

Accidents and Supervision

Guidance Training

42 C.F.R. §§483.25 (h) (1) and (2)

F323



1

Notes:

- Introduce yourself and the other presenters
- Welcome the participants
- Provide logistical information such as location of restrooms, vending machines, etc., if appropriate.

Today's Agenda

- Regulation
- Interpretive Guidelines
- Investigative Protocol
- Determination of Compliance
- Deficiency Categorization



2

[Provide each participant with a copy of the Guidance.]

First, let us begin by discussing what you have received in your training materials. Today's agenda consists of the topic areas that make up the components of the Guidance you received. We will discuss each component in detail and talk about how to employ them during the survey process.

Regulatory Language

Accidents and Supervision F323

- The facility must ensure that:
 - The resident environment remains as free of accident hazards as is possible; and
 - Each resident receives adequate supervision and assistance devices to prevent accidents.



3

[Read slide.]

Tags F323 and F324 are collapsed into one tag: F323. ASPEN has been modified to reflect this change. Once this Guidance is effective, noncompliance with the regulation at 42 C.F.R. 483.25(h)(1) and (2) will be cited at F323.

Accidents & Supervision

Interpretive Guidelines



Interpretive Guidelines Components

- Intent
- Definitions
- Overview
- Systems Approach
- Supervision
- Resident Risks & Environmental Hazards
- Investigative Protocol
- Determination of Compliance
- Deficiency Categorization



5

The Guidance contains information about the intent of the regulation, explanation of pertinent terms, an overview of the Guidance, a discussion about what is a systems approach, detailed information about the requirement to provide supervision, and a discussion of certain resident risks and environmental hazards. The Guidance also contains an investigative protocol and information about determining compliance and severity levels.

Intent

- Ensure the resident environment remains as free of accident hazards as possible.
- Ensure each resident receives adequate supervision and assistance devices to prevent accidents



6

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

Methods to Meet Intent

- Identifying hazards and risks;
- Evaluating and analyzing hazards and risks;
- Implementing interventions to reduce hazards and risks; and
- Monitoring for effectiveness and modifying interventions as indicated.



7

In order to meet the intent of the regulation, the guidance provides information about four possible methods to help ensure the environment is as free from accident hazards as possible and that each resident receives adequate supervision and assistance devices to prevent accidents.

Possible methods include:

- Identifying hazards and risks;
- Evaluating and analyzing hazards and risks;
- Implementing interventions to reduce hazards and risks; and
- Monitoring for effectiveness and modifying interventions as indicated.

Definition: Accident

- Unexpected or unintentional incident
- May result in injury or illness
- Not an adverse outcome directly related to treatment or care



8

“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).

Definition: Avoidable Accident

- Facility failed to:
 - Identify environmental hazard and resident risk
 - Evaluate/analyze hazard and risk
 - implement interventions
 - Monitor and modify interventions as needed



9

The guidance distinguishes between an “avoidable accident” and an “unavoidable accident.”

An “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 risk; 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.

Definition: Unavoidable Accident

- Accident occurred despite facility's efforts to:
 - Identify environmental hazard and resident risk
 - Evaluate/analyze hazard and risk
 - implement interventions
 - Monitor and modify interventions as needed



10

“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 risk; and
- Implement interventions, including adequate supervision, consistent with 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.

Definition: Assistance/Assistive Device

- Any device used by or in care of a resident to promote, supplement, or enhance the resident's function and/or safety.
- Examples: handrails, grab bars, transfer lifts, canes, wheelchairs, etc.



11

“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.”

Definition: Environment/Resident Environment

- “Environment” refers to the resident environment.
- “Resident environment” includes the physical surroundings to which the resident has access (e.g., room, unit, common use areas, and facility grounds, etc.).



12

The words “environment” and “resident environment” are synonymous in the Guidance.

[Read slide.]

Definition: Hazards

- “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.



13

[Read slide.]

Definition: Risk

- “Risk” refers to any external factor or characteristic of an individual resident that influences the likelihood of an accident.



For the purposes of this Guidance, “risk” is defined as any external force or characteristic of an individual resident that influences the likelihood of an accident.

Definition: Supervision/Adequate Supervision

- “Supervision/Adequate Supervision” refers to an intervention and means of mitigating the risk of an accident.
- 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.



