
CMS Manual System

Department of Health &
Human Services (DHHS)

Pub. 100-07 State Operations Provider Certification

Centers for Medicare &
Medicaid Services (CMS)

Transmittal 48

Date: JUNE 12, 2009

SUBJECT: Revisions to Appendix PP, “Guidance to Surveyors of Long Term Care Facilities”

I. SUMMARY OF CHANGES: This instruction revises Appendix PP, “Guidance to Surveyors” for several regulatory Tags, however, the regulatory language is unchanged. Tag F255, “Private Closet Space” is deleted and the regulatory language is moved to Tag F461.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: June 12, 2009

IMPLEMENTATION DATE: June 12, 2009

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/ §483.10(j)/Access and Visitation Rights/Tag F172
R	Appendix PP/§483.10(m)/Married Couples/Tag F175
R	Appendix PP/§483.15(a)/Dignity/Tag F241
R	Appendix PP/§483.15(b)/Self-Determination and Participation/Tag F242
R	Appendix PP/§483.15(e)(1)/Accommodation of Needs/Tag F246
R	Appendix PP/§483.15(e)(2)/Notice Before Room or Roommate Change/Tag F247
R	Appendix PP/§483.15(h)/Safe, Clean, Comfortable and Homelike Environment/Tag F252
D	Appendix PP/§483.15(h)(4)/Private Closet Space/Tag F255
R	Appendix PP/§483.15(h)(5)/Adequate and Comfortable Lighting/Tag F256
R	Appendix PP/§483.35(i)/Sanitary Conditions/Tag F371
R	Appendix PP/§483.70(d)(2)(iv)/Resident Rooms/Tag F461
	Appendix PP/§483.70(f)/Resident Call System/Tag F463

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.**

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§483.10(j) - Access and Visitation Rights

§483.10(j)(1) - The resident has the right and the facility must provide immediate access to any resident by the following:

- (i) Any representative of the Secretary;**
- (ii) Any representative of the State;**
- (iii) The resident's individual physician;**
- (iv) The State long term care ombudsman (established under section 307 (a)(12) of the Older Americans Act of 1965);**
- (v) The agency responsible for the protection and advocacy system for developmentally disabled individuals (established under part C of the Developmental Disabilities Assistance and Bill of Rights Act);**
- (vi) The agency responsible for the protection and advocacy system for mentally ill individuals (established under the Protection and Advocacy for Mentally Ill Individuals Act);**
- (vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and**
- (viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.**

§483.10(j)(2) - The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time.

Interpretive Guidelines: §483.10(j)(1) and (2)

The facility must provide immediate access to any representative of the Secretary of the Department of Health and Human Services, the State, the resident's individual physician, the State long term care ombudsman, or the agencies responsible for the protection and advocacy of *individuals with developmental disabilities or mental illness*. The facility cannot refuse to permit residents to talk with surveyors. Representatives of the Department of Health and Human Services, the State, the State *long term care* ombudsman system, and protection and advocacy

agencies for *individuals with developmental disabilities or mental illness* are not subject to visiting hour limitations.

Immediate family or other relatives are not subject to visiting hour limitations or other restrictions not imposed by the resident. *Likewise, facilities must provide 24-hour access to other non-relative visitors who are visiting with the consent of the resident. These other visitors are subject to “reasonable restrictions” according to the regulatory language. “Reasonable restrictions” are those imposed by the facility that protect the security of all the facility’s residents, such as keeping the facility locked at night; denying access or providing limited and supervised access to a visitor if that individual has been found to be abusing, exploiting, or coercing a resident; denying access to a visitor who has been found to have been committing criminal acts such as theft; or denying access to visitors who are inebriated and disruptive.* The facility may change the location of visits to assist care giving or protect the privacy of other residents, if these visitation rights infringe upon the rights of other residents in the facility. For example, a resident’s family visits in the late evening, which prevents the resident’s roommate from sleeping.

An individual or representative of an agency that provides health, social, legal, or other services to the resident has the right of “reasonable access” to the resident, which means that the facility may establish guidelines regarding the circumstances of the visit, such as location. *If there are problems with the facility’s provision of reasonable privacy for resident to meet with these representatives, refer to §483.10(e), Privacy and Confidentiality, Tag F164.*

Procedures: §483.10(j)(1) and (2)

Do residents and family members know that they are able to visit 24-hours a day? *Do non-relative visitors know they are also able to visit 24-hours a day, but* subject to reasonable restrictions as defined above? If you identify problems during *resident, family, or group* interviews, determine how the facility ensures *24-hour* access to:

- Representatives of the State;
- Representatives of the U.S. Department of Health and Human Services;
- The resident’s individual physician;
- Representatives of the State long-term care ombudsman;
- Representatives of agencies responsible for protecting and advocating rights of persons with mental illness or developmental disabilities;
- *Immediate* family or *other* relatives; and
- Other visitors, *subject to reasonable restrictions as defined above.*

