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Department of Health &
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SUBJECT: Revisions to Appendix PP – Guidance to Surveyors for Long Term Care Facilities

I. SUMMARY OF CHANGES: This revision includes interpretive guidelines, an investigative protocol, and severity guidance for 42 CFR 483.25(h)(1) and (2) Accidents. This information is intended to replace all current text contained in the Guidance to Surveyors for current Tags F323 and F324. The guidance for F323 and F324 is combined under one tag, F323.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: August 6, 2007

IMPLEMENTATION DATE: August 6, 2007

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

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

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/§483.25(h)(1) and (2)/F323/Accidents
D	Appendix PP/§483.25(h)(2)/F324

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.**

F323

(Rev. 27; Issued: 08-17-07; Effective/Implementation: 08-17-07)

§483.25(h) Accidents.

The facility must ensure that –

(1) The resident environment remains as free from accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

Intent: 42 CFR 483.25(h) (1) and (2) Accidents and Supervision

The intent of this requirement is to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents. This includes:

- *Identifying hazard(s) and risk(s);*
- *Evaluating and analyzing hazard(s) and risk(s);*
- *Implementing interventions to reduce hazard(s) and risk(s); and*
- *Monitoring for effectiveness and modifying interventions when necessary.*

DEFINITIONS

Definitions are provided to clarify terms related to providing supervision and other interventions to prevent accidents.

- *“Accident” refers to any unexpected or unintentional incident, which may result in injury or illness to a resident. This does not include adverse outcomes that are a direct consequence of treatment or care that is provided in accordance with current standards of practice (e.g., drug side effects or reaction).*
 - *“Avoidable Accident” means that an accident occurred because the facility failed to:*
 - *Identify environmental hazards and individual resident risk of an accident, including the need for supervision; and/or*
 - *Evaluate/analyze the hazards and risks; and/or*

- *Implement interventions, including adequate supervision, consistent with a resident’s needs, goals, plan of care, and current standards of practice in order to reduce the risk of an accident; and/or*
 - *Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current standards of practice.*
 - *“Unavoidable Accident” means that an accident occurred despite facility efforts to:*
 - *Identify environmental hazards and individual resident risk of an accident, including the need for supervision; and*
 - *Evaluate/analyze the hazards and risks; and*
 - *Implement interventions, including adequate supervision, consistent with the resident’s needs, goals, plan of care, and current standards of practice in order to reduce the risk of an accident; and*
 - *Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current standards of practice.*
 - *“Assistance Device” or “Assistive Device” refers to any item (e.g., fixtures such as handrails, grab bars, and devices/equipment such as transfer lifts, canes, and wheelchairs, etc.) that is used by, or in the care of a resident to promote, supplement, or enhance the resident’s function and/or safety.*
- NOTE: The currently accepted nomenclature refers to “assistive devices.” Although the term “assistance devices” is used in the regulation, the Guidance provided in this document will refer to “assistive devices.”*
- *“Environment” refers to the resident environment. (See definition for “resident environment.”)*
 - *“Fall” refers to unintentionally coming to rest on the ground, floor, or other lower level, but not as a result of an overwhelming external force (e.g., resident pushes another resident). An episode where a resident lost his/her balance and would have fallen, if not for staff intervention, is considered a fall. A fall without injury is still a fall. Unless there is evidence suggesting otherwise, when a resident is found on the floor, a fall is considered to have occurred.¹*
 - *“Hazards” refer to elements of the resident environment that have the potential to cause injury or illness.*

- *“Hazards over which the facility has control” are those hazards in the resident environment where reasonable efforts by the facility could influence the risk for resulting injury or illness.*
- *“Free of accident hazards as is possible” refers to being free of accident hazards over which the facility has control.*
- *“Resident environment” includes the physical surroundings to which the resident has access (e.g., room, unit, common use areas, and facility grounds, etc.).*
- *“Risk” refers to any external factor or characteristic of an individual resident that influences the likelihood of an accident.*
- *“Supervision/Adequate Supervision” refers to an intervention and means of mitigating the risk of an accident. Facilities are obligated to provide adequate supervision to prevent accidents. Adequate supervision is defined by the type and frequency of supervision, based on the individual resident’s assessed needs and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident.*

OVERVIEW

Numerous and varied accident hazards exist in everyday life. Not all accidents are avoidable. The frailty of some residents increases their vulnerability to hazards in the resident environment and can result in life threatening injuries. It is important that all facility staff understand the facility’s responsibility, as well as their own, to ensure the safest environment possible for residents.

The facility is responsible for providing care to residents in a manner that helps promote quality of life. This includes respecting residents’ rights to privacy, dignity and self determination, and their right to make choices about significant aspects of their life in the facility.

For various reasons, residents are exposed to some potential for harm. Although hazards should not be ignored, there are varying degrees of potential for harm. It is reasonable to accept some risks as a trade off for the potential benefits, such as maintaining dignity, self-determination, and control over one’s daily life. The facility’s challenge is to balance protecting the resident’s right to make choices and the facility’s responsibility to comply with all regulations.

The responsibility to respect a resident’s choices is balanced by considering the potential impact of these choices on other individuals and on the facility’s obligation to protect the residents from harm. The facility has a responsibility to educate a resident, family, and staff regarding significant risks related to a resident’s choices. Incorporating a

resident's choices into the plan of care can help the facility balance interventions to reduce the risk of an accident, while honoring the resident's autonomy. Consent by resident or responsible party alone does not relieve the provider of its responsibility to assure the health, safety, and welfare of its residents, including protecting them from avoidable accidents. While Federal regulations affirm the resident's right to participate in care planning and to refuse treatment, the regulations do not create the right for a resident, legal surrogate, or representative to demand the facility use specific medical interventions or treatments that the facility deems inappropriate. The regulations hold the facility ultimately accountable for the resident's care and safety. Verbal consent or signed consent forms do not eliminate a facility's responsibility to protect a resident from an avoidable accident.

An effective way for the facility to avoid accidents is to commit to safety and implement systems that address resident risk and environmental hazards to minimize the likelihood of accidents.^{2,3} A facility with a commitment to safety:

- Acknowledges the high-risk nature of its population and setting;*
- Develops a reporting system that does not place blame on the staff member for reporting resident risks and environmental hazards;*
- Involves all staff in helping identify solutions to ensure a safe resident environment;*
- Directs resources to address safety concerns; and*
- Demonstrates a commitment to safety at all levels of the organization.*

A SYSTEMS APPROACH

Establishing and utilizing a systematic approach to resident safety helps facilities comply with the regulations at 42 CFR §483.25(h)(1) and (2). Processes in a facility's system approach may include:

- Identification of hazards, including inadequate supervision, and a resident's risks of potentially avoidable accidents in the resident environment;*
- Evaluation and analysis of hazards and risks;*
- Implementation of interventions, including adequate supervision and assistive devices, to reduce individual risks related to hazards in the environment; and*
- Monitoring for effectiveness and modification of interventions when necessary.*

A key element of a systematic approach is the consistent application of a process to consistently address identified hazards and/or risks. Risks may pertain to individual

residents, groups of residents, or the entire facility. Hazards may include, but are not limited to, aspects of the physical plant, equipment, and devices that are defective or are not used properly (per manufacturer's specifications), are disabled/removed, or are not individually adapted or fitted to the resident's needs. An effective system not only identifies environmental hazards and the resident's risk for an avoidable accident, but also the resident's need for supervision.

