any special food formulation, meal and snack patterns (including the time of supplement or medication consumption in relation to the meals), dislikes, and preferences (including ethnic foods and form of foods such as finger foods); meal/snack patterns, and preferred portion sizes.*

Fluid loss or retention can cause short term weight change. Much of a resident's daily fluid intake comes from meals; therefore, when a resident has decreased appetite, it can result in fluid/electrolyte imbalance. Abrupt weight changes, change in food intake, or altered level of consciousness are some of the clinical manifestations of fluid and electrolyte imbalance. Laboratory tests (e.g., electrolytes, BUN, creatinine and serum osmolality) can help greatly to identify, manage, and monitor fluid and electrolyte status.⁹

Altered Nutrient intake, absorption, and utilization. *Poor intake, continuing or unabated hunger, or a change in the resident's usual intake that persists for multiple meals, may indicate an underlying problem or illness. Examples of causes include:*

- The inability to consume meals provided (e.g., as a result of the form or consistency of food/fluid, cognitive or functional decline, arthritis-related impaired movement, neuropathic pain, or insufficient assistance);*
- Insufficient availability of food and fluid (e.g., inadequate amount of food or fluid or inadequate tube feedings);*
- Environmental factors affecting food intake or appetite (e.g., comfort and level of disruption in the dining environment);*
- Adverse consequences related to medications; and*
- Diseases and conditions such as cancer, diabetes mellitus, advanced or uncontrolled heart or lung disease, infection and fever, liver disease, hyperthyroidism, mood disorders, and repetitive movement disorders (e.g., wandering, pacing, or rocking).*

The use of diuretics and other medications may cause weight loss that is not associated with nutritional issues, but can also cause fluid and electrolyte imbalance/dehydration that causes a loss of appetite and weight.

Various gastrointestinal disorders such as pancreatitis, gastritis, motility disorders, small bowel dysfunction, gall bladder disease, and liver dysfunction may affect digestion or absorption of food. Prolonged diarrhea or vomiting may increase nutritional requirements due to nutrient and fluid losses. Constipation or fecal impaction may affect appetite and excretion.

Pressure ulcers and some other wounds and other health impairments may also affect nutritional requirements. A hypermetabolic state results from an increased demand for energy and protein and may increase the risk of weight loss or under-nutrition. Examples of causes include advanced chronic obstructive pulmonary disease (COPD), pneumonia and other infections, cancer, hyperthyroidism, and fever.

Early identification of these factors, regardless of the presence of any associated weight changes, can help the facility choose appropriate interventions to minimize any subsequent complications.¹⁰ Often, several of these factors affecting nutrition coexist.

Chewing abnormalities - Many conditions of the mouth, teeth, and gums can affect the resident's ability to chew foods. For example, oral pain, dry mouth, gingivitis, periodontal disease, ill-fitting dentures, and broken, decayed or missing teeth can impair oral intake.

Swallowing abnormalities - Various direct and indirect causes can affect the resident's ability to swallow. These include but are not limited to stroke, pain, lethargy, confusion, dry mouth, and diseases of the oropharynx and esophagus. Swallowing ability may fluctuate from day to day or over time. In some individuals, aspiration pneumonia can complicate swallowing abnormalities.¹⁰

NOTE: Swallowing studies are not always required in order to assess eating and swallowing; however, when they are indicated, it is essential to interpret any such tests in the proper context. A clinical evaluation of swallowing may be used to evaluate average daily oral function.¹¹

Functional ability - The ability to eat independently may be helped by addressing factors that impair function or by providing appropriate individual assistance, supervision, or assistive devices. Conditions affecting functional ability to eat and drink include impaired upper extremity motor coordination and strength or reduced range of motion (any of which may be hampered by stroke, Parkinson's disease, multiple sclerosis, tardive dyskinesia, or other neuromuscular disorders or by sensory limitations (e.g., blindness)). Cognitive impairment may also affect a resident's ability to use a fork, or to eat, chew, and swallow effectively.

Medications - Medications and nutritional supplements may affect, or be affected by, the intake or utilization of nutrients (e.g., liquid phenytoin taken with tube feedings or grapefruit juice taken with some antihyperlipidemics).¹² Medications from almost every pharmaceutical class can affect nutritional status, directly or indirectly; for example, by causing or exacerbating anorexia, lethargy, confusion, nausea, constipation, impairing taste, or altering gastrointestinal function. Inhaled or ingested medications can affect food intake by causing pharyngitis, dry mouth, esophagitis, or gastritis. To the extent possible, consideration of medication/nutrient interactions and adverse consequences should be individualized.

Goals and prognosis - Goals and prognosis refer to a resident's projected personal and clinical outcomes. These are influenced by the resident's preferences (e.g., willingness to participate in weight management interventions or desire for nutritional support at end-of-life), anticipated course of a resident's overall condition and progression of a disease (e.g., end-stage, terminal, or other irreversible conditions affecting food intake, nutritional status, and weight goals), and by the resident's willingness and capacity to permit additional diagnostic testing, monitoring and treatment.

Laboratory/Diagnostic Evaluation

Laboratory tests are sometimes useful to help identify underlying causes of impaired nutrition or when the clinical assessment alone is not enough to define someone's nutritional status.

Abnormal laboratory values may, but do not necessarily, imply that treatable clinical problems exist or that interventions are needed. Confirmation is generally desirable through additional clinical evaluation and evidence such as food intake, underlying medical condition, etc.¹³ For example, serum albumin may help establish prognosis but is only sometimes helpful in identifying impaired nutrition or guiding interventions. Serum albumin may drop significantly during an acute illness for reasons unrelated to nutrition; therefore, albumin may not improve, or may fall further, despite consumption of adequate amounts of calories and protein.

The decision to order laboratory tests, and the interpretation of subsequent results, is best done in light of a resident's overall condition and prognosis.¹⁴ Before ordering laboratory tests it is appropriate for the health care practitioner to determine and indicate whether the tests would potentially change the resident's diagnosis, management, outcome or quality of life or otherwise add to what is already known. Although laboratory tests such as albumin and pre-albumin may help in some cases in deciding to initiate nutritional interventions, there is no evidence that they are useful for the serial follow-up of undernourished individuals.¹⁴

NOTE: If laboratory tests were done prior to or after admission to the facility and the test results are abnormal, the physician or other licensed health care practitioner, in collaboration with the interdisciplinary team, reviews the information and determines whether to intervene or order additional diagnostic testing.

ANALYSIS

Analysis refers to using the information from multiple sources to include, but not limited to, the Resident Assessment Instrument (RAI), and additional nutritional assessments as indicated to determine a resident's nutritional status and develop an individualized care plan.

Resultant conclusions may include, but are not limited to: a target range for weight based on the individual's overall condition, goals, prognosis, usual body weight, etc; approximate calorie, protein, and other nutrient needs; whether and to what extent weight stabilization or improvement can be anticipated; and whether altered weight or nutritional status could be related to an underlying medical condition (e.g., fluid and electrolyte imbalance, medication-related anorexia, or an infection).

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

<i>Interval</i>	<i>Significant Loss</i>	<i>Severe Loss</i>
<i>1 month</i>	<i>5%</i>	<i>Greater than 5%</i>
<i>3 months</i>	<i>7.5%</i>	<i>Greater than 7.5%</i>
<i>6 months</i>	<i>10%</i>	<i>Greater than 10%</i>

The following formula determines percentage of weight loss:

$$\% \text{ of body weight loss} = (\text{usual weight} - \text{actual weight}) / (\text{usual weight}) \times 100$$

Based on analysis of relevant information, the facility identifies a clinically pertinent basis for any conclusions that a resident could not attain or maintain acceptable parameters of nutritional status.

Specification of the Nutritional Concern

A clear statement of the nature of the nutritional concern provides the basis for resident-specific interventions. Many residents have multiple coexisting issues. For example:

- Poor food and fluid intake: The resident has poor intake, is not consuming specific food groups, and has increased nutritional needs specific to clinical conditions. The resident also has lost significant weight over a few days while taking medications that may affect appetite.*
- Specific clinical conditions: The resident has an infection with fever and is in a hyper-metabolic state associated with an increased demand for energy and protein. The resident also has a neuromuscular disorder affecting the ability to eat or swallow, and has impaired cognition affecting attention and appetite.*

CARE PLANNING AND INTERVENTIONS

The management of nutrition in nursing homes involves various medical, psychosocial, ethical, and functional considerations. Based on information generated by the comprehensive assessment and any pertinent additional nutritional assessment, the interdisciplinary team (including a physician or other licensed health care practitioner and the resident or the resident's representative) develops an individualized care plan. The care plan addresses, to the extent possible, identified causes of impaired nutritional status, reflects the resident's goals and choices, and identifies resident-specific interventions and a time frame and parameters for monitoring. The care plan is updated as needed; e.g., as conditions change, goals are met, interventions are determined to be ineffective, or as specific treatable causes of nutrition-related problems (anorexia, impaired chewing, etc.) are identified. If nutritional goals are not achieved, different or additional pertinent approaches are considered and implemented as indicated. Pertinent documentation can help identify the basis (e.g., current resident status, comorbid conditions, prognosis, and resident choices) for nutrition-related goals and interventions.

Resident Choice

A resident or resident representative has the right to make informed choices about accepting or declining care and treatment. The facility can help the resident exercise those rights effectively by discussing with the resident (or the resident's representative) the resident's condition, treatment options (including related risks and benefits, and expected outcomes), personal preferences, and any potential consequences of accepting or refusing treatment. If the resident declines specific interventions, the facility must address the resident's concerns and offer relevant alternatives.

The facility's care reflects a resident's choices, either as offered by the resident directly or via a valid advance directive, or based on a decision made by the resident's surrogate or representative in accordance with state law. The presence of care instructions, such as an advance directive, declining some interventions does not necessarily imply that other support and care was declined or is not pertinent. When preferences are not specified beforehand, decisions related to the possible provision of supplemental or artificial nutrition should be made in conjunction with the resident or resident's representative in accordance with state law, taking into account relevant considerations such as condition, prognosis, and a resident's known values and choices.

NOTE: *The presence of a "Do Not Resuscitate" (DNR) order does not by itself indicate that the resident is declining other appropriate treatment and services. It only indicates that the resident has chosen not to be resuscitated if cardiopulmonary functions cease.*

Meeting Nutritional Needs

The scope of interventions to meet residents' nutritional needs depends on many factors, including, but not limited to a resident's current food intake, the degree of nutritional impairment or risk, resident choices, the response to initial interventions, and the feasibility of addressing underlying conditions and causes. Basic energy needs can generally be met by providing a diet that includes enough calories to stabilize current body weight. Adjustments may be necessary when factors exist such as those discussed within this document. For example, limits on dairy products may be desirable in individuals with lactose intolerance, and additional amounts of nutrients and calories may be needed for individuals with hypermetabolic states (e.g., fever, hyperthyroidism, acute wounds, or heart or lung disease), to try to keep the body from using lean body mass for energy and wound repair.

Diet Liberalization

Research suggests that a liberalized diet can enhance the quality of life and nutritional status of older adults in long-term care facilities.¹⁵ 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.

Weight-Related Interventions

For many residents (including overweight individuals), the resident's usual body weight prior to decline or admission is the most relevant basis for weight-related interventions. Basing interventions on ideal body weight can be misleading, because ideal body weight has not been definitively established for the frail elderly and those with chronic illnesses and disabilities.

The care plan includes nutritional interventions that address underlying risks and causes of weight loss (e.g., the need for eating assistance, reduction of medication side effects, and additional food that the resident will eat) or unplanned weight gain. It is important that the care plan address insidious, abrupt, or sudden decline in intake or insidious weight loss that does not trigger review of the Nutritional Status Resident Assessment Protocol (RAP); for example, by intensifying observation of intake and eating patterns, monitoring for complications related to poor intake, and seeking underlying cause(s).

Many risk factors and some causes of weight loss can be addressed, at least partially, while others may not be modifiable. In some cases, certain interventions may not be indicated or appropriate, based on individual goals and prognosis.

Weight stability, rather than weight gain, may sometimes be the most pertinent short-term or long-term objective for the nutritionally at-risk or compromised resident. After an acute illness or as part of an advanced or end-stage medical condition, the resident's weight and other nutritional parameters may not return to previous levels and may stabilize at a lower level, sometimes indefinitely.

NOTE: *There should be a documented clinical basis for any conclusion that nutritional status or significant weight change are unlikely to stabilize or improve (e.g., physician's documentation as to why weight loss is medically unavoidable).*

Weight Gain. *Unplanned weight gain in a resident may have significant health implications. Rapid or abrupt increases in weight may also indicate significant fluid excess. After assessing the resident for the cause of the weight gain, care plan interventions may include dietary alterations based on the resident's medical condition, choices, and needs. If the resident exercises his/her right to choose and declines dietary restrictions, the facility discusses with the resident the benefits of maintaining a lower*

weight and the possible consequences of not doing so. A health care practitioner can help inform the resident about the rationale for the recommended plan of care.

Environmental Factors

Appetite is often enhanced by the appealing aroma, flavor, form, and appearance of food. Resident-specific facility practices that may help improve intake include providing a pleasant dining experience (e.g., flexible dining environments, styles and schedules), providing meals that are palatable, attractive and nutritious (e.g., prepare food with seasonings, serve food at proper temperatures, etc.), and making sure that the environment where residents eat (e.g., dining room and/or resident's room) is conducive to dining.

Anorexia

The facility, in consultation with the practitioner, identifies and addresses treatable causes of anorexia. For example, the practitioner may consider adjusting or stopping medications that may have caused the resident to have dyspepsia or become lethargic, constipated, or confused, and reevaluate the resident to determine whether the effects of the medications are the reasons for the anorexia and subsequent weight loss.

Where psychosis or a mood disorder such as depression has been identified as a cause of anorexia or weight change, treatment of the underlying disorder (based on an appropriate diagnostic evaluation) may improve appetite. However, other coexisting conditions or factors instead of, or in addition to, depression, may cause or contribute to anorexia. In addition, the use of antidepressants is not generally considered to be an adequate substitute for appropriately investigating and addressing modifiable risk factors or other underlying causes of anorexia and weight loss.

Wound Healing

Healing of acute (e.g., postoperative) and chronic (e.g., pressure ulcer) wounds requires enough calories and protein so that the body will not use lean body mass (muscle) for energy and wound repair. However, to date, no routinely beneficial wound-specific nutritional measures have been identified.¹⁶

Care plan interventions for a resident who has a wound or is at risk of developing a wound may include providing enough calories to maintain a stable weight and a daily protein intake of approximately 1.2-1.5 gm protein/Kg body weight. The recommended daily protein intake may be adjusted according to clinical need and standards of clinical practice for situations in which more calories and protein are indicated. Sometimes, it may be most appropriate to try to encourage the resident to eat as many calories and as much protein as tolerated, because he/she does not desire or cannot tolerate more aggressive nutritional interventions.