F175

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§483.10(m) - Married Couples

The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

Interpretive Guidelines: §483.10(m)

The right of residents who are married to each other to share a room does not give a resident the right, or the facility the responsibility, to compel another resident to relocate to accommodate a spouse. The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose. If a married resident's spouse is admitted to the facility later and the couple want to share a room, the facility must provide a shared room as quickly as possible. However, a couple is not able to share a room if one of the spouses has a different payment source for which the facility is not certified (if the room is in a distinct part, unless one of the spouses elects to pay for his or her care). *This regulation does not prohibit the facility from accommodating residents who wish to room with another nursing home resident of their choice. For issues of residents being prohibited from rooming with persons of their choice, use §483.15(b)(3), Self-determination and Participation, Tag F242: "The resident has the right to make choices about aspects of his or her life in the facility that are significant to the resident."*

F241

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§483.15(a) - Dignity

The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

Interpretive Guidelines: §483.15(a)

"Dignity" means that in their interactions with residents, staff carries out activities that assist the resident to maintain and enhance his/her self-esteem and self-worth. *Some examples include (but are not limited to):*

- Grooming residents as they wish to be groomed (e.g., hair combed and styled, beards shaved/trimmed, nails clean and clipped);

- *Encouraging and* assisting residents to dress in their own clothes appropriate to the time of day and individual preferences *rather than hospital-type gowns*;
- Assisting residents to attend activities of their own choosing;
- Labeling each resident's clothing in a way that respects his or her dignity (e.g., placing labeling on the inside of shoes and clothing);
- Promoting resident independence and dignity in dining such as avoidance of:
 - Day-to-day use of plastic cutlery and paper/plastic dishware;
 - Bibs (*also known as clothing protectors*) instead of napkins (*except by resident choice*);
 - *Staff standing over residents while assisting them to eat*;
 - *Staff interacting/conversing only with each other rather than with residents. while assisting residents*;
- Respecting residents' private space and property (e.g., not changing radio or television station without resident's permission, knocking on doors and requesting permission to enter, closing doors as requested by the resident, not moving or inspecting resident's personal possessions without permission);
- Respecting residents *by* speaking respectfully, addressing the resident with a name of the resident's choice, *avoiding use of labels for residents such as "feeders,"* not excluding residents from conversations or discussing residents in community settings *in which others can overhear private information*;
- Focusing on residents as individuals when they talk to them and addressing residents as individuals when providing care and services;
- *Maintaining an environment in which there are no signs posted in residents' rooms or in staff work areas able to be seen by other residents and/or visitors that include confidential clinical or personal information (such as information about incontinence, cognitive status). It is allowable to post signs with this type of information in more private locations such as the inside of a closet or in staff locations that are not viewable by the public. An exception can be made in an individual case if a resident or responsible family member insists on the posting of care information at the bedside (e.g., do not take blood pressure in right arm). This does not prohibit the display of resident names on their doors nor does it prohibit display of resident memorabilia and/or biographical information in or outside their rooms with their consent or the consent of the responsible party if the resident is unable to give consent. (This restriction does not include the CDC isolation*

precaution transmission-based signage for reasons of public health protection, as long as the sign does not reveal the type of infection);

- *Grooming residents as they wish to be groomed (e.g., removal of facial hair for women, maintaining the resident's personal preferences regarding hair length/style, facial hair for men, and clothing style). NOTE: For issues of failure to keep dependent residents' faces, hands, fingernails, hair, and clothing clean, refer to Activities of Daily Living (ADLs), Tag F312;*
- *Maintaining resident privacy of body including keeping residents sufficiently covered, such as with a robe, while being taken to areas outside their room, such as the bathing area (one method of ensuring resident privacy and dignity is to transport residents while they are dressed and assist them to dress and undress in the bathing room). NOTE: For issues of lack of visual privacy for a resident while that resident is receiving ADL care from staff in the bedroom, bathroom, or bathing room, refer to §483.10(e), Privacy and Confidentiality, Tag F164. Use Dignity F241 for issues of visual privacy while residents are being transported through common areas or are uncovered in their rooms and in view of others when not receiving care; and*
- *Refraining from practices demeaning to residents such as keeping urinary catheter bags uncovered, refusing to comply with a resident's request for toileting assistance during meal times, and restricting residents from use of common areas open to the general public such as lobbies and restrooms, unless they are on transmission-based isolation precautions or are restricted according to their care planned needs. An exception can be made for certain restrooms that are not equipped with call cords for safety.*

Procedures: §483.15(a)

For a sampled resident, use *resident and family interviews as well as information from the Resident Assessment Instrument (RAI)* to consider the resident's former life style and personal choices made while in the facility to obtain a picture of *the resident's individual needs and preferences.*

Throughout the survey, observe: Do staff show respect for residents? When staff interact with a resident, do staff pay attention to the resident as an individual? Do staff respond in a timely manner to the resident's requests for assistance? *Do they explain to the resident what care they are doing or where they are taking the resident? Do staff groom residents as they wish to be groomed?*

In group activities, do staff *members* focus attention on the group of residents? Or, do staff *members* appear distracted when they interact with residents? For example, do *they* continue to talk with each other while doing a "task" for a resident(s) as if *the resident* were not present?