Identifying and addressing risks, including the potential for accidents, includes consideration of the environment, the resident's risk factors, and the need for supervision, care, and assistive devices. This will allow the facility to communicate information about observed hazards, identify resident-specific information, develop and implement an individualized plan of care to address each resident's needs and goals, and to monitor the results of the planned interventions. The plan of care should strive to balance the resident's wishes with the potential impact on other residents.

A systematic approach allows the facility to adjust its responses depending on the urgency of the situation and the hazards identified. The system includes a means for communicating the observations of hazards and the recording of resident specific information. Risks identified by the facility can pertain to individual residents or groups of residents. The facility-centered approach addresses risks for groups of residents; whereas, the resident-directed approach addresses risks for the individual residents.

Identification of Hazards and Risks

Identification of hazards and risks is the process through which the facility becomes aware of potential hazards in the resident environment and the risk of a resident having an avoidable accident. All staff (e.g., professional, administrative, maintenance, etc.) are to be involved in observing and identifying potential hazards in the environment, while taking into consideration the unique characteristics and abilities of each resident. The facility should make a reasonable effort to identify the hazards and risk factors for each resident. Various sources provide information about hazards and risks in the resident environment. These sources may include, but are not limited to, quality assurance activities, environmental rounds, MDS/RAPs data, medical history and physical exam, and individual observation. This information is to be documented and communicated across all disciplines.

Evaluation and Analysis

Evaluation and analysis is the process of examining data to identify specific hazards and risks and to develop targeted interventions to reduce the potential for accidents. Interdisciplinary involvement is a critical component of this process. Analysis may include, for example, considering the severity of hazards, the immediacy of risk, and trends such as time of day, location, etc.

Both the facility-centered and resident-directed approaches include evaluating hazard and accident risk data, analyzing potential causes for each hazard and accident risk, and

identifying or developing interventions based on the severity of the hazards and immediacy of risk. Evaluations also look at trends such as time of day, location, etc.

Implementation of Interventions

Implementation refers to using specific interventions to try to reduce a resident's risks from hazards in the environment. The process includes: Communicating the interventions to all relevant staff, assigning responsibility, providing training as needed, documenting interventions (e.g., plans of action developed by the Quality Assurance Committee or care plans for the individual resident), and ensuring that the interventions are put into action.

Interventions are based on the results of the evaluation and analysis of information about hazards and risks and are consistent with relevant standards, including evidence-based practice. Development of interim safety measures may be necessary if interventions cannot immediately be implemented fully.

Facility-based interventions may include, but are not limited to, educating staff, repairing the device/equipment, and developing or revising policies and procedures. Resident-directed approaches may include implementing specific interventions as part of the plan of care, supervising staff and residents, etc. Facility records document the implementation of these interventions.

Monitoring and Modification

Monitoring is the process of evaluating the effectiveness of interventions. Modification is the process of adjusting interventions as needed to make them more effective in addressing hazards and risks.

Monitoring and modification processes include:

- (1) Ensuring that interventions are implemented correctly and consistently;*
- (2) Evaluating the effectiveness of interventions;*
- (3) Modifying or replacing interventions as needed and*
- (4) Evaluating the effectiveness of new interventions.*

An example of facility-specific modification is additional training of staff when equipment has been upgraded. An example of a resident-specific modification is revising the plan of care to reflect the resident's current condition and risk factors that may have changed since the previous assessment.

SUPERVISION

Supervision is an intervention and a means of mitigating accident risk. Facilities are obligated to provide adequate supervision to prevent accidents. Adequacy of supervision is defined by type and frequency, based on the individual resident's assessed needs, and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident. Tools or items such as personal alarms can help to monitor a resident's activities, but do not eliminate the need for adequate supervision.

The resident environment may contain temporary hazards (e.g., construction, painting, housekeeping activities, etc.) that warrant additional supervision or alternative measures such as barriers to prevent access to affected areas of the resident environment.

Adequate supervision to prevent accidents is enhanced when the facility:

- Accurately assesses a resident and/or the resident environment to determine whether supervision to avoid an accident is necessary; and/or*
- Determines that supervision of the resident was necessary and provides supervision based on the individual resident's assessed needs and the risks identified in the environment.*

Resident Smoking

Some facilities permit residents to smoke tobacco products. In these facilities, assessment of the resident's capabilities and deficits determines whether or not supervision is required. If the facility identifies that the resident needs supervision for smoking, the facility includes this information in the resident's plan of care, and reviews and revises the plan periodically as needed.

The facility may designate certain areas for resident smoking. The facility must ensure precautions are taken for the resident's individual safety, as well as the safety of others in the facility. Such precautions may include smoking only in designated areas, supervising residents whose assessment and plans of care indicate a need for supervised smoking, and limiting the accessibility of matches and lighters by residents who need supervision when smoking. Smoking by residents when oxygen is in use is prohibited, and any smoking by others near flammable substances is also problematic. Additional measures may include informing all visitors of smoking policies and hazards.

Guidance concerning resident smoking regulations can be found in NFPA 101, the Life Safety Code at 19.7.4, Smoking, including requirements for signage, prohibiting smoking by residents classified as not responsible, and disposal of smoking materials. Refer to the guidance at 42 CFR 483.15(b)(3) [F242] for information about facilities that desire to be smoke-free.

Resident-to-Resident Altercations

NOTE: *An incident involving a resident who willfully inflicts injury upon another resident should be reviewed as abuse under the guidance for 42 CFR §483.13(b) at F223. “Willful” means that the individual intended the action itself that he/she knew or should have known could cause physical harm, pain, or mental anguish. Even though a resident may have a cognitive impairment, he/she could still commit a willful act. However, there are instances when a resident’s willful intent cannot be determined. In those cases, a resident-to-resident altercation should be reviewed under this tag, F323.*

It is important that a facility take reasonable precautions, including providing adequate supervision, when the risk of resident-to-resident altercation is identified, or should have been identified. Certain situations or conditions may increase the potential for such altercations, including, but not limited to:

- *A history of aggressive behaviors including striking out, verbal outbursts, or negative interactions with other resident(s); and/or*
- *Behavior that tends to disrupt or annoy others such as constant verbalization (e.g., crying, yelling, calling out for help), making negative remarks, restlessness, repetitive behaviors, taking items that do not belong to them, going into others’ rooms, drawers, or closets, and undressing in inappropriate areas. Although these behaviors may not be aggressive in nature, they may precipitate a negative response from others, resulting in verbal, physical, and/or emotional harm.*

The facility is responsible for identifying residents who have a history of disruptive or intrusive interactions, or who exhibit other behaviors that make them more likely to be involved in an altercation. The facility should identify the factors (e.g., illness, environment, etc.) that increase the risks associated with individual residents, including those (e.g., disease, environment) that could trigger an altercation. The care planning team reviews the assessment along with the resident and/or his/her representative, in order to identify interventions to try to prevent altercations.