Additional strategies for wound healing may be considered when indicated. A multivitamin/mineral supplement may be prescribed, however current evidence does not

definitively support any specific dietary supplementation (e.g., Vitamin C and Zinc) unless the resident has a specific vitamin or mineral deficiency.

Functional Factors

*Based on the comprehensive interdisciplinary assessment, the facility provides the necessary assistance to allow the resident to eat and drink adequately. A resident with functional impairment may need help with eating. Examples of such interventions may include, but are not limited to: ensuring that sensory devices such as eyeglasses, dentures, and hearing aids are in place; providing personal hygiene before and after meals, properly positioning the individual, providing eating assistance where needed, and providing the assistive devices/utensils identified in the assessment.*¹⁷

Chewing and Swallowing

In deciding whether and how to intervene for chewing and swallowing abnormalities, it is essential to take a holistic approach and look beyond the symptoms to the underlying causes. Pertinent interventions may help address the resident's eating, chewing, and swallowing problems and optimize comfort and enjoyment of meals. Examples of such interventions may include providing proper positioning for eating; participation in a restorative eating program; use of assistive devices/utensils; and prompt assistance (e.g., supervision, cueing, hand-over-hand) during every meal/snack where assistance is needed.

Treating medical conditions (e.g., gastroesophageal reflux disease and oral and dental problems) that can impair swallowing or cause coughing may improve a chewing or swallowing problem. Examples of other relevant interventions include adjusting medications that cause dry mouth or coughing, and providing liquids to moisten the mouth of someone with impaired saliva production.

Excessive modification of food and fluid consistency may unnecessarily decrease quality of life and impair nutritional status by affecting appetite and reducing intake.¹⁸ Many factors influence whether a swallowing abnormality eventually results in clinically significant complications such as aspiration pneumonia.¹⁹ Identification of a swallowing abnormality alone does not necessarily warrant dietary restrictions or food texture modifications. No interventions consistently prevent aspiration and no tests consistently predict who will develop aspiration pneumonia.²⁰ For example, tube feeding may be associated with aspiration, and is not necessarily a desirable alternative to allowing oral intake, even if some swallowing abnormalities are present.^{21,22}

Decisions to downgrade or alter the consistency of diets must include the resident (or the resident's representative), consider ethical issues (such as the right to decline treatment), and be based on a careful review of the resident's overall condition, correctable underlying causes of the risk or problem, the benefits and risks of a more liberalized diet, and the resident's preferences to accept risks in favor of a more liberalized food intake.

Medications

When a resident is eating poorly or losing weight, the immediate need to stabilize weight and improve appetite may supersede long-term medical goals for which medications were previously ordered. It may be appropriate to change, stop, or reduce the doses of medications (e.g., antiepileptics, cholinesterase inhibitors, or iron supplements) that are associated either with anorexia or with symptoms such as lethargy or confusion that can cause or exacerbate weight loss.²³ The medical practitioner in collaboration with the staff and the pharmacist reviews and adjusts medications as appropriate. (For additional Guidance related to medications, refer to 42 CFR 483.25(l)(1), F329, Unnecessary Drugs.)

Food Fortification and Supplementation

With any nutrition program, improving intake via wholesome foods is generally preferable to adding nutritional supplements. However, if the resident is not able to eat recommended portions at meal times or to consume between-meal snacks/nourishments, or if he/she prefers the nutritional supplement, supplements may be used to try to increase calorie and nutrient intake. Since some research suggests that caloric intake may increase if nutritional supplements are consumed between meals, and may be less effective when given with meals, the use of nutritional supplements is generally recommended between meals instead of with meals.²⁴ Taking a nutritional supplement during medication administration may also increase caloric intake without reducing the resident's appetite at mealtime.

Examples of interventions to improve food/fluid intake include:

- Fortification of foods (e.g., adding protein, fat, and/or carbohydrate to foods such as hot cereal, mashed potatoes, casseroles, and desserts);*
- Offering smaller, more frequent meals;*
- Providing between-meal snacks or nourishments; or*
- Increasing the portion sizes of a resident's favorite foods and meals; and providing nutritional supplements.*

Maintaining Fluid and Electrolyte Balance

If a resident has poor intake or abnormal laboratory values related to fluid/electrolyte balance, the care plan addresses the potential for hydration deficits.²⁵ Examples of interventions include adjusting or discontinuing medications that affect fluid balance or appetite; offering a variety of fluids (water, fruit juice, milk, etc.) between meals, and encouraging and assisting residents as appropriate. Serving (except to those with fluid restrictions) additional beverages with meals will also help increase fluid intake. Examples of ways to encourage fluid intake include maintaining filled water pitchers and

drinking cups easily accessible to residents (except those with fluid restrictions) and offering alternate fluid sources such as popsicles, gelatin, and ice cream.

Use of Appetite Stimulants

To date, the evidence is limited about benefits from appetite stimulants. While their use may be appropriate in specific circumstances, they are not a substitute for appropriate investigation and management of potentially modifiable risk factors and underlying causes of anorexia and weight loss.²⁶

Feeding Tubes

Feeding tubes have potential benefits and complications, depending on an individual's underlying medical conditions and prognosis, and the causes of his or her anorexia or weight loss. Possible feeding tube use, especially for residents with advanced dementia or at the end-of-life, should be considered carefully. The resident's values and choices regarding artificial nutrition should be identified and considered. The health care practitioner should be involved in reviewing whether potentially modifiable causes of anorexia, weight loss, and eating or swallowing abnormalities have been considered and addressed, to the extent possible. For residents with dementia, studies have shown that tube feeding does not extend life, prevent aspiration pneumonia, improve function or limit suffering.²⁷

End-of-Life

Resident choices and clinical indications affect decisions about the use of a feeding tube at the end-of-life. A resident at the end of life may have an advance directive addressing his or her treatment goals (or the resident's surrogate or representative, in accordance with State law, may have made a decision).

Decreased appetite and altered hydration are common at the end of life, and do not require interventions other than for comfort. Multiple organ system failure may impair the body's capacity to accept or digest food or to utilize nutrients. Thus, the inability to maintain acceptable parameters of nutritional status for someone who is at the end-of-life or in the terminal stages of an illness may be an expected outcome.

Care and services, including comfort measures, are provided based on the resident's choices and a pertinent nutritional assessment. The facility can help to support intake, to the extent desired and feasible, based on the information from the assessment and on considering the resident's choices.

If individualized approaches for end-of-life care are provided in accordance with the care plan and the resident's choices, then the failure to maintain acceptable parameters of nutritional status may be an expected outcome for residents with terminal conditions.

MONITORING

Monitoring after care plan implementation is necessary for residents with impaired or at-risk nutritional status, as well as for those whose current nutritional status is stable. Monitoring includes a review of the resident-specific factors identified as part of the comprehensive resident assessment and any supplemental nutrition assessment.

Identifying and reporting information about the resident's nutritional status and related issues such as level of consciousness and function are obtainable through various staff observations. For example, nursing assistants may be most familiar with the resident's habits and preferences, symptoms such as pain or discomfort, fluctuating appetite, and nausea or other gastrointestinal symptoms. More intensive and frequent monitoring may be indicated for residents with impaired or at-risk nutritional status than for those who are currently nutritionally stable. Such monitoring may include, but is not limited to, observing for and recognizing emergence of new risk factors (e.g., acute medical illness, pressure ulcers, or fever), evaluating consumption of between-meal snacks and nutritional supplements, and reviewing the continued relevance of any current nutritional interventions (e.g., therapeutic diets, tube feeding orders or nutritional supplements).

Evaluating the care plan to determine if current interventions are being followed and if they are effective in attaining identified nutritional and weight goals allows the facility to make necessary revisions. Subsequent adjustment of interventions will depend on, but are not limited to, progress, underlying causes, overall condition and prognosis. The resident's current nutritional and medical status helps the staff determine the frequency of reweighing the resident. For example, reweighing a resident within a week of initiating or substantially revising nutritional interventions to address anorexia or weight loss assists in monitoring responses to interventions. Monitoring residents who experience unplanned weight loss, including reweighing at least weekly until weight is stable or increasing and then routinely thereafter, helps clarify his/her responses to interventions. However in some residents, subsequent weight monitoring may not be clinically indicated (e.g., palliative care resident).

Nutrition-related goals may need to be modified, depending on factors such as further clarification of underlying causes (e.g., when evidence suggests that unmodifiable factors may prevent improved or stabilized nutritional status) and responses to current interventions. In some cases, the current plan of care may need to be modified and new or additional interventions implemented. The facility explains any decisions to continue current interventions when the resident's nutritional status continues to decline. For example, because the goal of care for someone with a terminal, advanced, or irreversible condition has changed to palliation.

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INVESTIGATIVE PROTOCOL

NUTRITIONAL STATUS

Objectives

- *To determine if the facility has practices in place to maintain acceptable parameters of nutritional status for each resident based on his/her comprehensive assessment.*
- *To determine if failure to maintain acceptable parameters of nutritional status for each resident was avoidable or unavoidable (the resident's clinical condition demonstrates that maintaining acceptable parameters is not possible).*
- *To determine if the resident has received a therapeutic diet when there is a nutritional indication.*

Use

Use this protocol for each sampled resident to determine through interview, observation and record review whether the facility is in compliance with the regulation, specifically:

- *To determine if residents maintained acceptable parameters of nutritional status, relative to his/her comprehensive assessment;*
- *For a resident who did not maintain acceptable parameters of nutritional status, to determine if the facility assessed and intervened (e.g., therapeutic diet) to enable the resident to maintain acceptable parameters of nutritional status, unless the resident's clinical condition demonstrated that this was not possible; and*
- *For a resident who is at nutritional risk, to determine if the facility has identified and addressed risk factors for, and causes of, impaired nutritional status, or demonstrated why they could not or should not do so.*

Procedures

Briefly review the RAI, care plan, and any additional relevant nutritional assessment information that may be available to identify facility evaluations, conclusions, and interventions to guide subsequent observations.

NOTE: *For the purposes of this investigation, conduct record reviews prior to meal observations to note the resident's therapeutic diet, food texture and level of required assistance with meals.*

1. Observation

Observe residents during the initial tour of the facility and throughout the survey process. To facilitate the investigation, gather appropriate information (e.g., dining style, nourishment list, schedules, and policies).

During observations, surveyors may see non-traditional or alternate approaches to dining services such as buffet, restaurant style or family style dining. These alternate dining approaches may include more choices in meal options, preparations, dining areas and meal times. Such alternate dining approaches are acceptable and encouraged.

While conducting the resident dining observations:

- Observe at least two meals during the survey;*
- Observe a resident's physical appearance for signs that might indicate altered nutritional status (e.g., cachectic) and note any signs of dental and oral problems;*
- Observe the delivery of care (such as assistance and encouragement during dining) to determine if interventions are consistent with the care plan;*
- Observe the serving of food as planned with attention to portion sizes, preferences, nutritional supplements, prescribed therapeutic diets and between-meal snacks to determine if the interventions identified in the care plan were implemented;*
- Follow up and note differences between the care plan and interventions and*
- Determine if staff responded appropriately to the resident's needs (e.g., for assistance, positioning, and supervision).*

2. Interview

Interview the resident, family or resident's representative to identify:

- Whether staff are responsive to the resident's eating abilities and support needs, including the provision of adaptive equipment and personal assistance with meals as indicated;*
- Whether the resident's food and dining preferences are addressed to the extent possible, e.g., whether the resident is offered substitutions or choices at meal times as appropriate and in accordance with his/her preferences;*
- Whether pertinent nutritional interventions, such as snacks, frequent meals, and calorie-dense foods, are provided; and*
- If the resident refused needed therapeutic approaches, whether treatment options, related risks and benefits, expected outcomes and possible consequences were*

discussed with the resident or resident's representative, and whether pertinent alternatives or other interventions were offered.

Interview interdisciplinary team members on various shifts (e.g., certified nursing assistant, registered dietitian, dietary supervisor/manager, charge nurse, social worker, occupational therapist, attending physician, medical director, etc.) to determine, how:

- Food and fluid intake, and eating ability and weight (and changes to any of these) are monitored and reported;*
- Nutrition interventions, such as snacks, frequent meals, and calorie-dense foods are provided to prevent or address impaired nutritional status (e.g., unplanned weight changes);*
- Nutrition-related goals in the care plan are established, implemented, and monitored periodically;*
- Care plans are modified when indicated to stabilize or improve nutritional status (e.g., reduction in medications, additional assistance with eating, therapeutic diet orders); and*
- A health care practitioner is involved in evaluating and addressing underlying causes of nutritional risks and impairment (e.g., review of medications or underlying medical causes).*

If the interventions defined, or the care provided, appear to be inconsistent with current standards of practice, interview one or more physicians or other licensed health care practitioners who can provide information about the resident's nutritional risks and needs. Examples include, but are not limited to:

- The rationale for chosen interventions;*
- How staff evaluated the effectiveness of current interventions;*
- How staff managed the interventions;*
- How the interdisciplinary team decided to maintain or change interventions; and*
- Rationale for decisions not to intervene to address identified needs.*

3. Record Review

Review the resident's medical record to determine how the facility:

- Has evaluated and analyzed nutritional status;*
- Has identified residents who are at nutritional risk;*
- Has investigated and identified causes of anorexia and impaired nutritional status;*
- Has identified and implemented relevant interventions to try to stabilize or improve nutritional status;*

- *Has identified residents' triggered Resident Assessment Instrument (RAI) for nutritional status;*
- *Has evaluated the effectiveness of the interventions; and*
- *Has monitored and modified approaches as indicated.*

Documentation

Documentation of findings and conclusions related to nutritional status may be found in various locations in the medical record, including but not limited to interdisciplinary progress notes, nutrition progress notes, the RAP summary, care plan, or resident care conference notes. Review of the documentation will help the surveyor determine how the facility developed approaches to meet each resident's nutritional needs. This information will help the surveyor determine whether a resident's decline or failure to improve his/her nutritional status was avoidable or unavoidable.

Assessment and Monitoring

Review information including the RAI, diet and medication orders, activities of daily living worksheets, and nursing, dietitian, rehabilitation, and social service notes. Determine if the resident's weight and nutritional status were assessed in the context of his/her overall condition and prognosis, if nutritional requirements and risk factors were identified, and if causes of the resident's nutritional risks or impairment were sought.