15

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: Commitment to Safety

A facility with a commitment to safety:

- Identifies risk
- Reports risk
- Involves all staff
- Utilizes resources
- Commitment to safety demonstrated at all levels of organization



16

A facility with a commitment to safety:

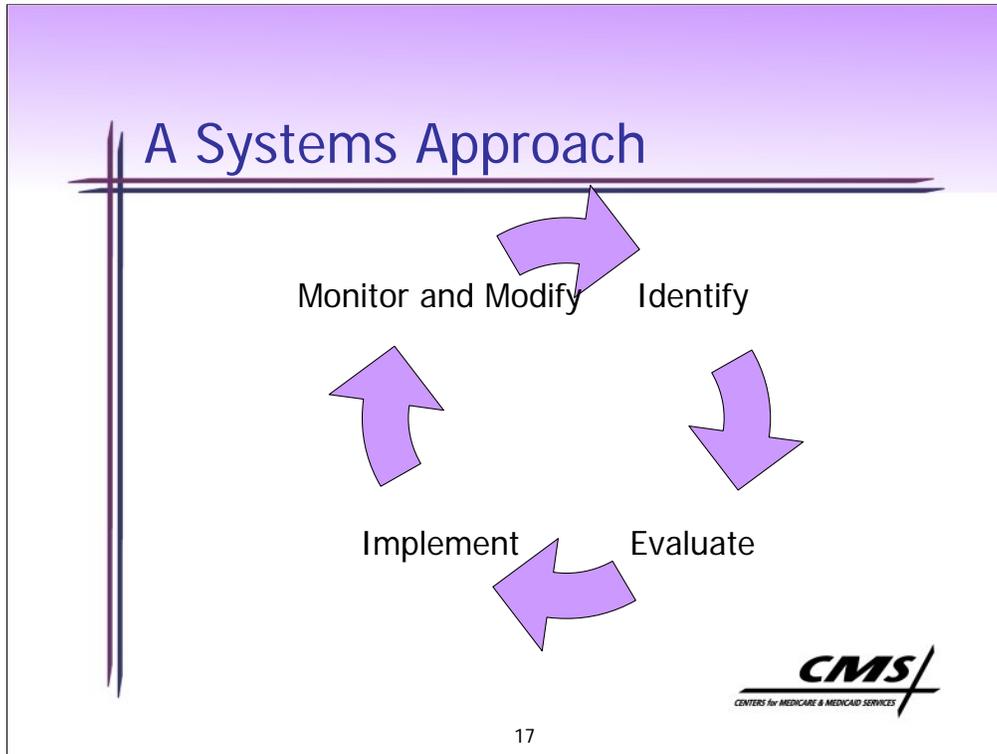
Acknowledges the high-risk nature of its activities;

Develops a reporting system that does not place blame on the staff member for reporting risks;

Involves all staff in the identification of solutions;

Directs resources to address safety concerns; and

Demonstrates a commitment to safety at all levels of the organization.



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. A key element of a systems approach is the consistent application of a process to address hazards and risks. Hazards may include aspects of the physical plant, equipments, and devices that are defective or not used properly. 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.

A facility's systems process may include:

- Identification of hazards, including the need for supervision;
- Evaluation of hazards and risk information;
- Implementation of interventions; and
- Monitoring for effectiveness and modification of interventions when necessary.

A Systems Approach Identification of Hazards and Risks

- Sources for identifying hazards may include:
 - Quality assurance activities
 - Environmental rounds
 - MDS/RAPS data
 - Medical history and physical exam
 - Individual observation



18

[Read slide.]

A Systems Approach Evaluation and Analysis

- The facility examines data gathered through identification of hazards and risks and applies it to the development of interventions to reduce the potential for accidents.
- Interdisciplinary involvement is a critical component of this process.



19

[Read 1st bullet.]

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.

[Read 2nd bullet.]

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.

A Systems Approach Implementation of Interventions

- The process includes:
 - Communicating the interventions to all relevant staff;
 - Assigning responsibility;
 - Providing training as needed;
 - Implementing and documenting interventions; and
 - Ensuring that interventions are implemented.



20

[Read slide.]

The interventions are implemented based on the results of evaluations and analysis of information about hazards and risks and are consistent with relevant standards. Development of interim safety measures may be necessary if interventions cannot be immediately implemented fully. An example might be putting up cones or supervising an area where a spill occurred until the spill can be cleaned up.