The interventions listed below include supervision and other actions that could address potential or actual negative interactions:

- *Providing safe supervised areas for unrestricted movement;*
- *Eliminating or reducing underlying causes of distressed behavior such as boredom and pain;*
- *Monitoring environmental influences such as temperatures, lighting, and noise levels;*
- *Evaluating staffing assignments to ensure consistent staff who are more familiar with the resident and who thus may be able to identify changes in a resident’s condition and behavior;*

- *Evaluating staffing levels to ensure adequate supervision (if it is adequate, it is meeting the resident's needs); and*
- *Ongoing staff training and supervision, including how to approach a resident who may be agitated, combative, verbally or physically aggressive, or anxious, and how and when to obtain assistance in managing a resident with behavior symptoms.*

RESIDENT RISKS AND ENVIRONMENTAL HAZARDS

This section discusses common, but not all, potential hazards found in the resident environment.

***NOTE:** The information included in the following sections is based on current standards of practice or “best practice” models as described in the industry literature.*

The physical plant, devices, and equipment described in this section may not be hazards by themselves. But they can become hazardous when a vulnerable resident interacts with them. Some temporary hazards in the resident environment can affect most residents who have access to them (e.g., construction, painting, and housekeeping activities). Other situations may be hazardous only for certain individuals (e.g., accessible smoking materials).

In order to be considered hazardous, an element of the resident environment must be accessible to a vulnerable resident. Resident vulnerability is based on risk factors including the individual resident’s functional status, medical condition, cognitive abilities, mood, and health treatments (e.g., medications). Resident vulnerability to hazards may change over time. Ongoing assessment helps identify when elements in the environment pose hazards to a particular resident.

Certain sharp items, such as scissors, kitchen utensils, knitting needles, or other items, may be appropriate for many residents but hazardous for others with cognitive impairments. Handrails, assistive devices, and any surface that a resident may come in contact with may cause injury, if the surface is not in good condition and free from sharp edges or other hazards.

Improper actions or omissions by staff can create hazards in the physical plant (e.g., building and grounds), environment, and/or with devices and equipment. Examples of such hazards might include fire doors that have been propped open, disabled locks or latches, nonfunctioning alarms, buckled or badly torn carpets, cords on floors, irregular walking surfaces, improper storage and access to toxic chemicals, exposure to unsafe heating unit surfaces, and unsafe water temperatures. Other potential hazards may include furniture that is not appropriate for a resident (e.g., chairs or beds that are too low or unstable as to present a fall hazard) and lighting that is either inadequate or so intense as to create glare. Devices for resident care, such as pumps, ventilators, and assistive devices, may be hazardous when they are defective, disabled, or improperly used (i.e., used in a manner that is not per manufacturer’s recommendations or current standards of practice).

Resident Vulnerabilities

Falls and unsafe wandering/elopement are of particular concern. The following section reviews these issues along with some common potential hazards.

Falls - The MDS defines a fall as unintentionally coming to rest on the ground, floor, or other lower level but not as a result of an overwhelming external force (e.g., resident pushes another resident). An episode where a resident lost his/her balance and would have fallen, if not for staff intervention, is considered a fall. A fall without injury is still a fall. Unless there is evidence suggesting otherwise, when a resident is found on the floor, a fall is considered to have occurred.¹

Some factors that may result in resident falls include (but are not limited to) environmental hazards, underlying medical conditions, medication side effects, and other factors (e.g., lower extremity weakness, balance disorders, poor grip strength, functional and cognitive impairment, visual deficits, etc.).

Older persons have both a high incidence of falls and a high susceptibility to injury.⁴ Falls can have psychological and social consequences, including the loss of self-confidence to try to ambulate. Evaluation of the causal factors leading to a resident fall helps support relevant and consistent interventions to try to prevent future occurrences. Proper actions following a fall include:

- Ascertaining if there were injuries, and providing treatment as necessary;*
- Determining what may have caused or contributed to the fall;*
- Addressing the factors for the fall; and*
- Revising the resident's plan of care and/or facility practices, as needed, to reduce the likelihood of another fall.*

NOTE: *A fall by a resident does not necessarily indicate a deficient practice because not every fall can be avoided.*

Unsafe Wandering or Elopement - Wandering is random or repetitive locomotion. This movement may be goal-directed (e.g., the person appears to be searching for something such as an exit) or may be non-goal-directed or aimless. Non-goal-directed wandering requires a response in a manner that addresses both safety issues and an evaluation to identify root causes to the degree possible. Moving about the facility aimlessly may indicate that the resident is frustrated, anxious, bored, hungry, or depressed. Unsafe wandering and elopement can be associated with falls and related injuries.⁵

Unsafe wandering may occur when the resident at risk enters an area that is physically hazardous or that contains potential safety hazards (e.g., chemicals, tools, and equipment, etc.). Entering into another resident's room may lead to an altercation or contact with hazardous items.⁵

While alarms can help to monitor a resident's activities, staff must be vigilant in order to respond to them in a timely manner. Alarms do not replace necessary supervision.

Elopement occurs when a resident leaves the premises or a safe area without authorization (i.e., an order for discharge or leave of absence) and/or any necessary supervision to do so. A resident who leaves a safe area may be at risk of (or has the potential to experience) heat or cold exposure, dehydration and/or other medical complications, drowning, or being struck by a motor vehicle. Facility policies that clearly define the mechanisms and procedures for monitoring and managing residents at risk for elopement can help to minimize the risk of a resident leaving a safe area without authorization and/or appropriate supervision. In addition, the resident at risk should have interventions in their comprehensive plan of care to address the potential for elopement. Furthermore, a facility's disaster and emergency preparedness plan should include a plan to locate a missing resident.⁵

Physical Plant Hazards

Supervision and/or containment of hazards are needed to protect residents from harm caused by environmental hazards. Examples of such hazards can range from common chemical cleaning materials to those caused by adverse water temperatures or improper use of electrical devices.

Chemicals and Toxins - Various materials in the resident environment can pose a potential hazard to residents. Hazardous materials can be found in the form of solids, liquids, gases, mists, dusts, fumes, and vapors. The routes of exposure for toxic materials may include inhalation, absorption, or ingestion.

For a material to pose a safety hazard to a resident, it must be toxic, caustic, or allergenic; accessible and available in a sufficient amount to cause harm. Toxic materials that may be present in the resident environment are unlikely to pose a hazard unless residents have access or are exposed to them. Some materials that would be considered harmless when used as designed could pose a hazard to a resident who accidentally ingests or makes contact with them.