Determine:

- *Whether the facility identified a resident's desirable weight range, and identified weight loss/gain;*
- *Whether the facility identified the significance of any weight changes, and what interventions were needed;*
- *Whether there have been significant changes in the resident's overall intake;*
- *Whether the reasons for the change were identified and if appropriate interventions were implemented;*
- *Whether the facility has calculated nutritional needs (i.e., calories, protein and fluid requirements) and identified risk factors for malnutrition;*
- *Whether the facility met those needs and if not, why;*
- *Whether the resident's weight stabilized or improved as anticipated;*
- *Whether a need for a therapeutic diet was identified and implemented, consistent with the current standards of practice;*
- *Whether the facility indicated the basis for dietary restrictions;*
- *Whether the reasons for dietary changes were identified and appropriate interventions implemented;*

- *Whether the facility accommodated resident choice, individual food preferences, allergies, food intolerances, and fluid restrictions and if the resident was encouraged to make choices;*
- *Whether the facility identified and addressed underlying medical and functional causes (e.g., oral cavity lesions, mouth pain, decayed teeth, poorly fitting dentures, refusal to wear dentures, gastroesophageal reflux, or dysphagia) of any chewing or swallowing difficulties to the extent possible;*
- *Whether the facility identified residents requiring any type of assistance to eat and drink (e.g., assistive devices/utensils, cues, hand-over-hand, and extensive assistance), and provided such assistance;*
- *Whether the facility has identified residents receiving any medications that are known to cause clinically significant medication/nutrient interactions or that may affect appetite, and determined risk/benefit;*
- *Whether the facility identified and addressed to the extent possible medical illnesses and psychiatric disorders that may affect overall intake, nutrient utilization, and weight stability;*
- *Whether the facility reviewed existing abnormal laboratory test results and either implemented interventions, if appropriate, or provided a clinical justification for not intervening (see note in Laboratory/Diagnostic Evaluation);*
- *Whether the resident's current nutritional status is either at or improving towards goals established by the care team; and*
- *Whether alternate interventions were identified when nutritional status is not improving or clinical justification is provided as to why current interventions continue to be appropriate.*

Care Plan

Review the comprehensive care plan to determine if the plan is based on the comprehensive assessment and additional pertinent nutritional assessment information. Determine if the facility developed measurable objectives, approximate time frames, and specific interventions to try to maintain acceptable parameters of nutritional status, based on the resident's overall goals, choices, preferences, prognosis, conditions, assessed risks, and needs.

If care plan concerns, related to nutritional status are noted, interview staff responsible for care planning about the rationale for the current plan of care. If questions remain after reviewing available information including documentation in the medical record, interview the resident's attending physician or licensed health care practitioner or the facility's medical director (e.g., if the attending physician or licensed health care practitioner is unavailable) concerning the resident's plan of care.

NOTE: *Because the physician may not be present in the facility and have immediate access to the resident's medical record when the surveyor has questions,*

allow the facility the opportunity to first provide any pertinent information to the physician before responding to the interview.

Care Plan Revision

Determine if the staff has evaluated the effectiveness of the care plan related to nutritional status and made revisions if necessary based upon the following:

- *Evaluation of nutrition-related outcomes;*
- *Identification of changes in the resident's condition that require revised goals and care approaches; and*
- *Involvement of the resident or the resident's representative in reviewing and updating the resident's care plan.*

Review of Facility Practices

Related concerns may have been identified that would suggest the need for a review of facility practices. Examples of such activities may include a review of policies, staffing, and staff training, functional responsibilities, and interviews with staff (to include but not limited to management). If there is a pattern of residents who have not maintained acceptable parameters of nutritional status without adequate clinical justification, determine if quality assurance activities were initiated in order to evaluate the facility's approaches to nutrition and weight issues.

Interviews with Health Care Practitioners

If the interventions defined, or the care provided, appear to be inconsistent with recognized standards of practice, interview one or more health care practitioners as necessary (e.g., physician, hospice nurse, dietitian, charge nurse, director of nursing or medical director). Depending on the issue, ask:

- *How it was determined that chosen interventions were appropriate;*
- *Why identified needs had no interventions;*
- *How changes in condition that may justify additional or different interventions were addressed; and*
- *How staff evaluated the effectiveness of current interventions.*

DETERMINATION OF COMPLIANCE (Appendix P)

Synopsis of Regulation (Tag F325)

This regulation requires that, based on the resident's comprehensive assessment, the facility ensures that each resident maintains acceptable parameters of nutritional status

unless the resident's clinical condition demonstrates that this is not possible, and that to the extent possible the resident receives a therapeutic diet when indicated.

Criteria for Compliance

The facility is in compliance with 42 CFR 483.25(i), Tag F325, Nutrition, if staff have:

- Assessed the resident's nutritional status and identified factors that put the resident at risk of not maintaining acceptable parameters of nutritional status;*
- Analyzed the assessment information to identify the medical conditions, causes and problems related to the resident's condition and needs;*
- Provided a therapeutic diet when indicated;*
- Defined and implemented interventions to maintain or improve nutritional status that are consistent with the resident's assessed needs, choices, goals, and recognized standards of practice, or provided clinical justification why they did not do so; and*
- Monitored and evaluated the resident's response to the interventions; and revised the approaches as appropriate, or justified the continuation of current approaches.*

If not, failure to maintain acceptable parameters of nutritional status is avoidable, cite at Tag F325.

Noncompliance with Tag F325

After completing the investigative protocol, the survey team must analyze the data to determine whether noncompliance with the regulation exists. Noncompliance must be established before determining severity. A clear understanding of the facility's noncompliance with requirements (i.e., deficient practices) is essential to determine how the deficient practice(s) relates to any actual harm or potential for harm to the resident.

Noncompliance with Tag F325 may include (but is not limited to) one or more of the following, including failure to:

- Accurately and consistently assess a resident's nutritional status on admission and as needed thereafter;*
- Identify a resident at nutritional risk and address risk factors for impaired nutritional status, to the extent possible;*
- Identify, implement, monitor, and modify interventions (as appropriate), consistent with the resident's assessed needs, choices, goals, and current standards of practice, to maintain acceptable parameters of nutritional status;*
- Notify the physician as appropriate in evaluating and managing causes of the resident's nutritional risks and impaired nutritional status;*

- *Identify and apply relevant approaches to maintain acceptable parameters of residents' nutritional status; and*
- *Provide a therapeutic diet when indicated.*

Potential Tags for Additional Investigation

If noncompliance with 42 CFR 483.25(i) has been identified, the survey team may have determined during the investigation of Tag F325 that concerns may also be present with related process and/or structure requirements. Examples of related process and/or structure requirements related to noncompliance with Tag F325 may include the following:

- *42 CFR 483.10, Tag F150, Resident Rights*
 - *Determine if the resident's preferences related to nutrition and food intake were considered.*
- *42 CFR §483.20(b)(1), Tag F272, Comprehensive Assessments*
 - *Determine if the facility assessed the resident's nutritional status and the factors that put the resident at risk for failure to maintain acceptable parameters of nutritional status.*
- *42 CFR §483.20(k), Tag F279, Comprehensive Care Plans*
 - *Determine if the facility developed a comprehensive care plan for each resident that includes measurable objectives, interventions/services, and time frames to meet the resident's needs as identified in the resident's assessment and provided a therapeutic diet when indicated.*
- *42 CFR §483.20(k)(2)(iii), Tag F280, Comprehensive Care Plan Revision*
 - *Determine if the care plan was periodically reviewed and revised as necessary by qualified persons after each assessment to maintain acceptable parameters of nutritional status and provided a therapeutic diet when indicated.*
- *42 CFR 483.20(k)(3)(ii), Tag F282, Provision of Care in Accordance with the Care Plan*
 - *Determine if the services provided or arranged by the facility were provided by qualified persons in accordance with the resident's written plan of care.*
- *42 CFR 483.25(j), Tag F327, Hydration*

- *Determine if the facility took measures to maintain proper hydration.*
- *42 CFR 483.25(k)(2), F328, Special Needs*
 - *Determine if the facility took measures to provide proper treatment and care for Parenteral and Enteral Fluids.*
- *42 CFR 483.25, Tag F329, Unnecessary Medicines*
 - *Determine if food and medication interactions are impacting the residents' dietary intake.*
- *42 CFR 483.30(a), Tag F353, Sufficient Staff*
 - *Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services, including supervision, based upon the comprehensive assessment and care plan.*
- *42 CFR 483.35(a)(1)(2), F361, Dietary Services - Staffing*
 - *Determine if the facility employs or consults with a qualified dietitian. If not employed full-time, determine if the director of food service receives scheduled consultation from the dietitian concerning storage, preparation, distribution and service of food under sanitary conditions.*
- *42 CFR 483.35(b), F362, Standard Sufficient Staff*
 - *Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.*
- *42 CFR 483.40(a)(1)(2), Tag F385, Physician Services – Physician Supervision*
 - *Determine if a physician supervised the medical aspects of care of each resident, as indicated, as they relate to medical conditions that affect appetite and nutritional status.*
- *42 CFR 483.75(h)(2)(ii), Tag F500, Use of Outsider resources*
 - *If the facility does not employ a qualified dietitian, determine if the professional services of a dietitian are furnished by an outside resource, meet professional standards and principles, and are timely.*
- *42 CFR 483.75(i)(2)(i)(ii), Tag F501, Medical Director*
 - *Determine if the medical director helped develop and implement resident care policies as they relate to maintaining acceptable*

parameters of nutritional status and the provision of therapeutic diets when indicated.

- 42 CFR 483.75(o), Tag F520, Quality Assessment and Assurance
 - o *Related concerns may have been identified that would suggest the need for a review of facility practices. Such activities may involve a review of policies, staffing and staff training, contracts, etc. and interviews with management, for example. If there is a pattern of residents who have not maintained acceptable parameters of nutritional status without adequate clinical justification, determine if quality assurance activities address the facility's approaches to nutrition and weight issues.*

DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for Tag F325 are as follows:

1. *Presence of harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services. Actual or potential harm/negative outcomes for F325 may include, but are not limited to:*
 - *Significant unplanned weight change;*
 - *Inadequate food/fluid intake;*
 - *Impairment of anticipated wound healing;*
 - *Failure to provide a therapeutic diet;*
 - *Functional decline; and*
 - *Fluid/electrolyte imbalance.*
2. *Degree of harm (actual or potential) related to the noncompliance. Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:*
 - *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and*
 - *If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.*

3. *The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.*

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F325. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, "Guidelines for Determining Immediate Jeopardy".)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance:

- *With one or more requirements of participation has caused/resulted in, or is likely to cause serious injury, harm, impairment, or death to a resident; and*
- *Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

NOTE: *The death or transfer of a resident who was harmed as a result of facility practices does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.*

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 4 may include, but are not limited to:

- *Continued weight loss and functional decline resulting from ongoing, repeated systemic failure to assess and address a resident's nutritional status and needs, and implement pertinent interventions based on such an assessment;.*
- *Development of life-threatening symptom(s), or the development or continuation of severely impaired nutritional status due to repeated failure to assist a resident who required assistance with meals;*
- *Substantial and ongoing decline in food intake resulting in significant unplanned weight loss due to dietary restrictions or downgraded diet textures (e.g., mechanic soft, pureed) provided by the facility against the resident's expressed preferences; or*
- *Evidence of cardiac dysrhythmias or other changes in medical condition due to hyperkalemia, resulting from the facility's failure to provide a potassium restricted therapeutic diet that was ordered.*

If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3 or the potential for more than minimal harm at Level 2 exists.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm that is not immediate jeopardy. The negative outcome can include, but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being.

Examples of avoidable actual resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- Significant unplanned weight change and impaired wound healing (not attributable to an underlying medical condition) due to the facility's failure to revise and/or implement the care plan to address the resident's impaired ability to feed him/herself;*
- Loss of weight from declining food and fluid intake due to the facility's failure to assess and address the resident's use of medications that affect appetite and food intake;*
- Unplanned weight change and declining food and/or fluid intake due to the facility's failure to assess the relative benefits and risks of restricting or downgrading diet and food consistency or to obtain or accommodate resident preferences in accepting related risks;*
- Decline in function related to poor food/fluid intake due to the facility's failure to accommodate documented resident food dislikes and provide appropriate substitutes or*
- A resident with known celiac disease (damage to the small intestine related to gluten allergy) develops persistent gastrointestinal symptoms including weight loss, chronic diarrhea, and vomiting, due to the facility's failure to provide a gluten-free diet (i.e., one free of wheat, barley, and rye products) as prescribed by the physician.*

NOTE: *If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to

maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

For Level 2 severity, the resident was at risk for, or has experienced the presence of one or more outcome(s) (e.g., unplanned weight change, inadequate food/fluid intake, impairment of anticipated wound healing, functional decline, and/or fluid/electrolyte imbalance), due to the facility's failure to help the resident maintain acceptable parameters of nutritional status.

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 2 may include, but are not limited to:

- Failure to obtain accurate weight(s) and to verify weight(s) as needed;*
- Poor intake due to the facility's intermittent failure to provide required assistance with eating, however, the resident met identified weight goals;*
- Failure to provide additional nourishment when ordered for a resident, however, the resident did not experience significant weight loss; and*
- Failure to provide a prescribed sodium-restricted therapeutic diet (unless declined by the resident or the resident's representative or not followed by the resident); however, the resident did not experience medical complications such as heart failure related to sodium excess.*

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services to maintain acceptable parameters of nutritional status and minimize negative outcomes places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

F371

(Rev.)

§483.35(i) Sanitary Conditions

The facility must –

§483.35(i)(1) Procure food from sources approved or considered satisfactory by Federal, State or local authorities; and

§483.35(i)(2) Store, prepare, distribute and serve food under sanitary conditions

INTENT: (Tag F371) 42 CFR 483.35(i) Sanitary Conditions

The intent of this requirement is to ensure that the facility:

- Obtains food for resident consumption from sources approved or considered satisfactory by Federal, State or local authorities; and*
- Follows proper sanitation and food handling practices to prevent the outbreak of foodborne illness. Safe food handling for the prevention of foodborne illnesses begins when food is received from the vendor and continues throughout the facility's food handling processes.*

DEFINITIONS

Definitions are provided to clarify terms related to sanitary conditions and the prevention of foodborne illness.