A Systems Approach Monitoring and Modification

- Monitoring and modification processes include:
 - Ensuring that interventions are implemented correctly and consistently;
 - Evaluating the effectiveness of interventions;
 - Modifying or replacing interventions as needed; and
 - Evaluating the effectiveness of new interventions.



21

[Read slide.]

When evaluating the facility's system, look at both facility-centered and resident-directed approaches. For a facility-centered approach, modification may include additional training of staff when equipment has been replaced with a newer model. For a resident-directed approach, modification may include revising the plan of care to reflect the resident's choices, current condition and risk factors that may have changed.

Supervision

- Supervision is an intervention and a means of mitigating accident risk.
- Adequacy is defined by the type and frequency of supervision.
- Adequate supervision may vary from resident to resident and from time to time for the same resident.



22

[Read slide.]

The use of tools or items such as personal alarms can help to monitor a resident's activities, but does not eliminate the need for staff vigilance and are not to be utilized in lieu of supervision.

Lack of Adequate Supervision

The lack of adequate supervision to prevent accidents occurs when the facility has:

- Failed to accurately assess a resident and/or the resident environment to determine whether supervision to avoid an accident or injury was necessary; and/or
- Determined supervision of the resident or resident environment was necessary, but failed to provide it.



23

[Read slide.]

Supervision Resident Smoking

- For a resident who smokes, assessment of the resident's abilities determine whether supervision is required.
- Precautions include:
 - Smoking only in designated areas
 - Supervising residents who need supervision
 - Limiting the accessibility of matches and lighters by the resident who needs supervision.



24

[Read slide.]

Smoking by residents when oxygen is in use is prohibited. Further guidance concerning resident smoking regulations can be found in NFPA 101, the Life Safety Code at 18.7.4 and 19.7.4, Smoking.

Refer to the guidance for 42 C.F.R. 483.15(b)(3) [F242] for information about facilities that desire to be smoke-free.

Supervision

Resident-to-Resident Altercations

- Facilities need to take reasonable precautions to prevent resident-to-resident altercations.
- Certain situations or conditions may increase potential for resident-to-resident altercations:
 - History of aggressive behavior
 - Negative interactions with other resident(s)
 - Disruptive or annoying behavior



25

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.

Supervision

Resident-to-Resident Altercations

- An incident involving a resident who willfully inflicts injury upon another resident should be reviewed as abuse under the guidance for 42 C.F.R. § 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.



26

[Read slide.]

Resident Risks and Environmental Hazards

- This section provides information regarding the most common, but not all, potential hazards.
- The physical plant, devices, and equipment described may not be hazards in and of themselves. It is the interaction between these potential hazards and the vulnerable resident that may lead to an accident.



27

[Read slide.]

The information included in the section “Resident Risk and Environmental Hazards” is based on current standards of practice or “best practice” models as described in the literature. The section is divided into three major categories of risks and hazards: Resident Vulnerabilities; Physical Plant Hazards; Devices/Equipment Hazards.

Resident Risks & Environmental Hazards: Resident Vulnerabilities

- Falls are defined as unintentionally coming to rest on the ground, floor, or other lower level, but not as a result of an overwhelming external force.
 - An episode where a resident loses his/his balance and would have fallen, if not for staff intervention, is considered a fall.
 - A fall without injury is still a fall.



28

Resident falls may be due to environmental hazards, as well as to the resident's underlying disease processes, medication side effects, and other individual risk factors such as lower extremity weakness, balance disorders, poor grip strength, or cognitive impairment.

[Read slide.]

The falls definition used in this Guidance is the same definition used in the MDS User's Manual.

Resident Risks & Environmental Hazards: Resident Vulnerabilities

Proper action following a fall includes:

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



29

[Read slide.]

Evaluation of the causal factors leading to a resident fall is necessary to provide consistent interventions to help prevent future occurrences.

Resident Risks & Environmental Hazards

Resident Vulnerabilities

- Unsafe Wandering: wandering is locomotion with no apparent destination and is most often associated with dementia.
 - Unsafe wandering occurs when the resident enters an area that is physically hazardous.
- Elopement occurs when a resident who needs supervision leaves a safe area without supervision.



30

[Read slide.]