Examples of materials that may pose a hazard to a resident include (but are not limited to):

- *Chemicals used by the facility staff in the course of their duties (e.g., housekeeping chemicals) and chemicals or other materials brought into the resident environment by staff, other residents, or visitors;*
- *Drugs and therapeutic agents;*
- *Plants and other "natural" materials found in the resident environment or in the outdoor environment (e.g., poison ivy).*

One source of information concerning the hazards of a material that a facility may obtain is its Material Safety Data Sheet (MSDS).⁶ The Occupational Safety and Health Administration (OSHA) requires employers to have a MSDS available for all hazardous

materials that staff use while performing their duties.⁷ MSDSs are available on-line for numerous chemicals and non-toxic materials, and should be reviewed carefully to determine if the material is toxic and poses a hazard. Poison control centers are another source of information for potential hazards, including non-chemical hazards such as plants.

NOTE: Toxicological profiles for a limited number of hazardous materials are accessible on the Agency for Toxic Substances & Disease Registry Web site.⁶

Water Temperature - Water may reach hazardous temperatures in hand sinks, showers, and tubs. Burns related to hot water/liquids may also be due to spills and/or immersion. Many residents in long-term care facilities have conditions that may put them at increased risk for burns caused by scalding. These conditions include: decreased skin thickness, decreased skin sensitivity, peripheral neuropathy, decreased agility (reduced reaction time), decreased cognition or dementia, decreased mobility, and decreased ability to communicate.⁸

The degree of injury depends on factors including the water temperature, the amount of skin exposed, and the duration of exposure. Some States have regulations regarding allowable maximum water temperature. Table 1 illustrates damage to skin in relation to the temperature of the water and the length of time of exposure.⁹

Table 1. Time and Temperature Relationship to Serious Burns

Water Temperature		Time Required for a 3 rd Degree Burn to Occur
155°F	68°C	1 sec
148°F	64°C	2 sec
140°F	60°C	5 sec
133°F	56°C	15 sec
127°F	52°C	1 min
124°F	51°C	3 min
120°F	48°C	5 min
100°F	37°C	Safe Temperatures for Bathing (see Note)

NOTE: Burns can occur even at water temperatures below those identified in the table, depending on an individual's condition and the length of exposure.

Based upon the time of the exposure and the temperature of the water, the severity of the harm to the skin is identified by the degree of burn, as follows.¹⁰

- First-degree burns involve the top layer of skin (e.g., minor sunburn). These may present as red and painful to touch, and the skin will show mild swelling.

- *Second-degree burns involve the first two layers of skin. These may present as deep reddening of the skin, pain, blisters, glossy appearance from leaking fluid, and possible loss of some skin.*
- *Third-degree burns penetrate the entire thickness of the skin and permanently destroy tissue. These present as loss of skin layers, often painless (pain may be caused by patches of first- and second-degree burns surrounding third-degree burns), and dry, leathery skin. Skin may appear charred or have patches that appear white, brown, or black.*

Electrical Safety - Any electrical device, whether or not it needs to be plugged into an electric outlet, can become hazardous to the residents through improper use or improper maintenance. Electrical equipment such as electrical cords can become tripping hazards. Halogen lamps or heat lamps can cause burns or fires if not properly installed away from combustibles in the resident environment. The Life Safety Code prohibits the use of portable electrical space heaters in resident areas.

Extension cords should not be used to take the place of adequate wiring in a facility. If extension cords are used, the cords should be properly secured and not be placed overhead, under carpets or rugs, or anywhere that the cord can cause trips, falls, or overheat. Extension cords should be connected to only one device to prevent overloading of the circuit. The cord itself should be of a size and type for the expected electrical load and made of material that will not fray or cut easily. Electrical cords including extension cords should have proper grounding if required and should not have any grounding devices removed or not used if required.

Power strips may not be used as a substitute for adequate electrical outlets in a facility. Power strips may be used for a computer, monitor, and printer. Power strips are not designed to be used with medical devices in patient care areas. Precautions needed if power strips are used include: installing internal ground fault and over-current protection devices; preventing cords from becoming tripping hazards; and using power strips that are adequate for the number and types of devices used. Overload on any circuit can potentially cause overheating and fire. The use of ground fault circuit interruption (GFCIs) may be required in locations near water sources to prevent electrocution of staff or residents.¹¹

The proper use of electric blankets and heating pads is essential to avoid thermal injuries. These items should not be tucked in or squeezed. Constriction can cause the internal wires to break. A resident should not go to sleep with an electric blanket or heating pad turned on. Manufacturer's instructions for use should be followed closely. Injuries and deaths have been related to burns and fires related to the use of heating pads. Most deaths are attributable to heating pads that generated fires, but most injuries are burns from prolonged use or inappropriate temperature setting. Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting.¹²

Lighting - The risk of an accident increases when there is insufficient light or too much light, which often results in glare. Vision among older persons varies widely; therefore, no single level of illumination can ensure safety for all residents. The proper amount of light depends on the resident's visual needs and the task he/she is performing.

An older person typically needs more light to see. However, a resident with cataracts or glaucoma may be overly sensitive to bright light, and excessive lighting could make it more difficult to see clearly and thereby increase his/her fall risk.¹³ Creating transitional zones between light and dark spaces helps to improve sight recovery and enable safer mobility. Providing extra visual cues that clearly define needed items or spaces in areas with limited or variable light can help to enable safe performance of tasks (e.g., turning on a light). Providing supplemental light near beds for patients who are mobile may assist in safe mobility at night.¹⁴

NOTE: *Refer to guidance for 42 CFR 483.15(h)(5) [F256] for lighting issues related to Quality of Life.*

Assistive Devices/Equipment Hazards

Assistive devices also can help to prevent accidents. Assistive devices and equipment can help residents move with increased independence, transfer with greater comfort, and feel physically more secure. However, there are risks associated with the use of such devices and equipment, and these risks need to be balanced with the benefits gained from their use. Training of staff, residents, family members and volunteers on the proper use of assistive devices/equipment is crucial to prevent accidents. It is also important to communicate clearly the approaches identified in the care plan to all staff, including temporary staff. It is important to train staff regarding resident assessment, safe transfer techniques, and the proper use of mechanical lifts including device weight limitations.

NOTE: *The Safe Medical Devices Act of 1990 (SMDA) requires hospitals, nursing homes, and other user facilities to report deaths, serious illnesses, and injuries associated with the use of medical devices to manufacturers and the Food and Drug Administration.*

Assistive Devices for Mobility - Mobility devices include all types of assistive devices, such as, but not limited to, canes, standard and rolling walkers, manual or non-powered wheelchairs, and powered wheelchairs. Three primary factors that may be associated with an increased accident risk related to the use of assistive devices include:

- 1. Resident Condition. Lower extremity weakness, gait disturbances, decreased range of motion, and poor balance may affect some residents. These conditions combined with cognitive impairment can increase the accident risks of using mobility devices. Unsafe behavior, such as failure to lock wheelchair brakes and trying to stand or transfer from a wheelchair unsafely, can result in falls and related injuries;*

2. *Personal Fit and Device Condition.* Devices can pose a hazard if not fitted and/or maintained properly.¹⁵ Personal fit, or how well the assistive device meets the individual needs of the resident, may influence the likelihood of an avoidable accident; and
3. *Staff Practices.* Mobility devices that a resident cannot readily reach may create a hazardous situation. Unsafe transfer technique used by staff may result in an accident. Inadequate supervision by staff of a resident during the initial trial period of assistive device use or after a change in the resident's functional status can increase the risk of falls and/or injury. Additionally, staff needs to ensure assistive devices properly fit the resident and the resident has received proper training in the use of the assistive device.