Are residents restricted from using common areas open to the public such as the lobby or common area restrooms? If so, determine if the particular area is restricted to the resident for

the resident's safety. For example, does the restroom lack a call cord for safety? If so, that restroom may be restricted from resident use. Are there signs regarding care information posted in view in residents' rooms? If these are observed, determine if such signs are there by resident or family direction. If so, these signs are allowable. If a particular resident has been restricted from common areas by the care team, confer with staff to determine the reason for the restriction.

Do staff members communicate personal information about residents in a way that protects the confidentiality of the information and the dignity of residents? This includes both verbal and written communications such as signage in resident rooms and lists of residents with certain conditions such as incontinence and pressure ulcers (or verbal staff reports of these confidential matters) at nursing stations in view or in hearing of residents and visitors. This does not include clinical information written in a resident's record.

Determine if staff *members respond in a dignified manner to* residents with cognitive impairments, such as *not contradicting* what residents are saying, and addressing what residents are trying to express (*the agenda*) behind their behavior. *For example, a resident with dementia may be attempting to exit the building in the afternoon, but the actual intent is a desire to meet her children at the school bus, as she did when a young mother. Allowing the behavior under supervision such as walking with the resident without challenging or disputing the resident's intent and conversing with the resident about the desire (tell me about your children) may assist the behavior to dissipate, and the staff member can then invite the resident to come along to have a drink or snack or participate in a task or activity. For more information about "agenda" behavior, see Rader, J., Tornquist, E, Individualized Dementia Care: Creative, Compassionate Approaches, 1995, New York: Springer Publishing Company, or Fazio, S. Seman, D., Stansell, J., Rethinking Alzheimer's Care. Baltimore: Health Professions Press, 1999.*

If the survey team identifies potential compliance issues regarding the privacy of residents during treatment, refer to *§483.10(e), Privacy and Confidentiality, Tag F164.*

F242

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§483.15(b) - Self-Determination and Participation

The resident has the right to--

- (1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;**
- (2) Interact with members of the community both inside and outside the facility; and**
- (3) Make choices about aspects of his or her life in the facility that are significant to the resident.**

Intent: §483.15(b)

The intent of this requirement is to specify that the facility must create an environment that is respectful of the right of each resident to exercise his or her autonomy regarding what the resident considers to be important facets of his or her life. *This includes actively seeking information from the resident regarding significant interests and preferences in order to provide necessary assistance to help residents fulfill their choices over aspects of their lives in the facility.*

Interpretive Guidelines: §483.15(b)

Many types of choices are mentioned in this regulatory requirement. The first of these is choice over “activities.” It is an important right for a resident to have choices to participate in preferred activities, whether they are part of the formal activities program or self-directed. However, the regulation at §483.15(f) Activities, F248 covers both formal and self-directed activities. For issues concerning choices over activities, use Tag F248.

The second listed choice is “schedules.” Residents have the right to have a choice over their schedules, consistent with their interests, assessments and plans of care. Choice over “schedules” includes (but is not limited to) choices over the schedules that are important to the resident, such as daily waking, eating, bathing, and the time for going to bed at night. Residents have the right to choose health care schedules consistent with their interests and preferences, and the facility should gather this information in order to be proactive in assisting residents to fulfill their choices. For example, if a resident mentions that her therapy is scheduled at the time of her favorite television program, the facility should accommodate the resident to the extent that it can.

If the resident refuses a bath because he or she prefers a shower *or a different bathing method such as in-bed bathing*, prefers it at a different time of day or on a different day, does not feel well that day, is uneasy about the aide assigned to help or is worried about falling, the staff member should make the necessary adjustments realizing the resident is not refusing to be clean but refusing the bath under the circumstance provided. The facility staff should meet with the resident to make adjustments in the care plan to accommodate his or her preferences.

NOTE: *For issues regarding choice over arrangement of furniture and adaptations to the resident’s bedroom and bathroom, see §483.15(e)(1), Accommodation of Needs, Tag F246.*

According to this requirement at §483.15(b)(3), residents have the right to make choices about aspects of their lives that are significant to them. One example includes the right to choose to room with a person of the resident’s choice if both parties are residents of the facility, and both consent to the choice.