- “**Cross-contamination**” refers to the transfer of harmful substances or disease-causing microorganisms to food by hands, food contact surfaces, sponges, cloth towels, or utensils which are not cleaned after touching raw food, and then touch ready-to-eat foods. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.¹*
- “**Danger Zone**” refers to temperatures above 41 degrees Fahrenheit (F) and below 135 degrees F that allow the rapid growth of pathogenic microorganisms that can cause foodborne illness. Potentially Hazardous Foods (PHF) or Time/Temperature Control for Safety (TCS) Foods held in the danger zone for more than 4 hours (if being prepared from ingredients at ambient temperature) or 6 hours (if cooked and cooled) may cause a foodborne illness outbreak if consumed.*
- “**Dry Storage**” refers to storing/maintaining dry foods (canned goods, flour, sugar, etc.) and supplies (disposable dishware, napkins, and kitchen cleaning supplies).*

- **“Food Contamination”** refers to the unintended presence of potentially harmful substances, including, but not limited to microorganisms, chemicals or physical objects in food.²
- **“Food Preparation”** refers to the series of operational processes involved in getting foods ready for serving, such as: washing, thawing, mixing ingredients, cutting, slicing, diluting concentrates, cooking, pureeing, blending, cooling, and reheating.
- **“Food Service/Distribution”** refers to the processes involved in getting food to the resident. This may include holding foods hot on the steam table or under refrigeration for cold temperature control, dispensing food portions for individual residents, family style and dining room service, or delivering trays to residents’ rooms or units, etc.
- **“Foodborne Illness”** refers to illness caused by the ingestion of contaminated food or beverages.
- **“Highly Susceptible Population”** refers to persons who are more likely than the general population to experience foodborne illness because of their susceptibility to becoming ill if they ingest microorganisms or toxins. Increased susceptibility may be associated with immuno-compromised health status, chronic disease and advanced age.
- **“Pathogen”** refers to an organism capable of causing a disease (e.g., pathogenic bacteria or viruses).
- **“Potentially Hazardous Food (PHF)”** or **“Time/Temperature Control for Safety (TCS) Food”** refers to food that requires time/temperature control for safety to limit the growth of pathogens or toxin formation.
- **“Ready-to-Eat Food”** 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).
- **“Storage”** refers to the retention of food (before and after preparation) and associated dry goods.
- **“Toxins”** refer to poisonous substances that are produced by living cells or organisms (e.g., pathogenic bacteria) that cause foodborne illness when ingested.

OVERVIEW

Nursing home residents risk serious complications from foodborne illness as a result of their compromised health status. Unsafe food handling practices represent a potential source of pathogen exposure for residents. Sanitary conditions must be present in health care food service settings to promote safe food handling.

Effective food safety systems involve identifying hazards at specific points during food handling and preparation, and identifying how the hazards can be prevented, reduced or eliminated. It is important to focus attention on the risks that are associated with

foodborne illness by identifying critical control points (CCPs) in the food preparation processes that, if not controlled, might result in food safety hazards. Some operational steps that are critical to control in facilities to prevent or eliminate food safety hazards are thawing, cooking, cooling, holding, reheating of foods, and employee hygienic practices.

Web sites for additional information regarding safe food handling to minimize the potential for foodborne illness include:

- National Food Safety Information Network's Gateway to Government Food Safety Information at www.FoodSafety.gov;
- United States Food & Drug Administration Food Code Web site at <http://www.cfsan.fda.gov/~dms/primecon.html>;
- United States Food & Drug Administration Hazard Analysis Critical Control Point <http://www.cfsan.fda.gov/~dms/hret2toc.html>, (Operator's Manual) and <http://www.cfsan.fda.gov/~dms/hret3toc.html> (Regulator's manual).

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. The uniform resource locator addresses were current as of the date of this publication.

TYPES OF FOOD CONTAMINATION

Food contaminants fall into 3 categories: biological, chemical, and physical.

Biological Contamination

Biological contaminants are pathogenic bacteria, viruses, toxins, and spores that contaminate food. The two most common types of disease producing organisms are bacteria and viruses. Parasites may also contaminate food, but are less common.

- **Pathogenic Bacteria** - Not all bacteria in food cause illness in humans. For example, live cultures of *Lactobacillus* bacteria are added to yogurt to enhance digestion. However, some bacteria can be pathogenic and thus may cause illness or death (e.g., some strains of *Escherichia Coli*). It is vital to control the growth of bacteria during food storage and preparation because raw or uncooked food may naturally contain pathogenic organisms (e.g., *Salmonella* in poultry).

Several factors which may influence the growth of bacteria include:

- *Hazardous nature of the food. Although almost any food can be contaminated, certain foods are considered more hazardous than others and are called “potentially hazardous foods (PHF) or Time/Temperature Controlled for Safety (TCS)” food. Examples of PHF/TCS foods include ground beef, poultry, chicken, seafood (fish or shellfish), cut melon, unpasteurized eggs, milk, yogurt and cottage cheese;*
- *Acidity (pH) of the food. More acidic food (i.e., pH < 5), such as pineapple, vinegar, and lemon juice, inhibits bacterial growth;*
- *Water percentage of the food. Foods that have a high level of water (e.g., fruits and vegetables) encourage bacterial growth; and*
- *Time and temperature control of the food. Time in conjunction with temperature controls is critical. The longer food remains in the danger zone, the greater the risks for growth of harmful pathogens. Bacteria multiply rapidly in a moist environment in the danger zone. Freezing does not kill bacteria. Rapid death of most bacteria occurs at 165 degrees F or above.*

NOTE: *Some foods may be considered a TCS food needing time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. Examples include foods held for later service (e.g., cooked rice, refried beans, grilled sautéed onions, or baked potatoes).*

- **Viruses** - *Viruses cannot reproduce without a living host (animal or human). While they cannot reproduce in or on food, viruses may survive long enough in or on a food to be transmitted to a new host. Two viruses that are well known for being spread by poor food handling practices are Hepatitis A and Norovirus (formerly known as Norwalk virus).*
- **Toxins** - *Toxins are poisonous substances that come from a variety of sources. Some pathogens (e.g., Staphylococcus aureus and Clostridium botulinum) produce toxins as a byproduct of their growth. Most toxins are not destroyed by high temperatures. A PHF/TCS food that is allowed to remain in the danger zone long enough for the bacteria to produce toxins will become unsafe to eat.*
- **Spores** - *A spore is an inactive form of an organism that is highly resistant to extreme temperatures, acidity, and dehydration. The organism is reactivated once conditions become favorable for its growth. Two common spore-forming pathogens are Bacillus cereus and Clostridium botulinum. Temperature control is the way to minimize the danger associated with spore-forming organisms.*

Chemical Contamination

The most common chemicals that can be found in a food system are cleaning agents (such as glass cleaners, soaps, and oven cleaners) and insecticides. Chemicals used by

the facility staff, in the course of their duties, may contaminate food (e.g., if a spray cleaner is used on a worktable surface while food is being prepared it becomes exposed to a chemical). An inadequately identified chemical may be mistaken for an ingredient used in food preparation. For example, incorrectly stored (e.g., dishwashing liquid stored in a syrup bottle) or unlabeled (e.g., white granulated cleaner that looks like salt) cleaning products may be inadvertently added to food and cause illness. It is recommended that chemical products including, but not limited to cleaning supplies, be stored separately from food items.

Physical Contamination

Physical contaminants are foreign objects that may inadvertently enter the food. Examples include but are not limited to staples, fingernails, jewelry, hair, glass, metal shavings from can openers, and pieces of bones.

FACTORS IMPLICATED IN FOODBORNE ILLNESSES

Many pathogens contribute to foodborne outbreaks in facilities. Several factors that cause pathogen growth include, but are not limited to:

- Poor personal hygiene - Employee health and hygiene are significant factors in preventing foodborne illness. This has been demonstrated in the population at large³, commercial food service establishments⁴, and in nursing facilities⁵. Foodborne illness in nursing homes has been associated with Norovirus. Because "infectious" individuals (persons capable of transmitting an infection or communicable disease whether they be colonized or infected) are a source of Norovirus, proper hand washing techniques and exclusion of infectious workers from handling food are critical for prevention of foodborne illness.
- Inadequate cooking and improper holding temperatures - Poorly cooked food promotes the growth of pathogens that may cause foodborne illness. The PHF/TCS foods require adequate cooking and proper holding temperatures to reduce the rapid and progressive growth of illness producing microorganisms, such as *Salmonellae* and *Clostridium botulinum*.
- Contaminated equipment - Equipment can become contaminated in various ways including, but not limited to:
 - Poor personal hygiene;
 - Improper sanitation; and
 - Contact with raw food (e.g., poultry, eggs, seafood, and meat).
- Unsafe food sources - Unsafe food sources are sources not approved or considered satisfactory by Federal, State, or local authorities. Nursing homes are

not permitted to use home-prepared or home-preserved (e.g., canned, pickled) foods for service to residents³.

NOTE: *Family members or other resident guests who bring in food for that resident's consumption are not subject to this prohibition.*

Pathogenic Microorganisms and Strategies for their Control

The table below illustrates the more commonly identified ingestible items which have been associated with the listed illness-producing organisms. The primary agents are the organisms that have been associated with the ingestible food source⁷. Further, the primary control strategies list the preventive actions to inhibit the growth of these organisms.

Source of Contamination	Primary Agents of Concern	Primary Control Strategies
A. Hazards that are likely to occur - strategies that must be in place to prevent foodborne illness.		
Eggs, raw or unpasteurized	• <i>Salmonella</i>	• PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to ready-to-eat foods
Poultry, raw	• <i>Campylobacter</i> • <i>Salmonella</i>	• PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to ready-to-eat foods
	• <i>Clostridium perfringens</i>	• PHF/TCS • Cook to proper temperature
Meat, raw	• <i>E. coli</i> 0157:H7 • <i>Salmonella</i> • <i>Campylobacter</i>	• PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to ready-to-eat foods
	• <i>Clostridium perfringens</i>	• PHF/TCS • Cook to proper temperature
Infectious food workers	• Norovirus • Hepatitis A virus • <i>Shigella</i> • <i>Salmonella</i>	• Exclusion of infectious food workers • Proper hand-washing procedures • Avoid bare-hand contact with ready-to-eat foods
	• <i>Staphylococcus aureus</i>	• PHF/TCS • Proper hand-washing procedures • Avoid bare-hand contact with ready-to-eat foods
B. Hazards that may occur as a result of adulteration of food products, and for which good food handling practices are needed to minimize the potential for foodborne illness transmission.		
Fruits and vegetables, fresh	• <i>E. coli</i> O157:H7 • <i>Salmonella</i> • Norovirus • Hepatitis A virus • <i>Shigella</i>	• Wash prior to use (unless pre-washed) • Keep cut and raw fruits and vegetables refrigerated
Ready-to-eat meat and poultry products	• <i>Listeria monocytogenes</i>	• Proper refrigeration during storage
Pasteurized dairy products	• <i>Listeria monocytogenes</i>	• Proper refrigeration during storage
Ice	• Norovirus	• Cleaning and sanitizing the internal components of the ice machine according to manufacturers' guidelines

PREVENTION OF FOODBORNE ILLNESS

Food Handling and Preparation

Proper food preparation, storage, and handling practices are essential in preventing foodborne illness. Education, training, and monitoring of all staff and volunteers involved in food service, as well as establishing effective infection control and quality assurance programs help maintain safe food handling practices.

Approaches to create a homelike environment or to provide accessible nourishments may include a variety of unconventional and non-institutional food services. Meals or snacks may be served at times other than scheduled meal times and convenience foods, ready-to-eat foods, and pre-packaged foods may be stored and microwave heated on the nursing units. Whatever the approach, it is important that staff follow safe food handling practices.

Employee Health

Employees who handle food must be free of communicable diseases and infected skin lesions. (See the requirement at 42 CFR 483.65(b) (2) regarding preventing the spread of infection.) Bare hand contact with foods is prohibited.

Hand Washing, Gloves, and Antimicrobial Gel

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 setting⁸.

The appropriate use of utensils such as gloves, tongs, deli paper and spatulas is essential in preventing foodborne illness. Gloved hands are considered a food contact surface that can get contaminated or soiled. Failure to change gloves between tasks can contribute to cross-contamination. Disposable gloves are a single use item and should be discarded after each use.

NOTE: *The use of disposable gloves is not a substitute for proper hand washing with soap and water.*

Hair Restraints/Jewelry/Nail Polish

Dietary staff must wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent their hair from contacting exposed food. Dietary staff maintaining nails that are clean and neat, and wearing intact disposable gloves in good condition, and that are changed appropriately will also help reduce the spread of microorganisms. Since jewelry can harbor microorganisms, it is recommended that dietary staff keep jewelry to a minimum and cover hand jewelry with gloves when handling food⁹.

Food Receiving and Storage

When food is brought into the nursing home, inspection for safe transport and quality upon receipt and proper storage helps ensure its safety. Keeping track of when to discard perishable foods and covering, labeling, and dating all foods stored in the refrigerator or freezer is indicated.

When food is brought into the facility from an off-site kitchen (any kitchen that is not operated by the facility) and the food preparation entity is approved or considered satisfactory by and is inspected by other federal, State, or local authorities, verify the last approved inspection of the supplier and continue to inspect the facility for safe food handling and storage and food quality.

- **Dry Food Storage** - Dry storage may be in a room or area designated for the storage of dry goods, such as single service items, canned goods, and packaged or containerized bulk food that is not PHF/TCS. The focus of protection for dry storage is to keep non-refrigerated foods, disposable dishware, and napkins in a clean, dry area, which is free from contaminants. Controlling temperature, humidity, rodent and insect infestation helps prevent deterioration or contamination of the food. Dry foods and goods should be handled and stored to maintain the integrity of the packaging until they are ready to use. It is recommended that foods stored in bins (e.g., flour or sugar) be removed from their original packaging.

Keeping food off the floor and clear of ceiling sprinklers, sewer/waste disposal pipes, and vents can also help maintain food quality and prevent contamination. Desirable practices include managing the receipt and storage of dry food, removing foods not safe for consumption, keeping dry food products in closed containers, and rotating supplies.

- **Refrigerated Storage** - PHF/TCS foods must be maintained at or below 41 degrees F, unless otherwise specified by law. Frozen foods must be maintained at a temperature to keep the food frozen solid.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microorganisms. Inadequate temperature control during refrigeration can promote bacterial growth. Adequate circulation of air around refrigerated products is essential to maintain appropriate food temperatures. Foods in a walk-in unit should be stored off the floor.