Assistive Devices for Transfer - Mechanical assistive devices for transfer include, but are not limited to, portable total body lifts, sit-to-stand devices, and transfer or gait belts. The resident assessment helps to determine the resident's degree of mobility and physical impairment and the proper transfer method; for example, whether one or more caregivers or a mechanical device is needed for a safe transfer. Residents who become frightened during transfer in a mechanical lift may exhibit resistance movements that can result in avoidable accidents. Communicating with the resident and addressing the resident's fear may reduce the risk.

Factors that may influence a resident's risk of accident during transfer include staff availability, resident abilities, and staff training.¹⁶ The resident's ability to communicate and identify physical limitations or to aid in the transfer will help determine the need for an assistive device, such as a mechanical lift.

Devices Associated with Entrapment Risks - Devices can be therapeutic and beneficial; however, devices are not necessarily risk free so it is important to weigh the relative risks and benefits of using certain devices. For example, while physical restraints may be used to treat a resident's medical symptom, the devices may create a risk for entrapment. Physical restraints are defined in the SOM at F221 as any manual method, physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily and that restricts freedom of movement or normal access to one's body.

In 1992, the Food and Drug Administration (FDA) issued a Safety Alert entitled "Potential Hazards with Restraint Devices".¹⁷ Serious injuries, as well as death, have been reported as a result of using physical restraints. Some physical restraints carry a risk of severe injury, strangulation, and asphyxiation. Restrained residents may be injured or die when they try to remove restraints, to ambulate while restrained, or due to an improperly fitted or used device.

Regardless of the purpose for use, bed rails (also referred to as "side rails," "bed side rails," and "safety rails") and other bed accessories (e.g., transfer bar, bed enclosures), while assisting with transfer and positioning, can increase resident safety risk. Bed rails

include rails of various sizes (e.g., full length rails, half rails, quarter rails) that may be positioned in various locations on the bed. In 1995, the FDA issued a Safety Alert entitled “Entrapment Hazards with Hospital Bed Side Rails.”¹⁸ Residents most at risk for entrapment are those who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, acute urinary retention, etc. that may cause them to move about the bed or try to exit from the bed. The timeliness of toileting, appropriateness of positioning, and other care-related activities can contribute to the risk of entrapment.¹⁹

Entrapment may occur when a resident is caught between the mattress and bed rail or in the bed rail itself. Technical issues, such as the proper sizing of mattresses, fit and integrity of bed rails or other design elements (e.g., wide spaces between bars in the bed rails) can also affect the risk of resident entrapment.¹⁹

The use of a specialty air-filled mattress or a therapeutic air-filled bed may also present an entrapment risk that is different from rail entrapment with a regular mattress. The high compressibility of an air-filled mattress compared to a regular conventional mattress requires appropriate precautions when used for a resident at risk for entrapment. An air-filled mattress compresses on the side to which a person moves, thus raising the center of the mattress and lowering the side. This may make it easier for a resident to slide off the mattress or against the rail. Mattress compression widens the space between the mattress and rail. When a resident is between the mattress and rail, the mattress can re-expand and press the chest, neck, or head against the rail. While using air therapy to prevent and treat pressure ulcers, facilities should also take precautions to reduce the risk of entrapment. Precautions may include following manufacturer equipment alerts and increasing supervision.²⁰

NOTE: *42 CFR 483.13(a), F221, applies to the use of physical restraints. 42 CFR 483.25(h)(2), F323 applies to assistive devices that create hazards (e.g., devices that are defective; not used properly or according to manufacturer’s specifications; disabled or removed; not provided or do not meet the resident’s needs (poor fit or not adapted); and/or used without adequate supervision when required).*

ENDNOTES

¹ *Centers for Medicare & Medicaid Services. (December 2002 revised June 2006). Revised Long-Term Care Facility Resident Assessment Instrument User’s Manual. Version 2.0, 3-146.*

² *Pizzi, L.T., Goldfarb, N.I., Nash, D.B. (2002). Promoting a culture of safety. In: K.G. Shojania, B.W. Duncan, K.M. McDonald, & R.M. Wachter (Eds.), Evidence Report/Technology Assessment, No. 43. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved February 9, 2004 from <<http://www.ahrq.gov/clinic/ptsafety/chap40.htm>>.*

- ³ Singer, S.J., Gaba, D.M., Geppert, J.J., et al. (2003). *The culture of safety: Results of an organization-wide survey in 15 California hospitals.* *Qual Saf Health Care*, 12, 112-118.
- ⁴ American Geriatrics Society, British Geriatrics Society American Academy of Orthopedic Surgeons Panel on Falls Prevention. (2001). *Guideline for the prevention of falls in older persons.* *J Am Geriatr Soc*, 49, 664–672.
- ⁵ Boltz, M. (2003). *Litigation Issues Related To Wandering and Elopement.* The John A. Hartford Foundation Institute for Geriatric Nursing, New York University, The Steinhardt School of Education, Division of Nursing. Retrieved November 30, 2005 from http://www.hartfordign.org/resources/special_topics/spectopics.html>
- ⁶ Agency for Toxic Substances & Disease Registry web site at <http://www.atsdr.cdc.gov/toxpro2.html>.
- ⁷ US Dept. of Labor, Occupational Safety and Health Standards, 29 CFR 1910.1200 (g)(1) and (2)
- ⁸ Katcher, L.K. (1981). *Scald Burns from Hot Tap Water.* *Journal of Am Med Assoc.*, 246(11), 1219-1222.
- ⁹ Moritz, A.R., Henriques F.C. Jr. (1947). *Studies of Thermal Injury: II. The Relative Importance of Time and Surface Temperatures in the Causation of Cutaneous Burns.* *Am J Pathology*, 23, 695-720.
- ¹⁰ US Dept. of Health and Human Services. Centers for Disease Control and Prevention. (June 12, 2003). *Emergency Preparedness & Response. Burns.* Retrieved November 8, 2005 from <<http://www.bt.cdc.gov/masstrauma/burns.asp>>
- ¹¹ Electrical Safety Foundation International. *Plug into Electrical Safety.* Retrieved February 9, 2004 from <<http://www.nesf.org/index.html>>.
- ¹² US Dept. of Health and Human Services. Food and Drug Administration. (December 12, 1995). *Public Health Advisory: Hazards Associated with the Use of Electric Heating Pads.*
- ¹³ Tideiksaar, R. (1998). *Falls in Older Persons: Prevention and Management (2nd Edition).* Baltimore, MD: Health Profession Press.
- ¹⁴ Warren, M. (2001), *Occupational Therapy Practice Guidelines for Adults with Low Vision,* The American Occupational Therapy Association, Inc.