If a facility changes its policy to prohibit smoking, it must allow current residents who smoke to continue smoking in an area that maintains the quality of life for these residents. Weather

permitting, this may be an outside area. Residents admitted after the facility changes its policy must be informed of this policy at admission. (See [§483.10\(b\)\(1\)](#)).

Procedures: §483.15(b)

During resident and family interviews, determine if the resident is able to exercise her/his choices regarding personal activities, including whether the facility provides assistance as needed to the resident to be able to engage in their preferred activities on a routine basis.

During resident and family interviews, determine what time the resident awakens and goes to sleep, and whether this is the resident's preferred time. Also determine whether the facility is honoring the resident's preferences regarding the timing (morning, afternoon, evening and how many times a week) for bathing and also the method (shower, bath, in-bed bathing). Obtain further information as necessary from observations and staff interviews. If the resident is unaware of the right to make such choices, determine whether the facility has actively sought information from the resident and/or family (for a resident unable to express choices) regarding preferences and whether these choices have been made known to caregivers.

F246

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§483.15(e) - Accommodation of Needs

A resident has the right to --

§483.15(e)(1) - Reside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and

Interpretive Guidelines: §483.15(e)(1)

“Reasonable accommodations of individual needs and preferences,” means the facility’s efforts to individualize the resident’s *physical* environment. *This includes the physical environment of the resident’s bedroom and bathroom, as well as individualizing as much as feasible the facility’s common living areas.* The facility’s physical environment and staff behaviors should be directed toward assisting the resident in maintaining and/or achieving independent functioning, dignity, and well-being to the extent possible in accordance with the resident’s own *needs and* preferences.

NOTE: *For issues regarding the psychosocial environment experienced by the resident, such as being ignored by staff, being made to feel unwelcome or that their care needs are burdensome to staff, refer to §483.15(a), Tag F241, Dignity.*

The facility is responsible for evaluating each resident's unique needs and preferences and ensuring that the environment accommodates the resident to the extent reasonable and does not endanger the health or safety of individuals or other residents. This includes making adaptations of the resident's bedroom and bathroom furniture and fixtures, as necessary to ensure that the resident can (if able):

- *Open and close drawers and turn faucets on and off;*
- *See her/himself in a mirror and have toiletry articles easily within reach while using the sink;*
- *Open and close bedroom and bathroom doors, easily access areas of their room and bath, and operate room lighting;*
- *Use bathroom facilities as independently as possible with access to assistive devices (such as grab bars within reach) if needed; and*
- *Perform other desired tasks such as turning a table light on and off, using the call bell; etc.*

NOTE: *If a resident cannot reach her/his clothing in the closet, if the resident does not have private closet space, or if the resident does not have needed furniture (such as a chair) refer to §483.15(h)(4) and §483.70(d)(2)(iv), Tag F461.*

The facility should strive to provide reasonably sufficient electric outlets to accommodate the resident's need to safely use her/his electronic personal items, as long as caution is maintained to not overload circuits. The bedroom should include comfortable seating for the resident and task lighting that is sufficient and appropriate for the resident's chosen activities. The facility should accommodate the resident's preferences for arrangement of furniture to the extent space allows, including facilitating resident choice about where to place their bed in their room (as long as the roommate, if any, concurs). There may be some limitations on furniture arrangement, such as not placing a bed over a heat register, or not placing a bed far from the call cord so as to make it unreachable from the bedside.

The facility should also ensure that furniture and fixtures in common areas frequented by residents are accommodating of physical limitations of residents. Furnishings in common areas should enhance residents' abilities to maintain their independence, such as being able to arise from living room furniture. The facility should provide seating with appropriate seat height, depth, firmness, and with arms that assist residents to arise to a standing position. One method of accommodating residents of different heights and differing types of needs in common areas is through the use of different sizes and types of furniture.

NOTE: *If residents are prohibited from using common area restrooms, the lobby, or dining rooms outside of meal times, refer to §483.15(a), Tag F241, Dignity. For issues of sufficient lighting, refer to §483.15(h)(5), Tag F256, Adequate and Comfortable Lighting.*

Staff should strive to reasonably accommodate the resident's needs and preferences as the resident makes use of the physical environment. This includes ensuring that items the resident needs to use are available and accessible to encourage confidence and independence (such as grooming supplies reachable near the bathroom sink), needed adaptive equipment (such as door handle grippers) are maintained in place, and functional furniture is arranged to accommodate the resident's needs and preferences, etc. This does not apply to residents who need extensive staff assistance and are incapable of using these room adaptations.