Practices to maintain safe refrigerated storage include:

- *Monitoring food temperatures and functioning of the refrigeration equipment daily and at routine intervals during all hours of operation;*
- *Placing hot food in containers (e.g., shallow pans) that permit the food to cool rapidly;*
- *Separating raw animal foods (e.g., beef, fish, lamb, pork, and poultry) from each other and storing raw meats on shelves below fruits, vegetables or other ready-to-eat foods so that meat juices do not drip onto these foods; and*
- *Labeling, dating, and monitoring refrigerated food, including, but not limited to leftovers, so it is used by its use-by date, or frozen (where applicable) or discarded.*

NOTE: *Chemical products, including, but not limited to cleaning supplies, should be stored away from food items.*

Safe Food Preparation

Many steps in safe food preparation must be controlled or monitored to prevent foodborne illness. Identification of potential hazards in the food preparation process and adhering to critical control points can reduce the risk of food contamination and thereby prevent foodborne illness.

Commercially pre-washed, pre-cut, and pre-packaged lettuce and other fruits and vegetables are considered edible without further preparation.

- ***Cross-Contamination*** - *Cross-contamination can occur when harmful substances or disease-causing microorganisms are transferred to food by hands, food contact surfaces, sponges, cloth towels, or utensils that are not cleaned after touching raw food and then touch ready-to-eat goods. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods. Examples of ways to reduce cross-contamination include, but are not limited to:*

- *Store raw meat (e.g., beef, pork, lamb, poultry, and seafood) separately and in drip-proof containers and in a manner that prevents cross-contamination of other food in the refrigerator;*
- *Between uses, store towels/cloths used for wiping surfaces during the kitchen's daily operation in containers filled with sanitizing solution at the appropriate concentration per manufacturer's specifications (see Manual Washing and Sanitizing section). Periodically testing the sanitizing solution helps assure that it maintains the correct concentration¹⁰.*

Wash and sanitize cutting boards made of acceptable materials (e.g., hardwood, acrylic) between uses, consistent with applicable code¹¹, and

- *Clean and sanitize work surfaces and food-contact equipment (e.g., food processors, blenders, preparation tables, knife blades, can openers, and slicers) between uses.*

- **Thawing** - Thawing frozen foods is often the first step in food preparation. Thawing food at room temperature is not acceptable because the food is within the danger zone for rapid bacterial proliferation. Recommended methods to safely thaw frozen foods include:
 - Thawing in the refrigerator, in a drip-proof container, and in a manner that prevents cross-contamination;
 - Completely submerging the item under cold water (at a temperature of 70 degrees F or below) that is running fast enough to agitate and float off loose ice particles;
 - Thawing the item in a microwave oven, then cooking and serving it immediately afterward; or
 - Thawing as part of a continuous cooking process.
 - **Final Cooking Temperatures** - Cooking is a critical control point in preventing foodborne illness. Cooking to heat all parts of food to the temperature and for the time specified below will either kill dangerous organisms or inactivate them sufficiently so that there is little risk to the resident if the food is eaten promptly after cooking. Monitoring the food's internal temperature for 15 seconds determines when microorganisms can no longer survive and food is safe for consumption. Foods should reach the following internal temperatures:
 - Poultry and stuffed foods - 165 degrees F;
 - Ground meat (e.g., ground beef, ground pork), ground fish, and eggs held for service - at least 155 degrees F;
 - Fish and other meats - 145 degrees F for 15 seconds;
 - Unpasteurized eggs when cooked to order in response to resident request and to be eaten promptly after cooking;- 145 degrees F for 15 seconds; until the white is completely set and the yolk is congealed; and
 - When cooking raw animal foods in the microwave, foods should be rotated and stirred during the cooking process so that all parts of the food are heated to a temperature of at least 165 degrees F, and allowed to stand covered for at least 2 minutes after cooking to obtain temperature equilibrium.
- NOTE:** Fresh, frozen, or canned fruits and vegetables that are cooked do not require the same level of microorganism destruction as raw animal foods. Cooking to a hot holding temperature (135 degrees F) prevents the growth of pathogenic bacteria that may be present in or on these foods.
- **Reheating Foods** - Reheated cooked foods present a risk because they have passed through the danger zone multiple times during cooking, cooling, and reheating. The PHF/TCS food that is cooked and cooled must be reheated so that all parts of the food reach an internal temperature of 165 degrees F for at least 15 seconds before holding for hot service. Ready-to-eat foods that require heating before consumption are best taken directly from a sealed container

(secured against the entry of microorganisms) or an intact package from an approved food processing source and heated to at least 135 degrees F for holding for hot service.

Although proper reheating will kill most organisms of concern, some toxins, such as that produced by Staphylococcus aureus, cannot be inactivated by reheating food.

NOTE: *Using the steam table to reheat food is unacceptable since it does not bring the food to the proper temperature within acceptable timeframes.*

- **Cooling** - *Improper cooling is a major factor in causing foodborne illness. Taking too long to chill PHF/TCS foods has been consistently identified as one factor contributing to foodborne illness. Foods that have been cooked and held at improper temperatures promote the growth of disease-causing microorganisms that may have survived the cooking process (e.g., spore-formers). Cooled food items can be re-contaminated by unsanitary handling practices or cross-contaminated from other food products, utensils, and equipment.*

Large or dense food items, such as roasts, turkeys, soups, stews, legumes, and chili may require interventions (e.g., placing foods in shallow pans, cutting roasts into smaller portions, utilizing ice water baths, and stirring periodically) in order to be chilled safely within an allowed time period. These foods take a long time to cool because of their volume and density. If the hot food container is tightly covered, the cooling rate may be slowed further, leading to longer cooling times during which the food remains in the danger zone. Cooked potentially hazardous foods that are subject to time and temperature control for safety are best cooled rapidly within 2 hours, from 135 to 70 degrees F, and within 4 more hours to the temperature of approximately 41 degrees F. The total time for cooling from 135 to 41 degrees F should not exceed 6 hours.

- **Modified Consistency** - *Residents who require a modified consistency diet may be at risk for developing foodborne illness because of the increased number of food handling steps required when preparing pureed and other modified consistency foods. When hot pureed, ground, or diced food drop into the danger zone (below 135 degrees F), the mechanically altered food must be reheated to 165 degrees F for 15 seconds.*
- **Pooled Eggs** - *Pooled eggs are raw eggs that have been cracked and combined together. The facility should crack only enough eggs for immediate service in response to a resident's requests or as an ingredient immediately before baking. Salmonella infections associated with unpasteurized eggs can be prevented by using pasteurized shell eggs or egg products in foods that require pooling of eggs or foods that will not be thoroughly cooked, such as but not limited to Caesar dressing, Hollandaise or Béarnaise sauce and French toast.*

The U.S. Department of Agriculture, Food Safety and Inspection Service, Salmonella Enteritidis (SE) Risk Assessment states "A partial list of persons with increased

susceptibility to infectious agents includes persons with chronic diseases, and nursing home residents. The elderly are particularly susceptible to infectious agents such as SE for a number of reasons. The disproportionate impact of severe complications and death from Salmonellosis in the elderly is illustrated by epidemiologic evidence.” Waivers to allow undercooked unpasteurized eggs for resident preference are not acceptable. Pasteurized shell eggs are available and allow for safe consumption of undercooked eggs.

NOTE: Raw eggs with damaged shells are also unsafe because of the potential for contamination.

Food Service and Distribution

Various systems are available for serving and distributing food items to residents. These include but are not limited to tray lines, portable steam tables transported to a unit or dining area, open shelved food transport carts with covered trays, or enclosed carts that have hot and cold compartments. Some systems incorporate a heating element (pellet) under each plate of hot food. The purpose of these systems is to provide safe holding and transport of the food to the resident’s location. Food safety requires consistent temperature control from the tray line to transport and distribution to prevent contamination (e.g., covering food items). The length of time needed to transport trays is more critical when the food is simply covered and transported in open or closed carts without a heated and cooled environment.

- **Tray line and Alternative Meal Preparation and Service Area** - The tray line may include, but is not limited to the steam table where hot prepared foods are held and served, and the chilled area where cold foods are held and served. A resident’s meal tray may consist of a combination of foods that require different temperatures. Food preparation or service area problems/risks to avoid include, but are not limited to:
 - Holding foods in danger zone temperatures which are between 41 degrees F and 135 degrees F;
 - Using the steam table to heat food;
 - Serving meals on soiled dishware and with soiled utensils; and
 - Handling food with bare hands or improperly handling equipment and utensils.

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. Foods may be reheated (only once) to 165 degrees F. Reheated foods are best discarded if not eaten within two hours after reheating¹².

Food Distribution - Dining locations include any area where one or more residents eat their meals. These can be located adjacent to the kitchen or a distance from the kitchen, such as residents’ rooms and dining rooms in nursing units on other floors or wings of the building. Potential food handling problems/risks associated with food distribution include:

- Staff distributing trays without first properly washing their hands; and
- Serving food to residents after collecting soiled plates and food waste, without proper hand washing.

Snacks - Snacks refer to those foods that are served between meals or at bed time. Temperature control and freedom from contamination are also important when ready-to-eat or prepared food items for snacks are sent to the unit and are held for delivery; or stored at the nursing station, in a unit refrigerator or unit cupboards. Food handling risks associated with food stored on the units may include but are not limited to:

- Food left on trays or countertops beyond safe time and/or temperature requirements;
- Food left in refrigerators beyond safe "use by" dates (including, but not limited to foods that have been opened but were not labeled, etc.);
- Food stored in a manner (open containers, without covers, spillage from one food item onto another, etc.) that allows cross-contamination; and
- Failure to maintain refrigerated food temperatures at safe levels;

Special Events - Facility-sponsored special events, such as cookouts and picnics where food may not be prepared in the facility's kitchen and is served outdoors or in other locations, require the same food safety considerations

Transported Foods - If residents take prepared foods with them out of the facility (e.g., bag lunches for residents attending dialysis, clinics, sporting events, or day treatment programs), the foods must be handled and prepared for them with the same safe and sanitary approaches used during primary food preparation in the facility. Appropriate food transport equipment or another approach to maintaining safe temperatures for food at special events can help prevent foodborne illness.

Ice - Appropriate ice and water handling practices prevent contamination and the potential for waterborne illness. Ice must be made from potable water. Ice that is used to cool food items (e.g., ice in a pan used to cool milk cartons) is not to be used for consumption. Keeping the ice machine clean and sanitary will help prevent contamination of the ice. Contamination risks associated with ice and water handling practices may include, but are not limited to:

- Staff who use poor hygiene, fail to wash hands adequately, or handle ice with their bare hands are not following appropriate infection control practices when dispensing water and ice; and
- Unclean equipment, including the internal components of ice machines that are not drained, cleaned, and sanitized as needed and according to manufacturer's specifications.

Refrigeration - A potential cause of foodborne illness is improper storage of PHF/TCS food. The refrigerator must be in good repair and keep foods at or below 41 degrees F. The freezer must keep frozen foods frozen solid. 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. Measure whether the temperature of a PHF/TCS food that has been inside for at least 24 hours is 41 degrees or less;
- To make sure the cooling process is effective, measure the temperature of a PHF/TCS that has a prolonged cooling time (e.g., one in a large, deep, tightly covered container). Determine if it is in the danger zone;
- Check for situations where potential for cross-contamination is high (e.g., raw meat stored over ready-to-eat items);
- Check the firmness of frozen food and inspect the wrapper to determine if it is intact enough to protect the food; and
- Interview food service personnel regarding the operation of the refrigerator and the freezer.

EQUIPMENT AND UTENSIL CLEANING AND SANITIZATION

A potential cause of foodborne outbreaks is improper cleaning (washing and sanitizing) of contaminated equipment. Protecting equipment from contamination via splash, dust, grease, etc. is indicated. Dishwashing machines, operated according to the manufacturer specifications, wash, rinse, and sanitize dishes and utensils using either heat or chemical sanitization. Manual dishwashing is often used for pots and pans, or when the dishwashing machine is not operational.

Machine Washing and Sanitizing

Dishwashing machines use either heat or chemical sanitization methods. The following are specifications according to the U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration Food Code (or according to manufacturer's directions) for each method.

- High Temperature Dishwasher (heat sanitization):
 - o Wash 150-165 degrees F wash; and
 - o Final Rinse 180 degrees F final rinse (160 degrees F at the rack level/dish surface reflects 180 degrees F at the manifold, which is the area just before the final rinse nozzle where the temperature of the dish machine is measured); or
165 degrees F for a stationary rack, single temperature machine.
- Low Temperature Dishwasher (chemical sanitization):
 - o Wash 120 degrees F wash; and
 - o Final Rinse 50 ppm (parts per million) hypochlorite (chlorine) on dish surface in final rinse.

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 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 or a chemical solution maintained at the correct concentration, based on periodic testing, and for the effective contact time according to manufacturer's guidelines.

After washing and rinsing, dishes and utensils are sanitized by immersion in either:

- Hot water (at least 171 degrees F) for 30 seconds; or*
- A chemical sanitizing solution used according to manufacturer's instructions. Chemical sanitization requires greater controls than hot water sanitization. If explicit instructions are not provided by the manufacturer, the recommended sanitization concentrations are as follows:*
 - o Chlorine 50-100 ppm minimum 10 second contact time*
 - o Iodine 12.5 ppm minimum 30 second contact time*
 - o QAC space (Quaternary) 150-200 ppm concentration and contact time per Manufacturer's instructions (Ammonium Compound)*

A high concentration of sanitation solutions may be potentially hazardous (see manufacturer's instructions). Improper test strips yield inaccurate results when testing for chemical sanitation.

Drying food preparation equipment and utensils with a towel or cloth may increase risks for cross contamination.

Cleaning Fixed Equipment

When cleaning fixed equipment (e.g., mixers, slicers, and other equipment that cannot readily be immersed in water), the removable parts are washed and sanitized and non-removable parts are cleaned with detergent and hot water, rinsed, air-dried and sprayed with a sanitizing solution (at the effective concentration). Finally, the equipment is reassembled and any food contact surfaces that may have been contaminated during the process are re-sanitized (according to the manufacturer's instructions). Service area wiping cloths are cleaned and dried or placed in a chemical sanitizing solution of appropriate concentration.