- ¹⁵ Taylor, J.A., Brown, A.K., Meredith, S., Ray, W.A. (2002). *The fall reduction program: a comprehensive program for reduction of falls and injuries in long-term care residents*. Nashville, TN: Department of Preventive Medicine, Vanderbilt University School of Medicine.
- ¹⁶ US Dept. of Veterans Affairs, Office of Occupational Safety and Health. (January, 2003). *Safe Patient Movement and Handling Guide*.
- ¹⁷ US Dept. of Health and Human Services. Food and Drug Administration. (July 15, 1992). *FDA Safety Alert: Potential Hazards with Restraint Devices*.
- ¹⁸ US Dept. of Health and Human Services. Food and Drug Administration. (August 23, 1995). *FDA Safety Alert: Entrapment Hazards with Hospital Bed Side Rails*.
- ¹⁹ US Dept. of Health and Human Services, Food and Drug Administration, Hospital Bed Safety Workgroup. (April 2003), *Clinical Guidance For the Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities, and Home Care Settings*. Retrieved November 11, 2005 from <http://www.fda.gov/cdrh/beds/>.
- ²⁰ Miles, S. (June 2002). *Death between bedrails and air pressured mattresses*. *J Am Geriatr Soc*, 50(6), 1124-5.

NOTE: References to non-CMS/HHS sources or sites on the Internet included above or later in this document 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. URL addresses were current as of the date of this publication.

INVESTIGATIVE PROTOCOL
ACCIDENTS AND SUPERVISION

Objectives

- *To determine if the facility has identified hazard(s) present in the resident environment and the individual resident's risks for an avoidable accident posed by those hazards;*
- *To determine if a resident accident was avoidable or unavoidable;*
- *To evaluate whether the facility provides an environment that is as free as possible of hazards over which the facility has control, and minimizes the potential for harm; and*
- *To determine if the facility provides adequate supervision and assistive devices to prevent avoidable accidents.*

Use

Use this protocol:

- *For a sampled resident who is at risk for, or who has a history of accidents, falls, or unsafe wandering/elopement, to determine if the facility provided care and services, including assistive devices as necessary, to prevent avoidable accidents and to reduce the resident's risk to the extent possible;*
- *For a sampled resident who is at risk for accidents or who creates a risk to others, to determine if the facility has provided adequate supervision; and*
- *For identified hazards/risks, to determine if there are facility practices in place to identify, evaluate and analyze hazards/risks; implement interventions to reduce or eliminate the hazards/risks, to the extent possible; and monitor the effectiveness of the interventions.*

Procedures

Observe the general environment and sampled resident environment. For a sampled resident, briefly review the assessment and plan of care to determine whether the facility identified resident risks and implemented interventions as necessary to guide observations during the investigation. For a newly admitted resident at risk for avoidable accidents, determine if the staff assessed and provided appropriate care from the day of admission. Corroborate observations through interview and record review.

1. Observation

The survey team should make observations and investigate potential hazards that may be encountered throughout the survey. The existence of hazards may indicate a more serious problem; for example, that the organization lacks an effective system to identify and correct the problem independently. The previous discussion of specific common hazards guides surveyors to look for items indicating a failure or absence of an organization's systems and processes to enable safety.

During observation of the facility, the survey team may see individual residents who are smoking tobacco products. Whether or not these residents are part of the sample, the issue of facility fires is important enough that the survey team should determine if the situation is hazardous, requiring further investigation.

Observe the environment for the presence of potential/actual hazards including, but not limited to, the following:

- Accessibility of chemicals, toxics or other hazards such as housekeeping chemicals and supplies, medications, sharp utensils/tools, and cigarette lighters/smoking materials;*
- Environmental conditions such as unstable or slippery floor surfaces, loose hand rails, excessive water temperatures, electrical hazards, insufficient or excessive light (glare), arrangement of living spaces, obstacles in corridors, unsupervised access into or egress out of the facility, low or loose toilet seats, defective or non-functioning beds, or malfunctioning wheelchair brakes;*
- Staff responses to verbal calls for help and alarms such as door, personal, and equipment alarms, and call bells;*
- Assistive devices/equipment (e.g., mobility devices, lifts and transfer aids, bed rails, call lights, physical restraints, pumps, belts) that are defective; not used properly or according to manufacturer's specifications; disabled or removed; not provided or do not meet the resident's needs (poor fit or not adapted); and/or used without adequate supervision, in relation to the facility's assessment of the resident; and/or*
- Staff response to potential/actual hazard(s) (e.g., cleaning up spilled liquids in a resident area, keeping residents away from the hazard).*

For a sampled resident at risk, observe whether staff implement the care plan consistently over time and across various shifts. Observe how staff respond to any identified resident hazards. Observe how staff supervise the resident, such as during transfers and/or meals, and if caregivers have removed or modified observed hazards. During observations of the interventions, follow up on deviations from the plan of care, as well as potential negative outcomes.

For a resident who smokes, the facility's determination regarding the resident's abilities and capabilities would indicate whether supervision is required. If the resident is found to need supervision for smoking, this information is included in the resident's plan of care. Observe sampled resident(s) in the facility's designated smoking area. If the resident's care plan states supervision is required while smoking, confirm that supervision is provided. For others, note any concerns such as difficulty holding or lighting a cigarette or burned areas in clothing that may indicate the need for supervision.

Observe the resident to determine how the resident's risk influences his/her vulnerability to the observed potential hazard(s) and potential for an accident. Evaluate how the resident's risks relate to the observed potential hazards such as:

- The resident's access to the hazard and the ability to react appropriately; and/or*
- The adequacy of the supervision provided for the resident who has been assessed to need supervision in relation to the identified potential hazard(s).*

2. Interview

Conduct interviews to determine the relationship between the resident's risk and hazards.

Interview the resident, family, and/or responsible party to the degree possible to identify:

- If the resident and/or responsible party reported, or helped identify the resident's risks for an accident and significant hazards in the resident's environment;*
- If the resident and/or responsible party was aware of or identified a potential hazard for other residents;*
- If the resident and/or responsible party reported a hazard or potential risk to staff; and*
- How and when staff responded to a hazard once it was identified.*

Interview staff to determine:

- If they were aware of planned interventions to reduce a resident's risk for an avoidable accident;*
- If they reported potential resident risks or environmental hazards to the supervisor or others according to facility policy;*
- If they acted to correct an immediate hazard, such as spilled liquids; and*

- *If they are aware of, and follow facility procedures correctly to remove or reduce hazards.*

3. Record Review

Assessment and Evaluation: Review the RAI and other documents such as progress notes, physician orders, and nurses' and consultants' notes regarding the assessment of the resident's overall condition and risk factors to determine if the facility identified the resident's risk for avoidable accidents, evaluated and analyzed any risks, implemented interventions to try to prevent accidents and reduce the resident's risks, and monitored and modified interventions as necessary.