Alarms can help to monitor the activities of a resident, but they require staff vigilance to respond in a timely manner. Alarms should not be used in lieu of staff supervision.

Resident Risks & Environmental Hazards: Resident Vulnerabilities

- Facility policies that define mechanisms and procedures can help to mitigate the risk of a resident leaving a safe area without staff supervision.
- The resident should have interventions in their comprehensive plan of care to address the potential for elopement.
- A facility's disaster and emergency preparedness plan should include a plan to locate a missing resident.



31

Unsafe wandering and elopement are concerns in almost every facility. Many accidents are a result of these behaviors. There are things facilities can do to mitigate the risk of an accident resulting from unsafe wandering and elopement.

[Read slide.]

Resident Risks & Environmental Hazards: Physical Plant Hazards

- Chemicals and Toxics
- Water Temperature
- Electrical Safety
- Lighting



32

Another area of concern is physical plant hazards. Hazards may include chemicals and toxics, water temperature, electrical safety, and lighting. These are not the only potential hazards but more detail about these categories is described in the guidance.

Physical Plant Hazards: Chemicals & Toxics

- Potentially hazardous materials include:
 - Chemicals used by facility staff in the course of their duties;
 - Drugs & therapeutic agents; and
 - Plants and other natural materials found indoors or outdoors
- Facilities are required to have the Material Safety Data Sheet (MSDS).
- Poison control centers are also a source of information for potential hazards.



33

[Read slide]

The Material Safety Data Sheets are available on-line for numerous chemicals and non-toxic materials. The Material Safety Data Sheets should be reviewed carefully to determine if the material is toxic and poses a hazard.

Physical Plant Hazards: Water Temperature

- Water may reach temperatures in hand sinks, showers, and tubs that can scald a resident.
- Some states have regulations regarding the specific maximum water temperature that is allowed.



34

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.

Table 1 in the Guidance illustrates damage to skin in relation to the temperature of the water and the length of time of exposure. The Guidance also provides examples of what constitutes first, second, and third degree burns.

Physical Plant Hazards: Electrical Safety

- The use of electrical space heaters are prohibited in resident care areas.
- The wires on electric blankets should not be tucked in or squeezed.
- A resident should not go to sleep with electric blankets or heating pads turned on.
- The use of GFCI's may be required near water sources.



35

[Read slide.]

“GFCI” stands of Ground Fault Circuit Interruption

This section of the Guidance also provides information about power strips, extension cords, and other devices that may be found in the nursing home.

Physical Plant Hazards: Lighting

- There is variability in vision, thus no single level of illumination is recommended.
- Creating transitional zones between light and dark spaces helps to improve sight recovery.
- Providing extra visual cues that clearly define needed items can help to enable safe performance of tasks.
- Providing supplemental light near beds for patients may assist in safe mobility at night.



36

[Read slide.]

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 for Mobility

- Mobility devices include canes, walkers, and wheelchairs.
- There are 3 reasons why a resident may be at risk of an accident:
 - Resident condition
 - Personal fit and device condition
 - Staff practices



37

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.

Three primary factors that may be associated with an increased accident risk related to the use of assistive devices include: resident condition; personal fit and device condition; and staff practices.

- Resident Condition such as 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.
- Personal Fit and Device Condition. Devices can pose a hazard if not fitted and/or maintained properly. Personal fit, or how well the assistive device meets the individual needs of the resident, may influence the likelihood of an avoidable accident.
- 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/Equipment Hazards: Assistive Devices for Transfer

- Transfer devices include portable total body lifts, sit-to-stand devices, and transfer belts.
- Factors that place a resident at risk include:
 - Staff availability
 - Resident abilities
 - Staff training



38

[Read slide.]

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.

Assistive Devices/Equipment Hazards: Devices Associated with Entrapment Risks

- Bed rails and bed accessories can pose increased risk to resident safety.
- Entrapment may occur when a resident slips between the mattress, regular or air-filled, and the bed rail.
- Improper sizing of mattresses and bent bed rails increase the risk of resident entrapment.



39

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.

In 1995, the FDA issued a Safety Alert entitled "Entrapment Hazards with Hospital Bed Side Rails." 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.

Assistive Devices/Equipment Hazards: Devices Associated with Entrapment Risks

NOTE: 42 C.F.R. § 483.13(a), F221, applies to the use of physical restraints. 42 C.F.R. § 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).