Staff should interact with the resident in a way that takes into account the physical limitations of the resident, assures communication, and maintains respect; for example, getting down to eye level with a resident who is sitting, speaking so a resident with limited hearing who reads lips can see their mouth when they speak, utilizing a hearing amplification device such as a pocket-talker if the resident has such a device, etc. Residents who use glasses, hearing aids, or similar devices should have them in use (except when the resident refuses), clean, and functional.

Procedures: §483.15(e)(1)

Observe the resident using her/his room and common areas and interview the resident if possible to determine if the environment has been adapted as necessary to accommodate the resident's needs and preferences, as described above. Observe staff/resident interactions to determine if staff members adapt their interactions so that a resident with limited sight or hearing can see and hear them. Are hearing aids and glasses in use, clean, and functional? Determine if staff keep needed items within the resident's reach and provide necessary assistance (set up) to help maintain the resident's independent use of their environment to the maximum extent possible for the resident. Determine if the resident has the call system within reach and is able to use it if desired. (This does not include a resident who is too severely impaired to comprehend or is comatose.) Some residents need adaptations for limited hand dexterity or other physical limitations, such as larger buttons that can be pushed by a fist or bright colors to accommodate visual limitations.

Review the extent to which the facility adapts the physical environment to enable residents to maintain unassisted functioning. These adaptations include, but are not limited to:

- Furniture and adaptive equipment that enable residents to stand independently, transfer without assistance (e.g., arm supports, correct chair height *and depth*, firm support), maintain body symmetry, participate in resident-preferred activities, and promote mobility and independence for residents in going to the bathroom (e.g., grab bars, elevated toilet seats).
- Easily useable fixtures, drawer handles, faucets, etc.;
- Personal items kept within reach for independent use in the bathroom; and
- Bedroom furniture arranged to the residents' preferences as much as possible.

Determine if staff use appropriate measures to facilitate communication with residents who have difficulty communicating. *For example, do staff communicate at eye level, and do they remove a resident from noisy surroundings if that resident is having difficulty hearing what is said?*

If the facility has outdoor smoking areas, how have they accommodated residents when the weather is inclement?

F247

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

A resident has a right to—

§483.15(e)(2) - Receive notice before the resident's room or roommate in the facility is changed.

Interpretive Guidelines §483.15(e)(2)

The facility should be sensitive to the trauma a move or change of roommate causes some residents, and should attempt to be as accommodating as possible. This includes learning the resident's preferences and taking them into account when discussing changes of rooms or roommates and the timing of such changes. For a resident who is being moved at the facility's request, a staff member should explain to the resident the reason for the move and support the resident by providing the opportunity to see the new location and meet the new roommate, and to ask questions about the move. For a resident who is receiving a new roommate, a staff member should give the resident as much notice and information about the new person as possible, while maintaining confidentiality regarding medical information. The facility should support a resident whose roommate has passed away by providing a little time to adjust (a couple days if possible) before moving another person into the room, depending on the resident's level of connection to the previous roommate. The facility should provide necessary social services for a resident who is grieving over the death of a roommate. If the survey team identifies potential compliance issues related to social services, refer to §483.15(g)(1), Social Services, Tag F250.

F252

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§483.15(h) - Environment

The facility must provide--

§483.15(h)(1) - A safe, clean, comfortable and homelike environment, allowing the resident to use his or her personal belongings to the extent possible;

Interpretive Guidelines: §483.15(h)(1)

For purposes of this requirement, “environment” refers to any environment in the facility that is frequented by residents, including (*but not limited to*) the residents’ rooms, bathrooms, hallways, *dining areas, lobby, outdoor patios*, therapy areas and activity areas. A determination of “homelike” should include the resident’s opinion of the living environment.

A “homelike environment” is one that de-emphasizes the institutional character of the setting, to the extent possible, and allows the resident to use those personal belongings that support a homelike environment. A personalized, homelike environment recognizes the individuality and autonomy of the resident, provides an opportunity for self-expression, and encourages links with the past and family members. *The intent of the word “homelike” in this regulation is that the nursing home should provide an environment as close to that of the environment of a private home as possible. This concept of creating a home setting includes the elimination of institutional odors, and practices to the extent possible. Some good practices that serve to decrease the institutional character of the environment include the elimination of:*

- Overhead paging and piped-in music throughout the building;
- *Meal service in the dining room using trays (some residents may wish to eat certain meals in their rooms on trays);*
- *Institutional signage labeling work rooms/closets in areas visible to residents and the public;*
- *Medication carts (some innovative facilities store medications in locked areas in resident rooms);*
- *The widespread and long-term use of audible (to the resident) chair and bed alarms, instead of their limited use for selected residents for diagnostic purposes or according to their care planned needs. These devices can startle the resident and constrain the resident from normal repositioning movements, which can be problematic. For more information about the detriments of alarms in terms of their effects on residents and alternatives to the widespread use of alarms, see the 2007 CMS satellite broadcast training, “From Institutionalized to Individualized Care,” Part 1, available through the National Technical Information Service and other sources such as the Pioneer Network;*
- *Mass purchased furniture, drapes and bedspreads that all look alike throughout the building (some innovators invite the placement of some residents’ furniture in common areas); and*
- *Large, centrally located nursing/care team stations.*

Many facilities cannot immediately make these types of changes, but it should be a goal for all facilities that have not yet made these types of changes to work toward them. A nursing facility

is not considered non-compliant if it still has some of these institutional features, but the facility is expected to do all it can within fiscal constraints to provide an environment that enhances quality of life for residents, in accordance with resident preferences.