Endnotes

- ¹ *The Partnership for Food Safety and Education. (2006). Food Safety Glossary. Retrieved September 25, 2006 from <http://www.fightbac.org/content/view/15/22/>.*
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- ³ *Mead, P.S., Slutsker, L., Dietz, V., McCaig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., & Tauxe, R.V. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases*, 5(5), 607-625.*
- ⁴ *Hedberg, C.W., Smith, S.J., Kirkland, E., Radke, V., Jones, T.F., Selman, C.A., & EHS-NET Working Group. (2006). Systematic environmental evaluations to identify food safety differences between outbreak and non-outbreak restaurants. *Journal of Food Protection*, 69(9). Need Pages*
- ⁵ *Centers for Disease Control and Prevention Outbreak Surveillance Data. (2006). Annual Listing of Foodborne Disease Outbreaks, United States, 1990-2004. Retrieved September 25, 2006 from http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm*
- ⁶ *U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Code (p. 48).*
- ⁷ *International Association of Food Protection. (1999). Procedures to Investigate Foodborne Illness (5th edition). Des Moines, IA: Author. [Prepared by the Committee on Communicable Diseases Affecting Man.]*
- ⁸ *U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 43).*
- ⁹ *U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (pp. 43-45).*
- ¹⁰ *U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 66).*
- ¹¹ *U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (pp. 103-104; 123).*
- ¹² *U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 114).*

INVESTIGATIVE PROTOCOL

SANITARY CONDITIONS

Objectives

- *To determine if the facility obtained food safe for consumption from approved sources;*
- *To determine if the facility stores, prepares, distributes, and serves food in a sanitary manner to prevent foodborne illness;*
- *To determine if the facility has systems (e.g., policies, procedures, training, and monitoring) in place to prevent the spread of foodborne illness and minimize food storage, preparation and handling practices that could cause food contamination and could compromise food safety; and*
- *To determine if the facility utilizes safe food handling from the time the food is received from the vendor and throughout the food handling processes in the facility.*

Use

Use this protocol to investigate compliance at F371 (§483.35(i) (1) and (2)).

Procedures

Adhere to sanitary requirements (e.g., proper washing hands when entering the kitchen and between tasks, use of hair restraints) when assessing the kitchen and meal service throughout the survey process. During the initial tour of the facility and throughout the survey, observe the kitchen(s) and food service area(s) and review planned menus to determine when to assess food preparation processes. Observe subsequent kitchen/food services during times when food is being stored, prepared, cooked, plated, transported, and distributed to determine if safe food handling practices are being followed. Corroborate observations through interview, record review, and other appropriate documentation.

NOTE: *When a facility receives food from an off-site kitchen (any kitchen not operated by the facility), determine whether the food was obtained from an approved source.*

1. Observation

Conduct the following observations:

- *Food procurement procedures:*
 - *Determine whether food meets safe and sanitary conditions related to when, where, and how the food was received for residents consumption.*

- *Check invoices from food vendors when necessary to verify the source of food acquisition and the date of delivery.*
- *Food preparation procedures:*
 - *Observe staff food handling practices, such as proper hand washing, the appropriate use of utensils, glove, and hairnets;*
 - *Observe food labeling and dates (e.g., used by dates);*
 - *Observe food handling practices that have potential for cross-contamination (e.g., use of food contact surfaces and equipment to prepare various uncooked and ready-to-eat foods);*
 - *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;*
 - *If a PHF/TCS food is prepared from ingredients at room temperature, determine if it was cooled to 41 degrees F within 4 hours. For example, when observing tuna or chicken salad preparation, determine when the salad was prepared, then measure the current temperature; and*
 - *Observe staff preparing modified consistency (e.g., pureed, mechanical soft) PHF/TCS foods to determine whether food safety was compromised.*

Service of food during meal times -

- *Observe the staff measuring the temperature of all hot and cold menu items. Cold foods should be at or below 41 degrees F when served. Hot foods should be at 135 degrees F or above when served.*

Service after meal times:

- *Observe whether facility personnel are operating the dish washing machine according to the manufacturer's specifications. Evaluate sanitization with a calibrated thermometer (for a high temperature machine), chlorine test tape (for a low temperature machine), or other manufacturer recommended method;*
- *Check whether the facility has the appropriate equipment and supplies to evaluate the safe operation of the dish machine and the washing of pots and pans (e.g., maximum registering thermometer, appropriate chemical test strips, and paper thermometers);*
- *Evaluate sanitization during manual pot and pan washing (3-step process). Test the final rinse water temperature if using hot water for sanitization or the concentration of chemical sanitizer being used. Determine if the appropriate test strip for that chemical is being utilized;*

- *Observe stored dishes, utensils, pots/pans, and equipment for evidence of soiling. These items should be stored in a clean dry location and not exposed to splash, dust or other contamination; and*
- *Evaluate whether proper hand washing is occurring between handling soiled and clean dishes to prevent cross-contamination of the clean dishes.*

Storage of food:

- *Observe for evidence of pests, rodents and droppings and other sources of contamination in food storage areas;*
- *Observe food labeling and dates (e.g., used by dates);*
- *Observe that foods are stored off of the floor, and clear of ceiling sprinklers, sewer/waste disposal pipes and cleaning chemicals;*
- *Observe whether the facility has canned goods that have a compromised seal (e.g., punctures); and*
- *Observe whether staff access bulk foods without touching the food.*

2. Interview

During the course of the survey, interview the staff who performs the task about the procedures they follow to procure, store, prepare, distribute, and serve food to residents. Request clarification from the dietary supervisor/manager or qualified dietitian concerning the following:

- *What is the facility's practice for dealing with employees who come to work with symptoms of contagious illness (e.g., coughing, sneezing, diarrhea, vomiting) or open wounds;*
- *How does the facility identify problems with time and temperature control of PHF/TCS foods and what are the processes to address those problems;*
- *Whether the facility has, and follows, a cleaning schedule for the kitchen and food service equipment; and*
- *If there is a problem with equipment, how staff informs maintenance and follows up to see if the problem is corrected.*

3. Record Review

In order to investigate identified food safety concerns, review supporting data, as necessary, including but not limited to:

- *Any facility documentation, such as dietary policies and procedures, related to compliance with food sanitation and safety. Determine if the food service employees have received training related to such compliance;*

- *Food temperature records from the tray line, refrigerator/freezer temperature records, and dishwasher records;*
- *Maintenance records, such as work orders and manufacturer's specifications, related to equipment used to store, prepare, and serve food; and*
- *Facility infection control records regarding surveillance for foodborne illness and actions related to suspected or confirmed outbreaks of gastrointestinal illnesses.*

4. Review of Facility Practices

Review of facility practices may include, but is not limited to, review of policies and procedures for sufficient staffing, staff training, and following manufacturer's recommendations as indicated. In order to establish if the facility has a process in place to prevent the spread of foodborne illness, interview the staff to determine how they:

- *Monitor whether the facility appropriately procures, stores, prepares, distributes, and serves food;*
- *Identify and analyze pertinent issues and underlying causes of a food safety concern (e.g., refrigerator or dishwasher malfunction);*
- *Implement interventions that are pertinent and timely in relation to the urgency and severity of a concern; and*
- *Monitor the implementation of interventions and determine if additional modification is needed.*

DETERMINATION OF COMPLIANCE (TASK 6, APPENDIX P)

Synopsis of Regulation (F371)

The sanitary conditions requirement has two aspects. The first aspect requires that the facility procures food from sources approved or considered satisfactory by Federal, State, or local authorities. The second aspect requires that the facility stores, prepares, distributes, and serves food under sanitary conditions to prevent foodborne illness.

Criteria for Compliance

The facility is in compliance with 42 CFR 483.35(i) (1)(2), Sanitary Conditions, if staff:

- *Procures, stores, handles, prepares, distributes, and serve food to minimize the risk of foodborne illness;*
- *Maintains PHF/TCS foods at safe temperatures, cools food rapidly, and prevents contamination during storage;*
- *Cooks food to the appropriate temperature and holds PHF/TCS food at or below 41 degrees F or at or above 135 degrees F;*

- *Utilizes proper hand washing and personal hygiene practices to prevent food contamination; and*
- *Maintains equipment and food contact surfaces to prevent food contamination.*

If not, cite at Tag F371.

Noncompliance for F371

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for Tag F371 may include, but is not limited to, failure to do one or more of the following:

- *Procure, store, handle, prepare, distribute, and serve food in accordance with the standards summarized in this guidance;*
- *Maintain PHF/TCS foods at safe temperatures, at or below 41 degrees F (for cold foods) or 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;*
- *Store raw foods (e.g., meats, fish) in a manner to reduce the risk of contamination of cooked or ready-to-eat foods;*
- *Cook food to the appropriate temperature to kill pathogenic microorganisms that may cause foodborne illness;*
- *Cool food in a manner that prevents the growth of pathogenic microorganisms;*
- *Utilize proper personal hygiene practices (e.g., proper hand washing and the appropriate use of gloves) to prevent contamination of food; and*
- *Use and maintain equipment and food contact surfaces (e.g., cutting boards, dishes, and utensils) to prevent cross-contamination.*

Potential Tags for Additional Investigation

During the investigation of 42 CFR §483.35(i)(1)(2), the surveyor may have identified concerns related to these requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are related outcome, process, and structure requirements that may be considered:

- *42 CFR 483.25(g)(2), F322, Nasogastric Tubes*
 - *Determine if residents have experienced nausea, vomiting, diarrhea, or other gastrointestinal symptoms as a result of the failure to store, handle, administer, or remove and discard tube feeding solutions in a safe and sanitary manner.*

- 42 CFR 483.25(i), F325, Nutrition
 - Determine if multiple residents have experienced nausea, vomiting, diarrhea, or other gastrointestinal symptoms related to foodborne illness, which may impact their nutritional status.
- 42 CFR 483.30(a)(b), F353 Sufficient Staffing
 - Determine if the facility has sufficient staffing to meet the needs of the resident.
- 42 CFR 483.35(a)(1)(2), F361, Dietary Services - Staffing
 - Determine if the facility employs or consults with a qualified dietitian. If not employed full-time, determine if the director of food service receives scheduled consultation from the dietitian concerning storage, preparation, distribution and service of food under sanitary conditions.
- 42 CFR 483.35(b), F362, Standard Sufficient Staff
 - Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.
- 42 CFR 483.35(h) Paid Feeding Assistant
 - Determine if the Feeding Assistant has successfully completed a State-approved training course that meets Federal requirements and that the Feeding Assistant is utilizing proper techniques to prevent foodborne illness.
- 42 CFR 483.65(a), F441, Infection Control
 - Determine if the facility's infection control program included investigation, control, and prevention of foodborne illness.
- 42 CFR 483.65(b)(3), F444, Handwashing Techniques
 - Determine if the facility has practices in place to prevent the spread of infection, including proper hand washing techniques.
- 42 CFR 483.70(c)(2), F456, Maintain All Essential Equipment
 - Determine if the equipment in the kitchen, such as refrigerators, food carts, tray line equipment, freezers, dishwashers, ovens, stoves, and ranges etc. is maintained in safe operating condition and according to manufacturers' specifications.
- 42 CFR 483.70(h), F465, Other Environmental Conditions
 - Determine if the kitchen physical environment, such as, floors, walls, ceilings, and vent hoods are safe, clean, and sanitary.
- 42 CFR 483.70(h)(4), F469, Effective Pest Control Program
 - Determine if the facility has maintained an effective pest control program so that it remains free of pests and rodents. Determine whether there is evidence of roaches, ants, flies, mice, etc. in food storage, preparation and service areas.

- 42 CFR 483.70(o) (2) (i) (ii), F520, Quality Assessment and Assurance
 - o Determine whether the quality assessment and assurance committee seeks and reviews concerns related to foodborne illness, and food safety and sanitation to develop and implement appropriate actions to correct identified quality deficiencies when indicated.

IV. DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for Tag F371 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of the presence of unsanitary conditions. Actual or potential harm/negative outcome for Tag F371 may include, but is not limited to:

- Foodborne illness; or
- Ingestion or potential ingestion of food that was not procured from approved sources, and stored, prepared, distributed or served under sanitary conditions.

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility's noncompliance caused, resulted in, allowed or contributed to the actual or potential for harm.

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or
- If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.

3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F371. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- *Has allowed/caused/resulted in or is likely to allow/cause/result in serious injury, harm, impairment, or death to a resident; and*
- *Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventive or corrective measures.*

NOTE: *The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance, which allowed or caused the immediate jeopardy.*

Examples of negative outcomes that occurred or have the potential to occur at Severity Level 4 as a result of the facility's deficient practices may include:

- *A roast (raw meat) thawing on a plate in the refrigerator had bloody juices overflowing and dripping onto uncovered salad greens on the shelf below. The contaminated salad greens were not discarded and were used to make salad for the noon meal;*
- *The facility had a recent outbreak of Norovirus after the facility allowed a food worker who was experiencing vomiting and diarrhea to continue preparing food. Observations and interviews indicate that other food service staff with gastrointestinal illnesses are also permitted to prepare food; and*
- *The facility purchased unpasteurized shell eggs for all cooking purposes. The cook prepared and served sunny-side-up eggs with barely cooked yolks (i.e., not cooked to at least 145 degrees F for at least 15 seconds) for fourteen residents' breakfasts. Using unpasteurized, shell eggs to prepare undercooked eggs for eating increased the risk of residents being infected with Salmonella, which could lead to a life-threatening illness. The facility did not have a system in place to minimize foodborne illness in the preparation of undercooked unpasteurized eggs.*

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Severity Level 3 indicates noncompliance that results in actual harm that is not immediate jeopardy. The negative outcome can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being. Therefore, a Level 3 deficiency is indicated when unsafe food handling and inadequate sanitary conditions result in actual harm to residents. Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- *Outbreak of nausea and vomiting occurs in the facility related to the inadequate sanitizing of dishes and utensils; and*
- *Episode of food poisoning occurs because facility had an event in which tuna, chicken, and potato salads served in bulk were not kept adequately chilled and were still left out for eating after 5 hours.*

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Severity Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

As a result of the facility's noncompliance, the potential for food contamination and/or growth of pathogenic microorganisms exists. Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 2 may include, but are not limited to:

- *Food service workers sliced roast pork on the meat slicer. The meat slicer was not washed, rinsed, and sanitized after usage. The facility failed to educate and train staff on how to clean and sanitize all kitchen equipment;*
- *During the initial tour of the kitchen, two food service workers were observed on the loading dock. One was smoking and the other employee was emptying trash. Upon returning to the kitchen, they proceeded to prepare food without washing their hands; and*
- *Upon inquiry by the surveyor, the food service workers tested the sanitizer of the dish machine, the chemical rinse of the pot-and-pan sink, and a stationary bucket used for wiping cloths. The facility used chlorine as the sanitizer. The sanitizer tested less than 50 ppm in all three locations. Staff interviewed stated they were unaware of the amount of sanitizer to use and the manufacturer's recommendations to maintain the appropriate ppm of available sanitizer.*

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

The failure of the facility to procure, prepare, store, distribute and handle food under sanitary conditions places this highly susceptible population at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.



483.25(i) Nutrition (F325) Surveyor Training: Interpretive Guidance Investigative Protocol

With regard to the revised guidance F325 Nutrition, there have been significant changes. Specifically, F325 and F326 were merged. However, the regulatory language has remained the same. The revisions to F325 were made to provide definition, education, explanation, and examples for the surveyors to reference.