Determine if the facility assessment is consistent with or corroborated by documentation within the record and reflects the status of the resident for:

- *Behavior such as unsafe wandering, elopement, ingesting nonfood items, altercations with others;*
- *Hearing, visual, and sensory impairments;*
- *Impaired physical functioning, balance, or gait problems;*
- *Diagnoses that could relate to safety awareness and safe practices, such as Alzheimer's and other dementias, arthritis, Parkinson's disease, seizure disorder, osteoporosis, cardiovascular/cerebrovascular diseases, depression/psychosis;*
- *Symptoms/conditions that could affect safety risk, such as vertigo, postural hypotension, or acute illness;*
- *Use of physical restraints and/or other devices that might limit movement;*
- *Medications that could affect function, level of consciousness, gait, balance, visual acuity, or cognitive ability, use such as antidepressants, anticholinergic medications, anti-hypertensives, diuretics, psychotropic medications, or initiation of new medication therapy; and*
- *History of falls.*

Plan of Care: Review the plan of care to determine if the facility developed interventions based on the resident's risks to try to prevent avoidable accidents, and if the plan was modified as needed based on the response, outcomes, and needs of the resident.

If the resident has had an accident, review the record to determine if the accident is:

- *The result of an order not being followed; and/or*

- *A care need not being addressed; and/or*
- *A plan of care not being implemented.*

In addition, determine if the facility (1) investigated the cause of the accident and (2) if indicated, implemented revised interventions to prevent additional avoidable accidents.

Plan of Care Revision: Determine if the facility has monitored a resident's condition and the effectiveness of the plan of care interventions and has made revisions (or has documented justification for continuing the existing plan) based upon the following:

- *The outcome and/or effects of goals and interventions;*
- *Resident failure to comply with the plan of care and interventions;*
- *Input by the resident and/or the responsible person; and*
- *Changes in condition such as the ability to make decisions, cognition, functional impairment, or changes in the medication regimen.*

4. Review of Facility Practices

The presence or absence of effective facility practices to provide a safe resident environment can influence the likelihood of an accident occurring and subsequent harm to a resident(s). Hazards that have been allowed to exist for a long time, or a facility history of similar problems, could indicate inadequate or ineffective facility practices.

If, during the tour, surveyors identify care delivery, hazards or potential hazards, or a history of resident accidents, the survey team should share the findings with the entire team and determine who will lead the investigation of the facility's systems for identifying, evaluating and preventing avoidable accidents or hazards. Review of facility practices may involve a review of policies and procedures, staffing, staff training, and equipment manufacturer's information, as well as interviews with staff and management. If there is a pattern of accidents involving one or more residents, determine how the facility evaluates its responses to the accidents. Determine if the facility ensured that the resident environment remained as free of accident hazards as possible and if each resident received adequate supervision and assistive devices to try to prevent accidents by:

- *Identifying potential hazards and risks (may require various strategies to gather such information);*
- *Evaluating and analyzing the information gathered to identify the underlying causes of the hazard and/or risk;*

- *Implementing interventions that addressed the causes and prioritized actions based on severity of the hazard and immediacy of the risk; and*
- *Monitoring implementation of interventions and determining if modification is needed.*

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation

The requirements at 42 CFR 483.25(h)(1) and (2) have three aspects. The first aspect requires that a resident's environment remains as free of accident hazards as possible; the second aspect requires that the facility provide adequate supervision; and the third is that the facility provides assistive devices to prevent accidents.

Criteria for Compliance

The facility's responsibility to accommodate individual needs and preferences and abide by the resident's right to choice and self-determination must be balanced against compliance with F323 to protect the resident. Documentation regarding the resident's choices will assist the survey team in making compliance decisions.

NOTE: *It is important to remember that not all accidents in a facility, regardless of outcome to a resident, are necessarily due to facility noncompliance. A resident can sustain bodily injury as a result of an accident over which the facility had no control (i.e., an unavoidable accident). The survey team needs to review the situation that led to the injury or potential for injury, as well as the facility practices, and resident's rights, preferences, and choices, to determine if the potential or negative outcome was avoidable or unavoidable.*

Compliance with 42 CFR 483.25(h)(1) and (2), F323, Accidents and Supervision

For the resident who has had an accident or was assessed at risk for an avoidable accident, the facility is in compliance with this requirement, if staff have:

- *Identified hazards and risk of an avoidable accident based on the facility's assessment of the resident environment and the resident, including the need for supervision and/or assistive devices;*
- *Evaluated/analyzed the hazards and risks;*
- *Implemented interventions, including adequate supervision and/or assistive devices, to reduce the risks of an accident that were consistent with a resident's needs, goals, plan of care, and current standards of practice;*

- *Provided assistive devices consistent with a resident's needs;*
- *Properly deployed and maintained resident specific equipment (e.g., lifts, canes, wheelchairs, walkers);*
- *Provided a safe environment, such as by monitoring chemicals, wet floors, cords and other equipment;*
- *Operated equipment in accordance with manufacturer's recommendations and resident need;*
- *Provided and maintain a secure environment (e.g., resident room, unit, common use areas, stairs and windows, facility grounds, etc.) to prevent negative outcomes (e.g., prevent falling/tumbling down stairs or jumping from windows or eloping through exit doors) for residents who exhibit unsafe wandering and/or elopement behavior (regardless of whether ambulatory, in wheelchair or using walker); and*
- *Monitored the effectiveness of the interventions and modified the interventions as necessary, in accordance with current standards of practice.*

If not, cite F323.

Noncompliance for F323

After completing the investigation, determine whether or not compliance with the regulation exists. Noncompliance for F323 may include, but is not limited to, one or more of the following failures to:

- *Provide each resident an environment that is as free as possible from hazards over which the facility has control, such as assuring safe storage of toxic chemicals and medications, and safe use of equipment and electrical appliances;*
- *Provide adequate supervision for a resident who has exhibited unsafe wandering and/or has a risk of and/or a history of elopement;*
- *Identify and correct hazards such as non-functional alarms or call systems, disabled locks, fire doors that have been propped open, irregular walking surfaces, inadequate lighting or unsafe water temperatures;*
- *Supervise and monitor a resident who smokes and whose comprehensive assessment and plan of care indicates a need for supervision;*
- *Provide assistive devices and/or appropriate training for the use of assistive devices, based upon the assessed needs of the resident;*

- *Monitor for defective or disabled equipment, such as pumps, ventilators or other equipment, or the improper use of assistive devices;*
- *Assess, develop interventions, and/or revise the plan of care for a resident who has experienced falls, or who is identified as having risk factors for falling; and*
- *Assess, develop interventions, and/or revise the plan of care for a resident who has exhibited or has a risk for unsafe wandering or elopement.*

Potential Tags for Additional Investigation

During the investigation of 42 CFR 483.25(h)(1) and (2), the surveyor may have identified concerns related to outcome, process, and/or structure requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are examples of related outcome, process, and/or structure requirements that should be considered:

- *42 CFR 483.13(a), F221, Restraints*
 - *Determine if staff attempted alternative approaches prior to the use of a restraint and if a medical indication for its use is present.*
- *42 CFR 483.13(b), F223, Abuse*
 - *Determine if the resident was free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.*
- *42 CFR 483.20(b)(1), F272, Comprehensive Assessments*
 - *Determine if the facility comprehensively assessed resident-specific risk factors (including potential causes) and assessed the need for and use of assistive devices.*
- *42 CFR 483.20(k)(1), F279, Comprehensive Care Plans*
 - *Determine if the facility developed a plan of care based on the comprehensive resident assessment consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and with current standards of practice, and that includes measurable objectives and approximate timetables, specific interventions and/or services including necessary supervision and/or any assistive devices needed to prevent accidents to the extent possible.*
- *42 CFR 483.20(k)(2), F280, Comprehensive Care Plan Revision*

- *Determine if the plan of care was reviewed and revised periodically, as necessary, related to preventing accidents, supervision required, and the use of assistive devices.*
- *42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards*
 - *Determine if services and care were provided for the use of assistive devices, supervision, and prevention of accidents in accordance with accepted professional standards.*
- *42 CFR 483.30(a), F353, Sufficient Staff*
 - *Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services, including supervision, based upon the comprehensive assessment and care plan, to prevent accidents, as possible.*
- *42 CFR 483.75(o), F520, Quality Assessment and Assurance*
 - *Determine whether the quality assessment and assurance committee has identified issues, and developed and implemented appropriate plans of action to correct identified quality deficiencies in relation to hazards, accident prevention, and supervision of residents.*

V. DEFICIENCY CATEGORIZATION (Part V, 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 F323 are as follows:

- 1. Presence of harm/negative outcome(s) or potential for negative outcomes because of presence of environmental hazards, lack of adequate supervision to prevent accidents, or failure to provide assistive devices to prevent accidents. Actual or potential harm/negative outcome for F323 may include, but is not limited to:*
 - *Injuries sustained from falls and/or unsafe wandering/elopement;*
 - *Resident-to-resident altercations;*
 - *Thermal burns from spills/immersion of hot water/liquids;*
 - *Falls due to environmental hazards;*

- *Ingestion of chemical substances; and*
 - *Burns related to smoking materials.*
2. *Degree of harm (actual or potential) related to the noncompliance. Identify how the facility 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; and*
 - *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 F323. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, **Guidelines for Determining Immediate Jeopardy.**)*

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

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

- *Has allowed, caused, or resulted in (or is likely to allow, cause, or 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 always remove a finding of Immediate Jeopardy. The facility is required to implement specific actions to correct the noncompliance which allowed or caused the Immediate Jeopardy.*

When considering Severity Level 4, the survey team must have already determined noncompliance in the facility practices to provide a safe resident environment. Examples of negative outcomes that occurred or have the potential to occur as a result of the noncompliance might include the following:

- *Esophageal damage due to ingestion of corrosive substances;*
- *Loss of consciousness related to head injuries;*
- *3rd degree burn, or a 2nd degree burn covering a large surface area;*
- *Fracture or other injury that may require surgical intervention and results in significant decline in mental and/or physical functioning;*
- *Electric shock due to use of unsafe or improperly maintained equipment;*
- *Entrapment of body parts, such as limbs, head, neck, or chest that cause injury or death as a result of defective or improperly latched side rails or spaces within side rails, between split rails, between rails and the mattress, between side rails and the bed frame, or spaces between side rails and the head or foot board of the bed;*
- *Entrapment of body parts, such as limbs, head, neck, or chest that causes or has the potential to cause serious injury, harm, impairment or death as a result of any manual method, physical or mechanical device, material, or equipment;*
- *Fall(s) that resulted in or had the potential to result in serious injury, impairment, harm or death (e.g. fracture or other injury that may require surgical intervention and/or results in significant decline in mental and/or physical functioning), and the facility had no established measure(s) or practice(s), or ineffective measure(s) or practice(s), that would have prevented the fall or limited the resident's injury; or*
- *Unsafe wandering and/or elopement that resulted in or had the potential to result in serious injury, impairment, harm or death (e.g., resident leaves facility or locked unit unnoticed and sustained or had potential to sustain serious injury, impairment, harm or death), and the facility had no established measure(s) or practice(s), or ineffective measure(s) or practice(s), that would have prevented or limited the resident's exposure to hazards.*

NOTE: *If Immediate Jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.*

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

Severity Level 3 indicates noncompliance that results in actual harm and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being.

When considering Severity Level 3, the survey team must have already determined noncompliance in the facility practices to provide a safe resident environment. As a result of the noncompliance, a negative outcome occurred. Some examples of compromise include:

- *Short-term disability;*
- *Pain that interfered with normal activities;*
- *2nd degree burn;*
- *Fracture or other injury that may require surgical intervention and does not result in significant decline in mental and/or physical functioning;*
- *Medical evaluation was necessary, and treatment beyond first aid (e.g., sutures) was required;*
- *Fall(s) that resulted in actual harm (e.g., short-term disability; pain that interfered with normal activities; fracture or other injury that may require surgical intervention and does not result in significant decline in mental and/or physical functioning; or medical evaluation was necessary, and treatment beyond first aid (e.g., sutures) was required) and the facility had established measure(s) or practice(s) in place that limited the resident's potential to fall and limited the resident's injury and prevented the harm from rising to a level of immediate jeopardy; or*
- *Unsafe wandering and/or elopement that resulted in actual harm and the facility had established measure(s) or practice(s) in place that limited the resident's exposure to hazards and prevented the harm from rising to a level of immediate jeopardy.*

NOTE: *Unsafe wandering or elopement that resulted in actual harm and the facility had no established measure(s) or practice(s), or ineffective measure(s) or practice(s) that would have prevented or limited the resident's exposure to hazards should be cited at Level 4, Immediate Jeopardy.*

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

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

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.

When considering Severity Level 2, the survey team must have already determined noncompliance in the facility practices to provide a safe resident environment. As a result of the noncompliance, a negative outcome occurred, or the potential for a negative outcome exists, such as the following:

- Bruising, minor skin abrasions, and rashes;*
- Pain that does not impair normal activities;*
- 1st degree burn;*
- Medical evaluation or consultation may or may not have been necessary, and treatment such as first aid may have been required;*
- Fall(s) which resulted in no more than minimal harm (e.g., bruising or minor skin abrasions; pain that does not impair normal activities; or medical evaluation or consultation may or may not have been necessary, and/or treatment such as first aid may have been required) because the facility had additional established measure(s) or practice(s) that limited the resident's potential to fall or limited the injury or potential for injury; or*
- Unsafe wandering and/or elopement, which resulted in no more than minimal harm because the facility had additional established measure(s) or practice(s) that limited the resident's exposure to hazards. For example, a resident with Alzheimer's disease left the locked unit and was quickly found unharmed on another unit, and the building was considered a safe environment, as there was no way for the resident to leave the building.*

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

The failure of the facility to provide a safe environment and adequate supervision places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.