A “homelike” or homey environment is not achieved simply through enhancements to the physical environment. It concerns striving for person-centered care that emphasizes individualization, relationships and a psychosocial environment that welcomes each resident and makes her/him comfortable.

In a facility in which most residents come for a short-term stay, the "good practices" listed in this section are just as important as in a facility with a majority of long term care residents. A resident in the facility for a short-term stay would not typically move her/his bedroom furniture into the room, but may desire to bring a television, chair or other personal belongings to have while staying in the facility.

Although the regulatory language at this tag refers to “safe,” “clean,” “comfortable,” and “homelike,” for consistency, the following specific F-tags should be used for certain issues of safety and cleanliness:

- *For issues of safety of the environment, presence of hazards and hazardous practices, use §483.25(h), Accidents, Tag F323;*
- *For issues of fire danger, use §483.70(a) Life Safety from Fire, Tag F454;*
- *For issues of cleanliness and maintenance of common living areas frequented by residents, use §483.15(h)(2), Housekeeping and Maintenance, Tag F254;*
- *For issues of cleanliness of areas of the facility used by staff only (e.g., break room, medication room, laundry, kitchen, etc.) or the public only (e.g., parking lot), use §483.70(h), Tag F465 Other Environmental Conditions; and*
- *Although this Tag can be used for issues of general comfortableness of the environment such as furniture, there are more specific Tags to use for the following issues:*
 - *For issues of uncomfortable lighting, use §483.15(h)(5), Tag F256 Adequate and Comfortable Lighting;*
 - *For issues of uncomfortable temperature, use §483.15(h)(6), Tag F257 Comfortable and Safe Temperature Levels; and*
 - *For issues of uncomfortable noise levels, use §483.15(h)(7), Tag F258 Comfortable Sound Levels.*

Procedures: §483.15(h)(1)

During interviews, ask residents and families whether they think the facility is striving to be as homelike as possible, and whether they have been invited to bring in desired personal property items (within space constraints). Observe bedrooms of sampled residents for personalization.

By observing the residents' surroundings, what can the survey team learn about their everyday life and interests? Their life prior to residing in the facility? Observe for family photographs, books and magazines, bedspreads, knickknacks, mementos, and furniture that belong to the residents. For residents who have no relatives or friends, and have few assets, determine the extent to which the *facility* has assisted these residents to make their rooms homelike, if they so desire. *If potential issues are discovered, ask responsible staff about their efforts to provide a homelike environment and to invite residents to bring in personal belongings.*

NOTE: *Many residents who are residing in the facility for a short-term stay may not wish to personalize their rooms nor bring in many belongings. If they express no issues regarding homelike environment or personal property during interviews, there is no need to conduct further investigations for those residents.*

F256

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§483.15(h)(5) - Environment

The facility must provide –

§483.15(h)(5) Adequate and comfortable lighting levels in all areas;

Interpretive Guidelines §483.15(h)(5)

“Adequate lighting” means levels of illumination suitable to tasks the resident chooses to perform or the facility staff must perform.

“Comfortable lighting” means lighting *that* minimizes glare and provides maximum resident control, where feasible, over the intensity, location, and direction of illumination so that visually impaired residents can maintain or enhance independent functioning.

As a person ages, their eyes usually change so that they require more light to see what they are doing and where they are going. An adequate lighting design has these features:

- *Sufficient lighting with minimum glare in areas frequented by residents;*

- *Even light levels in common areas and hallways, avoiding patches of low light caused by too much space between light fixtures, within limits of building design constraints;*
- *Use of daylight as much as possible;*
- *Elimination of high levels of glare produced by shiny flooring and from unshielded window openings (no-shine floor waxes and light filtering curtains help to alleviate these sources of glare);*
- *Extra lighting, such as table and floor lamps to provide sufficient light to assist residents with tasks such as reading;*
- *Lighting for residents who need to find their way from bed to bathroom at night (e.g., red colored night lights preserve night vision); and*
- *Dimming switches in resident rooms (where possible and when desired by the resident) so that staff can tend to a resident at night with limited disturbances to them or a roommate. If dimming is not feasible, another option may be for staff to use flashlights/pen lights when they provide night care.*

Some facilities may not be able to make some of these changes due to voltage or wiring issues. For more information about adequate lighting design for long term care facilities, a facility may consult the lighting guidance available from the Illuminating Engineering Society of North America, which provides authoritative minimum lighting guidance.