Federal Regulatory Language

The facility must ensure that a resident—

- **483.25(i)(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and**
- **483.25(i)(2) Receives a therapeutic diet when there is a nutritional problem.**

Intent

The intent of this requirement is that the resident maintains, to the extent possible, acceptable parameters of nutritional status and that the facility

- Provides care and services to each resident as identified in their comprehensive assessment
- Recognizes, evaluates, and addresses the needs of the resident at risk for, or already experiencing, impaired nutrition

Intent (cont'd)

Provides a therapeutic diet that takes into account the resident's clinical condition or other appropriate intervention, when there is nutritional indication

Training Objectives

- Describe the relationship between the regulation and the nutrition guidance
- Describe the care process related to nutrition
- Identify when the Investigative Protocol would be used

Training Objectives (cont'd)

- Describe and apply components of the Investigative Protocol
- Identify compliance with the regulation as it relates to nutrition
- Appropriately categorize the severity of noncompliance



483.25(i) Nutrition

Interpretive Guidelines

Definitions

- Acceptable Parameters of Nutritional Status
- Albumin
- Anemia
- Anorexia
- Artificial Nutrition
- Avoidable/Unavoidable
- Clinically Significant
- Current Standards of Practice
- Dietary Supplements
- Insidious Weight Loss
- Nutritional Supplements
- Parameters of Nutritional Status
- Qualified Dietitian
- Therapeutic Diet
- Usual Body Weight

Acceptable Parameters of Nutritional Status

Refers to factors that reflect that the individual's nutritional status is adequate, relative to his/her overall condition and prognosis.

Albumin

Refers to the body's major plasma protein, essential for maintaining osmotic pressure and also serving as a transport protein.

Anemia

Refers to a decrease in the percentage of blood cells relative to total blood volume.

Anorexia

Refers to a loss of appetite, including loss of interest in seeking and consuming food.

Artificial Nutrition

Refers to chemically balanced mix of nutrients and fluids to sustain life, usually administered via percutaneous endoscopic gastrostomy tube (peg tube).

Avoidable

The resident did not maintain acceptable parameters of nutritional status and the facility did not do one or more of the following:

- evaluate the resident's clinical condition and nutritional risk factors
- define and implement interventions that are consistent with resident's needs, resident goals and recognized standards of practice
- monitor and evaluate the impact of the interventions or revise the interventions as appropriate

Unavoidable

The resident did not maintain acceptable parameters of nutritional status even though the facility:

- evaluated the resident's clinical condition and nutritional risk factors
- defined and implemented interventions that are consistent with resident needs, goals and recognized standards of practice
- monitored and evaluated the impact of the interventions

Clinically Significant

Refers to the effects, results, or consequences that materially affect or are likely to affect an individual's physical, mental, or psychological well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

Current Standards of Practice

Refers to approaches to care, procedures, techniques, treatments, etc., that are based on research or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.

Dietary Supplements

Refers to nutrients (e.g. vitamins, minerals, amino acids, and herbs) that are added to a person's diet when they are missing and not consumed in enough quantity

Nutritional Supplements

Refers to dietary substances intended to supply nutrients (e.g., vitamins, minerals, fatty acids or amino acids) that are missing or not consumed in sufficient quantity in a person's diet. These substances may also be referred to as food supplements.

Insidious Weight Loss

Refers to a gradual, unintended, progressive weight loss over time.

Parameters of Nutritional Status

Refers to factors (e.g., weight, food/fluid intake, and pertinent laboratory values) that reflect the resident's nutritional status

Qualified Dietitian

Refers to one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association or as permitted by state law, on the basis of education, training, or experience in identification of dietary needs, planning and implementation of dietary programs.

Therapeutic Diet

Refers to a diet ordered by a physician or practitioner as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide mechanically altered food when indicated.

Usual Body Weight

Refers to the resident's usual weight through adult life or a stable weight over time.

Overview

Nutrients are essential substances for critical metabolic processes, the maintenance and repair of cells and organs, and energy to support daily functioning.

Other key factors affecting nutritional status

- The body may not absorb or use nutrients effectively
- Age-related loss of muscle mass, strength and function
- Wasting that occurs as a consequence of illness and inflammatory processes
- Disease causing changes in mental status

Other key factors affecting nutritional status (cont'd)

- Changes to the ability to eat and taste food may occur in later life

Nutritional Assessment

An in-depth assessment will identify factors that existed prior to admission, such as insufficient intake, progressive weight loss/gain, CVA, or recent surgery.

Assessment

- Interdisciplinary Approach
- General Appearance with Height/Weight
- Food and Fluid Intake Parameters
- Nutrient Utilization
- Chewing Difficulties
- Swallowing Abnormalities

Assessment (cont'd)

- Functional Abilities
- Medications
- Goals and Prognosis
- Laboratory/Diagnostic Evaluation

Analysis

- Refers to use of information from Resident Assessment Instrument (RAI)
 - Comprehensive and Quarterly
- Additional assessments as indicated
 - Caloric, Protein, and Fluid Needs Analysis
- Specific to the nature of the nutritional abnormality

Care Planning and Interventions

- Resident Choice
- Meeting Nutritional Needs
- Diet Liberalization
- Weight-Related Interventions
- Weight Gain

Care Planning and Interventions (cont'd)

- Environmental Factors
- Anorexia
- Wound Healing
- Functional Factors
- Chewing and Swallowing Factors
- Medications

Care Planning and Interventions (cont'd)

- Food Fortification and Supplementation
- Maintaining Fluid and Electrolyte Balance
- Use of Appetite Stimulants
- Feeding Tubes
- End of Life

Monitoring

- To ensure intervention has stabilized nutritional concern
- Review of factors contributing to the resident's nutritional deficits for changes

Monitoring (cont'd)

- Monitor new risk factors that do not develop after the intervention
- Current intervention may need modification



Investigative Protocol Nutrition

Use this protocol to investigate
compliance at 483.25(i)(1)(2) tag F325

Objectives

To determine if the facility has practices in place to maintain acceptable parameters of nutritional status for each resident based on his/her comprehensive assessment.

Objectives (cont'd)

To determine if the resident has received a therapeutic diet when there is a nutritional indication.

Objectives (cont'd)

To determine if failure to maintain acceptable parameters of nutritional status for each resident was avoidable or unavoidable.

Investigation Procedures

- Observation
- Interviews
- Record Review

Observation

- Initial Tour
- Resident Observations
- Dining Observation

Observation – Resident Dining

- Observe two meals during the survey, including an observation on the first day if a meal is being served during the tour, and an evening meal.
- At least one meal observation should be conducted after the record review.

Interview

- Interview resident and responsible party to identify:
 - Participation in care planning and decision making
 - Consideration of nutritional interventions
 - Results/effectiveness of nutritional interventions and care approaches

Interview (cont'd)

- Interview interdisciplinary team members to determine:
 - Impact of nutritional assessment on resident
 - Clinical rationale of nutritional intervention
 - Awareness of any signs and symptoms of nutritional deficits requiring clinical interventions

Interview (cont'd)

Interview interdisciplinary team members to determine:

- Physician response to notification of suspected functional impairments related to nutritional deficits
- Dietitian assessment and communication

Interview (cont'd)

If interventions defined or care provided are inconsistent with current standards of practice, interview one or more physicians or other licensed health care practitioners who can address resident's nutritional status.

Record Review

Review the resident's medical record to determine how the facility:

- Evaluated and analyzed nutritional status
- Identified residents who are at nutritional risk
- Evaluated the effectiveness of the interventions

Record Review (cont'd)

- Investigated and identified causes of anorexia and impaired nutritional status
- Identified and implemented relevant interventions to try to stabilize or improve nutritional status
- Monitored and modified approaches as indicated

Documentation

Findings and conclusions related to nutritional status may be found in various locations in the medical record, including but not limited to interdisciplinary progress notes, nutrition progress notes, the RAI summary, care plan, or resident care conference notes.

Assessment and Monitoring

Review information including

- RAI
- Diet and medication orders
- Activities of daily living worksheets
- Nursing, dietitian, rehabilitation, and social service notes.

Care Plan

- Review the comprehensive care plan to determine if the plan is based on the comprehensive assessment and additional pertinent nutritional assessment information

Care Plan (cont'd)

- Determine if the facility developed measurable objectives, approximate time frames, and specific interventions to maintain acceptable parameters of nutritional status, based on the resident's overall goals, choices, preferences, prognosis, conditions, assessed risks, and needs

Interview with Health Care Practitioners

If the interventions defined, or the care provided, appear to be inconsistent with recognized standards of practice, interview one or more health care practitioners.

Review of Facility Practices

Investigate whether the facility has a system in place to identify residents with nutritional deficiencies or risk and a process in place to consistently address identified needs.

42 CFR 483.25(i) (1)(2)

Nutrition

DETERMINATION OF COMPLIANCE (Appendix P)

Determination of Compliance

Did the facility:

- Ensure that each resident maintains acceptable parameters of nutritional status unless the resident's clinical condition demonstrates that this is not possible, and
- Ensure to the extent possible the resident receives a therapeutic diet when indicated?

Criteria for Compliance with F325

The facility is in compliance if staff:

- Assessed the resident's nutritional status and identified factors that put the resident at risk of not maintaining acceptable parameters of nutritional status; and
- Analyzed the assessment information to identify the medical conditions, causes and problems related to the resident's condition and needs.

Criteria for Compliance with F325 (cont'd)

The facility is in compliance if staff:

- Defined and implemented interventions to maintain or improve nutritional status that are consistent with the resident's assessed needs, choices, goals, and recognized standards of practice, or provided clinical justification why they did not do so
- Provided a therapeutic diet when indicated.

Criteria for Compliance with F325 (cont'd)

The facility is in compliance if staff:

- Monitored and evaluated the resident's response to the interventions; and
- Revised the approaches as appropriate, or justified the continuation of current approaches.

Noncompliance with F325

Determination of noncompliance occurs after:

Failure to

- Completing the investigative protocol, and
- The team analysis of data to determine whether noncompliance with the regulation exists.

Noncompliance with F325 (cont'd)

Noncompliance with F325 may include (but is not limited to) one or more of the following:

Failure to

- Accurately and consistently assess a resident's nutritional status on admission and as needed thereafter
- Identify a resident at nutritional risk and address risk factors for impaired nutritional status, to the extent possible

Noncompliance with F325 (cont'd)

May include failure to:

- Identify, implement, monitor, and modify interventions consistent with the resident's assessed needs, choices, goals, and current standards of practice, to maintain acceptable parameters of nutritional status.
- Notify the physician as appropriate in evaluating and managing causes of the resident's nutritional risks and impaired nutritional status.

Additional Investigation

Potential Tags for Additional Investigation

DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Severity Determination

Key Components

- Harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services,
- Degree of harm (actual or potential) related to compliances, and
- Immediacy of correction required

Determining Actual or Potential Harm

Actual or potential harm/negative outcomes for F325 may include:

- Significant unplanned weight change
- Inadequate food/fluid intake
- Impairment of anticipated wound healing
- Failure to provide a therapeutic diet, as ordered
- Functional decline
- Fluid/electrolyte imbalance.

Determining Degree of Harm

How the facility practices caused, resulted in, allowed, or contributed to harm (actual/potential)

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise or discomfort:
- If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.

Severity Level 4 Deficiency Categorization

**Immediate Jeopardy to
Resident's Health or Safety**

Level 4 Immediate Jeopardy

Has allowed/caused/resulted in, or is likely to cause serious injury, harm, impairment, or death to a resident and

Level 4 Immediate Jeopardy (cont'd)

Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Severity Level 4 Example

Development of life-threatening symptom(s), or the development or continuation of severely impaired nutritional status due to repeated failure to assist a resident who required assistance with meals.

Severity Level 4 Example

Substantial and ongoing decline in food intake resulting in significant unplanned weight loss due to dietary restrictions or downgraded diet textures (e.g., mechanic soft, pureed) provided by the facility against the resident's expressed preferences.

Severity Level 3 Deficiency Categorization

Actual Harm that is *not* Immediate Jeopardy

The negative outcome can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being.

Severity Level 3 Example

Significant unplanned weight change and impaired wound healing (not attributable to an underlying medical condition) due to the facility's failure to revise and/or implement the care plan to address the resident's impaired ability to feed him/herself.

Severity Level 3 Example

Unplanned weight change and declining food and/or fluid intake due to the facility's failure to assess the relative benefits and risks of restricting or downgrading diet and food consistency or to obtain or accommodate resident preferences in accepting related risks.

Severity Level 2 Deficiency Categorization

No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

Level 2 Deficiency Categorization

- Noncompliance that results in a resident outcome of no more than minimal discomfort, and/or
- Has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being.

Severity Level 2 Example

Failure to provide additional nourishment when ordered for a resident; however, the resident did not experience significant weight loss.

Severity Level 2 Example

Failure to provide a prescribed sodium-restricted therapeutic diet (unless declined by the resident or the resident's representative or not followed by the resident); however, the resident did not experience medical complications such as heart failure related to sodium excess.



Severity Level 1 Deficiency Categorization

**No Actual Harm with Potential
for Minimal Harm**

Level 1 Deficiency Categorization

The failure of the facility to provide appropriate care and services to maintain acceptable parameters of nutritional status and minimize negative outcomes places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

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Questions?



§483.35(i) Sanitary Conditions (F371) Surveyor Training: Interpretive Guidance Investigative Protocol



With regard to the revised guidance F371 Sanitary Conditions, there have been significant changes. Specifically, F370 and F371 were merged. However, the regulatory language has remained the same. The revisions to F371 were made to provide definition, education, explanation, and examples for the surveyors to reference.

Federal Regulatory Language

The facility must —

- §483.35(i)(1) Procure food from sources approved or considered satisfactory by Federal, State or local authorities; and
- §483.35(i)(2) Store, prepare, distribute and serve food under sanitary conditions.

Intent

The intent of this requirement is to ensure that the facility:

- Obtains food for residents' consumption from approved sources, and
- Follows proper sanitation and food handling practices to prevent the outbreak of foodborne illnesses.

Training Objectives

- Describe the relationship between the regulation and the interpretive guidance
- Describe how to use the investigative protocol
- Describe and apply components of the investigative protocol

Training Objectives (cont'd)

- Identify areas of non-compliance with the sanitary conditions regulation
- Appropriately categorize the scope and severity of noncompliance

Definitions

- **Cross-contamination**
- **Danger Zone**
- **Dry Storage**
- **Food Contamination**
- **Food Preparation**
- **Food Service/Distribution**
- **Foodborne Illness**
- **Highly Susceptible Population**
- **Pathogen**
- **Potentially Hazardous Food (PHF)**
- **Ready-to-Eat Food**
- **Storage**
- **Toxins**

Cross-contamination

The transfer of harmful substances or disease-causing microorganisms to food by hands, food contact surfaces, sponges, cloth towels, or utensils that are not cleaned after touching raw food, and then touch ready-to-eat foods.

Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.

Danger Zone

Temperatures above *41* degrees Fahrenheit (F) and below *135* degrees F that allow the rapid growth of pathogenic microorganisms that can cause foodborne illness.

Potentially Hazardous Foods or Time/Temperature Control for Safety foods held in the *danger zone* for more than *4* hours if being prepared from ingredients at ambient temperature, or *6* hours if cooked and cooled, may cause a foodborne illness if consumed.

Dry Storage

Storing/maintaining dry foods (e.g., canned goods, flour, sugar) and supplies (disposable dishware, napkins and kitchen cleaning supplies).

Storage

The retention of food (before and after preparation) and associated dry goods.

Food Contamination

The unintended presence of potentially harmful substances, including but not limited to microorganisms, chemicals or physical objects in food.

Food Preparation

The series of operational processes involved in getting foods ready for serving, such as: washing, thawing, mixing ingredients, cutting, slicing, diluting concentrates, cooking, pureeing, blending, cooling and reheating.

Foodborne Illness

Illness caused by the ingestion of contaminated food or beverages.

Food Service/Distribution

The processes of getting food to the resident:

- Holding foods hot on the steam table or under refrigeration for cold temperature control
- Dispensing food portions for individual residents
- Family style and dining room service
- Delivering trays to residents' rooms or units

Highly Susceptible Population

Persons who are more likely than the general population to experience foodborne illness because of their susceptibility to becoming ill if they ingest microorganisms or toxins (e.g., immunocompromised, chronic disease and advanced age).

Ready-to-Eat Food

Pathogen

An organism capable of causing a disease (e.g., pathogenic bacteria or viruses).

Potentially Hazardous Food (PHF or TCS)

Food that requires time/temperature control for safety to limit the growth of pathogens or toxin formation

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., tuna, chicken or egg salad).

Toxins

Poisonous substances that are produced by living cells or organisms (e.g., pathogenic bacteria) that cause foodborne illness when ingested.

Interpretive Guidance Overview

- The risk of foodborne illness
- Importance of effective food safety systems
- Identification of hazards and Critical Control Points (CCPs)
- Operational steps to eliminate hazards

Types of Food Contamination

- Biological
- Chemical
- Physical

Biological Contamination

- Most common types of disease producing organisms
- Pathogenic bacteria, viruses, toxins, and spores contaminate food
- Parasites

Pathogenic Bacteria

- Non-harmful vs. harmful bacteria
- Food storage and preparation

Factors Influencing Bacterial Growth

- Hazardous nature of the food
- Acidity (pH) of the food
- Water percent of the food
- Time and temperature control of the food

Viruses

- Require a host for reproduction
- Examples:
 - Hepatitis A
 - Norovirus (formerly known as Norwalk virus)

Toxins

- Origin
 - Staphylococcus aureus
 - Clostridium botulinum
- Poisonous substances
- Variety of sources

Spores

- Origin
- Reactivation and favorable conditions for growth
- Temperature control

Chemical Contamination

- Cleaning supplies should be stored separately from food items.
- The most common chemicals include but are not limited to glass cleaners, soaps, oven cleaners and insecticides.

Chemical Contamination (cont'd)

- An inadequately identified chemical inadvertently mistaken as a food product added to food can cause illness.

Physical Contamination

Foreign objects that may inadvertently enter food.

Examples:

- Hair
- Fingernails
- Pieces of glass

Other Factors Implicated In Foodborne Illnesses

- Poor personal hygiene
- Inadequate cooking and improper holding temperatures
- Contaminated equipment
- Unsafe food sources

Surveying Facilities That Receive Food Prepared By Off-site Kitchens

When a nursing home receives food services from an off-site location, the surveyor must assess whether the facility is compliant with 42 CFR 483.35 (i).

Culture Change Provisions

- Family members or other resident guests who bring in food for the resident's consumption are not regulated under this Federal tag.
 - Many State regulations address this issue.

Pathogenic Microorganisms and Strategies for Their Control

- Commonly identified ingestible items associated with illness-producing organisms
- Primary agents of concern (hazards) are organisms associated with the food source
- PHF/TCS primary control strategies to minimize potential for foodborne illness outbreak

Interpretive Guidance

Source of Contamination	Primary Agents of Concern	PHF/TCS Primary Control Strategies
Fruits and vegetables, fresh	E. coli O157:H7 Salmonella Norovirus Hepatitis A virus Shigella	Cook to proper temperature Prevention of cross- contamination to ready-to-eat foods
Ready-to-eat meat and poultry products	Listeria monocytogenes	Proper refrigeration during storage
Pasteurized dairy products	Listeria monocytogenes	Proper refrigeration during storage
Ice	Norovirus	Cleaning and sanitizing the internal components of the ice machine according to manufacturers' guidelines

Interpretive Guidance

Source of Contamination	Primary Agents of Concern	PHF/TCS Primary Control Strategies
Eggs, raw or unpasteurized	Salmonella	Cook to proper temperature Prevention of cross-contamination to ready-to-eat foods
Poultry, raw	Campylobacter Salmonella Clostridium perfringens	Cook to proper temperature Prevention of cross-contamination to ready-to-eat foods
Meat, raw	E. coli 0157:H7 Salmonella Campylobacter Clostridium perfringens	Cook to proper temperature Prevention of cross-contamination to ready-to-eat foods
Infectious food workers	Norovirus Hepatitis A virus Shigella Salmonella Staphylococcus aureus	Exclusion of infectious food workers Proper hand washing procedures Avoid bare-hand contact with ready-to-eat foods

Prevention of Foodborne Illness

- Food Handling and Preparation
- Employee Health
- Hand washing, Gloves, Antimicrobial Gel
- Hair Restraints/Jewelry/Nail Polish

Safe Food Storage

- Dry Food Storage should be maintained in a clean and dry area free of contaminants
- Refrigerator Storage Safe Practices include:
 - Monitoring temperatures
 - Proper handling of hot food
 - Separation of raw animal foods and vegetables
 - Labeling, dating and monitoring foods

Safe Food Preparation

- Cross-Contamination
- Thawing
- Final Cooking Temperatures
- Reheating Food



Interpretive Guidance

Process	Food Item	Temperatures
Final Cooking Temperatures	Poultry and stuffed foods	165 degrees F
	Ground Meat	155 degrees F
	Fish and Other Meats	145 degrees F
	Unpasteurized eggs	145 degrees F
Reheated Foods	Internal temperature	165 degrees F
	Intact package	135 degrees F

Interpretive Guidance

Process	Time	Temperatures
Cooling	Within 2 hours	From 135 degrees F to 70 degrees F
	Within 4 hours	Cooled to 41 degrees F
	Total time cooling not to exceed 6 hours	Cooled from 135 degrees F to 41 degrees F

Prevention of Foodborne Illness

- Cooling
- Modified Consistency
- Pooled Eggs

Food Service and Distribution

- Tray line, alternative meal preparation and service area
- Food distribution
- Snacks
- Special events
- Transported foods
- Ice
- Refrigeration

Equipment and Utensil Cleaning and Sanitization

- Machine Washing and Sanitizing
- Manual Washing and Sanitizing
- Cleaning Fixed Equipment

Equipment and Utensil Cleaning and Sanitization (cont'd)

Wiping Cloths

- Service area wiping cloths are cleaned and dried, or
- Placed in a chemical sanitizing solution of appropriate concentration.

Investigative Protocol Sanitary Conditions

Use this protocol to investigate compliance at F371 (483.35(i) (1) and (2)).

Objectives

- To determine if the facility procured food from approved sources
- To determine if the facility stores, prepares, distributes, and serves food in a sanitary manner to prevent foodborne illness

Objectives (cont'd)

To determine if the facility has systems (e.g. policies, procedures, training, and monitoring) in place to prevent the spread of foodborne illness and compromising of food safety

Objectives (cont'd)

To determine if the facility utilizes safe food handling from the time the food is received from the vendor and throughout the food handling processes in the facility

Procedures

- Observations
- Interviews
- Record Reviews
- Review of Facility Practices

Observe Food Procurement Procedures

- Observe when, where and how food is procured
- Concurrently with the observations, review:
 - Invoices
 - Vendor records
 - Source verification

Observe Food Preparation Procedures

- Food handling practices
- Food labeling and dates
- Hand washing
- Handling of potential cross-contamination foods
- Acceptable cooking and cooling temperatures

Observe Service of Food during Trayline Operations

- Observe staff measuring the temperature of all hot and cold menu items
- Cold foods should be at or below 41 degrees F
- Hot foods should be at or above 135 degrees F

Observe Dish Room Operations

- Observe whether staff are properly operating dish machine and evaluate sanitization processes
- Check for proper equipment and supplies to evaluate dish machine operation
- Observe the three-step process of manual pot and pan washing

Observe Service of Food after Meal Times

- Observe stored dishes, utensils, pots/pans, and equipment for evidence of soiling
- Evaluate whether proper hand washing is occurring between handling soiled and clean dishes to prevent cross-contamination of the clean dishes

Observe Food Storage

- Look for evidence of pests, rodents and droppings and other sources of contamination
- Observe whether foods are labeled and dated
- Observe whether foods are stored off of the floor

Observe Food Storage (cont'd)

- Check for canned goods that have a compromised seal
- Observe whether staff access bulk foods without touching the food

Interview

During the course of the survey, interview multiple staff who perform the task, about the procedures they follow to procure, store, prepare, distribute and serve food to residents.

Record Reviews

- Resident records
- Dietary/kitchen policies and procedures
- Maintenance records, such as work orders and manufacturer's specifications, related to equipment used to store, prepare, and serve food
- Facility infection control records

Review of Facility Practices

Review facility documents and interview staff to establish if the facility has processes and practices to promote food safety and prevent the spread of foodborne illness

42 CFR 483.35(i) (1)(2) Sanitary Conditions

DETERMINATION OF COMPLIANCE (Appendix P)

Determination of Compliance

Did the facility:

- Procure food from approved sources?
- Properly store, prepare, distribute and serve foods for residents' consumption?

Criteria for Compliance with F371

The facility is in compliance if staff:

- Procures, stores, handles, prepares, distributes, and serves food to minimize the risk of foodborne illness
- Maintains PHF/TCS foods at safe temperatures, cools food rapidly, and prevents contamination during storage

Criteria for Compliance with F371 Cont'd)

The facility is in compliance if staff:

- Cook food to the appropriate temperature and hold PHF/TCS foods cold or hot
- Utilizes proper hand washing and personal hygiene practices to prevent food contamination
- Maintains equipment and food contact surfaces to prevent food contamination

Noncompliance with F371

May include, but is not limited to, one or more of the following, failure to:

- Procure, store, handle, prepare, distribute, and serve food in accordance with the standards summarized in this guidance

Noncompliance with F371 (cont'd)

Failure to:

- Maintain PHF/TCS foods at safe temperatures, at or below 41 degrees F (for cold foods) or at or above 135 degrees F (for hot foods)
 - Exception: during preparation, cooking, or cooling
- Ensure that PHF/TCS food plated for transport was not out of temperature control for more than four hours.

Noncompliance with F371 (cont'd)

Failure to:

- Store raw foods properly to reduce the risk of contamination of cooked or ready-to-eat foods
- Ensure that foods are cooked to the appropriate temperature and cooled properly to prevent foodborne illness

Additional Investigation

Potential Tags for Additional Investigation

DEFICIENCY CATEGORIZATION(Part IV, Appendix P)

Severity Determination Key Components

- Harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services,
- Degree of harm (actual or potential) related to noncompliance, and
- Immediacy of correction required.

Determining Actual or Potential Harm

Actual or potential harm/negative outcomes for F371 may include:

- Foodborne illness; or
- Ingestion or potential ingestion of food that was not procured from approved sources, prepared, distributed or served under sanitary conditions.

Determining Degree of Harm

How the facility practices caused, resulted in, allowed, or contributed to harm (actual/potential)

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
- If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.

Severity Level 4 Deficiency Categorization

**Immediate Jeopardy to
Resident's Health or Safety**

Level 4 Immediate Jeopardy

- Has allowed/caused/resulted in, or is likely to cause serious injury, harm, impairment, or death to a resident; and

Level 4 Immediate Jeopardy (cont.)

- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Level 4 Example

- A roast thawing on a plate in the refrigerator had bloody juices overflowing and dripping onto uncovered salad greens on the shelf below.
- The contaminated salad greens were not discarded and were used to make salad for the noon meal.

Level 4 Example

- The facility had a recent outbreak of Norovirus as a result of a food worker experiencing episodes of vomiting and diarrhea, and the facility allowed the staff to continue preparing food.
- Observations and interviews indicate that there are other food service staff experiencing gastrointestinal illnesses who are still permitted to prepare food.

Severity Level 3 Deficiency Categorization

**Actual Harm that is *not* Immediate
Jeopardy**

The negative outcome may include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being.

Level 3 Example

An outbreak of nausea and vomiting occurs in the facility related to the inadequate sanitizing of dishes and utensils.

Level 3 Example

A mild episode of food poisoning occurred because the facility had a special event in which tuna, chicken, and potato salads served in bulk were not kept adequately chilled and were left out for eating after 5 hours.

Severity Level 2 Deficiency Categorization

No Actual Harm with potential
for more than minimal harm that
is not Immediate Jeopardy

Level 2 Deficiency Categorization

- Noncompliance that results in a resident outcome of no more than minimal discomfort, and/or
- Has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being.

Level 2 Example

- Food service workers sliced roast pork on the meat slicer.
- The meat slicer was not washed, rinsed, and sanitized after usage.
- During the dietary service system assessment, two days later, the surveyor observed the meat slicer soiled with dried meat underneath the blade.
- The facility failed to educate and train staff on how to clean and sanitize all kitchen equipment.

Level 2 Example

- During the tour of the kitchen, two food service workers were observed on the loading dock.
- One was smoking and the other employee was emptying trash.
- Upon returning to the kitchen, they proceeded to prepare food without washing their hands.

Severity Level 1 Deficiency Categorization

No Actual Harm with Potential for
Minimal Harm

Level 1 Deficiency Categorization

The failure of the facility to procure, prepare, store, distribute and handle food under sanitary conditions places this highly susceptible population at risk for more than minimal harm.

Therefore, Severity Level 1 does not apply for this regulatory requirement.

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