[Read slide.]

Investigative Protocol

Accidents & Supervision



Investigative Protocol

Components

- Objectives
- Use
- Procedures



42

The components of the investigative protocol include the objectives, explanation of when to use the protocol, and procedures for conducting the investigation.

Investigative Protocol: Objectives

- To determine if the facility has identified hazards present in the resident environment and the individual resident's risk for an avoidable accident posed by the hazard;
- To determine if a resident accident was avoidable or unavoidable;
- To evaluate whether the facility provides and environment that is as safe as possible; and
- To determine if the facility provided adequate supervision and assistive devices to prevent avoidable accidents.



43

[Read slide.]

Investigative Protocol: Use

- Use this protocol:
 - For a sampled resident who is at risk 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;
 - 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, to determine if there are facility practices in place to analyze hazards; implement interventions to reduce the hazards; and monitor the effectiveness of the interventions.



[Read slide.]

Investigative Protocol: Procedures

- Observe the environment for the presence of potential/actual hazards:
 - Accessibility of chemicals;
 - Conditions in the environment;
 - Staff response to alarms and verbal calls for help;
 - Assistive devices that are defective; and
 - Staff response to potential and actual hazards.



45

[Read slide.]

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

Investigative Protocol: Procedures

- Interview the resident and his/her family to identify:
 - If the resident was aware of his/her risk of an accident;
 - If the resident was aware of hazards for other residents;
 - If the resident reported a hazard to staff; and
 - How and when staff responded to a hazard once it was identified.



46

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

[Read slide.]

Investigative Protocol: Procedures

- Interview staff to determine:
 - If they were aware of planned interventions to reduce a resident's risk;
 - If they reported potential resident risks;
 - If they took action to correct an immediate hazard; and
 - If they received training regarding facility procedures to remove or reduce hazards.



47

[Read slide.]

Investigative Protocol: Procedures

- Record Review: Assessment & Evaluation
 - Determine if the facility assessment is consistent with the record and reflects the resident's:
 - Risk of unsafe wandering and elopement
 - Hearing, visual, and sensory impairments
 - Diagnoses of Alzheimer's and other dementias
 - Medication use
 - History of falls



48

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 risks and implemented appropriate interventions.

Determine if the facility assessment is consistent with the record and reflects the resident's:

- Risk of unsafe wandering and elopement
- Hearing, visual, and sensory impairments
- Diagnoses of Alzheimer's and other dementias
- Medication use
- History of falls

Investigative Protocol: Procedures

- Record Review: Plan of Care
 - If the resident has had an accident, review the record to determine if it was:
 - 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.



49

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

[Read slide.]

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

Investigative Protocol: Procedures

- Review facility practices.
 - Determine if the facility:
 - Identified potential hazards and risks;
 - Evaluated information gathered to identify the causes of the risks;
 - Implemented interventions; and
 - Monitored implementation of interventions.



50

[Read slide.]

If, during the tour, general observations of care delivery, hazards or potential hazards, or a history of resident accidents have been identified, it is incumbent on the survey team to share the findings with the entire team and determine who will be the lead for the investigation of the facility systems.

Review of facility practices may involve review of policies and procedures, staffing, staff training, as well as interviews with management.

Determination of Compliance

Components

- Synopsis of Regulation
- Criteria for Compliance
- Noncompliance
- Potential Tags for Additional Investigation



51

The section in the Guidance on Determination of Compliance includes:

- Synopsis of Regulation
- Criteria for Compliance
- Noncompliance
- Potential Tags for Additional Investigation

Determination of Compliance Synopsis of Regulation (F323)

- The requirement at 42 CFR 483.25(h)(1) and (2) has three aspects:
 - a resident's environment remains as free of accident hazards as possible;
 - the facility provides adequate supervision; and
 - the facility provides assistive devices to prevent accidents.



52

[Read slide.]

Determination of Compliance

42 CFR 483.25(h) (1) and (2), F323

- For the resident who has had an accident, the facility is in compliance with this requirement if staff have:
 - Identified hazards;
 - Evaluated the hazards;
 - Implemented interventions;
 - Provided assistive devices; and
 - Provided a secure environment.



53

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.