The following are additional visual enhancements a facility should consider making as fiscal constraints permit in order to make it easier for residents with impaired vision to see and use their environment:

- *Use of contrasting color between flooring and baseboard to enable residents with impaired vision to determine the horizontal plane of the floor;*
- *Use of contrast painting of bathroom walls and/or contrasting colored toilet seats so that residents with impaired vision can distinguish the toilet fixture from the wall; and*
- *Use of dishware that contrasts with the table or tablecloth color to aid residents with impaired vision to see their food.*

Procedures: §483.15(h)(5)

Ask residents who receive resident interviews if they have sufficient lighting in all the areas they frequent in the facility that meets their needs, including (but not limited to):

- *Available task lighting if this is desired;*
- *Elimination of excessive glare from windows and flooring;*

- *Wayfinding nighttime lighting for those residents who need it to find the bathroom); and*
- *Lights that can be dimmed, if desired, to eliminate being awakened by staff who are tending to their roommate.*

Observe sampled residents throughout the survey and note if they are having difficulty reading or doing tasks due to insufficient lighting, or if they are wearing sunglasses or visors indoors due to glare, if they have difficulty seeing food on their plate, experiencing squinting or shading their eyes from glare or other signs that lighting does not meet their needs.

If these are observed, question the resident (if they are able to converse) as to how the lighting situation assists or hinders their pursuit of activities and independence. Discuss with staff these issues, their efforts to alleviate the problems, and any electrical issues in the building's design that prevent making some of these changes.

F371

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§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: *The food procurement requirements for facilities are not intended to restrict resident choice. All residents have the right to accept food brought to the facility by any visitor(s) for any resident.*

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	<ul style="list-style-type: none"> • Salmonella 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to ready-to-eat foods
Poultry, raw	<ul style="list-style-type: none"> • Campylobacter • Salmonella 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to ready-to-eat foods
	<ul style="list-style-type: none"> • Clostridium perfringens 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature
Meat, raw	<ul style="list-style-type: none"> • E. coli O157:H7 • Salmonella • Campylobacter 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to ready-to-eat foods
	<ul style="list-style-type: none"> • Clostridium perfringens 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature
Infectious food workers	<ul style="list-style-type: none"> • Norovirus • Hepatitis A virus • Shigella • Salmonella 	<ul style="list-style-type: none"> • Exclusion of infectious food workers • Proper hand-washing procedures • Avoid bare-hand contact with ready-to-eat foods
	<ul style="list-style-type: none"> • Staphylococcus aureus 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • E. coli O157:H7 • Salmonella • Norovirus • Hepatitis A virus • Shigella 	<ul style="list-style-type: none"> • Wash prior to use (unless pre-washed) • Keep cut and raw fruits and vegetables refrigerated
Ready-to-eat meat and poultry products	<ul style="list-style-type: none"> • Listeria monocytogenes 	<ul style="list-style-type: none"> • Proper refrigeration during storage
Pasteurized dairy products	<ul style="list-style-type: none"> • Listeria monocytogenes 	<ul style="list-style-type: none"> • Proper refrigeration during storage
Ice	<ul style="list-style-type: none"> • Norovirus 	<ul style="list-style-type: none"> • 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

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/>.
- ² The Partnership for Food Safety and Education. (2006). Food Safety Glossary. <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm>
- 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:
 - o Determine whether food meets safe and sanitary conditions related to when, where, and how the food was received for residents consumption.
 - o Check invoices from food vendors when necessary to verify the source of food acquisition and the date of delivery.
- Food preparation procedures:
 - o Observe staff food handling practices, such as proper hand washing, the appropriate use of utensils, glove, and hairnets;

- o Observe food labeling and dates (e.g., used by dates);
- o 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);
- o 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;
- o 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
- o 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
 - o 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
 - o 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
 - o 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
 - o 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
 - o 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
 - o 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
 - o 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
 - o 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
 - o 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
 - o 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
 - o 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.

F461

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§483.70(d)(1)(vi) - Resident Rooms

Bedrooms must --

§483.70(d)(1)(vi) - Have at least one window to the outside; and

Interpretive Guidelines **§483.70(d)(1)(vi)**

A facility with resident room windows, as defined by Section *18.3.8 of the 2000* edition of the Life Safety Code, or that open to an atrium in accordance with Life Safety Code can meet this requirement for a window to the outside.

In addition to conforming with the Life Safety Code, this requirement was included to assist the resident’s orientation to day and night, weather, and general awareness of space outside the facility. The facility is required to provide for a “safe, clean, comfortable and homelike environment” by deemphasizing the institutional character of the setting, to the extent possible. Windows are an important aspect in assuring the homelike environment of a facility. *The allowable window sill height shall not exceed 36 inches. The window may be operable.*

Probes: §483.70(d)(1)(vi)

Is there at least one window to the outside?

§483.70(d)(1)(vii) Have a floor at or above grade level.

Interpretive Guidelines §483.70(d)(1)(vii)

“At or above grade level” means a room in which *the room* floor is at or *above the surrounding exterior* ground level.

Probes: §483.70(d)(1)(vii)

Are the bedrooms at or above ground level?

§483.70(d)(2) -The facility must provide each resident with--

- (i) A separate bed of proper size and height for the convenience of the resident;**
- (ii) A clean, comfortable mattress;**
- (iii) Bedding, appropriate to the weather and climate; and**

Probes: §483.70(d)(2)(i), (ii), and (iii)

Are mattresses clean and comfortable?

Is bedding appropriate to weather and climate?

§483.70(d)(2)(iv) Functional furniture appropriate to the resident’s needs, and individual closet space in the resident’s bedroom with clothes racks and shelves accessible to the resident.

§483.15(h)(4) Private closet space in each resident room, as specified in §483.70(d)(2)(iv) of this part;

Interpretive Guidelines: §483.70(d)(2)(iv) *and* §483.15(h)(4)

“Functional furniture appropriate to the resident’s needs” means that the furniture in each resident’s room contributes to the resident attaining or maintaining his or her highest practicable level of independence and well-being. In general, furnishings include a place to put clothing away in an organized manner that will let it remain clean, free of wrinkles, and accessible to the resident while protecting it from casual access by others; a place to put personal effects such as pictures and a bedside clock, and furniture suitable for the comfort of the resident and visitors (e.g., a chair).

For issues with arrangement of room furniture according to resident needs and preferences, see §483.15(e), Accommodation of Needs, Tag F246.

“*Clothes racks and shelves accessible to the resident*” means that residents can get to **and reach** their **hanging** clothing whenever they choose.

“*Private closet space*” means that each resident’s clothing is kept separate from clothing of roommate(s).

The term “closet space” is not necessarily limited to a space installed into the wall. For some facilities without such installed closets, compliance may be attained through the use of storage furniture such as wardrobes. Out-of-season items may be stored in alternate locations outside the resident’s room.

Probes: §483.70(d)(2)(iv) and §483.15(h)(4)

Functional furniture: Is there functional furniture, appropriate to resident’s needs?

Closet space: Is there individual closet space with accessible clothes racks and shelves? *If the resident is able to use a closet, can the resident get to and reach her/his hanging clothing as well as items from shelves in the closet?*

§483.70(d)(3) - CMS, or in the case of a nursing facility the survey agency, may permit variations in requirements specified in paragraphs (d)(1)(i) and (ii) of this section relating to rooms in individual cases when the facility demonstrates in writing that the variations--

- (i) Are in accordance with the special needs of the residents; and**
- (ii) Will not adversely affect residents’ health and safety.**

Interpretive Guidelines: §483.70(d)(3)

A variation must be in accordance with the special needs of the residents and must not adversely affect the health or safety of residents. Facility hardship is not part of the basis for granting a variation. Since the special needs of residents may change periodically, or different residents may be transferred into a room that has been granted a variation, variations must be reviewed and considered for renewal whenever the facility is certified. If the needs of the residents within the room have not changed since the last annual inspection, the variance should continue if the facility so desires.

Interpretive Guidelines: §483.70(d)(1)(i):

As residents are transferred or discharged from rooms with more than four residents, beds should be removed from the variance until the number of residents occupying the room does not exceed four.

F463

(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)

§483.70(f) Resident Call System

The nurses' station must be equipped to receive resident calls through a communication system from--

- (1) Resident rooms; and
- (2) Toilet and bathing facilities.

Intent: §483.70(f)

The intent of this requirement is that residents, when in their rooms and toilet and bathing areas, have a means of directly contacting caregivers. In the case of an existing centralized nursing station, this communication may be through audible or visual signals and may include "wireless systems." *In those cases in which a facility has moved to decentralized nurse/care team work areas, the intent may be met through other electronic systems that provide direct communication from the resident to the caregivers.*

Interpretive Guidelines: §483.70(f)

This requirement is met only if all portions of the system are functioning (e.g., system is not turned off at the nurses' station, the volume too low to be heard, the light above a room or rooms is not working), *and calls are being answered. For wireless systems, compliance is met only if staff who answer resident calls, have functioning devices in their possession, and are answering resident calls.*

Probes: §483.70(f)

Is there a functioning communication system from rooms, toilets, and bathing facilities *in which resident calls are received and answered by staff?*