Determination of Compliance

42 CFR 483.25(h) (2), F323

- For the resident who has had an accident, the facility is in compliance with this requirement if staff have:
 - Identified hazards;
 - Evaluated the hazards;
 - Implemented adequate supervision; and
 - Monitored the effectiveness of the supervision and modified the interventions as necessary.



[Read slide.]

Determination of Compliance

42 CFR 483.25(h) (1) F323

- The facility is in compliance with this requirement if the staff have:
 - Maintained the general resident environment and equipment;
 - Received training and periodic monitoring regarding use of resident-specific equipment;
 - Provided a safe environment during general housekeeping activities; and
 - Operated equipment in accordance with manufacturer's recommendations and resident need.



55

[Read slide.]

Determination of Compliance

Noncompliance For F323

- Noncompliance may include, but is not limited to, failure to:
 - Provide each resident with an environment that is safe;
 - Provide adequate supervision;
 - Address hazards;
 - Provide assistive devices; and
 - Assess and develop interventions.



[Read slide.]

Determination of Compliance

Potential Tags for Additional Investigation

- 42 C.F.R. 483.13(a), F221, Restraints
- 42 C.F.R. 483.13(b), F223, Abuse
- 42 C.F.R. 483.20(b)(1), F272, Comprehensive Assessments
- 42 C.F.R. 483.20(k)(1), F279, Comprehensive Care Plans
- 42 C.F.R. 483.20(k)(2), F280, Comprehensive Care Plan Revision



57

During the investigation of 42 C.F.R. § 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:

- F221, Restraints
- F223, Abuse
- F272, Comprehensive Assessments
- F279, Comprehensive Care Plans
- F280, Comprehensive Care Plan Revision

Determination of Compliance Potential Tags for Additional Investigation

- 42 C.F.R. 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
- 42 C.F.R. 483.30(a), F353, Sufficient Staff
- 42 C.F.R. 483.75(o), F520, Quality Assessment and Assurance



58

- F281, Services Provided Meet Professional Standards
- F353, Sufficient Staff
- F520, Quality Assessment and Assurance

Deficiency Categorization Severity Determination

- The key elements for severity determination are:
 - Presence of harm or potential for negative outcomes;
 - Degree of harm (actual or potential); and
 - The immediacy of correction required.



59

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.

[Read slide.]

Deficiency Categorization

Severity Level 4 Considerations

- Immediate jeopardy to resident health or safety
- The facility's noncompliance:
 - Has allowed or could allow serious injury, or death to a resident; and
 - Requires immediate correction, as the facility either created the situation or allowed the situation to continue.



60

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.

[Read slide.]

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.

Deficiency Categorization

Severity Level 4 Considerations

Examples of Level 4 might include:

- Esophageal damage;
- Loss of consciousness;
- 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;



61

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;

Deficiency Categorization

Severity Level 4 Considerations

- 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;



62

- 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;

Deficiency Categorization

Severity Level 4 Considerations

- 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.



63

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.

Deficiency Categorization

Severity Level 3 Considerations

- Actual harm that is not immediate jeopardy
- May include clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being.



64

[Read slide.]

Deficiency Categorization

Severity Level 3 Considerations

Examples of Level 3 might 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;



65

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;

Deficiency Categorization

Severity Level 3 Considerations

- 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



[Read slide.]

Deficiency Categorization

Severity Level 3 Considerations

- 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.



67

[Read slide.]

Deficiency Categorization

Severity Level 3 Considerations

- 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.



68

[Read slide.]

The reason for this is that the combination of actual harm and a lack of system to prevent or limit the resident's exposure to the hazard creates the potential for immediate jeopardy.

Deficiency Categorization

Severity Level 2 Considerations

- No actual harm with potential for more than minimal harm that is not immediate jeopardy
- Noncompliance resulted in:
 - No more than minimal discomfort to the resident; and/or
 - The potential to compromise resident's ability to maintain or reach his/her highest practicable level of well-being.



[Read slide.]

Deficiency Categorization

Severity Level 2 Considerations

Examples of Level 2 Severity might include:

- 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;



70

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;

Deficiency Categorization

Severity Level 2 Considerations

- 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



71

[Read slide.]

Deficiency Categorization

Severity Level 2 Considerations

- 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.



72

[Read slide.]

Deficiency Categorization

Security Level 1 Considerations

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



[Read slide.]